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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 on the protection of workers from the risk related to exposure to carcinogens or mutagens at work

{COM(2018) 171 final} - {SWD(2018) 87 final}

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Glossary

Term or acronym	*Meaning or definition*
ACSH	Advisory Committee on Safety and Health at Work
ANSES	French Agency for Food, Environmental and Occupational Health & Safety
As	Arsenic
ASA	Finnish Register of Workers Exposed to Carcinogens (altistuminen syöpäsairauden vaaraa aiheuttaville tekijöille (ASA-luettelo))
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
BeST	Beryllium Science and Technology Association
BLV	Biological Limit Value
BGV	Biological Guidance Value
CAD	Chemical Agents Directive (Directive 98/24/EC)
CAREX	CARcinogen EXposure database
CBD	Chronic Beryllium Disease
Cd	Cadmium
CLP	Classification, Labelling and Packaging Regulation (Regulation (EC) No 1272/2008)
CMD	Carcinogens and Mutagens Directive (Directive 2004/37/EC)
DALY	Disability-Adjusted Life Year
DMA	Dimethylarsinic acid
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EIG	Employers Interest Group
EP	European Parliament
ERR	Exposure Risk Relationship
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FinJem	Finnish Job Exposure Matrix
GIG	Governments Interest Group
HSE	Health and Safety Executive
IARC	International Agency for Research on Cancer
ICdA	International Cadmium Association
ICT	Information and communication technology
INRS	Institut National de Recherche et Sécurité
IOM	Institute of Occupational Medicine
LTCR	Life Time Cancer Risk
mg	Milligram
MEGA	Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz
MMA	Monomethylarsonic acid
MOCA	4,4'-Methylene-bis(2-chloroaniline)

Term or acronym	*Meaning or definition*
MSs	Member States
NACE	Nomenclature des Activités Économiques dans la Communauté Européenne
NAIC	North American Industry Classification System
Ni-Cd	Nickel-Cadmium
OEL	Occupational Exposure Limit (Value)
OJ	Official Journal
OSH	Occupational Safety and Health
ppm	parts per million
RAC	Risk Assessment Committee of ECHA
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
REGEX	Registry of Subjects Occupationally Exposed to Carcinogens
RIVM	The Netherlands National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu)
RMMs	Risk Management Measures
RPA	Risk & Policy Analysts Ltd
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Socio- Economic Assessment Committee of ECHA
SMEs	Small and Medium Sized Enterprises
STEL	Short Term Exposure Limit
SUMER	Surveillance Médicale des Expositions aux Risques Professionnelles
SVHC	Substance of Very High Concern
SWD	Staff Working Document
t	tonnes
TFEU	Treaty on the Functioning of the EU
TWA	Time-Weighted Average
µg	Microgram
UN	United Nations
UK	United Kingdom
US	United States
US-OSHA	US-Occupational Safety and Health Administration
WHO	World Health Organisation
WIG	Workers Interest Group
WPC	Working Party 'Chemicals at the Workplace’
WTP	Willingness to pay

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

In the State of the Union Address 2017[1] President Juncker emphasized the need to avoid social dumping in Europe by joining efforts and delivering on the European Pillar on Social Rights[2]. The Pillar - jointly proclaimed by the Commission, the European Parliament and the Council on 17 November 2017 at the Social Summit in Gothenburg - identifies workers' right to healthy, safe and well-adapted work environment, including protection from carcinogens, as one of the main principles. Protection of workers' health, by continuously reducing occupational exposures to carcinogenic and mutagenic substances, is a concrete action of the Juncker Commission to deliver on this key priority. This has been clearly stated in the Commission Communication on "Safer and Healthier Work for All"[3].

Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers' life and health as the two following combined (musculoskeletal disorders and circulatory diseases). Its negative impact is also far greater than that of work-related accidents[4]. It brings about suffering to workers and their close ones, poor quality of life, undermined wellbeing and, in the worst case, death.

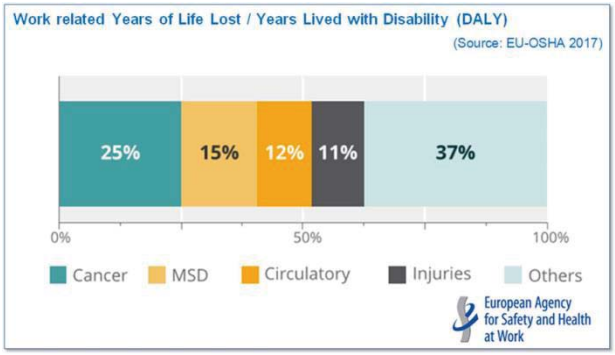

Figure 1: Work-related health problems cause the highest DALY in the European Union

Reducing exposure to carcinogens and mutagens at the workplace by setting EU-wide occupational exposure limit values (OELs) would effectively contribute to the prevention of cancer cases and death, as well as other significant non-cancer health problems caused by these substances. Consequently, it increases the length, quality and productivity of the working lives of European workers, contributes to better productivity and competitiveness of the EU, and improves the level playing field for businesses.

For this reason this Commission has initiated a continuous process of updating the Carcinogens and Mutagens Directive (CMD)[5] to keep abreast with the new scientific and technical developments, and taking account of its stakeholders' views. This is in line with the Directive itself, which requires that OELs must be set for all those carcinogens or mutagens for which this is possible in the light of the available information. Consistency

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1 State of the Union Address 2017, available at: https://ec.europa.eu/commission/state-union-2017_en

2 European Pillar of Social Rights, November 2017, available at: https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

3 Communication from the Commission "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final: .http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

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

5 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

with the REACH Regulation[6] is ensured in this respect. The finalised REFIT OSH evaluation[7] as well as the preliminary conclusions of the REACH REFIT evaluation[8] have underscored and fed into this process.

Updating and reviewing the CMD has now become a continuous process:

Two legislative amendments updating the CMD, of May 2016[9] and January 2017[10], addressing together 20 carcinogens, have been proposed. The first amendment was adopted by the co-legislators end 2017[11] and on the second the Council adopted a general approach on 15 June 2017. The European Parliament's first reading position is expected in the first quarter of 2018.

For further amendments including the one at hand, the Commission follows the same process as for the two previous proposals; it has conducted a two-stage consultation of the European Social Partners[12,13] in accordance with Article 154 of the Treaty on the Functioning of the European Union (TFEU).

Both workers' and employers' organisations confirmed that the five carcinogens selected for this amendment of the CMD are of high relevance for the protection of workers (see Annex 2 for more information) and encouraged the Commission to continue the preparatory work for the establishment of OELs for those priority carcinogens:

- **Cadmium and its inorganic compounds under the scope of the CMD**
- **Beryllium and inorganic beryllium compounds under the scope of the CMD**
- **Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the CMD[14]**
- **Formaldehyde**
- **4,4'-Methylene-bis(2-chloroaniline) (MOCA)**

Estimates show that this proposal, when adopted, in longer term would improve working conditions for over1 000 000 EU workers and prevent over 22 000 cases of work-related ill health[15].

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

7 Ex-post evaluation of the EU occupational safety and health Directives (REFIT evaluation)SWD(2017) 10 final, available at: http://www.cc.cec/sg/vista/home?documentDetails&DocRef=SWD/2017/10&ComCat=SPINE

8 REACH REFIT evaluation (REACH Review 2017), available at: https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

9 COM(2016) 248 final of 13 May 2016, Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

10 COM(2017)11 final of 10 January 2017, Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

11 Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, available at: http://eur-lex.europa.eu/eli/dir/2017/2398/oj

12 Consultation Document of 26.07.2017, First phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EC to include binding occupational exposure limit values for additional carcinogens and mutagens, C(2017) 5191 final.

13 Consultation Document of 10.11.2017, Second phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EC to include binding occupational exposure limit values for additional carcinogens and mutagens, C(2017) 7466 final.

14 The first three carcinogens listed above are substance groups which comprise a large number of priority compounds (Cadmium: 11, Beryllium: 9 and Arsenic: 26 compounds, respectively). The criteria for prioritisation and selection procedure for the retained substances or groups are presented in Annex 6.

Given the level of scientific and technical knowledge required to identify measures, which at the same time adequately protect workers and are practically feasible for industries, the European Commission bases proposals in this area on opinions developed by the tripartite Advisory Committee on Safety and Health at Work (ACSH). The opinions of ACSH take into account scientific basis, which is indispensable to underpin OSH legislation. With a view to mainstream scientific advice and in line with the Commission Communication on "Safer and Healthier Work for All", the Commission for this proposal sought advice from both, the Scientific Committee on Occupational Exposure Limits (SCOEL) and the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). The purpose of this impact assessment is to verify, on the basis of available socioeconomic data, the robustness of ACSH opinions and, eventually to consider some complementary measures, which could be proposed, based on further scientific information.

Member States authorities, employers' and workers' representative bodies within the framework of the tri-partite ACSH strongly anticipate the legal clarity and increased protection which would be the result of lower OELs on these substances.

The analysis presented in this document should be read in conjunction with the earlier impact assessment (IA)[16] for the first proposal, which provided an exhaustive consideration of the CMD, the policy and legal context.

The most essential points are carried over and supplemented by additional information and analysis regarding these five additional carcinogens.

2. PROBLEM DEFINITION

2.1. What is/are the problems?

Carcinogenic and mutagenic substances lead not only to cancers, but to also other important health problems. For example, exposure to beryllium, in addition to lung cancer, also causes incurable chronic beryllium disease. If effective measures are put in place to prevent high exposures of the five substances under consideration, their positive impact would be much broader than cancer prevention alone – in longer term the proposal would improve working conditions for over 1 000 000 EU workers and protect over 22 000 workers from significant health problems.

Furthermore, ineffective prevention of the exposure to carcinogens would have negative consequences for business such as higher costs and reduced productivity due to absenteeism, lost expertise and distorted competition; and for Member States due to increased social security costs and missed tax revenues.

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

[15] RPA (2018) draft final report.Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC.

[16] Commission Staff Working Document, Impact Assessment, accompanying the proposal for a Directive of the European Parliament and the Council amending Directive 2004/37/EC on the protection of workers from the risks related to carcinogens or mutagens at work (SWD(2016)152/2), available at: https://ec.europa.eu/social/BlobServlet?docId=16877&langId=en

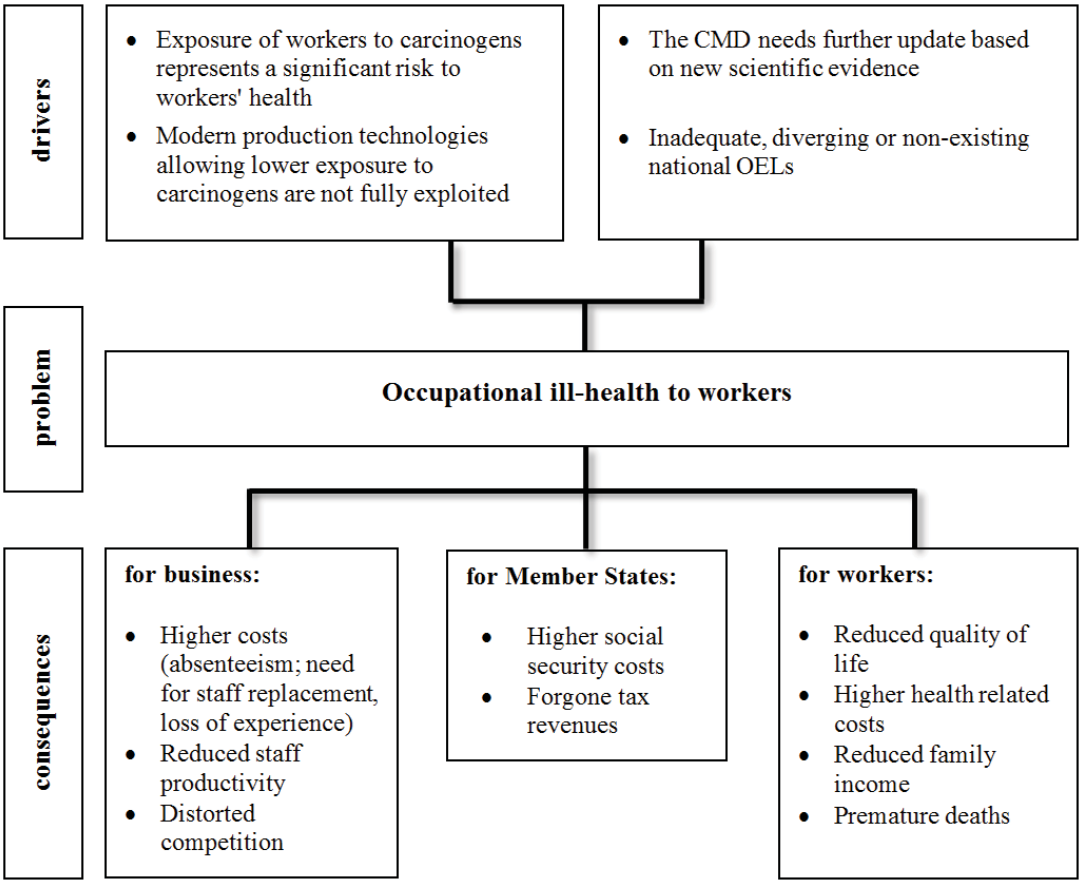

Figure 2: Problem tree

2.2. What are the problem drivers?

2.2.1. Exposure of workers to carcinogens represents a significant risk to workers' health

This section presents an overview of the estimated numbers[17,18,19] of workers exposed to the substances subject to this initiative and a short explanatory summary for each substance. More detailed information, e.g. on estimated ranges, breakdown of relevant sectors etc., is provided in Annex 7.

Different sources compile different estimates of the total number of exposed workers. For the purpose of this impact assessment for each substance the most reliable number has been taken forward for the baseline scenarios and for the cost-benefit assessments related to the retained options for establishing limit values.

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

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

19 See footnote 15

Table 1: Summary of estimates taken forward for the assessment of options

Carcinogen	Exposed workforce (number of workers)	Typical exposure levels	Major occupational exposure route
Cadmium and its inorganic compounds	**10 000** *Range of 2900 – 300 000 between different estimates*	5 µg/m³ to 50µg/m³; with extreme values up to 400 µg/m³	Inhalation of cadmium-containing dusts and fumes. Incidental ingestion of dust at work from contaminated hands, cigarettes or food.
Beryllium and inorganic beryllium compounds	**54 000** *Range of 14 000 – 74 000 (depending on which of the three datasets chosen Construction sector: 7 000 – 41 000*	0.19 µg/m^3 – 2.78 µg/m^3	Inhalation of beryllium-containing dusts and fumes. Dermal exposure is relevant for non-carcinogenic ill-health effects.
Arsenic acid and its salts, as well as inorganic arsenic compounds	**7 900 –15 300** *In addition: 18 000-102 000 potentially exposed below the lowest assessed OELs*	0.1 µg/m3 – 45 µg/m3 with extreme values up to 312 µg/m3 in the domestic glass sector	Inhalation of arsenic containing particulates. Ingestion (skin-to-mouth) exposure may be significant in specific situations.
Formaldehyde	**990 000** *Range of 990 000 – 2 200 000 between different estimates*	0.1 mg/m^3 – 3 mg/m^3 Higher values estimated for the hospitals, embalmers, veterinary activities (HEV sectors)	Inhalation as the main route. Ingestion and absorption through the skin not negligible.
4,4'-Methylene-bis(2-chloroaniline) (MOCA)	**350** *1 200 workers may potentially be indirectly exposed*	0.1 µg/m^3 – 5 µg/m^3, with extreme values up to 15 µg/m^3	Absorption through the skin after contact with contaminated sites. Inhalation and ingestion represent minor sources.
Total workforce assessed:	~ **1 070 000**		
Based on RPA (2018)			

Cadmium and its inorganic compounds under the scope of the CMD

The data collected for this impact assessment estimates a number of 10 000 workers currently exposed to cadmium and its inorganic compounds. However, only limited extrapolation from the responses received to some of the sectors has been possible and some indications of exposure could not be confirmed.

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

Beryllium and inorganic beryllium compounds under the scope of the CMD

Ten industrial sectors such as foundries, glass and laboratories were identified in which workers are at risk of exposure to beryllium. RPA (2018) study[20] used two compounds for this assessment, beryllium and beryllium oxide. Copper, aluminium, magnesium and nickel are widely alloyed with beryllium. These are a cause of worker exposure and are included in the assessment. Approximately 80% of all beryllium in the EU is used in copper beryllium alloys.

The study concludes that further research and, in particular, survey data is required to establish whether there is an issue, and if yes - to what extent, with beryllium in construction.

Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the CMD

The considered exposure data distinguishes between two groups:

- Workers for which available data shows that they are exposed at higher levels as demonstrated by measurements, modelling or from comparison to similar processes.
- Other workers who may potentially be occupationally exposed. The latter group either works in sectors and with processes where arsenic may be present in raw materials at considered relatively low levels, or they work in high-exposure sectors (as the copper sector), but likely are not routinely working with the high-exposure processes covered by the monitoring of workplace concentrations.

Exposure to arsenic compounds occurs, for example, in copper and zinc production, as well as in the glass, electronics and chemical sectors.

Formaldehyde

In addition to formaldehyde manufacturing, it is used in a wide variety of products such as adhesives and sealants, coating products, polymers, biocides and laboratory chemicals; activities such as building and construction work; and in the manufacturing of leather and fur, pulp, paper and paper products, textile and wood and wood products.

Formaldehyde is also used for tissue preservation in embalming fluids and as a disinfectant in pathology departments and autopsy rooms, usually in the form of formalin (i.e. mixture of formaldehyde, water, and methyl alcohol).

4,4'-Methylene-bis(2-chloroaniline) (MOCA)

After the sunset date of 22 November 2017, as set by Annex XIV to REACH, MOCA can only be used by the downstream users in the supply chain of the only applicant for authorisation. However, the authorisation has not yet been granted.

Exposed workers work in the plastics sector, where MOCA is used for moulding of polyurethane elastomer parts at 89 sites across the EU.

Exposure to the carcinogens addressed in this impact assessment leads to significant health consequences for workers.

The table below shows the current and future burden of cancer and other health effects related to the occupational exposure to the five substances under consideration. Given the long latency period of the concerned illnesses, the future health burden is estimated over a 60 year period.

20 See footnote 15

However, the disease burden on workers is likely to be underestimated due to several limitations of the data/calculations.

First, the study quantified burden of only those cancers and other adverse health effects which are known to be caused by the lowest exposures (so-called most sensitive endpoints). However, workers may develop additional types of cancer and diseases at higher exposure levels that have not been quantified in the study (see table 2 below). When establishing an OEL at a certain level to prevent the most sensitive endpoints, the other diseases will be prevented as well.

Second, the estimates relate only to sectors where exposure currently exists and therefore do not represent the total burden of possible past exposure. More information on limitations is given in chapter 6.

Table 2: Current and future disease burden related to occupational exposure to carcinogens (number of cases)

Carcinogen	Health effects caused	Current* disease burden (quantified)	Future** disease burden (quantified)
Cadmium and its inorganic compounds	Lung cancer (quantified), bladder, kidney and prostatic cancer (not quantified)	11	6
	Proteinurea (quantified), osteoporosis and respiratory effects (not quantified)	500	280
Beryllium and inorganic beryllium compounds	Chronic beryllium disease (quantified), allergy or asthma symptoms, beryllium respiratory sensitisation, skin sensitisation, cardiovascular, renal, hepatic and haematological effects (not quantified)	3 807	4 602
Arsenic acid and its salts, as well as inorganic arsenic compounds	Lung cancer (quantified) cancer in the skin, liver, lungs, bladder and kidney (not quantified)	17	20
	Peripheral neuropathy (quantified), cardiovascular effects and immunotoxicity, skin changes and blackfoot disease (not quantified)	905	574
Formaldehyde	Nasopharyngeal cancer (quantified), leukaemia, tumour induction (not quantified)	330	7
	Sensory irritation (quantified), potential cancer precursor effects (not quantified)	19 200	19 200
4,4'-Methylene-bis(2-chloroaniline) (MOCA)	Lung cancer, bladder cancer (quantified)	0	0
TOTAL		**24 770**	**24 689**
** The current disease burden is estimated over the past 40 years* *** The future health burden is estimated over a 60 year period*			
Based on RPA (2018)			

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

Under the CMD, employers must identify and assess risks to workers associated with exposure to 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.

For some chemical agents, the CMD establishes binding OELs. The fact that OELs are established does not affect the underpinning obligations of the employer to comply with other obligations, including to reduce the exposure of his/her workers to carcinogenic and mutagenic substances to as low a level as is technically possible (minimised exposure).

The existence of OELs provides clarity and are very relevant benchmarks for employers enabling them to know exactly the levels above which exposure cannot occur. OELs also allow employers to determine the level below which his/her risk management measures should aim to comply with the obligation to reduce the exposure to as low a level as is technically possible. They also support enforcement authorities in controlling that employers are putting in place the relevant risk management measures, including those that could contribute to the exposure below the OELs.

Under the CMD the European Parliament and the Council shall set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

For the substances covered in this impact assessment, for none of which an EU OEL exists, the scientific advice has been provided by SCOEL (cadmium, beryllium, formaldehyde) and RAC (arsenic and MOCA). The tripartite ACSH has adopted opinions for all five. It is therefore appropriate to consider updating the CMD based on the above-mentioned information. Further information on the scientific advice and ACSH opinions is provided in Annexes 1 and 2, respectively.

2.2.3. Diverging national OELs create different competing conditions and protection levels across the EU

While no EU OELs have been established for the five carcinogens considered under this initiative, there is a diverse situation as for legal protection at national level. For each substance there is a range of national OELs and a number of Member States that have not set OELs. The table below summarises the divergences:

Table 3: National OELs in EU Member States

Carcinogen	Lowest (strictest) national OEL (mg/m^3)	Highest (least strict) national OEL (mg/m^3)	Member States with no OEL
Cadmium and inorganic compounds	0.002 BE, PL, PT, ES, SE	0.05 FR, LT	3 IT, LU, MT

Beryllium and inorganic beryllium compounds	0.00005 PT (inhalable fraction)	0.05 AT, EL, SK, SI	4 IT, LU, MT, NL
Arsenic acid and its salts, as well as inorganic arsenic compounds	0.01 CY, IE, LV, PT, RO, ES, SE	0.2 FR (As_2O_3)	3 IT, LU, MT
Formaldehyde	0.15 NL	3 CY	5 BE, IT, LU, MT, ES
4,4'-Methylene-bis(2-chloroaniline) (MOCA)	0.005 IE, UK	0.22 FR, EL, RO	12 BG, CY, CZ, EE, DE, HU, IT, LV, LT, LU, MT, SE*
* *In Sweden working with this substance requires permission from the Swedish environmental authority before it can be used.*			
Based on RPA (2018)			

Diverging national OELs not only lead to different workers protection levels across the EU but also distort competition. For example, PT firms need to comply with an OEL 1000 times smaller (i.e. stricter) than firms in AT, EL, SK and, therefore, their investments on protective measures/equipment would be higher. These national differences may lead to complications for businesses operating in different EU Member States. Annex 5 presents an overview of all national OELs in EU Member States for the substances considered under this initiative.

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

State-of-the-art industrial production processes allowing for the further reduction of occupational exposure to carcinogenic, mutagenic and other hazardous substances in the workplace exist but their adoption is not generalised. One possible reason is that decisions of business are often influenced by short-term cost assumptions rather than long-term benefits.

For example, exposure to cadmium and MOCA could be further reduced by a higher degree of automation, e.g. in plating and coating processes and in the production of nickel-cadmium batteries[21], and regarding exposure to MOCA, also in the manufacture of rubber products[22].

Risk management measures, such as improved local exhaust ventilation systems, would reduce exposure of workers to formaldehyde e.g. during the wood panel production[23], to arsenic acid and its salts in manufacturing of copper foils[24] and in recycling facilities, and

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

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

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

[24] RAC (2017): Opinion on Arsenic acid and its inorganic salts. Available at: https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

to beryllium in manufacturing of alloys and ceramics[25], to levels which would be more protective of workers health.

2.3. How will the problem evolve?

In the absence of EU action, the consequences described above will continue. Estimations on the numbers of deaths and health costs in case no action is taken regarding the carcinogens covered in this report are, where available, described in the baseline scenario[26] in section 6.

The general obligations set by the CMD, employers' actions and measures adopted by Member States contribute overall to lowering exposures. Exposure levels have generally been decreasing in the past years and this positive trend could continue in the future. Substitution may be possible for some carcinogens in the future, also the numbers of workers in the industries using these carcinogens may change, and technological developments could facilitate lower exposure concentrations.

Future forecasts in this area are however far from certain due to scarcity of relevant data and the fact that market forces such as raw material and energy prices, developing technology, as well as regulatory changes can drive decreases or increases in use which are not easy to predict. Even if trends were overall positive, as explained above, the existing employers' practices as well as protective measures at Member State level do not always reflect available scientific and technological knowledge. Further demographic changes increase the life expectancy of workers exposed and, therefore, the chances to develop the illnesses mentioned in table 2.

Member States usually do not inform the Commission on their intentions to revise existing or determine new OELs in their national legislation; national administrations represented in the ACSH are aware of the preparatory work at EU level and therefore it is likely they will await its results in order not to duplicate efforts.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

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

On the basis of this provision, Article 16 (1) of the CMD provides a specific legal basis for action, allowing for adoption of limit values in respect of those carcinogens or mutagens for which this is possible, having regard to the available information, including scientific and technical data.

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

[26] The estimates presented only relate to the sectors where exposure to the carcinogens specified currently occurs and do not represent the total burden of past occupational exposure. The total burden from all past occupational exposure to these carcinogens would require consideration of sectors where occupational exposure no longer takes place and which are not relevant to the problem definition for this IA.

Addressing the social dimension of the European Union by putting forward a proposal for a Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens is included in the Joint Declaration on the EU's legislative priorities for 2018-2019[27].

The 2016-2019 "Roadmap on carcinogens" convenant initiated by the Dutch and Austrian governments as well as the European social partners[28] supports and accompanies the process of regular CMD updates.

3.2. Subsidiarity: Necessity and added value of EU action

Scientific knowledge about carcinogenic chemicals is constantly developing and technological progress enables improvements in protection of workers. In order to ensure that the mechanisms for protecting workers from carcinogenic chemicals established in the CMD are as effective as possible, the Directive needs to be kept up to date with those developments. Updating CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States.

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

Improved clarity and enforcement

Establishing new OELs will provide common reference points that are used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements. OELs can also be used by process plant and machinery designers when planning new, or considering alterations, to existing process plants.

Clear support for establishing OELs for the substances subject to this initiative has been expressed from key stakeholders as it clearly results from the two phases of the consultation of the social partners and the opinions of the tripartite ACSH.

Concerning formaldehyde, the employers' and workers' representatives[29] in 2016 signed a common letter addressed to the Commission[30] requesting to include it already in the second amendment to the CMD.

Ensuring the same minimum level of protection across the EU

In case of all carcinogenic chemical agents where OELs are proposed in this initiative at least 15 Member States have not yet established legally enforceable OELs for at least one of the substances. For example, 12 Member States have set no limits for MOCA – the same is true for 5 Member States in the case of formaldehyde.

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

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27 The Parliament, the Council and the Commission.Joint Declaration on the EU's legislative priorities for 2018-19, https://ec.europa.eu/commission/publications/joint-declaration-eus-legislative-priorities-2018_en

28 https://roadmaponcarcinogens.eu/about/the-roadmap/

29 Formacare, the CEFIC sector group for formaldehyde, the European Panel Federation, the European Trade Union Confederation, the European Automobile Manufacturers' Association, the European Tyre and Rubber Manufacturers' Association and the European Phenolic Resins Association

30 Letter of 15 July 2016 to the Commission.Request to include Formaldehyde in the Annex III of the Carcinogen and Mutagen Directive 2004/37/EC

Contribution to a levelplaying field

Employers' orgnisations stressed in their response to the social partner consultation that setting EU OELs helps to provide a levelplaying field for industry. Setting EU OELs will not completely eliminate the differences between Member States, as they retain the possibility to adopt more protective measures. However, it will limit the scope for divergences and enhance certainty that there is a core definition and/or enforceable exposure limit for all concerned carcinogens in all Member States. The examples of the currently existing EU OELs (e.g. for benzene) show that a majority of Member States in practice adopt these values directly.

Assuming burdens at EU level related to derivation of limit values

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

Given the limited resources for OSH at national level, this could release funds to be redirected into other OSH priorities.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

This initiative implements principle 10 of the European Pillar of Social Rights ("Healthy, safe and well-adapted work environment") directly contributing to a high level of workers' health and safety by eventually reducing the exposure to carcinogens and mutagens at the workplace.

Modernising the legal framework setting updated OELs on exposure to carcinogens was also identified as the key priority in the OSH field by the Commission Communication 'Safer and Healthier Work for All' of 10 January 2017.

4.2. Specific objectives

The specific objectives are:

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

4.3. Consistency with other EU policies

Charter of Fundamental Rights of the EU

The objectives of the initiative are consistent with Article 2 (Right to life) and Article 31 (Right to fair and just working conditions) of the EU Charter of Fundamental Rights. Ensuring a safe and healthy work environment is a strategic goal for the European Commission as mentioned in the Communication above.

REACH Regulation

The REACH Regulation[31], adopted in 2006, consolidated and developed several parts of the EU chemicals legislation – principally those relating to risk assessment and the adoption of the risk management measures. The REACH Regulation established the 'registration' of all chemicals above 1 tonne produced or imported in the EU market and 'authorisation' and 'restriction' as risk management measures to control the exposures of chemicals, including substances of very high concern (SVHC), at the workplace or for industrial uses.

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

Restrictions of the presence of carcinogens, mutagens and reprotoxic substances in mixtures and in articles and their use in industrial processes, established under REACH, apply for two of the substances (arsenic compounds, cadmium and its inorganic compounds), subject of this legislative proposal, and two of these substances (arsenic acid and its salts and MOCA can only be used after an authorisation has been granted by the European Commission.

Furthermore, cadmium and five other cadmium compounds have been identified as SVHC for possible inclusion in Annex XIV to REACH, the Authorisation list. A detailed description and the status of the five substances under REACH is presented in Annex 10.

For the preparation of this impact assessment and for the development of the scientific opinions on the proposed limit values, data from the 'registration' dossiers prepared by manufacturers and importers, as well as data that became available to ECHA's Risk Assessment Committee (RAC) and to the Socio-Economic Assessment Committee (SEAC) during the development of opinions for the Commission to decide on authorisations for certain uses or in the restriction process under REACH have been used.

This is a direct result of the REACH REFIT exercise focussing on streamlining the process of generating scientific advice.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

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

A simplified outline of the process for the development of EU OELs for carcinogens is set out here. A more detailed description is provided for in Annex 9.

[31] See footnote 6

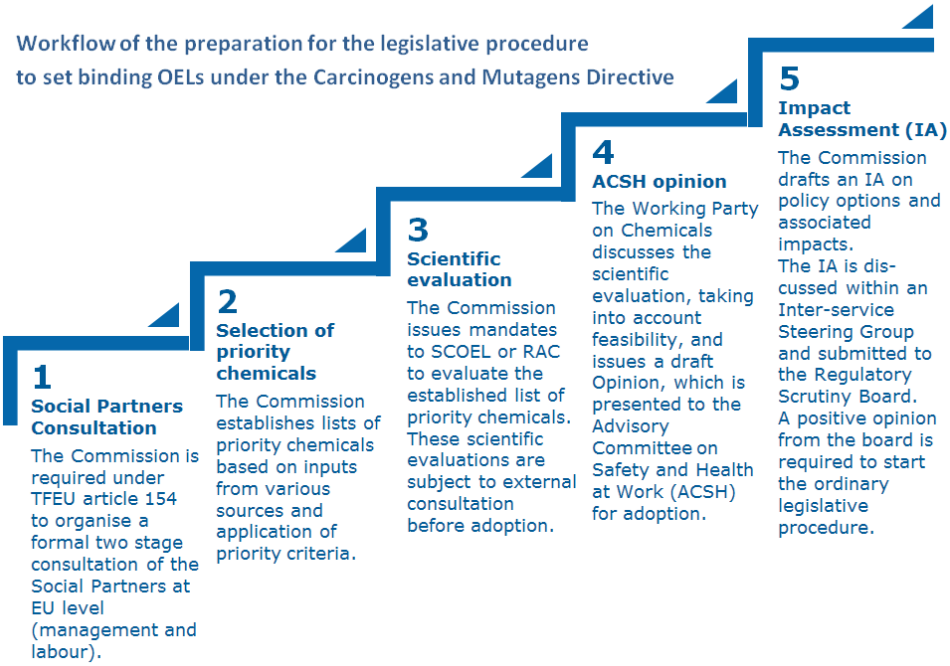

Figure 3: Simplified workflow of preparation for EU OEL setting under CMD

The selection of the specific five carcinogens / groups of carcinogens considered in this impact assessment was based on a consultative approach, including opinions issued by ACSH and formal two-stage consultation of the social partners.

It was agreed by all relevant stakeholders, taking into account factors such as the potential to cause adverse health effects, degree of evidence of such effects, as well as their severity, potency and reversibility, that the five substances are of high relevance for the protection of workers. Commission's intention to prepare for the establishment of OELs for those priority carcinogens was confirmed and encouraged by all the stakeholders.

Considering the occupational cancer burden, it is important to note that when identifying a priority substance, stakeholders look at the whole range of potential negative health effects (carcinogenic and non-carcinogenic) which could be prevented by establishing an EU level OEL. For example, concerning formaldehyde although an impact on cancer prevention is somewhat limited, it will have a major impact on prevention of other relevant non-cancer health problems such as sensory irritation (preventing around 19 200 cases) which otherwise would cause sufferings to these workers and compromise their quality of life. As formaldehyde (and the other four substances) falls under CMD, in order to prevent the whole range of health problems, an OEL can only be established under this directive.

5.2. Retained options for establishing binding OELs under the CMD

The reference limit values per substances, for which explicit calculations have been made by RPA (2018), are presented below.

In addition to the baseline scenario, OELs have been considered at the level proposed by the ACSH and at one or two additional reference points (e.g. the strictest limit value observed among Member States). It needs to be noted that, the most stringent national OEL might not always be feasible as an EU standard for the following reasons: Firstly, the substances subject to this proposal are used in many different industries, and for some

industries it might be difficult to comply with strict OELs due to their specific production processes. Member States with the strictest OELs might not host these industries having problems to comply with the strictest OEL. Secondly, industries are at different stages in their maturity and use varying technologies and processes. Thus, in Member States and industries with more advanced and automated production processes it would be easier to reach a low OEL. These considerations will be taken into account in the analysis substance by substance.

Table 4: Options matrix of OELs (inhalable)

Carcinogen	Option 1 Baseline	Other options		
Cadmium and its inorganic compounds	no EU OEL	1 µg/m^3 (ACSH)	4 µg/m^3 (ACSH transition value)	10 µg/m^3
Beryllium and inorganic beryllium compounds	no EU OEL	0.1 µg/m^3	0.2 µg/m^3 (ACSH)	0.6 µg/m^3 (ACSH transition value)
Arsenic acid and its salts, inorganic arsenic compounds	no EU OEL	10 µg/m^3 (ACSH)	25µg/m^3	50µg/m^3
Formaldehyde	no EU OEL	0.15 mg/m^3	0.37 mg/m^3 (ACSH)	0.6 mg/m^3
4,4'-Methylene-bis(2-chloroaniline) (MOCA)	no EU OEL	5 µg/m^3	10 µg/m^3 (ACSH)	20 µg/m^3

5.3. Options discarded at an early stage

Several other options 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

For most carcinogens even a very low OEL does not completely eliminate the risk of triggering a cancer. 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 already have replaced use of the concerned chemical agents with safer alternatives.

Wherever substitution is a suitable alternative for use of the chemical agents in question the CMD already requires this, regardless of the existence 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.

B. Providing industry-specific scientific information without amending CMD

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.

C. 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. This would require much improved data collection which 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 significantly[32]. This option alone would therefore not be effective in ensuring the same level of minimum protection across the EU.

D. Industry self-regulation

Certain industry initiatives like voluntary product stewardship programmes by companies and sectors, or autonomous social partner agreements, are not legally binding and not applied in all sectors or companies concerned.

Such agreements are very useful tools to improve the situation over time, however, due to the fact that their rules and obligations for members are not always implemented and thus enforced by national authorities, these initiatives can only be considered as complementary tools.

E. Regulation under other EU instruments (REACH)

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

The OSH Directives and REACH are complementary, and clear synergies between REACH and worker protection legislation can be seen – these are set out in more detail in section 4.3 of this report and in Annex 10.

In the case of the present proposal, setting binding OELs under the CMD is the appropriate regulatory instrument. Among the reasons in support of this approach there is the fact that CMD covers worker exposure to carcinogenic agents released by any work

[32] EU-OSHA."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

activity, whether produced intentionally or not, and whether available on the market or not, such as process generated substances in the workplace. Furthermore, CMD is intended to set OELs, which are an important part of the wider OSH approach to managing chemical risks[33].

F. Directly adopting the most stringent national OEL

For most of the carcinogens some Member States adopted OELs more stringent than considered in this proposal. It could be argued that such OELs could be made binding across the EU based on an assumption that what is achievable in one Member State should be achievable in all.

However, the EU sets minimum standards in this area and OELs need to be seen in the context of the minimisation principle. This means that industries have the obligation to minimise exposure below existing OELs if that is technically feasible.

G. Guidance documents

As non-regulatory alternatives, guidance documents or examples of good practice could be developed and disseminated in co-operation with the EU-OSHA and/or the ACSH and its relevant working party. This could also include the development of awareness raising campaigns for employers and workers alike on the prevention of risks arising from workers' exposure to categories 1A and 1B carcinogenic and mutagenic substances. However guidance documents by itself would not be considered effective enough in reaching the objectives of this initiative. They are complementary and provide an added value to setting OELs.

H. Adapted solutions for SMEs

SMEs should not be generally exempted from the scope of the initiative as their exclusion would mean that a very significant number of European workers would not be covered by health and safety at work legislation, with a clear distortion and inequality in the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS AND HOW DO THEY COMPARE?

6.1. Assessed options and how they compare

This chapter provides an analysis of options per chemical agent, indicating first the baseline scenario, followed by a multi-criteria analysis of likely impacts and an assessment of the preferred option compared to the baseline. Finally, a summary assessment of the retained options is presented.

Different policy options presented in the options matrix in chapter 5.2 have been compared based on the methodology outlined in detail in Annex 4. Other options than those supported by the ACSH in its opinions, such as the most stringent OEL, are presented as reference points for the assessment of the ACSH options, to establish whether these are at reasonable levels and, therefore appropriate, to follow. The ACSH as a tripartite committee is an important body to establish consensus and to effectuate the preferences of governments, workers and employers. This consensus, as a result, ensures the effectiveness and enforcement of new OELs to be established. An OEL that is backed

[33] For a detailed analysis of the differences between CMD and REACH see section 4.2, page 34, of SWD(2016)152/2.

by governments, employers as well as workers has secured the acceptance by the three groups and therefore will be easier to implement and to enforce.

The introduction of an OEL is expected to result in a reduction in the occupational exposure to the carcinogen concerned. The extent of such reduction depends on the current levels of exposure, as well as on the projected future levels of exposure in the absence of the proposed measure, i.e. the 'baseline scenario'.

The baseline or "no policy change" option includes all relevant EU-level and national policies and measures which are assumed to continue being in force, in the absence of further EU action. The baseline takes into account how the problem would evolve, considering all relevant societal, economic and technical developments that would probably occur in the following decades. It includes an assessment of how the situation is likely to change in terms of the number of people exposed, exposure concentrations, mortality, investment in Risk Management Measures (RMM), forthcoming changes in national OELs or protective regulation, self-regulatory initiatives, development of new technologies/growing use of substitutes, as well as any other relevant factors.

Given the complementarity between the regulation under REACH and minimum requirements established through the CMD, the past and present REACH measures have been specifically taken into account in assessing the baseline and the impacts of the proposed CMD measures for all substances in this report.

Analytical methods and challenges

For a given reduction in exposure levels, the expected decrease in the incidence of cancer cases and ill health is estimated over a given timeframe attributable to the carcinogen in question. The data in this section have been modelled over a period of 60 years using a static discount rate[34]. The health benefits of avoided cancer cases and deaths are expressed in monetary terms by applying standard evaluation methods[35], in line with the Better Regulation Toolbox guidance.

The cost assessment is largely based on consultations with companies in the specific sectors. The model calculates the costs for a group of similar companies incurred in reducing air exposure to a target OEL based on an assumed sequence of RMM[36] implementation which is determined by suitability, effectiveness, and cost. The Better Regulation Toolbox guidance was followed for the cost calculations.

The benefits and costs of possible OELs are measured against the baseline, meaning that only marginal costs and marginal benefits are taken into account (for example, additional costs added to the current costs to comply with REACH regulations). Concerning environmental impacts, it can be expected that, unless an OEL were to force companies to substitute the carcinogen for another substance or to discontinue production in the EU, such impacts would be minimal.

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[34] The static discount rate is 4%: this is taken over the 60 year period. A dynamic discount rate is taken in the sensitivity analysis. The dynamic rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 40 years.

[35] The valuation of health impacts was undertaken based on two approaches. Approach one is the application of a single willingness to pay (WTP) value to each case and approach two is the use of disability adjusted life years (DALYs) and their monetisation.

[36] The model considers following types of RMMs: Local Exhaust Ventilation (LEV), extraction at source; Worker enclosures (WE), i.e. physical separation of workers in an enclosure or control room; Respiratory Protective Equipment (RPE); General Dilution Ventilation (GDV); Organisational & hygiene measures (OH).

Transposition and enforcement costs for the public sector for all substances are expected to be limited, taking into account that the transposition can be done for more substances at the same time.

There are, however, significant challenges related to the presented analysis. First of all, the disease burden on workers is likely to be underestimated due to several limitations of the study.

When considering the disease burden, only the most sensitive cancer endpoint and the most sensitive other adverse health effects have been considered. However, workers may develop additional types of cancer and diseases at higher exposure levels than the doses for the most sensitive endpoints. Those other cancers / adverse health effects, that will be prevented as well, could not be taken into account when calculating in particular the benefits of the proposed OELs, leading to an underestimation of the potential benefits.

Furthermore, regarding occupational cancer, 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. It can therefore be difficult to establish a causal relationship between cancer cases and exposure to a specific carcinogen. Moreover, occupational cancers may develop decades after exposures – including during retirement – complicating the possibility of identifying a causal link. As a result, the health benefits presented in this report are likely to be underestimated.

The 60 year-time frame of the assessment poses also a challenge of anticipating future industrial developments, technological progress, changes in work organisation, etc. It is difficult to predict future trends in the use of the substances under consideration and therefore in occupational exposures, and how these trends will impact the baseline. Similarly, the assessment of the impact on international competitiveness and innovation could only be based on consultations and the model assumptions of RPA (2018), but not substantiated with hard evidence.

Finally, data on the number of workers exposed is generally scarce and unreliable, and data on the current exposure levels across EU Member States is not always available.

Therefore, the baseline shows more modest figures than other recent studies[37] that estimated past burdens of disease.

Further methodological information is to be found in Annex 4.

Assessment and comparison of options

Regarding health considerations, health impacts could not be fully quantified and all methods using stated preference show uncertain components (e.g. the income and wealth of a person). Thus, a number of other qualitative considerations were taken into account on top of the quantitative calculations. Such considerations include the limitations of the data, and the uncertainty of health effects and scarce epidemiological evidence, as explained above. Moreover, the different timeframes for costs and benefits can also skew a purely quantified calculation. Often, significant parts of costs occur as capital expenditures in the years following the OEL setting, but health benefits, considering the long latency periods for cancer, can occur up to 50 years later. The rather high discount rate of 4% set by the Better Regulation guidelines thus reduces net present value of the benefits more importantly than that of the costs.

[37] Most notably: RPA and FOBIG (2017): The Cost of Occupational Cancer in the EU-28. Final Report prepared for European Trade Union Institute (ETUI).

This impact assessment aims to balance health considerations against economic impacts, by proposing OELs that are still economically feasible while protecting a maximum number of workers.

The study accompanying the impact assessment assessed the different levels without any transitional period. However, the ACSH identified sectors that might find it initially difficult to comply with the OEL proposed, and thus suggested to include transitional periods. The duration of these periods was established by the governments, workers and employers, as they have the expert knowledge about technological development in different sectors. It is assumed that these transitional periods are necessary for companies to develop their production processes to be able to comply with the OELs proposed.

Concluding, the proposal aims to take a balanced approach and to prevent industries from closures or sever disadvantages in particular Member States due to e.g. adopting the most stringent OELs. Furthermore, the CMD lays down the minimum requirements and Member States are free to introduce more stringent provisions.

The comparison tables used to compare the different options against the baseline scenario in terms of effectiveness, efficiency and coherence apply the following ranking symbols:

'0' – baseline, '≈' – similar to baseline, '+' more efficient/effective or coherent than baseline; '++' – much more efficient/effective or coherent than baseline; '-' – less efficient/effective or coherent than baseline; '- -' – much less efficient/effective or coherent than baseline.

6.1.1. Cadmium and its inorganic compounds

Baseline

At present, neither cadmium nor any cadmium compounds have been included in Annex XIV of REACH, the 'Authorisation List'. However, a number of relevant compounds are at earlier stages of the process, which may lead to their eventual inclusion into Annex XIV.

The exposure concentrations have been declining on average by 3% per year.[38] Individual consultation responses, however, have not identified any significant decreases over time. For the future, 0% change in exposure levels and numbers of workers exposed are expected.

In the absence of any further action a limited number of cases of cancer and up to 280 new cases of proteinuria are expected in the coming 60 years. This has been estimated to have a health cost of up to EUR 68 million. However, the fact that only one main cancer (lung) and one main non cancer health effect (elevated proteinuria[39]) have been quantified indicates that the estimated burden resulting from not preventing it can likely be higher.

Table 5: Baseline scenario over 60 years for cadmium and its inorganic compounds

Types of cancer caused	Lung cancer (quantified), kidney and prostatic cancer (not quantified)
Other adverse health effects	Proteinurea (quantified), osteotoxic (toxic to the bones) and respiratory effects (not quantified)
Number of exposed workers	10 000
Change exp. Level	Past: -7% p.a. (level and workers) Future: 0%

[38] This is a generic value that generates a combined 7% decline in the exposed workforce and exposure concentrations; this value is consistent with previous Commission impact assessments.

[39] Proteinuria is the presence of excess proteins in the urine.

Change no. of exposed workers	Past: -7% p.a. (level and workers) Future: 0%
Current disease burden (CDB) - no. of cancer cases	11
Future disease burden (FDB) - no. of cancer cases	5.8
CDB no. of other adverse health effects	500
FDB no. of other adverse health effects	180-280*
Exp. no. of deaths FDB cancer	5
Exp. no. of deaths FDB other adverse health effects	6-8
Monetary value FDB cancer	EUR 5 million
Monetary value FDB other adverse health effects	EUR 9-63 million
Based on RPA (2018) ** Workforce turns over at 5% p.a.*	

Impacts of the policy options

The table below shows the multi-criteria analysis, summarizing both the monetised impacts as well as those that are assessed qualitatively.

Compliance and administrative costs for companies are the largest cost burden across all options. There are between 100 and 150 mainly large companies with workforce exposed to significant levels of cadmium in the EU[40]. The costs are estimated over a 60 year period, with capital expenditures of EUR 412 million and EUR 35 million operating expenditures discounted to a present value for an OEL of 1 µg/m^3.

If the strictest value were to be adopted without any transition period, it could be that a very limited number of companies or business units might relocate (the OELs in competitor countries are higher) or close down, with some associated job losses. This could have some negative consequences for competitiveness as well as innovation. However, a transition period with a higher initial value (as in option 3) would make it possible for companies to anticipate the changes, gradually introduce improvements and plan necessary investments. As a result it is not expected that any closures or job losses would occur. A transition period will also mitigate any negative impact on competitiveness and innovation.

The companies in the key sectors are generally large enterprises, and **only limited evidence of SMEs in the key sectors has been found**[41]. The increase in costs due to having to implement more or better RMMs is calculated to represent in the region of 1.4% of average turnover at the 1 µg/m^3 OEL.

There is no impact expected for consumers or the environment.

The main benefits across all options come from avoided ill-health, in particular avoided lung cancer and elevated proteinurea cases vis-à-vis the baseline. RPA (2018) monetised the health benefits for cadmium for 181 cases of elevated proteinuria under the constant workforce scenario for the baseline, but up to 280 cases can be prevented under an

[40] Located in the Czech Republic, Italy, Germany, France, the Netherland, Poland and the UK.

[41] There could be a few SMEs in particular in the recycling sector. However, since concentrations in the recycling sector are not that high and they are likely to decline significantly in the future as their source is most likely very old TVs or incorrect handling of batteries. In terms of the costs, there should not be a big cost problem for the SMEs in the recycling sector.

assumed workforce turnover of 5% p.a. Options 2 and 3 are also associated with a significant positive effect on simplification and level playing field as currently 80% of Member States' OELs are above the option 2 value and 75% above the option 3 value. This is particularly relevant for this industry where a significant number of affected companies operate across borders.

Table 6: Multi-criteria analysis for cadmium and its inorganic compounds

Impact	Stakeholders affected	Option 2 1 µg/m^3 (ACSH)	Option 3 4 µg/m^3 (Lowest value, ACSH transition value)	Option 4 10 µg/m^3 (Highest value)
Economic impacts				
Compliance and administrative costs	Companies	***€447million assuming that no transition period is established***	***€79–116 million***	***€14-44 million***
Transposition & enforcement	Public sector	***Limited costs***	***Limited costs***	***Limited costs***
Benefits from reduced ill health	Reduction in cancer cases	***6***	***6***	***4***
	Reduction in cases elevated proteinuria	***181***	***176***	***92***
	Employers	***Moderate costs avoided:*** *€1.0-€1.4 million*	***Moderate costs avoided:*** *€0.9-€1.3 million*	***Limited costs avoided:*** *€0.5-€0.7 million*
	Public sector	***Moderate costs avoided:*** *€4.6-€6.7 million*	***Moderate costs avoided:*** *€4.5-€6.5 million*	***Moderate costs avoided:*** *€2.4-€3.4 million*
Single-market: consumers	Consumers	***No/very low impacts identified***		
Simplification /level playing field	Companies	***Significant positive impact*** % of MS currently above the OEL: 80%	***Significant positive impact*** % of MS currently above the OEL: 75%	***Significant positive impact*** % of MS currently above the OEL: 55%
International competitiveness	Companies	***Potential negative impact, if no transition period is established***		***Moderate impact***
Specific MSs/regions	MSs	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL?, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	AT, BG, HR, CY, CZ, DK?, FR, HU, IE, LV, LT, NL, SI, SE, UK
Social impacts				
Ill health avoided	Workers & families	€9m-€59m	€9m-€57m	€5m-€30m
Employment	Jobs lost	*Limited impact*	*Very limited impact*	*Very limited impact*
Environmental impacts				
Environmental releases	Environment	***No impact/limited impact***		
Recycling – loss of business	Recycling companies	***Negative impact if no transition period is established***	***No impact/limited impact***	
Based on RPA (2018); NB: a transition period was not considered in the analysis				

Comparison of the policy options

Concerning the effectiveness, an OEL of 1 µg/m^3 (Option 2) appears as the most effective option as it will prevent all the cases of cancer and proteinuria expected under the baseline. Moreover, the ACSH agreement on the Option 2 value has to be considered when looking at the effectiveness of option 2. This OEL is backed by employers as well as workers and would thus be easier to implement and to enforce.

Concerning the efficiency, the costs of option 2 are significant. The Employers Interest Group noted in the ACSH opinion[42] that a fundamental change to the OSH risk management strategy in the cadmium industry, along with the redesign and commissioning of more complex air cleaning systems, will be required by option 2. However, by combining the OEL of 1 µg/m^3 with a transition period of 7 years at 4 µg/m^3 the costs for employers and also the impact on employment are mitigated, thus the efficiency of this option is increased.

Concerning coherence, establishing an OEL following option 2 also increases the coherence of the CMD with other EU policy objectives, including the Charter for fundamental rights. It also increases complementarity with REACH, as outlined in chapter 4. Moreover, establishing new OELs will increase legal clarity, provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements, and will also contribute to a level-playing field for businesses across the EU (see chapter 3). Coherence with general EU priorities and policies, as well as with the Charter of Fundamental Rights, is considered to be the highest for the strictest OEL, as it is the most protective of workers' health.

Option 2, with a transitional period of 7 years at the level of option 3, is therefore the preferred option.

Table 7: Cadmium and its inorganic compounds – comparison of options

Criteria	Option 1: Baseline	Option 2: 1 µg/m^3 (ACSH opinion)	Option 3: 4 µg/m^3	Option 4: 10 µg/m^3
Effectiveness	0	+	+	≈
Efficiency	0	-	-	≈
Coherence	0	++	+	+

6.1.2. Beryllium and inorganic beryllium compounds

Baseline

Around 54 000 workers in the EU are exposed to beryllium and its inorganic compounds. The sectors using beryllium that have been examined for this impact assessment are foundries, metal fabrication, transport, ICT, specialist manufacturers, medical devices, glass, construction, laboratories and recycling.

The construction sector has been excluded from the baseline scenario, as there was little reliable data about exposed workers and affected enterprises in this sector. This exclusion might lead to an underestimation of the numbers of workers exposed to beryllium, in particular in light of the large workforce in this sector. In addition, there is a lack of published data for the monetisation of chronic beryllium disease.

[42] The Employers Interest Group highlighted their preference of the use of an exposure biomarker over an OEL for the prevention of systemic adverse effects. The Workers Interest Group supported the approach of delivering an exposure-risk-relationship (ERR) for these compounds.

Beryllium is not on the authorisation list of REACH at present and there are no restrictions. As such, these regulatory mechanisms are not imparting any direct impact on worker exposures.

For the current burden of disease, it is assumed that the numbers of workers in these sectors have decreased by 1% per year and the exposure concentrations have decreased by 3% per year. The estimates for the future burden of disease are based on the assumption that the number of workers exposed to beryllium and its inorganic compounds and the associated exposure concentrations will slightly decrease. The main significant end health point for exposure to beryllium is chronic beryllium disease.

In the absence of any further action, further 4 602 new cases of chronic beryllium disease are expected in the coming 60 years. Further, the estimated latency period for the disease is as short as two years, whereas the estimated treatment period is as long as thirty years with fatality rate of 10%. This has been estimated to have a health cost between EUR 420 million and EUR 1.9 billion.

The below table illustrates the baseline scenario for beryllium and its inorganic compounds.

Table 8: Baseline scenario over 60 years for beryllium and inorganic beryllium compounds

Types of health effect caused	Chronic beryllium disease (quantified), allergy or asthma symptoms, beryllium respiratory sensitisation, skin sensitisation, cardiovascular, renal, hepatic and haematological effects (not quantified)
No. of exp. workers	54 071 (excluding construction sector)
Change in exposure levels	Past: -3% per year Future: Expected 2% per year reduction
Change number of exposed workers	Past: -1% per year Future: Expected 3% per year reduction
Current disease burden (CDB) - no. of chronic beryllium disease cases	Exposure in sectors considered in this study over the past 40 years: 3 807
Future disease burden (FDB) - no. of chronic beryllium disease cases	3 068 -4 602*
Exp. no. of deaths (FDB) from chronic beryllium disease	307 - 460*
Monetary value FDB from adverse health effects	EUR 290 million – EUR 1.9 billion
Based on RPA (2018) **Workforce turns over at 5% p.a.*	

Impacts of the policy options

The table below shows the multi-criteria analysis, summarizing both the monetised impacts as well as those that are assessed qualitatively in this report.

Compliance and administrative costs for companies are the largest cost burden across all options. **Beryllium is mostly used by SMEs**. There are about 5 800 companies consisting of 92% small, 7% middle and 1% large enterprises in the EU (excluding the construction sector) with workforce exposed to beryllium.

The costs for businesses are estimated over a 60-year period and discounted to present value. At an OEL of 0.1 µg/m^3, the capital expenditures for all businesses are estimated to be EUR 875 million with operating expenditures of EUR 128 million. At an OEL of 0.2 µg/m^3, the capital expenditures for all businesses are estimated to be EUR 87 million with operating expenditures of EUR 47 million. At an OEL of 0.6 µg/m^3, the capital

expenditures for all businesses are estimated to be EUR 26 million with operating expenditures of EUR 16 million.

For small companies, the costs per firm are estimated to range for an OEL of 0.1 µg/m^3 between EUR 21 425 to EUR 28 577, for an OEL of 0.2 µg/m^3 between EUR 9 214 to EUR 14 904 and for an OEL of 0.6 µg/m^3 between EUR 2 862 to EUR 4 940. The highest costs will be faced by small companies in the sectors foundries, metal fabrication and laboratories. For all of the three options the costs for a small company as a % of turnover is less than 0.25%.

Stakeholders have expressed doubts about the feasibility for certain processes to achieve exposures below 0.2 µg/m^3 and that these processes could move outside the EU if a lower OEL is set. Under the strictest OEL of 0.1 µg/m^3, up to 4% of companies could potentially close due to technical difficulties achieving such a low OEL.

Only the lowest OEL would have a likely negative impact on competitiveness due to companies exiting the market and (1) removing the provision of specialist services completely and (2) causing a concentration of the market into a small number of companies. Substitution is rarely an option for production with beryllium. However, companies are expected to be able to comply with OELs above 0.2 µg/m^3 and international competitiveness should not be affected, taking into account a proposed transitional period. The aspects likely to be affected are innovation, research and development leading to new products in high technology areas where beryllium plays a key role such as electric cars and solar power. It is not possible though to determine the extent of these effects. Also, the global nature of the markets using beryllium means that companies using the substance outside of the EU will be at a competitive advantage where any regulatory requirements in force locally are lower than the proposed harmonised OELs.

There is no impact on employment for an OEL starting with the lowest feasible OEL of 0.2 µg/m^3. Moreover, there is no impact expected for consumers or the environment.

The main benefits across all options come from avoided ill-health, in particular from avoided cases of chronic beryllium disease vis-à-vis the baseline and from improved level playing field for companies.

Table 9: Multi-criteria analysis for beryllium and inorganic beryllium compounds, excluding construction

Impact	Stakeholders affected	Option 2 <=0.1 µg/m^3 (Lowest value)	Option 3 0.2 µg/m^3 (ACSH)	Option 4 0.6 µg/m^3 (Highest value, ACSH transition value)
Economic impacts				
Compliance costs	Companies	***> €1 billion***	***€130 million***	***€40 million***
Company closures	Companies	***Significant impact***	***No impact***	***No impact***
Transposition and enforcement costs	Public sector	***Limited costs*** 95% of MS would have to transpose	***Limited costs*** 80% of MS would have to transpose	***Limited costs*** 80% of MS would have to transpose
Benefits from reduced ill health	Reduction in CBD cases	2 800 -3 100	2 400	1 600
	Employers	***Moderate*** *> €17 million*	***Moderate*** *€15 million*	***Moderate*** *€10 million*
	Public sector	***Moderate*** *> €25 million*	***Moderate*** *€21 million*	***Moderate*** *€15 million*

Impact	Stakeholders affected	Option 2 <=0.1 µg/m^3 (Lowest value)	Option 3 0.2 µg/m^3 (ACSH)	Option 4 0.6 µg/m^3 (Highest value, ACSH transition value)
Single-market: competition/ level playing field	Companies	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 'no difference'	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 6	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 6
Single-market: consumers	Consumers	***Limited impact***		
Simplification	Companies	***Significant positive*** % of MS currently above the OEL: 95%	***Significant positive*** % of MS currently above the OEL: 80%	***Significant positive*** % of MS currently above the OEL: 80%
Specific MSs/regions	Member States	***Significant*** AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK, plus IT, LU, MT, NL, PT	***Significant*** AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT	***Significant*** AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT
Health and social impacts				
Deaths avoided	Workers & families	***Significant*** 270 - 302	***Moderate*** 223	***Moderate*** 150
Ill health avoided including intangible costs	Workers & families	> €240 million	€200 million	*< €140 million*
Employment – social cost (salary lost)	Workers	***Moderate*** €17 – 180 million	***None***	***None***
Environmental impacts				
Environmental releases	All		***Neutral impact***	
*Based on RPA (2018);**NB: a transition period was not considered in the analysis***				

Comparison of the preferred policy option

Concerning the effectiveness, option 2 would have the most positive effect on preventing deaths and ill health but option 3 is quite closely matched. Option 3 is also the result of in-depth discussions between the representatives of workers, employers and governments in the ACSH. This OEL, backed by stakeholders, would thus be easier to implement and to enforce. The workers noted that an OEL should in the future possibly go lower than 0.2 µg/m^3 to optimally protect workers.

Beryllium is a respiratory sensitiser. Beryllium and beryllium compounds can also cause allergic contact dermatitis or a granulomatous skin reaction in humans. Beryllium compounds have been shown to be skin sensitisers in animal experiments. A notation for dermal and respiratory sensitisation is therefore recommended.

Concerning the efficiency, option 3 has the best cost-benefit ratio. The Employers Interest Group noted in the ACSH opinion[43] that achieving an OEL of 0.2 µg/m^3 is a very challenging target in terms of technical feasibility. Therefore, the impacts on companies can be further mitigated by combining the OEL of 0.2 µg/m^3 with a transition period of 5 years at 0.6 µg/m^3. Concerning the efficiency, the benefits outweigh the costs for option 3. Moreover, by combining the OEL of 0.2 µg/m^3 with a transition period of 5 years at 0.6 µg/m^3 the negative impact on companies created by possible additional costs can be further mitigated.

Concerning coherence, establishing an OEL following option 3 also increases the coherence of the CMD with other EU policy objectives, including the Charter for fundamental rights. It increases complementarity with REACH, as outlined in chapter 4. It will provide legal clarity and a common reference point that can be used as a practical tool by employers (particularly important for SMEs), workers and enforcers to assess compliance with the general CMD requirements, and will also contribute to a level-playing field for businesses across the EU (see chapter 3). Coherence with general EU priorities and policies, as well as with the Charter of Fundamental Rights, is considered to be the highest for the strictest OEL, as it is the most protective of workers' health.

Option 3, with a notation 'Sensitisation (dermal and respiratory)', and with a transitional period of 5 years at the level of option 4, is therefore the preferred option.

Table 100: Beryllium and inorganic beryllium compounds – comparison of options

Criteria	Option 1: Baseline	Option 2: 0.1 µg/m^3 (Lowest value)	Option 3: 0.2 µg/m^3 (ACSH opinion)	Option 4: 0.6 µg/m^3 (ACSH transition value)
Effectiveness	0	++	+	+
Efficiency	0	-	++	+
Coherence	0	++	++	+

6.1.3. Arsenic acid and its salts, as well as inorganic arsenic compounds

Between 7 900 to 15 300 workers are estimated to be exposed to inorganic arsenic compounds, and 18 000 to 102 000 workers are potentially exposed at levels below the lowest OEL assessed.

The calculations, by not including the larger number of workers (those potentially exposed), underestimates the total current burden of exposure. Moreover, the dose-response relationship (DRR) estimated as part of this study is based on limited available data. The estimate must be considered quite uncertain and to represent the order of magnitude only.

Inorganic arsenic compounds are intentionally used in the glass sector, electronics sector and the primary zinc sector. Whereas a large number of workers a few decades ago were exposed at high levels to arsenic, the number of workers and exposure levels have decreased markedly due to restriction of some of the main uses of arsenic compounds and due to implementation of better RMMs.

[43] The Workers Interest Group noted that the OEL should be reviewed in due time with a view to lowering it to be protective against beryllium sensitisation.

Unintentional use in raw materials occurs in the non-ferrous metal sector, the ferrous base metal sector, the energy sector and the chemical sector. Concerning the unintentional use, arsenic is present typically in concentrations below 0.1%. However, it cannot be excluded that some workers, e.g. in maintenance works in settings with arsenic-rich dusts, could be exposed at levels above the lowest of the assessed OELs. In the sectors with the major exposure to inorganic arsenic compounds, the arsenic is present as unintentional constituent of raw materials and it is anticipated that these exposures will not be influenced by any actions under REACH.

For the major sectors, no significant trend in exposed workforce is observed, but where data is available the number of workers exposed at high levels shows a decrease. The future trend is set at -1%. As for the exposure concentrations, with expected increasing arsenic concentrations in the raw materials, as well as potential further exposures, for example in recycling, the exposure concentrations would increase if nothing else was done. However, this increase will likely be counterbalanced by RMMs.

In the absence of any further action a limited number of cases of cancer and 574 cases of neurotoxic effects are expected in the coming 60 years. This has been estimated to have a combined health cost of EUR 39.6 million. Other related health effects such as cancer of skin, urinary bladder, kidney, liver and prostate have not been taken into account.

The below table illustrates the baseline scenario.

Table 11: Baseline scenario over 60 years for arsenic acid and its salts, as well as inorganic arsenic compounds

Types of cancer caused	Lung cancer (quantified) cancer in the skin, liver, lungs, bladder and kidney (not quantified)
Other adverse health effects	Peripheral neuropathy (quantified), cardiovascular effects and immunotoxicity, skin changes and black foot disease (not quantified)
No. of exp. Workers	7 900-15 300 (assessed) 18 000 – 102 000 (potentially exposed at levels below the lowest OEL assessed)
Change exp. Level	Past: -8% Future: -1%
Change no. of exp. Workers	Past: -2% Future: 0
Current disease burden (CDB) - no. of cancer cases	17.2 *
Future disease burden (FDB) - no. of cancer cases	20
Current disease burden (CDB) - no. of peripheral neuropathy cases	905 *
FDB no. of other adverse health effects	574
Exp. no. of deaths FDB cancer	16
Exp. no. of deaths FDB, other adverse health effects	None
Monetary value FDB cancer	EUR 16.356 million
Monetary value FDB other adverse health effects	EUR 23.31 million
* Excludes burden of disease from exposure to prohibited applications; first of all the former use in CCA wood preservatives, CCA-preserved wood, other biocides and pesticides which have been major exposure sources. According to CAREX data, these applications accounted for half of the exposed workforce in 1993/97.	
Based on RPA (2018)	

Impacts of the policy options

Overall, the estimated compliance costs are very small compared to industry activities. For an OEL of 10 µg/m^3, one-off capital expenditures of businesses amount to EUR 11 million, and recurring operating costs to EUR 10 million. The estimated compliance costs over the 60 year period are below 0.5% of industry turnover per exposed worker. For a majority of affected companies, the measures needed to achieve compliance are respiratory protective equipment and therefore, the costs are more or less proportional to the number of workers. The highest impacts would be in the first year with relative high investment costs that need to be financed. The most affected sector is expected to be the copper sector. Comparing the compliance costs (CAPEX and OPEX) per exposed worker in the copper sector with that annual turnover, these represent a maximum of 5% of turnover in the first year. Although this could be challenging in case the affected company would have limited access to finance, it is still considered manageable.

Overall, **there is no indication of significant issues for SMEs in any of the affected sectors.** While a few of the affected production sites/companies in the copper sector are relatively small, they are owned by larger companies and therefore they might not be formally SMEs. It means that they are likely to have access to technical expertise and financial resources that will ease the compliance with the considered OELs.

The impacts of introducing any of the OELs on competition and competitiveness are estimated to be relatively modest and no significant impact on innovation is expected. Employment and the environment are also not expected to be affected by any of the options.

The main benefits across all options stem from avoided ill-health, in particular from avoided cases of lung cancer and peripheral neuropathy disease vis-à-vis the baseline and from an increased level playing field for companies.

The applications for authorisation under REACH for diarsenic trioxide have been studied for the preparation of this report. Increased releases to the environment are not expected from the application of lower OELs. Companies using arsenic acid and inorganic arsenic compounds have to comply with the Industrial Emissions Directive 2010/75/EU (integrated pollution prevention and control), as well as with site specific environmental permissions.

The multi-criteria analysis in the table below summarises the main impacts.

Table 12: Multi-criteria analysis for arsenic acid and its salts, as well as inorganic arsenic compounds

Impact	Stakeholders affected	Option 2 10 µg/m^3 (ACSH)	Option 3 25 µg/m^3 (Mean value)	Option 4 50 µg/m^3 (Highest value)
Economic impacts				
Compliance costs	Companies exposing their workers	***€21.2 million***	***€11 million***	***€1.6 million***
Transposition costs	Public sector	***Limited impact***	***Limited impact***	***Limited impact***
Benefits from reduced ill health	Reduction in number of cancer cases	***3***	***2***	***1***
	Reduction in numbers of peripheral neuropathy cases	***574***	***468***	***393***
	Employers avoided costs	***€2.8 million***	***€2.3 million***	***€1.9 million***
	Public sector avoided	***€1.3 million***	***€1.1 million***	***€0.9 million***

	costs			
Single-market: competition		***Limited impact - no closures expected***		
Single-market: consumers		***No impact***	***No impact***	***No impact***
Single-market: internal market	Companies / Positive impact /level playing field	Reduction of highest OEL/lowest OEL ratio from 71 to 4	Reduction of highest OEL/lowest OEL ratio from 71 to 9	Reduction of highest OEL/lowest OEL ratio from 71 to 18
International competitiveness		***No impact***	***No impact***	***No impact***
SMEs		***No or very limited impact***	***No impact***	***No impact***
Specific MS/regions	MSs that would have to change OELs Companies that might be impacted	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, HR, CZ, FR, EL, HU, IT, LU, MT, PT, SK, SI, UK
Social impacts				
Ill health avoided – lung cancer and peripheral neuropathy (incl. intangible costs)	Workers & families	***€9 to €34 million***	***€7 to €28 million***	***€5to €23 million***
Other health points	Workers & families	Additional ill-health from other types of cancer and non-cancer endpoints not included in the assessment (expected to be lower than the assessed endpoints)		
Employment	Workers	***No impact***	***No impact***	***No impact***
Environmental impacts				
Environmental releases		***No impact*** (expected that exhaust air from ventilation systems is filtered before released to the environment)		
Recycling – loss of business	Recycling companies	***No impact***		
Recycling – durability of consumer goods, etc.		***No impact***		
Based on RPA (2018)				

Concerning effectiveness, option 2 will have the most positive impact on prevention of deaths and ill health compared to the baseline and other options. In addition, option 2 is a result of in-depth discussions between the representatives of workers, employers and governments in the ACSH and would thus be the easiest to implement and to enforce.

Concerning efficiency, the benefits outweigh the costs for all options. This is also the case for the most stringent OEL under option 2, where the calculation shows that benefits of almost 26 million EUR (method 1) outweigh costs of some 21 million EUR over 60 years. However, the ACSH noted that the OEL could be technically challenging for the copper smelting sector, and a prolonged transitional period may be necessary. No other concerns about technical feasibility, overall costs or impact on competitiveness outside the EU have been raised by employers' representatives or government representatives.

Concerning coherence, option 2 also increases the coherence of the CMD with other EU policy objectives, including the Charter for fundamental rights. It will increase the complementarity with REACH, as outlined in chapter 4. Moreover, it will provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements, and will also

contribute to a level-playing field for businesses across the EU (see chapter 3). Coherence with general EU priorities and policies, as well as with the Charter of Fundamental Rights, is considered to be the highest for the strictest OEL, as it is the most protective of workers' health.

Option 2, with a transition period for copper smelting, is therefore the preferred option.

Table 13: arsenic acid and its salts, as well as inorganic arsenic compounds – comparison of options

Criteria	Option 1: Baseline	Option 2: 10 µg/m^3 (ACSH opinion)	Option 3 25 µg/m^3 (Mean value)	Option 4 50 µg/m^3 (Highest value)
Effectiveness	0	++	+	+
Efficiency	0	+	+	+
Coherence	0	++	+	+

6.1.4. Formaldehyde

Baseline

Around 990 000 workers are estimated to be exposed to formaldehyde. Formaldehyde is used in a wide array of economic sectors, ranging from agriculture, forestry and fishing, manufacturing of food products, manufacture of textiles, manufacture of leather and related products, manufacture of wood and products of wood and cork - except furniture, manufacture of paper and paper products, manufacture of chemicals and chemical products, manufacture of basic pharmaceutical products and pharmaceutical preparations, manufacture of rubber and plastic products, etc. to professional, scientific and technical activities, human health and funeral and related activities. Given the many and various economic sectors formaldehyde is used in, there is only limited availability and reliability of sector-specific data (i.e. exposed workers/companies; exposure concentrations and currently implemented RMMs).[44]

REACH is not expected to impact the baseline. Formaldehyde is registered under REACH. However, its intermediate use in resins and chemical synthesis is not covered under REACH[45], and formaldehyde-based resins are also not registered as they are considered as polymers. This includes resin manufacturing which is a major use of formaldehyde. Formaldehyde use is also covered under other regulations. For example, the use of formaldehyde in biocidal applications is covered by the Biocidal Product Regulation and wood-based panels are covered under EN standards.

[44] No information was received from the consultation process for the following sectors which are sectors that may have high costs for implementing the proposed OEL: Manufacture of textiles (NACE Code C13), manufacture of paper and paper products (NACE Code C17). The exposure concentrations for these sectors have been taken from a 2013 study by TNO Triskelion for Formacare.
For Human health activities (NACE Code Q86) information was received only from Germany and the Netherlands. No information was also received for the sectors: manufacturing of food products (NACE Code C10), leather and related products (NACE Code C15), rubber and plastic products (NACE Code C22), electrical equipment (NACE Code C27), motor vehicles, trailers and semi-trailers (NACE Code C29), furniture (NACE Code C31), and the construction of buildings (NACE Code F41). Literature review provided the basis for the values used in these sectors.

[45] Concluded from the risk management option analysis (RMOA) performed by ANSES in 2016 and from further clarification between ANSES and industry.

The current burden of disease has been estimated assuming that the number of workers in the relevant sectors has been decreasing by 3% per annum and the exposure concentrations have not changed. The number of cases expected to occur in the future is given below. It is assumed that the number of workers and exposure concentrations will remain stable in the future.

In the absence of any further action a limited number of cancers and 19 200 cases of sensory irritation are expected in the coming 60 years. This has been estimated to have a combined health cost between EUR 1.4 billion and EUR 8 billion.

The below table illustrates the baseline scenario for formaldehyde.

Table 14: Baseline scenario over 60 years for formaldehyde

Types of cancer caused	Nasopharyngeal cancer (quantified), leukaemia, tumour induction (not quantified)
Other adverse health effects	Sensory irritation (quantified), potential cancer precursor effects (not quantified)
No. of exp. Workers	990 000
Change exp. Level	Past: -5% p.a. (exp. level & workers) Future: 0%
Change no. of exp. Workers	Past: -3% p.a. (exp. level & workers) Future: 0%
Current disease burden (CDB) - no. of cancer cases	330 per year (due to past exposure)
Future disease burden (FDB) - no. of cancer cases	7*
CDB no. of other adverse health effects	19 200 cases of sensory irritation
FDB no. of other adverse health effects	19 200 cases of sensory irritation*
Exp. no. of deaths FDB cancer	3
Exp. no. of deaths FDB other adverse health effects	0
Monetary value FDB cancer	EUR 4 million to EUR 3 billion
Monetary value FDB other adverse health effects	EUR 1 billion to EUR 5 billion
Based on RPA (2018) In case of formaldehyde due to the cumulative nature of cancer risk, the burden caused by the two modelled health endpoints is the same under both the worker 'turnover' and 'no turnover' scenarios.	

Impacts of the policy options

SCOEL has derived an OEL of 0.37 mg/m^3 with a corresponding short-term exposure limit (STEL) of 0.738 mg/m^3 since sensory irritation is a concentration rather than a cumulative dose-driven effect[46]. The costs and benefits for STEL values could not be monetised for formaldehyde.

Formaldehyde is a well-known contact allergen to the skin (skin sensitiser). A notation 'sensitisation (dermal)' is therefore recommended by SCOEL.

It is estimated that 133 926 small enterprises, 8 384 medium and 9 039 large enterprises have workers exposed to formaldehyde to some degree in the EU. EU MS with more than 10 000 enterprises using formaldehyde are France, Germany, Italy, Poland, Spain

[46] There are insufficient criteria to develop a dose response relationship with effects at other selected short-term exposure limits (STELs); and there are potential issues for measuring the STEL which are discussed in the study accompanying the impact assessment.

and the United Kingdom. No enterprises are expected to cease trading as a result of the introduction of any of the considered OELs. As a result, no impacts on competition are envisaged and also no significant impact on innovation is expected.

All options are associated with compliance and administrative costs for companies. However, **the compliance costs associated with meeting even the strictest OELs represent less than 1% of SMEs' total turnover in the different sectors that would be affected**. Consequently, workers are overall unlikely to lose their jobs as a result of the introduction of any of the OELs. Moreover, businesses may be able to absorb these cost increases without significant impacts on prices and, therefore on competitiveness or on consumers. For all small enterprises, an OEL of 0.37 mg/m^3 would lead to estimated capital expenditures of EUR 21 million, but save the businesses operating costs of EUR 8 million, totalling costs at 13 million over 60 years. Similarly, medium enterprises would face capital expenditures of EUR 257 million and save operating expenditures of EUR 81 million over 60 years.

Currently, businesses using formaldehyde face different OELs in different MS, with the ratio of the highest OEL to the lowest OEL being 20:1. In the event that an OEL of 0.6 mg/m^3 is introduced, that ratio would reduce to 4:1[47], to approximately 2:1 under an OEL of 0.37 mg/m^3. Greater harmonisation will also benefit those businesses which already, or might wish to, operate in multiple Member States.

The main benefits across all options come from avoided ill-health, in particular from avoided cases of nasopharyngeal cancer and sensory irritation vis-à-vis the baseline. Moreover, there is a significant positive impact from increased competition and from a level playing field for companies.

Table 13: Multi-criteria analysis for formaldehyde

Impact	Stakeholders affected	Option 2 0.15 mg/m^3 (Lowest value)	Option 3 0.37 mg/m^3 (ACSH)	Option 4 0.6 mg/m^3 (Highest value)
Economic impacts				
Compliance costs	Companies	€10.34 billion	€1.72 billion	€0.07 billion
Transposition costs	Public sector	Limited impact	Limited impact	Limited impact
Benefits from reduced ill health	Reduction in cases (lung cancer)	*7*	*7*	*7*
	Reduction in cases (sensory irritation)	***19 200*** *(*on any given day)	***19 200*** *(*on any given day)	***19 200*** *(*on any given day)
	Reduction in DALYs	***115 510***	***115 510***	***115 510***
	Employers (avoided costs)	***€0.03 million***	***€0.03 million***	***€0.03 million***
	Public sector (avoided costs)	***€181 million***	***€181 million***	***€181 million***
Single market: competition	No. of company closures	*0*	*0*	*0*
Single-market: consumers	Consumers	***No impacts identified***	***No impacts identified***	***No impacts identified***
Single market: internal market	Companies	***Significant positive impact*** Reduction of highest	***Significant positive impact*** Reduction of highest	***Positive impact*** Reduction of highest

[47] NL has the lowest OEL for formaldehyde of 0.15 mg/m3.

		OEL/lowest OEL ratio from 20:1 to 'no difference'	OEL/lowest OEL ratio from 20:1 to 2:1	OEL/lowest OEL ratio from 20:1 to 4:1
International competitiveness	Companies	***Limited impact***	***Limited impact***	***Limited impact***
Specific MSs/regions	MSs	All except NL	BE, BG, HR, CY, CZ, DK, EL, EE, HU, IT, LV, LT, LU, MT, PL, RO, SI, ES, UK	BE, BG, HR, CY, EL, IT, LU, MT, RO, ES, UK
Social impacts				
Ill health avoided (incl. intangible costs)	Workers & families	***€1 billion or €5 billion*** (depending on method applied)		
Employment	Jobs lost	***No impacts identified***		
	Social cost	***No impacts identified***		
Environmental impacts				
Environmental releases	Environment	***Limited impacts*** under all options		
Recycling – loss of business	Recycling companies	***Limited impacts*** under all options		
Notes: All costs/benefits are incremental to the baseline (PV over 60 years).				
Based on RPA (2018)				

Concerning effectiveness, the positive effects on prevention of death and ill health are closely matched for all three options. All are expected to prevent 7 cases of cancer and 19 200 cases of sensory irritation compared to the baseline. However, option 3 is a result of in-depth discussions between the representatives of workers, employers and governments in the ACSH and the backing of all stakeholders will make it the easiest to implement and to enforce.

Concerning the efficiency, option 2 is the most costly for business while not resulting in higher benefits in comparison to the remaining options. Benefits outweigh costs in both option 3 and 4, and in case of option 3 the Employers Interest Group in the ACSH did not note any difficulties in complying with the OEL of 0.37 mg/m^3 other than for some specific processes[48]. No transition measures were requested by Employers Interest Group with regard to this OEL.

Concerning coherence, establishing an OEL following option 3 increases the coherence of the CMD with other EU policy objectives, including the Charter for fundamental rights. It increases complementarity with REACH, as outlined in chapter 4. It will provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements, and will also contribute to a level-playing field for businesses across the EU (see chapter 3). The stricter the adopted OEL, the more coherence is expected in general. However, in this case all options score similar in terms of coherence.

Option 3, with a notation 'dermal sensitisation ' is therefore the preferred option.

Table 146: Formaldehyde – comparison of options

[48] The Employers Interest Group of the ACSH noted that in some companies and for specific tasks, complying with the proposed OEL seems technically difficult, in particular for companies proceeding to gluing and varnishing using mixtures with formaldehyde or formaldehyde releasing resins. For those companies, achieving the proposed OEL would therefore require new equipment and/or organisational measures, which would entail additional investment and costs.

Criteria	Option 1: Baseline	Option 2: 0.15 mg/m^3 (lowest value)	Option 3: 0.37 µg/m^3 (ACSH opinion)	Option 4: 0.6 mg/m^3 (Highest value)
Effectiveness	0	+	++	+
Efficiency	0	--	+	+
Coherence	0	++	++	++

6.1.5. 4,4'-Methylene-bis(2-chloroaniline) (MOCA)

Baseline

350 workers are estimated to be exposed to MOCA in the EU across around 89 production sites. In addition, about 1 200 workers are indirectly exposed to MOCA via the dermal route. Exposure is not expected to change in the future. The key sector using MOCA is the plastics sector. The assessment of the baseline is done for two scenarios: under the assumption that the REACH authorisation is granted and the use of MOCA continues for a period of time, and the assumption that authorisation is not granted and the use of MOCA discontinues.

Both the current burden on disease due to past exposure and the future burden of disease are estimated at relatively low numbers. The exposure risk relationships (ERR) based on workplace concentrations and urinary level, respectively, are both established by the RAC and considered to reflect the current knowledge about the lung cancer effects of the substance.

Table 15: Baseline scenario over 60 years for MOCA

Types of cancer caused	Lung cancer (quantified), bladder cancer (not quantified)
Other adverse effects	No sufficient data available
No. of exp. workers	350
Change exp. Level	Past - 4% Future -1%
Change no. of exp. workers	Past - 3% Future 0%
Current disease burden (CDB) - no. of cancer cases based on previous 50 years exposure	0.0005
Future disease burden (FDB) - no. of cancer cases	0.0036
Exp. no. of deaths FDB cancer	0.0019
Monetary value FDB cancer	EUR 3 000
Based on RPA (2018)	

Impacts of the policy options

The multi-criteria analysis indicating impacts and stakeholders affected is summarised below. The conclusions are drawn on the basis that the current levels of exposure is typically below the lowest of the OELs assessed and consequently the estimates are not sensitive to the number of exposed workers, the relationship between exposure and effects and the costs of cancer cases. The uncertainty is consequently related to the estimated exposure levels.

All affected companies of a possible OEL for MOCA are **SMEs**. In the application for authorisation under ECHA, 20% are micro, 65% are small and 15% are medium size

enterprises. Two thirds of estimated workers exposed to MOCA work in moulders at estimated 89 sites across the EU[49].

The total costs of compliance will depend mainly on the number of workers affected, as the main cost is estimated to be costs of monitoring, thus operating costs. The frequency for monitoring is determined nationally. For this impact assessment, it is assumed that companies will be required to undertake one monitoring programme to demonstrate compliance. Capital expenditures for businesses are not expected. The unit cost of monitoring is found to be independent from the company size, as it mostly depends on the consultant and laboratory used[50], and is thus expected to be affordable for all businesses, including microbusinesses. **The costs of monitoring are small and the economic impact on each company will be negligible**. Thus, establishing a reference OEL of (Option 2) or above 5 µg/m^3 (options 3 and 4) would not have any impact on competition, competitiveness, innovation, employment or consumer prices.

Establishing the reference OELs would have some positive impact on the level playing field and legal clarity. 13 MS[51] have an OEL higher than the lowest assessed OEL of 5 µg/m³ and 11 MS[52] do not have any OEL. Only three MS[53] have an OEL corresponding to the lowest assessed OEL of 5 µg/m³. The ratio of highest OEL/lowest OEL ratio is currently 44.

As exposure via the dermal route makes a substantial contribution to body burden, a skin notation is warranted for this carcinogen.

The applications for authorisation for MOCA under REACH have been studied for the preparation of this report. The operating conditions and the risk management measures that the applicants will have to comply with in case of a granted authorisation, will reduce workers exposure as well as releases to the environment. No releases to the environment are expected from the application of the proposed OEL.

Table 16: Multi-criteria analysis for MOCA

Impact	Stakeholders affected	Option 2 5 µg/m^3 (Lowest value)	Option 3 10 µg/m^3 (ACSH)	Option 4 20 µg/m^3 (Highest value)
Economic impacts				
Compliance and administrative costs	Companies exposing their workers	***€701 000***	***€701 000***	***€701 000***
Transposition and enforcement costs	Public sector	***Limited costs***	***Limited costs***	***Limited costs***
Benefits from reduced ill health	Employers	***Limited impact***	***Limited impact***	***No impact***
	Public sector	***Limited impact***	***Limited impact***	***No impact***
Single-market: competition		***No impact identified for all options***		
Single-market: consumers		***No impact identified for all options***		
Single-market: internal		***Limited impact of harmonisation effect of OEL***		

[49] According to the survey undertaken for the application for authorisation, users of MOCA are located in BE, DK, FR, IT, IE, EL, HU, PT, ES, NL and UK.

[50] In DK, for example, the costs for a monitoring programme consisting of 10 samples (4 personal samples and 6 stationary samples per company) are estimated to be €11,900; of these 47% are the costs of analysis

[51] AT, BE, DK, FI, FR, EL, NL, PL, PT, RO, SK, SI and ES

[52] BU, CY, CZ, EE, DE, HU, IT, LV, LT, LU and MT

[53] IE, UK and HR

market				
International competitiveness		***Limited impact of harmonisation effect of OEL***		
SMEs	**	Monitoring costs are not significant		
Specific MSs/regions	Public sector, Member States without an OEL or higher OELs.	AT, BE, BU, CZ, CY, DK, EE, EL, ES, DE, FI, FR, HU, IT, LV, LT, LU, MT NL, PL, PT, RO, SK, SI	AT, BE, BU, CZ, CY, DK, EE, EL, ES, DE, FI, FR, HU, IT, LV, LT, LU, MT NL, PL, PT, RO, SK, SI	BE, BU, CZ, CY, DK, EE, EL, ES, DE, FI, FR, HU, IT, LV, LT, LU, MT NL, PT, RO
	Companies (in MS with higher or without an OEL)	BE, DK, FR, EL, NL, PT, ES, HU, IT	BE, DK, FR, EL, NL, PT, ES, HU, IT	BE, DK, FR, EL, NL, PT, ES, HU, IT
Social impacts				
Ill health avoided	Workers & families	***Limited impact under all options***		
Employment	Workers	***No impacts under all options***		
Environmental impacts				
Environmental releases	Environment	***No impacts under all options***		
Recycling – loss of business *	Recycling companies	***No impacts under all options***		
Recycling – durability of * consumer goods, etc.	Manufacturers using secondary material	***No impacts under all options***		
* MOCA is transformed by the use and not present at any significant concentration in recycled articles ** All affected companies are micro sized enterprises and SMEs				
Based on RPA (2018)				

Comparison of the policy options

Concerning effectiveness, all assessed OELs would bring similar health effects as the baseline. However, option 3 was agreed in the tripartite ACSH[54] by all the Interest Groups. Thus, the endorsement by workers as well as employers will make it the easiest option to apply and enforce.

Regarding efficiency, the very low costs associated with all three options make them comparable with the baseline.

A substantial advantage of option 3 is its coherence and legal implications. Establishing an OEL following option 3 increases the coherence of the CMD with other EU policy objectives. In particular, it will significantly increase complementarity with REACH, especially that it is based on the same scientific advice. The new OEL will provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements. This is especially important in case of a substance like MOCA which is primarily used in SMEs. It will ensure legal stability and predictability for workers and companies irrespective of any potential changes in the future use of the substance. The OEL will also contribute to a level-playing field for businesses across the EU since at the moment 16 Member States have not yet established any national OELs (see chapter 2).

Option 3, with a notation 'skin', is therefore the preferred option.

[54] The ACSH strongly recommends the Commission to adopt a skin notation preferably with a footnote and recital on the importance of biomonitoring under Directive 2004/37/EC.

Table 17: MOCA – comparison of options

Criteria	Option 1: Baseline	Option 2: 5 µg/m^3 (Lowest value)	Option 3: 10 µg/m^3 (ACSH opinion)	Option 4: 20 µg/m^3 (median / mode)
Effectiveness	0	≈	+	≈
Efficiency	0	≈	≈	≈
Coherence	0	+	++	+

6.2. Summary of the retained options

It has been shown in the previous sections that the impacts of the considered measures for the protection of workers vary significantly for the different chemical agents and groups of chemicals assessed in this report.

The table below summarises the retained options assessed by a set of criteria. Where available evidence presented in this assessment is in a range, covering several criteria, the midpoint is used to avoid ambiguity.

i) Stakeholders' acceptance

For all five assessed carcinogens, the assessment validates the position expressed in the opinion of the tri-partite ACSH as the retained option. The following rating is applied:

XX –support by the ACSH

ii) Legal clarity

Setting OELs for the five carcinogens/groups of carcinogens will improve legal clarity for employers and workers. The number of Member States that would need to introduce or amend national OELs corresponding to the proposed EU value is used to gauge improvements in legal clarity.

XX – legal clarity will be improved in half or more of the Member States
X – legal clarity will be improved in less than half of the Member States

iii) Size of the problem

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

XXX – more than 100 000 exposed workers
XX – between 50 000 and 99 999 exposed workers
X – less than 50 000 exposed workers, and/or subject to REACH authorisation

iv) Health benefits

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

XXX – benefits over 100 million EUR
XX – benefits between 10 million EUR and 100 million EUR
X – benefits of less than 10 million EUR, and/or subject to REACH authorisation

v) Limited costs for business

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

XXX – costs below 10 million EUR, and/or subject to REACH authorisation
XX – costs between 10 and 100 million EUR

X – costs over 100 million EUR

Table 18: Summary of the retained options, by assessment criteria

Name of chemical agent	Retained option OEL	Stake-holder acceptance	Legal clarity	Size of the problem	Health benefit	Limited costs for businesses
Cadmium and its inorganic compounds	1 µg/m^3 4 µg/m^3 *(7 years transition period)*	XX	XX	X (XXX)[1]	XX	X (XX)[2]
Beryllium and inorganic beryllium compounds	0.2 µg/m^3 0.6 µg/m^3 *(5 years transition period)*	XX	XX	XX	XXX	X (XX)[2]
Arsenic acid and its salts, as well as inorganic arsenic compounds	10 µg/m^3	XX	XX	X (XXX)[1]	XX	XX
Formaldehyde	0.37 mg/m^3	XX	XX	XXX	XXX	X
4,4'-Methylene-bis (2-chloroaniline) (MOCA)	10 µg/m^3	XX	XX	X	X	XXX

[1] The estimates of the number of exposed workers vary according to the sources available.
XXX would apply if the highest estimates and not the value used in the model calculations would be used.
[2] During the transition period the expected costs for businesses are lower and would fall into category XX

7. Overall Impact of the Package of Retained Options

7.1. Impact on workers

The retained option package for the five substances under consideration should result in benefits in terms of avoided work-related ill-health and cancer cases and related monetised health benefits, including the related consequences such as suffering of workers and their caring families, a reduced quality of life or undermined wellbeing.

The study underlying the present assessment was limited to assessing the most sensitive cancer endpoint and the most sensitive other adverse health effect for each substance. Nevertheless, the chemical agents under consideration pose a range of other occupational hazards and the available data is not sufficient to estimate the magnitude of the global related health and socio/economic benefits for workers. As a result, and taking into account general estimates of costs related to these diseases, it could be expected that benefits for workers could be considerable.

The greatest assessable benefits are expected in relation to formaldehyde. The quantified benefits for workers from the avoidance of ill-health (nasopharyngeal cancer and sensory irritation only) are estimated from the use of two methods leading to a wide range of benefits, one resulting in a benefit of 1 000 million EUR and the other in a benefit of 5 000 million EUR.

Overall, the proposed 5 OELs would in the longer term improve working conditions for over 1 000 000 EU workers and protect over 22 000 workers from significant health problems.

7.2. Impact on businesses

As regards costs incurred by enterprises for risk reduction measures, the retained option will have some effect on capital and operating expenses for companies which will have to put in place additional protective and preventive measures. This will be in particular the case for cadmium and formaldehyde, where the total costs to industry of the retained option over the next 60 years are estimated to be about 448 million EUR and 1.72 billion EUR respectively. In case of the OEL for cadmium, mainly large companies would be affected and in case of formaldehyde the number of companies is high. Therefore, the cost per company in relative terms for both substances is expected to be modest.

For the majority of considered carcinogens, impacts cannot be fully quantified based on available data but impacts on costs and conduct of business (including small and medium enterprises) are expected to be less than 1% of annual company turnover, as only some adjustments will need to be done in specific cases to ensure full compliance. The retained options will not impose any additional information obligations and will therefore not lead to an increase in administrative burdens on enterprises.

Impact on SMEs

For cadmium and inorganic arsenic compounds, SMEs are not significantly represented in the relevant industries. By contrast, beryllium, formaldehyde and MOCA are largely used by SMEs.

Thus, SMEs specificities, their limitations and particular challenges have been duly taken into account in the overall analysis presented in chapter 6. The analysis has shown that usually costs which will be incurred by SMEs are affordable for the companies.

The most significant costs are foreseen for SMEs dealing with formaldehyde and beryllium. However, costs for SMEs remain well below 1% of their turnover, and no SME closures or employment effects are expected at the proposed OELs.

Many of the RMMs required to meet the OELs involve capital expenditure, and SMEs might face higher cost of finance compared to large companies. Furthermore, when it comes to company decisions regarding investment in the different measures required to ensure compliance with the proposed OELs, larger companies will be able to make those decisions in relation to total turnover figures, and not necessarily only in relation to the smaller amounts represented solely by activities relating to beryllium and formaldehyde.

However, even in the case of the most significant costs foreseen for SMEs in relation to formaldehyde and beryllium, costs for SMEs remain well below 1% of their turnover, and no SME closures or employment effects are expected at the proposed OELs.

Moreover, introduction of an OEL will only have a significant impact on companies which have not yet made the investments to protect workers either through closed systems or substitution of the substances where technically feasible.

Impact on competition and competitiveness

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

The retained options should not have a significant impact on the external competitiveness of EU firms. On the one hand, the detailed assessment provided above shows that in most cases additional compliance costs per firm are modest. On the other, while non-EU countries have established a wide range of exposure values that vary significantly across jurisdictions, the retained exposure values are not out of line with international practice.

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

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

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

7.3. Impact on Member States/national authorities

Member States with established OELs at the level of the retained option will be less affected than those having higher or no OEL in place. Each multi-criteria analysis above lists, for each option, the Member States that will have to enforce a stricter OEL. More details and national OELs for all substances are provided in Annex 5. The retained option should contribute, although not significantly, to mitigate financial loss of social security systems. Additional administrative and enforcement costs might be incurred by enforcing authorities. These costs are not quantifiable as the granularity of Member States' reporting of enforcement activity is not sufficient to distinguish costs related to a particular OEL. However, it is not expected for the costs to be significant. OEL enforcement will take place according to normal mechanisms for compliance improvement and enforcement, including informal conversations with employers as well as formal correspondence and legal enforcement action.

This will normally be brigaded for any given employer with other OSH provisions (for example, workplace transport, slips and trips, machinery safety, stress) rather than specific to OELs. Specific reporting would only be the case where Labour Inspectorates undertake targeted chemical carcinogen enforcement activity and OEL campaigns. Costs will therefore be generally affected by Labour Inspectorate resourcing, prioritisation and targeting. No assumption may be made that enforcement, a Member State competence, will receive (or demand) greater resourcing and priority as a result of an OEL being set.

At the same time, establishing OELs, and other explicit references to a given carcinogen in the CMD brings clarity regarding legal requirements, and so facilitates the work of inspectors by providing a helpful tool for compliance checks. Setting OELs at EU level would also limit the need for national administrations to conduct duplicating scientific analyses.

7.4. 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).

7.5. Subsidiarity, proportionality and REFIT

In view of the available scientific evidence it is necessary to establish new OELs for a number of substances for inhalation exposures including for information on other routes of exposure (e.g. dermal) which could contribute significantly to the overall body burden of the workers. The protection of workers health against risks arising from exposure to carcinogens is already covered by EU legislation, in particular by Directive 2004/37/EC (CMD), which can be amended at EU level after a two-stage consultation of the social partners. The retained option takes into account long and intensive discussions with all stakeholders (representatives from employees' associations, representatives from employers' associations, and representatives from governments), including consideration of socioeconomic feasibility.

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

Updating CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States, providing with a uniform level of minimum requirements designed to guarantee a better standard of health and safety. Action taken by individual states in response to available technical data would risk increasing divergences between Member States with potential competition on the basis of OELs set at different levels. Business would therefore continue to compete on an uneven playing field, which would hamper the operation of the internal market. Further, the proposal is based on a minimal degree of harmonisation of Member State systems which respects Member States' competences to set more stringent binding limit values.

The proportionality principle is fully respected as the scope of the proposal is limited to setting out the limit values for five additional agents by amending Annex III to the Directive on the basis of the scientific and technical data available, as provided by Article 16 (1) of the CMD.

Further, the proposal includes measures for mitigating burdens and supporting compliance. As indicated in the impact assessment, the costs are balanced and justified in light of the accrued and longer-term benefits in terms of reducing health risks arising from workers' exposure to carcinogens and saving lives.

The proposal also leaves the Member States the option of keeping or setting more favourable standards by allowing Member States to introduce more stringent OELs.

Finally, regarding the simplification and the efficiency improvement of the existing legislation, the proposal eliminates the need for Member States to conduct their own scientific analysis to establish OELs and brings clarity regarding the acceptable levels of exposure, facilitating the work of inspectors by providing a helpful tool for compliance checks. Employers also benefit from the simplification in ensuring legal compliance, particularly those operating in different Member States.

8. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

8.1. Monitoring arrangements

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

Table 19: Core indicators and their data sources

Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators
The reduction of occupational diseases and occupational related cancer cases in the EU	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 other non-cancer work-related health problems and illnesses in accordance with Regulation (EC) No 1338/2008[55]. - 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 EU	The costs related to occupational cancer for economic operators (e.g. loss of productivity) and social security systems in the EU.	The monitoring of this indicator will require the comparison of the expected figures on the burden of occupational cancer in terms of economic loss and health care costs and the collected figures on these matters after the adoption of the revision. The productivity loss and health care costs can be established on the basis of the data on the number of occupational cancer cases and the number of occupational cancer deaths (the arrangements for the collection of the data on occupational cancer cases are described supra in this table).

A two-stage compliance assessment (transposition and conformity checks) will be carried out by the Commission for the transposition of the limit values. At workplace, there is an obligation for employers to ensure thatthe exposure does not go above the limit values set out in Annex III to the Directive. The monitoring of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

At EU level, the Committee of Senior Labour Inspectors (SLIC) informs the Commission regarding problems relating to the enforcement of Directive 2004/37/EC. While collection of reliable data in this area is complex, the Commission and EU-OSHA are actively working on improving data quality and availability so that the actual impacts of the proposed initiative could be measured in a more accurate way and additional indicators could be developed in the future (e.g. in relation to mortality caused by occupational cancer). Ongoing projects include cooperation with national authorities on the European Occupational Diseases Statistics (EODS) data collection.

Legislative action needs to be followed up through effective implementation at the workplace. In this context, EU-OSHA is carrying out a Healthy Workplaces Campaign on dangerous substances in 2018-2019 raising awareness and providing good practice examples and has recently published the results of a feasibility study on the development

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

of a computer-assisted telephone survey to estimate workers' exposure to carcinogens in the EU[56]. Other initiatives include a Commission-funded project to establish by the end of 2019 a first version of a database on occupational exposure for some hazardous chemicals.

8.2. Evaluation arrangements

In accordance with Article 17a of Directive 89/391/EEC, every five years, Member States are required to submit a report to the Commission on the practical implementation of the EU OSH Directives, including Directive 2004/37/EC. Using these reports as a basis, the Commission is required to evaluate the implementation of Directive 2004/37/EC and, to inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health at Work of the results of this evaluation and, if necessary, of any initiatives to improve the operation of the regulatory framework.

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

56 Available at: https://osha.europa.eu/en/tools-and-publications/publications/summary-feasibility-study-development-computer-assisted-0/view

Annex 1: Procedural information

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

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

2. CONSULTATION OF THE RSB

The draft impact assessment report was submitted to the RSB on 30 January 2018. After a written procedure, the RSB issued a positive opinion on 23 February 2018.

The table below summarises the revisions introduced in response to the RSB considerations and recommendations for improvement:

Board Opinion's recommendations	Corresponding changes to the draft
Main considerations	
The report does not sufficiently explain the rationale, process and criteria for selecting which chemical substances require OELs, both in general and for this particular initiative.	Section 5.1 explains now in more detail the approach followed to select the priority carcinogens to be covered in this initiative. It also refers to Annex 9 of this report where the whole selection process - including the rationale, process and criteria for selecting priority substances - is described in detail.
The report does not fully explain to what extent alternatives to the OELs agreed by the tripartite ACSH Committee constitute plausible options.	The report clarifies in section 6.1 the importance of the ACSH to establish consensus and how other options are presented as reference points.
Further considerations	
The report should more fully and transparently explain the different steps of the process and the weighting of different prioritisation criteria for selecting which chemical substances require OELs. This discussion could also highlight possible differences in roles, structures and approaches between different bodies (e.g. SCOEL, ACSH and RAC). Doing so would help to clarify why this initiative appears to result in such modest impacts in terms of protection of workers from occupational cancers. The report should indicate how this limited selection of cancer-related chemical substances is compatible with the Commission's commitment to reach a total of 50 OELs by 2020. The report could also indicate how the Commission intends to proceed from here to reach this objective.	As indicated above the prioritisation process is described in further detail in section 5.1 and Annex 9. In this annex are also described the roles of the different bodies involved in the process of setting binding OELs. The text also clarifies (in the Introduction) that the scope of this initiative is much broader than just five substances. Three of concerned carcinogens are substance groups which comprise a large number of priority compounds (several tens). The revised text explains further the limitations of the data (notably the underestimation of the number of cases as only the most sensitive endpoints were assessed) in sections 2 and 6. The Introduction of this report clarifies the Commission's intention to continue this important work and to propose further binding OELs in the future with a view to protect more workers.

The report should clarify to what extent and under what circumstances the preferred option could deviate from the OELs agreed by the ACSH Committee. Building on the additional information from recommendation (1) above, the report could better explain the ACSH opinion and what risks follow from exceeding the limits that were agreed between governments, workers and employers.	The importance of the ACSH agreement in setting consensual OELs was clarified after the RSB opinion in section 6. Generally, the role of the ACSH is addressed throughout the report, in particular in the introduction, section 5, section 6 and Annex 9.
Given the possible need for significant upfront investments and the long latency of chronic diseases, costs are likely to be incurred long before the expected benefits materialise. The report could therefore better present the distribution of such costs and benefits over time. It could more clearly distinguish between one-off investments and operating costs.	The report now provides, per substance (in section 6), the capital and operational expenditures estimated.

3. EVIDENCE, SOURCES AND QUALITY

The assessment of health effects of the carcinogens subject to this proposal is based on the relevant scientific expertise from the Scientific Committee on Occupational Exposure Limits (SCOEL) and from the Committee for Risk Assessment (RAC).

SCOEL was set up by Commission Decision 95/320/EC106 to evaluate the health effects of chemical agents on workers at work. The work of the Committee directly supports Union regulatory activity in the field of occupational safety and health, when available.

RAC prepares the opinions of ECHA related to the risks of substances to human health and the environment. The work of RAC includes examining harmonised classification and labelling, evaluating whether the proposed restriction on manufacture, placing on the market or use of a substance is appropriate in reducing the risk to human health and the environment and assessing the applications for authorisation of chemicals. Moreover, opinions from RAC also support Union regulatory activity in the field of occupational safety and health, when available.

Both SCOEL and RAC develop high quality comparative analytical knowledge and ensure that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence. The Committees assist 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 both Committees are highly qualified, specialized, independent experts selected on the basis of objective criteria. They provide the Commission with Recommendations and Opinions that are helpful for the development of EU policy on workers protection.

For the purpose of this initiative, the Commission services have used the relevant chemical agent-related SCOEL and RAC recommendations which are summarised in the following table:

Table 20: Summary of SCOEL recommendations and RAC opinions for the five carcinogens

	SCOEL recommendation						RAC opinion			
Carcinogen:	**8 hrs TWA**	**STEL 15'**	**skin notation**	**other notations**	**others**	**SCOEL carc. group**	**8 hrs TWA**	**skin notation**	**others**	**LTCR**
Cadmium and its inorganic compounds [57]	1 µg/m^3 (inhalable fraction)	none	none		BLV: 2 µg Cd/g creatinine in urine(sampling time not critical)	C[58]				
Beryllium and inorganic beryllium compounds [59]	0,00002 mg/m^3 (inhalable fraction)	0,0002 mg/m^3	none	Sensitisation (dermal and respiratory)	BGV: 0.00004 mg beryllium/l urine (sampling time not critical)	C				
Arsenic acid and its salts, as well as inorganic arsenic compounds[60]							not derived		BGV[61]: 10 µg As/l urine (post-shift sample at end of a working week)	see following table

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

[58] genotoxic carcinogen for which a mode of action-based threshold is supported and a health-based OEL is proposed

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

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

[61] BGV is recommended to be updated when more data becomes available on the speciated As3+ and As5+ levels among European population

									as combined As3+, As5+ and MMA and DMA[62]	
Formaldehyde[63]	0,369 mg/m^3 (0,3 ppm)	0,738 mg/m^3 (0,6 ppm)		Sensitisation (dermal)		C				
4,4'-Methylene-bis(2-chloroaniline) (MOCA)[64,65]	not feasible to derive	not feasible to derive	x		BGV: see footnote[66]	A[67]	not derived	x	BGV: LoD of biomonitoring method (e.g. </= 0.5 µmol/mol creatinine, post shift sample end of the working week[68]	1 µg/m^3 : 9.65 x 10^{-6} 2 µg/m^3 : 1.93 x 10^{-5} 5 µg/m^3 : 4.83 x 10^{-5} 10 µg/m^3 9.65 x 10^{-5}

[62] Dietary sources, especially seafood may have a significant impact on total MMA (monomethylarsonic acid) and DMA (dimethylarsinic acid) levels

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

[64] RAC (2017): Opinion on 4,4'-methylene-bis-[2-chloroaniline] (MOCA). Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13641/opinion_moca_en.pdf/35756093-0eb9-e468-2ba2-786ca73c5aaa

[65] SCOEL (2010/2013): https://circabc.europa.eu/d/a/workspace/SpacesStore/c1212f38-05dd-4a76-9655-6303c9c4c93d/SUM%20174%204.4-Methylene-bis-(2-chloroaniline)%252c%20MOCA%202010%20with%20Annex%202013.pdf

[66] In the Annex to SCOEL/SUM/174 (2013) the following is stated: *"Since the general population is not exposed to MOCA, MOCA is not detected in the urine of occupationally non-exposed people. This means that urinary levels of occupationally non-exposed stay below the detection limit of the method, which typically lay around 1–1.5 µg/l (3.7–5 nmol/l, ~ 0.37–0.5 µmol/mol creatinine) with commonly used analytical methods, some methods reported to reach the detection limit of 0.1µg/l. Thus, the Biological Guidance Value (BGV) for MOCA corresponds to the detection limit of the biomonitoring method'.* SCOEL concluded that in occupationally exposed populations, urinary MOCA levels (total MOCA in the urine) below 5 µmol/mol creatinine can be reached using good working practices at the workplace. By referring to the cancer risk estimation by DECOS using linear extrapolations from animal testing, this urinary MOCA level corresponds to a cancer risk of 3–4 × 10^{-6}."

[67] non-threshold genotoxic carcinogen

[68] Using modern analytical methods, the limit of detection is usually 0.5 µmol/mol creatinine or below (See Annex to SCOEL/SUM/174 (2013): Recommendation for a Biological Guidance Value)

Excess lifetime (up to age 89) lung cancer risk estimates for workers exposed at different 8h-TWA concentrations of inorganic arsenic

(inhalable particulate fraction) for 40 years

Arsenic acid and its salts, inorganic arsenic compounds **exposure concentration – inhalable fraction (µg/m^3)**	**Excess lung cancer risk in EU workers (x10^{-3})**
10	1.4
5	0.71
2.5	0.36
1	0.14
0.5	0.07
0.25	0.036
0.1	0.014
0.01	0.0014

Studies performed by external consultants

The Commission published in February 2017 an open call for tender in order to carry out an assessment of the social, economic and environmental impacts of a number of policy options concerning the protection of workers health from risks arising from possible exposure to carcinogenic chemical agents at the workplace.

The main outputs were a study report containing full reports on 5 carcinogenic chemical agents and one other policy issues detailing the setting of occupational exposure limit values across the 28 EU MS and the main economic competitor countries of the EU.

The contract started on 18 July 2017 and runs until 17 February 2018. The outcome of this study provides the main basis for this Staff Working Document and is summarised in the relevant sections of this document.

Annex 2: Stakeholder consultation

1. Social Partner Consultation

1.1. Results of the first phase Social Partners consultation

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

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

Following a process described in more detail in Annex 6 of this report, the Commission identified a list of priority substances in the first phase consultation document[69], as follows:

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

(a) Cadmium and its inorganic compounds under the scope of the CMD

(b) Beryllium and inorganic beryllium compounds under the scope of the CMD

(c) Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the CMD

(d) Formaldehyde [CAS No 50-00-0]

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

(2) For a subsequent amendment, a first proposed list of the following three substances, which can be expanded, includes:

(f) Nickel compounds under the scope of the CMD

(g) Acrylonitrile [CAS No 107-13-1]

(h) Benzene [CAS No 71-43-2]

Workers' organisations

Three trade unions replied to the consultation: the European Trade Union Confederation (ETUC), European Confederation of Independent Trade Unions (CESI), European Federation of Building and Woodworkers (EFBWW). They all acknowledged the importance of the existing legislation and a need for further action.

[69] Consultation Document of 26.7.2017, First phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EU to include binding occupational exposure limit values for additional carcinogens and mutagens; C(2017) 5191 final.

Possible improvements to the EU legal framework

The workers' organisations agreed, broadly, with the issues described in the consultation document and confirmed the importance they attach to protecting workers from the health risks associated with exposure to carcinogens and mutagens. However, ETUC and EFBWW consider it necessary to extend the scope of the CMD to include reprotoxic substances, and to streamline this field with other policy areas such as public health and environment.

Concerning the approach regarding the third and fourth amendments, ETUC and EFBWW agree with the list of 8 priority substances identified by the Commission. CESI considers that the latest available data need to be used when revising the CMD.

As regards the other substances to be added to Annex III, while CESI suggests that they should be identified on the basis of sound and independent scientific research, ETUC and EFBWW insist that the target of binding OELs for 50 substances has to be achieved by 2020. ETUC has proposed a priority list of such substances. After 2020, the process of setting OELs should continue on a dynamic way in order to include most of the substances at the workplace.

With regard to Annex I to the CMD, ETUC considered important to include all processes generated substances for which IARC monographs are available. More specifically, concerning diesel engine exhaust emissions ETUC considers that it should be addressed as soon as possible, while not delaying the Commission's adoption of the third and fourth batches of proposals for revising the CMD. In the enclosed annex of its priority substances list ETUC has indicated it as a candidate for the fourth amendment. ETUC also suggests that the OEL for crystalline silica is set at 50 μ/m^3. EFBWW expressed similar views concerning diesel engine exhaust emissions and crystalline silica. CESI suggested carrying out in-depth study to identify other processes and / or process generated substances for inclusion in Annex I of the CMD.

Among other issues, ETUC and EFBWW stressed the need for more consistent and transparent criteria for setting OELs and for better cooperation between the expert groups working on OELs at the EU level as well as in Member States, and that purely health-based OELs should prevail whenever possible. Further, ETUC suggested the need to take into account multiple exposures and improve the availability and quality of data.

CESI and EFBWW considered that legislative initiatives should be complemented by other measures, for example, fostering preventative health-oriented behaviour and information on best available technology.

Apart from the revision of the CMD, ETUC and EFBWW suggested to adapt other EU legislation to establish a coherent strategy for fighting occupational cancers, e.g. concerning asbestos, solar radiation and others.

Willingness to enter into negotiations

The workers do not want to enter into negotiations under Article 155 TFEU concerning the third and fourth amendment of the CMD and urge the Commission to make progress on this.

Employers' organisations

Four employers' organisations replied to the consultation: BusinessEurope, the European Association of Craft Small and Medium-sized Enterprises (UEAPME), the European Chemical Employers Group (ECEG) and the Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET).

They supported the objective to effectively protect workers from occupational cancer, including by setting OELs at EU level. However, they also raised some concerns about the approach taken when setting such limit values.

Possible improvements to the EU legal framework

Concerning the issues identified in the consultation paper, the employers in principle supported further revisions of the CMD, subject to certain conditions. In their opinion, binding OELs should be set for priority substances only. The process of OELs setting should be based on sound scientific evidence, technical and economic feasibility, socio-economic impact assessment and opinion of the tripartite ACSH. While employers considered that the Commission's criteria for prioritising substances are relevant, they suggested that the criteria of technical and economic feasibility should also be included. BusinessEurope and CEEMET emphasized that proposing a series of substances on the basis of unofficial lists should be avoided, as should setting an arbitrary numerical target of additional binding OELs without clear criteria of prioritisation. UEAPME and CEEMET stressed the need to assess impact on SMEs and consider sectoral differences. Employers also highlighted a need to ensure coherence with other EU chemicals legislation and suggested that guides, examples of good practice and other tools can assist in implementing this Directive.

Concerning the third amendment, BusinessEurope overall, supported the Commission's approach. For subsequent amendments they stressed that inclusion of specific substances should depend on whether they meet the conditions / criteria mentioned above and whether the preparatory work has been completed. They emphasized the benefit of recommending Biological Limit Values, where scientifically justified and relevant. ECEG and CEEMET supported the overall process for developing and adopting binding OELs as long as the above criteria and processes are correctly applied. UEAPME, noted that without having seen concrete proposals for OELs it is not possible to take a complete position. They further suggested that the latest available data need to be used when revising the CMD (supported by CEEMET) and that too restrictive OELs could be very burdensome for employers leading to a risk of non-compliance.

Subject the above mentioned, the employers' organisations agreed with the Commission's current approach for periodic revision of Annex III of the CMD.

Concerning Annex I, UEAPME agreed with the Commission's approach for periodic revision. BusinessEurope and ECEG felt it was of limited benefit as it is often not clear to which specific substance exposure should be reduced or avoided and to which extent/level. Instead, BusinessEurope suggested to consider possibility to move substances already included in Annex I, where relevant, to Annex III, if the chemicals which are responsible for the hazard have been identified.

Willingness to enter into negotiations

The employers do not want to enter into negotiations under Article 155 TFEU as the existing preparatory procedures already involve Social Partners. Although, they are open to discussing in an informal way relevant issues.

1.2. Results of the second phase Social Partners consultation

The Commission launched a second phase consultation of the Social Partners. The consultation document considers the possible avenues for EU action to improve workers' protection against carcinogens or mutagens. The second phase consultation closed on 22 December 2017.

In the second phase consultation, the Commission indicated that adding new OELs for five chemicals – as specified in the first phase consultation – would be an appropriate action to be included in the third amendment of the CMD. For subsequent amendments of the CMD, a first candidate list of the following substances is given consideration:

- Nickel compounds that are carcinogens as defined in the Directive
- Acrylonitrile [CAS No 107-13-1]
- Benzene [CAS No 71-43-2]
- Diesel Engine Exhaust Emissions (DEEE). At least two approaches are being explored – to address this mixture as a process generated substance or to take a component-specific approach.

Furthermore, the Commission indicates that it will give due consideration to further suggestions received regarding the following substances:

- Crystalline silica: in light of the compromise reached between the European Parliament and the Council during the negotiations on the first amendment on the CMD, the Commission will assess the situation as soon as new evidence becomes available.
- Reprotoxic substances: the Commission will assess by the first quarter of 2019 the option of amending the scope of the CMD to include these substances. In addition, on-going work on the best way to tackle endocrine disrupters is being carried out.

Workers' organisations

Three workers' organisations replied to the second phase consultation: the European Public Service Union (EPSU), the European Trade Union Confederation (ETUC) and the European Federation of Building and Woodworkers (EFBWW).They all recognised the importance of further improving the existing legislative framework in line with the proposed Commission action and beyond.

Views on the possible avenues for EU action

As regards the scope of the CMD, ETUC insists on including reprotoxins and EFBWW sees the need to work on a concept to assess and evaluate exposures of workers to a mixture of dangerous and carcinogenic or mutagenic and reprotoxic substances.

The workers' organisations consider necessary the revision of Annex I. ETUC proposes to include all the work activities with a risk on occupational cancer, taking into account the findings of the IARC. In that sense, they suggest to introduce the wording "occupational exposure" in Article 2 and in the title of Annex I of the CMD. EPSU considers that Annex I should include activities such as cleaning, transport, laundry and waste disposal of hazardous drugs, personal care for patients under treatment of hazardous drugs, and preparation, administration or disposal of hazardous drugs, including cytotoxic drugs. ETUC also highlights the importance of addressing workers health and safety related to cytotoxic treatments. Finally, EFBWW suggests including DEEE in Annex I and stresses the need to map the use and emissions of work equipment with engines in order to identify the substances that are possible candidates for the CMD.

Concerning Annex III, the workers' organisations agree that the selection of the third batch and the first candidate list for the fourth batch is appropriate, as it includes substances that are among priority carcinogens. However, they underline that the list must be extended to reach the objective of setting 50 OEL by 2020. As regards the setting of OEL, ETUC points the need to define a consistent and more transparent methodology, asking the Commission to consider its priority substances list. EFBWW underlines that the OELs should be health based only, while ETUC stresses that socio-economic considerations might be relevant for adapting Annex III, although not for Annex I. As a final point, EPSU considers that including some cytotoxic drugs in Annex III would be possible, but other actions are needed to tackle the exposure to these substances.

With regard to specific substances, EFBWW calls on the Commission to set a BOEL of 0.3 ppm for formaldehyde, based in the SCOEL recommendation and, together with ETUC, consider that existing evidence on crystalline silica is sufficient to start the work and prepare a new BOEL of 0.05 mg/m^3 to be introduced in Annex III (common position between ETUC, EFBWW and IndustriAll adopted on 1st March 2017).

The workers' organisations agree that the amendment of the CMD should be part of a global strategy to prevent occupational cancer in Europe and urge the Commission to adopt a roadmap combining legislative initiatives (e.g. the revision of the Asbestos Directive and the revision of the Optical Radiation Directive) with non-legislative actions and mainstreaming work-related cancer prevention in other EU policies. ETUC highlights the need to integrate, in the framework of the roadmap, a gender perspective and to adopt specific rules for occupational exposures to substances such as endocrine disruptors and nanomaterials. ETUC proposes a future OSH legislation on chemicals built on three levels: a first block of general obligations defined in the Chemical Agents Directive (CAD), a second block of stricter obligations defined in the CMD for very high concern substances, and a third block of specific prohibitions. They are opened to the idea of merging CAD and CMD.

Among other issues, ETUC considers that the issue of enforcement of the CMD should be addressed by the Commission, as well as the coordination between workers protection and market regulations.

Willingness to enter into negotiations

The workers' organisations do not want to launch a negotiation procedure pursuant to Article 155 TFEU

Employers' organisations

Four employers' organisations replied to the second phase consultation: BusinessEurope, the European Association of Craft Small and Medium-sized Enterprises (UEAPME), the European Chemical Employers Group (ECEG) and the Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET). They confirmed their support to actions aiming to effectively protect workers from occupational cancer, including the setting OELs at EU level but underlined the need to ensure values that are proportionate and feasible.

Views on the possible avenues for EU action

Concerning the amendment of the scope of the CMD, UEAPME and CEEMET are against the inclusion of reprotoxic substances. BussinessEurope call on the Commission to ensure transparency, regular information and involvement of employers in the study that will be undertaken by contractors on behalf of the Commission on these substances. As regards DEEE, the employers' organisations agree on the complexity of the issue and, while UEAPME believes that the CMD is not the adequate piece of legislation to deal with them, BusinessEurope and CEEMET have reservations and think that work needs to continue to gather enough evidence and to assess the implications and the technical and economic feasibility of the different options.

The employers' organisations support the procedures for considering substances and setting OEL, underlining the need that they are based on the latest scientific information, proportionate and measurable and highlighting the importance of the tripartite system. UEAPME and CEEMET point that the limit values have to be set in a way which reduces workers exposure whilst still allowing SMEs to comply. CEEMET also proposes transitional measures where the new OEL will adversely affect industry and points that an arbitrary target of the addition of 50 new exposure limits should not be set, as OEL should only be proposed on an evidence-based approach and not in line with the precautionary principle.

Regarding the scientific body to provide information for the setting of OELs, BusinessEurope thinks that there should be a thorough assessment before any decision is taken, while CEEMET believes that SCOEL should be the one setting the limit values.

As regards the amendment of Annex III, the employers' organisations support the list of priority carcinogens included in the third batch. UEAPME points that any limit value lower than 200ng/m^3 for 15 min for beryllium, is severely challenging for SMEs, while complying with the limit value of 0,3 ppm of formaldehyde for 8h is technically difficult for companies in several industries.

BusinessEurope encourages the Commission to continue its preparatory work and consultations with the ACSH regarding the candidate list of substances for the fourth batch. Regarding crystalline silica, UEAPME believe that lowering the limit value would be technically impossible and too burdensome for small businesses.

Finally, ECEG, BusinessEurope and CEEMET stress the importance of other actions to achieve worker protection in addition to legislation, such as guidance documents, best practices, voluntary product stewardship programmes by companies and sectors, or social partner agreements.

Willingness to enter into negotiations

The employers' organisations do not want to engage into negotiations under Article 155 TFEU.

2. Consultation of the ACSH / WPC

The Advisory Committee on Safety and Health at Work (ACSH) has adopted opinions for all priority substances foreseen for the third amendment of the CMD[70].

The ACSH is proposing as possible approaches for these chemicals a binding OEL for all of them and in addition a skin notation for MOCA.

The opinions for all substances adopted by the ACSH are summarised below.

Regarding the options proposed referring to biological monitoring or binding biological limit values; it has to be kept in mind that it is currently legally not possible to establish such limit values under the CMD

Cadmium and its inorganic compounds under the scope of the CMD

The ACSH agreed on two approaches in its opinion, adopted on 31 May 2017:

- **Approach 1**:
  1 µg/m^3 (inhalable fraction, 8h TWA), with a transition period of 7 years (to end no later than 2027) at 4 µg/m3 (inhalable fraction, 8h TWA).
- **Approach 2**:
  To combine an airborne OEL with the biological monitoring value proposed by SCOEL which could be used as a mean of demonstrating control of workers' exposure in those Member States where biomonitoring is carried out. This would be based on complying with both the SCOEL biomonitoring value of 2 µg Cd/g creatinine in urine and the 8 hour TWA of 4 µg/m3 (respirable fraction) as

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

recommended by SCOEL/ OPIN/336 (page 10 paragraph 2, adopted 8th of February 2017).

Beryllium and inorganic beryllium compounds under the scope of the CMD

The ACSH adopted its opinion on 31 May 2017 putting forward the following values:

- An 8 hour TWA of 200 ng/m^3 (inhalable fraction) with a value of 600 ng/m^3 (inhalable fraction) during a transitional period of 5 years.

The biological value of 0.04 µg beryllium/l urine recommended by SCOEL is agreed, and the ACSH suggests that the OEL in Annex III of the CMD should include a footnote to indicate the importance of biomonitoring for beryllium exposure risk management.

Notations: dermal and respiratory sensitisation. No skin notation suggested.

Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the CMD

The ACSH adopted the following opinion on 19 October 2017:

- The three interests groups agreed on the need for an EU OEL for arsenic acid and its salts as well as inorganic arsenic compounds under the scope of the CMD of 10 µg/m^3 (TWA 8 hrs measured as arsenic) inhalable fraction. However after a preliminary assessment for one specific sector, copper smelting, it is currently not technically achievable to comply with.

- In addition the Commission impact assessment may identify other sectors which are in a similar situation. For all these sectors a prolonged transitional period may be necessary.

Formaldehyde

The ACSH adopted an opinion on 9 September 2016 putting forward the following values

- An 8 hour TWA of 0.3 ppm (0.369 mg/m^3) and a 15 min STEL of 0.6 ppm (0.738 mg/m^3)

SCOEL recommended in its opinion on formaldehyde to add a notation for dermal sensitisation. The ACSH has not discussed this notation; however, as formaldehyde is a well-known contact allergen to the skin (skin sensitiser) it is appropriate to add a notation 'sensitisation (dermal)'.

4,4'-Methylene-bis(2-chloroaniline) (MOCA)

The ACSH concludes in its opinion, adopted on 19 October 2017:

- The major exposure route of MOCA is the dermal route. Therefore there should be a skin notation in Annex III. The three interests groups agreed that biomonitoring is currently the best method to assess the total exposure to MOCA in occupational settings. However biomonitoring can be complemented with air monitoring.

- The three interests groups agreed an EU occupational airborne limit value for MOCA set at 10 µg/m^3 (8hrs TWA). Biomonitoring can be used to show compliance with this limit value.

- The ACSH strongly recommends the Commission to adopt a skin notation preferably with a footnote and recital advising on the importance of biomonitoring under Directive 2004/37/EC.

- The ACSH recognizes the challenge of establishing in the existing legal framework the most appropriate approach to effective risk management practice for MOCA, where biomonitoring is the best method for exposure assessment.

- The BGV of 5 µmol/mol creatinine stated in the previous opinion remains appropriate.

Annex 3: Who is affected and how?

PRACTICAL IMPLICATIONS OF THE INITIATIVE

I. Overview of benefits (direct and indirect) – Preferred option		
Stakeholders	**Amount of costs avoided**	**Description of benefits**
Workers	Ranging from very low benefits for MOCA to €1 to 5 billion for formaldehyde	More effective protection of their health, reducing suffering of workers and their families. Increased length, quality and productivity of their working lives, avoiding premature deaths.
Businesses	Ranging from very low benefits for MOCA to €15 million for beryllium	Reduced absenteeism, productivity losses and insurance payments. In addition, not quantified benefits include legal clarity, simplification in ensuring legal compliance and a more balanced level playing field for businesses across the EU.
Administrations	Ranging from very low benefits for MOCA to €181 million for formaldehyde	Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OEL eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.

II. Overview of costs – Preferred option						
Stakeholders	**Description of costs**	**Cadmium and its inorganic compounds**	**Beryllium and inorganic beryllium compounds**	**Arsenic acid and its salts, as well as inorganic arsenic compounds**	**Formaldehyde**	**4,4'-Methylene-bis(2-chloroaniline) (MOCA)**
		1 µg/m³ 4 µg/m³ ***(7 years transition period)***	**0.2 µg/m³ 0.6 µg/m³** ***(5 years transition period)***	**10 µg/m³**	**0.37 mg/m³**	**10 µg/m³**
Workers	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 (e.g. the newly established OELs).	***None***	***None***	***None***	***None***	***None***
Businesses	As duty holders, employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - implementation of the necessary risk management measures (e.g. substitution, closed systems, local exhaust ventilation, limitation of number of workers exposed, personal protection equipment) in order to comply with the new or revised OELs - implementation of a sampling strategy and airborne concentrations measurement programme for the chemical agents with a new or revised	***€447 million, assuming no transition period is established.***	***€130 million***	***€21.2 million***	***€1.72 billion***	***€701 000***

	OEL, as part of the risk assessment process and effectiveness check of the existing measures - ensure that the chemical agents included in Annex I will be managed in line with the provisions of the carcinogens and mutagens national legislation - ensure compliance with other provision in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OELs, health surveillance, if appropriate, for chemical agents now under the scope of the legislation, collection of records, information to competent authorities, etc.). Most of the listed actions are, however, business as usual.					
Administrations	Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts - design, if appropriate/needed, of special measures (e.g., transitional periods, exemptions, additional provisions for specific sectors, etc.) - 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	***Limited costs***	***Limited costs***	***Limited costs***	***Limited costs***	***Limited costs***

	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.					

Annex 4: Analytical methods used in this impact assessment

1. Estimations for the number of exposed workers

Typically, several sources for the numbers of exposed workers have been identified which, in some cases, provide very different estimates. All these estimates are presented in the reports (extrapolated over the whole EU for comparison purposes). The different sources were reviewed to determine when and how the estimates were derived and the compounds and workforce they cover. The most suitable estimate was then chosen for further modelling, taking into account (amongst others) the following factors:

- the compounds covered by the estimate (only the workforce exposed to CMD-relevant compounds was deemed relevant);
- the year in which the estimates were derived;
- the duration and frequency of exposure; and
- other factors, e.g. the employment/self-employment status of the worker (only employed workers within the scope of the CMD).

2. Impact on health

The impacts of the different policy options were quantified, to the extent possible, based on the methodology as described below**:**

Derivation of Exposure Risk Relationship (ERR) and Dose-Response Relationship (DRR) "above threshold"

The starting point for a cancer risk impact assessment or a non-cancer health impact assessment is the proposed OEL and the most recent substance evaluation by SCOEL or RAC.

For an impact analysis on health consequences of elevated exposure, it is necessary:

- to describe the ERR for (non-genotoxic) carcinogens above threshold;
- to select the most suitable ERR for genotoxic carcinogens, if not provided by SCOEL or RAC; and
- to derive a DRR above threshold.

With an ERR and DRR derived, it is possible to assign an excess cancer risk to any exposure level and to assign a fraction of the exposed which are expected to suffer a (non-cancer) health effect at an elevated exposure concentration.

Exposure Response Relationships – ERR

For carcinogens, frequently no OELs are derived if the carcinogen is regarded a genotoxic compound without a threshold for carcinogenicity. In this case, usually the classification as a carcinogen (according to the Classification, Labelling and Packaging Regulation –CLP-, IARC, or national cancer classification system) is reported. For some substances, SCOEL/RAC also reports excess risk levels, linked to various potential exposure levels (e.g., 1:1,000; 1:10,000; 1:100,000 or 4:1,000 to 4:100,000).

Three situations may occur:

SCOEL or RAC: (1) present a clear recommendation on the excess risk at various exposure levels, (2) present various excess risk quantifications, without deciding which one to use for further impact analysis; or (3): does not provide information on excess cancer risk at different exposure levels.

If the ERR is not already provided for a working lifetime exposure scenario, the respective transformation has to be calculated: working life time is assumed to be 40 years, with work day exposure for 8 hours/day, 5 day/week in 48 weeks of a year. It is a conservative estimate based on the most critical cancer site (cancer risk associated with highest risk).

For carcinogens with a "practical threshold" (Bolt and Huici-Montagud, 2008) SCOEL usually does not provide data on the "exposure risk relationship" or the "excess risk" to be assumed above threshold. If this information is not available unambiguously from the SCOEL/RAC document, the procedure presented above for carcinogens is followed, but limited to the range above the (practical) threshold (with zero excess risk at or below this cancer threshold).

Dose Response Relationships – DRR

To derive a DRR, usually the non-cancer endpoint regarded the most critical by SCOEL, is selected. Data from original toxicological studies, referenced by SCOEL, ECHA/RAC or national committees as being qualified and demonstrating a dose-response, are selected and searched for effect levels linked to a different fraction of the exposed (humans or animals). If not contradicted by the overall weight of evidence, this slope reported in such a study is adopted for the DRR.

However (1) different levels of "severity" are not discriminated for reasons of feasibility, (2) a change of the critical effect at higher exposure levels (with a potential different slope in dose response) is not considered, and similarly, (3) multiple effects occurring in parallel are not considered.

Therefore, the DRR does not cover all potential adverse effects above threshold (and, thus, systematically underestimates impact at high exposure levels). However, increases in severity, potential multiple effects or the change of the leading critical toxicity endpoint at such high exposure levels are described qualitatively.

With these restrictions in mind, the default approach is applied as follows:

The selected OEL (mostly from SCOEL) is used to define a zero response, i.e., 0 % of the exposed are assumed to suffer from the respective health effect, if exposed for all of their working life time to this OEL-air-concentration.

A three times higher concentration (3 x OEL) is usually assumed to correspond to a 10% incidence. This factor 3 is taken from the usual "LOAEC to NOAEC" – default and the corresponding increased incidence of affected persons.

Further extrapolations to higher concentrations are avoided, if not supported by substance specific data. Substance specific data are preferred to default approaches.

2. Monetisation of the health impacts

The current and future cases of ill health at have been estimated for both cancer and non-cancer endpoints using the following inputs:

- The ERRs and DRRs;
- The numbers of workers exposed;
- The exposure concentrations (the average concentrations [Arithmetic Mean or Geometric Mean] are taken as the basis for calculations); and
- Trends in the exposed workforce and exposure concentrations.

For some chemical agents, two scenarios were estimated:

- **A: actual exposure concentrations** – data one exposure concentrations collected, estimated, etc.; and
- **O: exposure concentrations** estimated on the basis of existing OELs – this scenario typically assumes that companies have achieved concentrations at 50% of the national OEL.

For some chemical agents, there are sufficient data to show that companies have achieved a substantially lower exposure concentration than demanded by the OELs and, consequently, the O scenario has not been modelled.

Cost categories considered

Specific guidance is provided in the BR Toolbox for health impacts (BR Tool #31). This is summarised in the table below.

Table 21: BR Toolbox on social impacts

Aspect	Guidance
Health impacts	Direct impacts Indirect impacts: does the option influence the socio-economic environment that can determine health status? *To assess direct and indirect health impacts monetary and non-monetary methodologies can be used.* Non-monetary approaches: QALYs, DALYs, HLYs, Monetary approaches: preference based approaches (WTP, WTA -> VOSL, VOLY), accounting-style approaches (cost of illness method=only medical expenses, human capital method=loss of future earnings in case of disability or premature death)
Source: RPA (2018)	

Focusing on the example of cancer, the costs of cancer can be divided into:

- **Direct costs:** These are the medical costs associated with the treatment of cancer and the non-medical costs that arise directly as a result of cancer. Direct medical costs are those associated with the treatment and services patients receive, including the cost of hospitalisation, surgery, physician visits, radiation therapy and chemotherapy/ immunotherapy. Depending on the structure of national health care provision, these costs may be borne fully or partially by the government (tax payers). Direct medical costs associated with cancer vary significantly by cancer type and also vary over time. Direct non-medical costs are expenditures as a result of cancer that are not involved in the direct purchasing of medical services. They include, for example, the

cost of transport to attend appointments (which may be borne by patients or their relatives/friends) and costs such as additional childcare or cleaning services.

- **Indirect costs:** These are the monetary losses associated with the time spent receiving medical care, including productivity losses due to time spent away from work or other usual activities and lost productivity due to premature death. Indirect costs may be incurred by the patient but also by their family/friends, for example, through providing unpaid care. Employers might also bear costs indirectly through inter alia loss of output; payments related to sick leave; administrative costs related to a worker's absence; additional recruitment costs; loss of experience/expertise; overtime working; compensation payments (although this may be covered by some form of employer's liability insurance); and insurance premiums. Depending on the national structure of social security provision, the government (tax payers) may also bear the costs of any disability/social security payments and will also suffer losses through foregone tax receipts.
- **Intangible costs:** These include the non-financial 'human' losses associated with cancer, e.g. reduced quality of life, pain, suffering, anxiety and grief.

In economic impact terms, the total social costs[71] of ill health are the measured by the costs borne for health care provision, together with lost output (including productivity losses), gross wage and non-wage labour costs of absent workers (such as loss of experience), administrative costs and the intangible costs. These represent the direct and indirect resource costs and the non-market 'external' costs of illness. The other costs listed above (e.g. insurance premiums) relate to what are commonly referred to as 'transfer payments', which do not give rise to net welfare effects. As a result, they are not considered in economic analyses, even though they may be important in financial terms to an individual worker or an employer.

3. The model

The endpoints for which the benefits (i.e. changes in the costs caused by ill health) have been estimated are summarised in the table below.

Table 22: Relevant endpoints

Chemical agent	Cancer endpoint	Non-cancer endpoint
As	Lung cancer	Peripheral neuropathy
Be	Lung cancer (but no workers above threshold)	Chronic Beryllium Disease (CBD)
Cd	Lung cancer	Increased proteinurea
Cr(VI)	Lung cancer	-
CH2O	Nasopharyngeal cancer	Sensory irritation
MOCA	Lung cancer	-
Source: RPA (2018)		

The key model inputs are summarised below. The inputs are those parameters whose variation changes the results and for which the model is run multiple times to derive a benefits curve.

[71] From a welfare economic perspective.

Table 23: Key model inputs

Parameter	Explanation
Rx: Estimate of the risk or fraction of workers affected	Exposure-Risk Relationship (ERR) or Dose-Response Relationship (DRR)
ExW: Exposed workforce	Number of workers exposed at different points in time
Cx: Exposure concentration	8-hr TWA that the workers are exposed to (real concentration, i.e. if PPE is currently worn, the measured concentrations are adjusted to take into account PPE where possible)

In addition to the inputs, the model is underpinned by a range of default assumptions regarding the onset of the disease and its effects. These assumptions differ by chemical agent but do not change depending on the variations in the input data. Some of these assumptions are a simplification of complex real life scenarios or best estimates where authoritative evidence could not be identified from readily available literature. The model, however, provides a good approximation of the order of magnitude of the expected impacts and the core calculations are supported by sensitivity analysis.

The key areas in which assumptions had to be made to enable the calculations are set out below.

Table 24: Key assumptions and their consequences for the sensitivity analysis

Parameter	Explanation
Onset of the disease	
MinEx	The minimum exposure duration required to develop the endpoint
MaxEx	The time required for all workers at risk to develop the endpoint
ModEx	The modelled exposure duration (the ERRs and DRRs are for a 40 year period)
Lat	The latency with which the effect is demonstrated
Dist	The distribution of cases over the period between MinEx and 40 years
The effects of the disease	
Mortality	Mortality rate as a result of the relevant condition
Value of a case	**Monetary value of a case taking into account the direct, indirect, and intangible costs**
Source: RPA (2018)	

Model outputs:

- The number of new cases for each health endpoint assigned to a specific year in the 60 year assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

Model inputs:

Estimate of the risk or fraction of workers affected

The estimate of the risk or fraction of workers affected:

For cancer: an Exposure-Risk-Relationship (ERR) i.e. excess risk of developing cancer due to lifetime occupational exposure to a chemical agent (taken here to mean 40 years); and

For non-cancer endpoints: a Dose-Response-Relationship (DRR), i.e. the proportion of workers that will develop an endpoint when exposed to a certain level.

Exposed workforce

Several scenarios are modelled for the exposed workforce. It is possible to take into account all the complexities of real life workforce changes within the framework of this study and these scenarios are theoretical constructs/simplifications which are designed to provide order of magnitude estimates without the need to construct a very large number of scenarios to cover all the types of workforce dynamics. Two distinct issues are covered under the term 'turnover'. Primarily, turnover refers to the natural turnover rate resulting from workers leaving their employer and new workers joining. In addition, it can refer to the turnover triggered by those that absent from work due to illness and replaced by others.

Exposure concentrations

Two scenarios have been modelled:

- ACTUAL (A) with data sourced from literature and consultation – this is the core scenario for cost-benefit calculations; and
- OEL (O) where exposure concentrations are assumed to be 50% of the national OEL – this is used as a check of the order of magnitude of scenario (A).

Assumptions

The model assumes that no cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has expired, see table below. The default MinEx is two years for cancer, a standard assumption for a chronic condition, and 0 years for non-cancer endpoints. Although data on minimum exposure periods are lacking and the data in the table below are generic estimates, a short MinEx has been chosen wherever appropriate to the minimum exposure periods in table below have been derived using a precautionary approach that maximises worker protection.

Table 25: Minimum & maximum exposure duration to develop a condition (MinEx&MaxEx)

Endpoint	MinEx (years)	MaxEx (years)
Cancer	2	40
Non-cancer endpoint default	1	2
Renal disease	1	20
Chronic beryllium disease	1	2
Sensory irritation	1 day	1 day
Peripheral neuropathy	1	2
Source: RPA (2018)		

Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over a 40 year period are assigned to specific years. However, the ERRs and DRRs developed under this study are for 40 years of exposure.

Cancer

For reasons of simplicity, the following approach is used to distribute the total 40-year cancer risk (i.e. not incidence but risk since incidence is delayed due to latency) over the 40 year period:

It is assumed that no risk arises until MinEx has expired. It is assumed that, subsequently, the distribution is linear, i.e. 0% of the excess risk arises in year 2 and 100% of the excess risk arises by year 40.

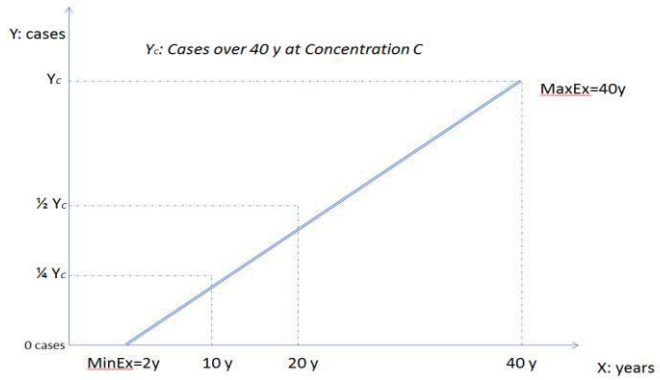

Figure 4: Lung cancer risk – distribution over time
Source: RPA (2018)

Default for non-cancer endpoints - including chronic beryllium disease

Typically, the fraction affected achieves that predicted by the DRR as soon as MaxEx expires and remains constant over the 40 year period (although the certainty of the 'fraction' estimated on the basis of the DRR increases towards the end of the period). As a default assumption, two years has been chosen as a conservative MaxEx and it is assumed that there will not be further increases of non-cancer effects from longer duration after MaxEx. The fraction affected that is calculated on the basis of the DRR is the same between 2 years and 40 years and increases in a linear manner between Year 0 and Year 2.

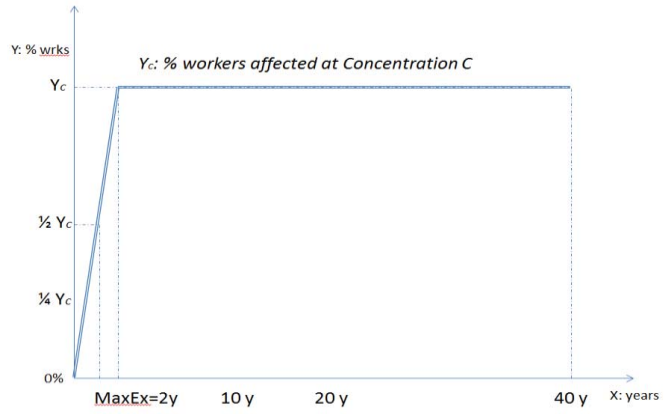

Figure 5: Non-cancer endpoints – fraction affected over time
Source: RPA (2018)

CH_2O: Sensory irritation

An example is provided below for sensory irritation (CH_2O). The DRR only tells us that the fraction affected = 2% (1 day), 2% (1 year), 2% 20 years, 2% (40 years). Workers may be affected after a few hours.

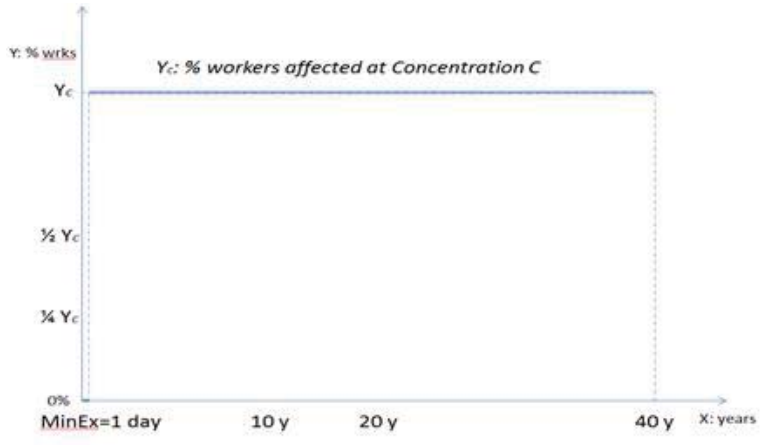

Figure 6: CH2O & sensory irritation
Source: RPA (2018)

Cadmium: kidney disease

Although the default for non-cancer effects is 2 years and then a constant fraction of workers affected until Year 40, the time typically needed for renal damage is longer than 2 years, e.g. 20 years. The distribution is expected to be largely linear [affected fraction (for 10 years of exposure) = affected fraction (for 40 years of exposure) x (10/ 20)].

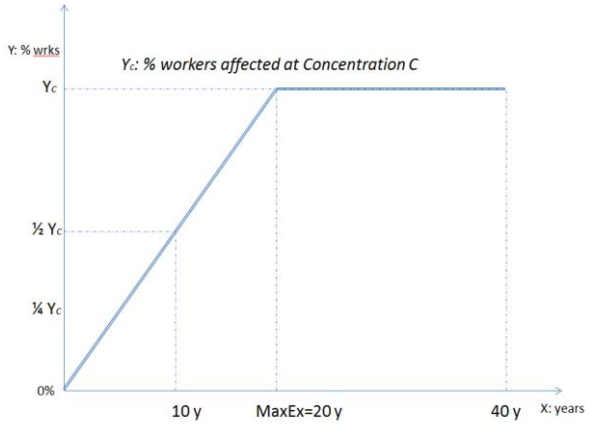

Figure 7: Kidney damage – fraction affected over time
Source: RPA (2018)

Latency

Cancer

By way of simplification, a single latency value is used for the calculation of the core scenario. According to Rushton et al (2012), all solid tumours are expected to have a latency of 10-50 years, meaning that the average latency is 30 years.

40 years of exposure and 30 years of latency would translate into a 70 year assessment period. However, in order for the assessment to be protective to workers (longer latency reduces the benefits since they are discounted more heavily) and to ensure consistency with previous impact assessments for the first and the second wave of new OELs under the CMD[72] which relied on an assessment period of 60 years, a latency period of 10 years is used in this study.

A 10 year assessment period means that all cases of cancer that develop on the basis of the risk over the 40 year period will be diagnosed and treated[73]within the assessment period of 60 years. This is shown graphically below.

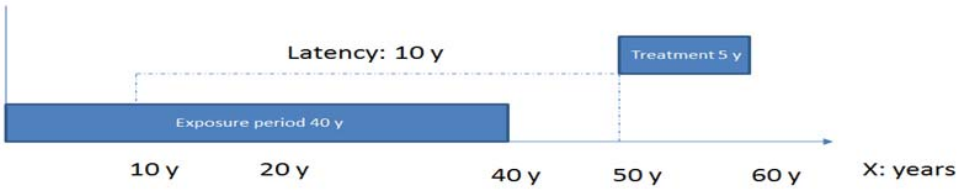

Figure 8: The assessment period
Source: RPA (2018)

Non-cancer endpoints

[72] These relied on a 60 year assessment period. http://ec.europa.eu/transparency/regdoc/rep/10102/2016/EN/SWD-2016-152-F1-EN-MAIN-PART-1.PDF, p. 20 and http://ec.europa.eu/transparency/regdoc/rep/10102/2017/EN/SWD-2017-7-F1-EN-MAIN-PART-1.PDF, p. 30

[73] The treatment period for cancer used in the model is five years.

The estimated latency period for the non-cancer endpoints in this study is either 0 years or 2 years. There is very limited evidence for latency of the relevant non-cancer conditions and these are study team assumptions derived for the purposes of the modelling for this study.

Table 26: Latency (Lat)

Endpoint	Lat (years)
Renal disease	0
Chronic beryllium disease	2
Sensory irritation	0
Peripheral neuropathy	0
Source: RPA (2018)	

The modelled exposure duration

The ERRs and DRRs are for a 40 year period. The modelled exposure duration is thus 40 years under the ExW-Constant scenario and 20 years under the ExW-Turnover scenario.

Whilst it is unlikely that a single worker is exposed to a chemical agent at a constant concentration throughout their whole working life, the 40 year period has been chosen in order to be protective to workers by assuming a worst-case scenario. In addition, the evidence used for the development of the ERR means that the greatest certainty about the ERR is at lifetime exposure, i.e. 40 years.

The effects of the disease

Mortality rate (MoR) as a result of the relevant condition is important since different monetary values are applied to mortality and morbidity. The mortality rates used in the model are given below.

Table 27: Mortality rate (MoR)

Endpoint	MoR (years)
Cancer - lung	80%
Cancer - nasopharynx	47%
End-stage renal disease	40%[74]
Chronic beryllium disease	10%
Sensory irritation	0%
Peripheral neuropathy	0%[75]
Source: RPA (2018)	

Treatment period

The treatment periods used in the model are given below. The end of the treatment period signifies either a fatal or illness-free outcome.

[74] Average for dialysis and transplant patients, see: http://www.lkdn.org/dialysis_life_expectency/KidneyDialysisLifeExpectancy.pdf

[75] Very few forms of peripheral neuropathy are fatal, see https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheet

Table 28: Treatment period

Endpoint	Treatment period (years)
Cancer	5
Non-cancer endpoint default	30
Renal disease	30
Chronic beryllium disease	30
Sensory irritation	No treatment required in most cases but where treatment required modelled as 1 year
Peripheral neuropathy	30
Source: RPA (2018)	

Monetary value of the relevant endpoint

The approach to the monetisation of ill health effects is based on the following approach.

Table 29: Benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[76]	Opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with cancer)
	Cost for employers (e.g. liability insurance)	Cost to employers due to insurance payments and absence from work
Indirect	Mortality – productivity loss	The economic loss to society due to premature death
	Morbidity – lost working days	Loss of earnings and output due to absence from work due to illness or treatment
Intangible	Approach 1 WTP: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY: Mortality	
	Approach 2 DALY: Morbidity	
Source: RPA (2018)		

Two approaches to the monetisation of intangibles have been adopted for the purposes of this study.

- Approach 1: Application of a single WTP value to each case; and
- Approach 2: Use of DALYs and their monetisation.

[76] A decision has been taken to include informal care costs in this analysis even though some elements of these costs may also have been included in individuals' willingness to pay values to avoid a future case of ill health. This decision may result in an overestimate of the benefits as generated by this study.

4. Benefits assessment

Workers & families

The direct and indirect resource costs are estimated using market-based information, for example, data on health care costs, and estimates of lost output (i.e. the value of a day's work).

Added to these are the 'human' or intangible costs associated with a case, which are measured in terms of an individual's willingness to pay for the reduction in the risk of mortality or morbidity (Approach 1) or monetised DALYs (Approach 2).

Under Approach 1, the most commonly used means of estimating individuals' WTP for a reduction in the risk of an illness is through the use of experimental markets and survey techniques (e.g. contingent valuation or contingent ranking studies) to directly elicit individuals' WTP for a reduction in the risk of death or morbidity.

The key measures are the value of a statistical life – a VSL – and the value of a case of morbidity (value of cancer morbidity VCM or value of morbidity VM). The VSL is essentially a measure of a change in the risk of fatality, where this is found by determining individuals' willingness to pay for a small change in risk which is then summed across the population at risk.

Employers

The benefits of introducing OELs have obvious benefits for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also reap benefits from their workers being less at risk of occupational illness. Such benefits include:

- higher labour productivity resulting from reductions in absenteeism and associated production losses;
- reduced administrative or legal costs relating to workers who are ill;
- reduced sick leave payments.

There is no risk of double counting the benefits regarding productivity for employers and workers in the totals.

Employers and workers –reduction of lost earnings and productivity losses

Individuals will incur costs associated with their inability to work in terms of a loss of earnings, including losses linked to days off for treatment as well as days off due to illness. Luengo-Fernandez et al (2013) developed estimate of the magnitude of such costs by member state in terms of an average cost per fatal or non-fatal cancer. These included what are referred to as "productivity losses" due to early death and then lost working days due to morbidity effects. Across all cancers, an average figure of EUR 5 047 is given for productivity losses and EUR 1 118 for the costs associated with lost working days due to morbidity effects (with these based on lost wages as the measure of lost output).

Public sector – avoided cost of healthcare

Cancer

Key data from Luengo-Fernandez, et al (2013) have been used for the calculation the avoided healthcare costs of illness. EUR 7 000 is used in the model as the average cost for "all cancers".

Non-cancer effects

In this impact assessment specific assumptions for chronic beryllium disease, elevated proteinurea, sensory irritation and peripheral neuropathy have been applied, detailed tables and summary tables are presented in [RPA 2017].

Sensitivity analysis

Key parameters to be varied:

- latency;
- a third scenario is modelled within the framework of the sensitivity analysis which assumes standard turnover rates based on Eurostat data resulting in an increase in the exposed workforce and, consequently, ill health by a factor of 4.6;
- trends over time (exposed workforce and concentrations); and
- influence of the fact that some workers have had higher concentrations in the past and reduction is only over a part of the period.

5. Cost model

The spreadsheet model calculates the cost of reducing exposure from one level to another, with the resulting sums being used to plot a cost curve. The model t calculates the costs for a group of similar companies incurred in reducing air exposure to a target OEL based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost. The model is run several times to construct a continuous cost curve.

Key model inputs and assumptions

95th percentile

All costs are calculated on the basis of compliance as the 95th percentile of the exposure concentrations. This reflects the fact that it is expected that companies may be asked to demonstrate compliance on this basis rather than on the basis of the average of the samples taken.

Discount rate

The static discount rate is 4%: this is taken over the 60 year period. A dynamic discount rate is taken in the sensitivity analysis. The dynamic rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 40 years.

Affected workers and workstations

Each company size was assumed to have an average number of workers affected and associated workstations requiring adjustment.

Table 30: Number of workers and workstations

Size of company	Number of workers affected by beryllium	Number of workstations
Small	2	1
Medium	7	4
Large	30	16
Source: RPA (2018)		

Three different costs, all present values for 60 years, are calculated: TOTAL, (CAPEX + OPEX) CAPEX, and OPEX.

RMMs considered

The model considers following types of RMMs:

- Local Exhaust Ventilation (LEV), extraction at source;
- Worker enclosures (WE), i.e. physical separation of workers in an enclosure or control room;
- Respiratory Protective Equipment (RPE);
- General Dilution Ventilation (GDV);
- Organisational & hygiene measures (OH).

For each type of RMM, several levels that companies can achieve have been defined (see RPA 2017 for details).

RMM effectiveness

Every RMM has a different level of effectiveness in reducing the workers exposure. The percentage reduction in exposure due to each type of RMM used in the analysis is shown below.

Table 31: Percentage reduction in exposure achieved with RMM

Type of RMM	% reduction in exposure
Discontinuation & Substitution	100%
Rework	50%
Full enclosure	99.5%
Partial enclosure	90%
Open hood	80%
No LEV	0%
Pressurised or sealed	99.5%
Simple enclosed cab	80%
No enclosure	0%
Breathing apparatus	99.5%
HEPA filter	95%
Simple mask	60%
No mask	0%
Organisational measures	30%
No organisational measures	0%
General dilution ventilation	30%

Type of RMM	% reduction in exposure
No general ventilation	0%
Source: RPA (2018)	

RMM costs

Costs have been estimated by company size band by type of RMM applied.

Table 32: Cost of various RMMs in EUR

Size of company	Small 2 workers exposed Exposed workers on 1 machine			Medium 27 workers exposed 14 machines			Large 75 workers 40 machines		
Type of RMM	CAPEX 2017	Life-span years	OPEX (% of CAPEX)	CAPEX 2017	Life-span years	OPEX (% of CAPEX)	CAPEX 2017	Life-span years	OPEX (% of CAPEX)
RWK: Rework	25,000			350,000			1,000,000		
LEV 3: Full enclosure	45,000	20	10%	440,000	20	10%	1,700,000	20	10%
LEV2: Partial enclosure	30,000	20	10%	240,000	20	10%	650,000	20	10%
LEV1: Open hood	7,000	20	10%	90,000	20	10%	260,000	20	10%
WE 2: Pressurised or sealed	30,000	20	10%	240,000	20	10%	650,000	20	10%
WE 1: Simple enclosed cab	7,000	20	10%	90,000	20	10%	260,000	20	10%
RPE 3: Breathing apparatus	2,600	2	1,000 %	35,000	2	1,000 %	100,000	2	1,000%
RPE2: HEPA filter	300	Mask: 1 month, Filter: 1 month	50%	4,000	Mask: 1 month, Filter: 1 month	50%	11,000	Mask: 1 month, Filter: 1 month	50%
RPE 1: Simple mask	500	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year	7,000	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year	20,000	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year
OH 1: Organisational measures	2,000		50%	27,000		50%	75,000		50%
GDV 1: General dilution ventilation	6,000	20	30%	40,000	20	30%	100,000	20	30%
Source: RPA (2018)									

The assumptions on the effectiveness and suitability individual RMMs are used to determine whether a specific RMM is suitable to reduce exposure in a specific sector by

the required degree. If several RMMs are suitable and effective enough, the cheapest one is selected. RMMs that companies already have in place are taken into account and a more effective RMM is chosen.

The total cost of reduction is then calculated as a sum of all company-level decisions.

Estimation of the costs of sampling and analysis

The costs of monitoring air concentrations (sampling and analysis) are estimated separately to the core model on the basis of data for several Member States (see detailed tables in[RPA 2018]).

6. Environmental impacts

Potential changes in OELs for the substances considered in this study may subsequently lead to additional or lower environmental impact. Many assumptions, which may or may not be realistic, would have to be included in an analysis of this environmental impact:

- Is the reduction of OELs mainly achieved by increased emissions from ventilation/ exhaust increase?
- Is air emission controlled and reduced, e.g., by filter systems?
- Is removed air integrated into secondary cycles with additional precipitation devices?
- Are filters subsequently disposed or treated (e.g., waste incineration)?
- Are there water screens established to collect and dispose aerosols from workplace?
- What is the link between water screens and effluent water to sewage systems?
- What is the current exact exposure scenario and the status of exposure reduction measures in place?

Because of these heterogeneous parameters, no general and realistic calculation on an environmental impact is possible. Qualitatively, it is assumed that changes in OEL will have limited consequences on environmental exposure and therefore there is only a low-priority need for quantitative consideration within the overall impact assessment.

Environmental impact profiles presented as four indices for all of the six substances have been established, independently from changes due to OEL changes.

- PBT-profile. Persistency, bioaccumulation and toxicity (PBT) are defined parameters under various regulations and are an important criterion for “substances of very high concern” (SVHC) under REACH.
- The “predicted no effect concentration” (PNEC) is an environmental hazard indicator. A currently already existing relevant risk for the environment can be deduced, if prevailing environmental exposure is close to the PNEC or even exceeds the PNEC. Therefore, we screened information on the ratio: “environmental exposure/ PNEC”, where ratios close to 1 would substantiate environmental concern (we did not discriminate the aquatic or soil compartment in detail for the purpose of this screening).

- Additional air emissions may be of primary concern as an entry pathway into the environment from industrial pathways, where workplace exposure is via aerosols/ dust or gases. Therefore we looked for indicators in respect to the degree emissions into environment from industrial processes contribute to the overall environmental burden (e.g., from power stations, traffic, natural sources, etc.).
- Finally the exposure pathway: "humans via the environment" has been considered. If current environmental concentrations already indicate / cause a health problem to humans (e.g., via food or drinking water exposure) without consideration of additional emissions from OEL changes, this should be acknowledged. However, no formal assessment of "humans via the environment" as would be required according to REACH guidance was performed, because of the input variables would be highly speculative.

From these four criteria we derive an attributed overall environmental weighting of the respective substance, with:

- "low" relevance, where most of the criteria above do not indicate concern;
- "moderate" relevance, where some of the criteria indicate relevant concern, but others do not;
- "significant" relevance, if most of the criteria indicate relevant concern; and
- "substantial" relevance, where any changes in environmental concentrations should be carefully observed, because the current status of the environmental impact by that substance already indicates the need for exposure reduction, as manifest from all four criteria.

7. Consultation exercise

The aim of the consultation activities was to collect more detailed information on the potential impacts of modifications to the CMD that is not available in published literature and internet searches. Although some information on OELs is available, limited information is available on concrete measures already in place and that would need to be implemented should limits be modified. The information sought via consultation therefore included sizes of companies, sectors and processes that would be affected, number of workers exposed, current air concentrations of chemical agents concerned (both 8 hour time weighted averages and 15 minute reference periods), risk management measures currently in place, as well as risk management measures that would need to be implemented should the OELs be modified and associated costs.

Consultation carried out for the purposes of this study consisted of three activities:

- questionnaires
- telephone interviews
- site visits.

Mixed methods were adopted to ensure that a large number of organisations and individuals were able to provide their views within the time constraints and resource limits. Using mixed methods also enabled the study team to gather varying details of information and to explore information further where the need arose.

Targeted Online Questionnaires

Stakeholders were initially contacted via email with an overview of the study and a link to the questionnaires. If the stakeholders preferred to answer the questionnaire in a Word document (so that it could be shared among several colleagues, for example), it was also possible to obtain these upon request.

Four separate questionnaires were drawn up, each one created to gather information from different stakeholder groups:

- Questionnaire 1 was aimed at companies whose workers were exposed to cadmium and its organic compounds, beryllium and its inorganic compounds, inorganic arsenic compounds, formaldehyde and 4,4'-Methylene-bis(2-chloroaniline) (MOCA);
- Questionnaire 2 for companies whose workers are exposed to Cr(VI) compounds from welding, plasma cutting and similar processes that generate fumes;
- Questionnaire 3 for occupational health and safety experts; and
- Questionnaire 4 for Member State authorities.

Telephone interviews

Both national experts and chemical agent experts were utilised for the purposes of the telephone interviews. Telephone interviews were requested both in the online questionnaires and via direct email and phone contact undertaken by the experts.

The purpose of the telephone interviews was to gain more insight into the answers provided in response to the questionnaires. It enabled more detailed information on processes to be collected, pinpointing exactly where exposure is likely to occur, what kinds of risk management measures are already in place and how effective they are, and what risk management measures would be required should limits be lowered and other potential ramifications for the company.

Site visits

Companies whose activities are likely to be affected by the potential modifications to the CMD were also asked whether they would be willing to welcome members of the study team for a site visit. These companies were asked both within the online questionnaire and within the telephone interviews.

The purpose of the site visits was to a gain a more concrete understanding of the risk management measures currently in place to protect against exposure to the chemical agents concerned, as well as of the risk management measures that would need to be implemented should the CMD be modified.

Staff attending the site visits were selected for their language capabilities and their knowledge of the chemical agent concerned, enabling more detailed information to be collected.

Other consultations

Trade unions

184 trade unions were contacted in order to inform them of the study and provide the opportunity to contribute information. Questionnaires with specific questions were not

drafted for trade unions as the information readily available to them is likely to vary from trade union to trade union. For this reason a set of basic questions were provided either via email or asked over the phone, and the experts carrying out the interview were able to ask more detailed questions in relation to the responses.

Six written responses were received in response to the requests. Trade unions predominantly provided information at a more general level (i.e. not particular to a specific chemical agent), with occasionally more specific data relating to a particular substance.

The trade unions viewed the Commission's efforts to expand the CMD positively, but were concerned that reprotoxic substances should also be included.

Information was provided by trade unions on the risks arising from exposure to carcinogens and mutagens at work. It was stated, for example, that the risks arising from exposure to carcinogens and mutagens at work are not immediately visible, and that inconsistencies exist within data with regard to cancers recognised as occupational diseases and the number of cancers attributable to occupational exposure, for example. More generally, it was underlined by the trade unions that the quality of the data on occupational cancers is rather low, with EU data on cancer containing little information on patients' occupations. The point was also raised that, due to the long latency period of some of the associated cancers, companies where exposure has taken place are unlikely to be burdened by the periods of absence associated with cancer.

With regard to the setting of OELs, it was indicated by the trade unions that clear criteria are needed in order to ensure greater transparency and consistency within the legislation.

Face-to-face meetings and additional conference calls

Two face to face meetings were held with the International Cadmium Association (ICdA); one in Paris and one in London. 10 conference calls have also been carried out with the ICdA, with 11th and 12th phone calls also planned for January 2018.

One face-to-face meeting was carried out with the Beryllium Science and Technology Association (BeST), and one more meeting is planned for the 22nd of January 2018. During this meeting information was provided on the different uses, processes, and relevant sectors. Furthermore, opinions were provided on whether or not an STEL would be appropriate for beryllium.

Laboratories

36 laboratories were also contacted to obtain sample quotes of monitoring costs for the chemical agents in question. Ten responded, with four able to provide beneficial information.

The questionnaires used and the results from the consultation exercise are presented in detailed tables in the RPA (2018) draft final report.

8. Review of the REACH CSRs

Identification of the relevant CSRs

In an attempt to gain further insight in current risk management measures and actual exposure levels at workplaces, chemical safety reports (CSRs) submitted under Regulation (EC) No 1907/2006 were assessed. Since CSRs are confidential, ECHA was requested to extract CSRs from registration dossiers for a limited number of 19 chemical agents belonging to the six (groups of) chemicals subject to this report. ECHA extracted all files attached in section 13 of the IUCLID datasets of all registrations for these 19 chemical agents. In some cases, these attachments did not represent complete CSRs, but rather other attachments (e.g. files intended to document strictly controlled intermediates for chemical agents registered as intermediates or only part A of the CSR, which typically only contains a statement that RMMs are implemented and communicated). The table below lists the chemical agents for which such attachments were extracted and the groups to which they belong.

Table 33: List of chemical agents for which CSRs were requested from ECHA

Chemical agent	CAS No.	Group
4,4'-methylenebis[2-chloroaniline]	101-14-4	4,4'-methylenebis[2-chloroaniline] (MOCA)
Beryllium oxide	1304-56-9	Beryllium and inorganic beryllium compounds
Beryllium	7440-41-7	Beryllium and inorganic beryllium compounds
Cadmium carbonate	513-78-0	Cadmium and inorganic cadmium compounds
Cadmium oxide	1306-19-0	Cadmium and inorganic cadmium compounds
Cadmium sulphide	1306-23-6	Cadmium and inorganic cadmium compounds
Cadmium	7440-43-9	Cadmium and inorganic cadmium compounds
Cadmium chloride	10108-64-2	Cadmium and inorganic cadmium compounds
Cadmium nitrate	10325-94-7	Cadmium and inorganic cadmium compounds
Cadmium hydroxide	21041-95-2	Cadmium and inorganic cadmium compounds
Lead, bullion	97808-88-3	Cadmium and inorganic cadmium compounds
Chromium trioxide	1308-38-9	Chromium (VI) compounds
Formaldehyde	50-00-0	Formaldehyde
Gallium arsenide	1303-00-0	Inorganic arsenic compounds including arsenic acid and its salts
Diasatriselenide	1303-36-2	Inorganic arsenic compounds including arsenic acid and its salts
Diarsenic trioxide	1327-53-3	Inorganic arsenic compounds including arsenic acid and its salts
Arsenic acid	7778-39-4	Inorganic arsenic compounds including arsenic acid and its salts
Lead, antimonial, dross	69029-51-2	Inorganic arsenic compounds including arsenic acid and its salts
Flue dust, lead-refining	69029-67-0	Inorganic arsenic compounds including arsenic acid and its salts
Source: RPA (2018)		

Under the REACH Regulation, substances can be registered with a full registration (FULL) or an intermediate registration (INT), if the substance is exclusively handled under strictly controlled conditions. In addition, registrations are often submitted by consortia of companies with a single lead company (LEAD) generally submitting the

complete CSR and all the members of such a joint submission (MEMBER) often only attaching Part A of the CSR (see above).

The following table summarises the registrations available per substance differentiated by the registration (FULL; INT) and submission type (LEAD, MEMBER).

Table 34: Available REACH registrations

Chemical agent	CAS No.	Number of registrations				
		Total	FULL LEAD	FULL MEMBER	INT LEAD	INT MEMBER
4,4'-methylenebis[2-chloroaniline]	101-14-4	*Potentially confidential*				
Beryllium oxide	1304-56-9					
Beryllium	7440-41-7					
Cadmium carbonate	513-78-0					
Cadmium oxide	1306-19-0					
Cadmium sulphide	1306-23-6					
Cadmium	7440-43-9					
Cadmium chloride	10108-64-2					
Cadmium nitrate	10325-94-7					
Cadmium hydroxide	21041-95-2					
Lead, bullion	97808-88-3					
Chromium trioxide	1308-38-9					
Formaldehyde	50-00-0					
Gallium arsenide	1303-00-0					
Diarsenictriselenide	1303-36-2					
Diarsenic trioxide	1327-53-3					
Arsenic acid	7778-39-4					
Lead, antimonial, dross	69029-51-2					
Flue dust, lead-refining	69029-67-0					
Total		**392**	**18**	**321**	**1**	**52**

Source: RPA (2018)

With the exception of cadmium carbonate, a single FULL LEAD registration and up to 204 FULL MEMBER registrations are available per substance. This is in agreement with the expectation since there is only a single lead company per consortium, but multiple member companies. In the case of cadmium carbonate, a company registering the substance as an intermediate under strictly controlled conditions acted as the lead company, while all members of the joint submission registered the substance with a full registration (potentially because they or their downstream users use the substance in other applications than an intermediate under strictly controlled conditions). Formaldehyde represents a special case, since registrations for this substance account for more than half of all registrations evaluated for all 19 chemical agents (207/392, 53 %). Among the 392 registrations, there are some registrations that are currently not active: 1 annulled, 4 revoked and 27 inactive registrations.

Evaluation of CSRs

While all 19 chemical agents are registered, a registration may or may not contain a complete CSR (as discussed above). Therefore, the attachments extracted by ECHA were further analysed to establish whether these constituted complete CSRs or other files. While the LEAD FULL registration is generally expected to contain the complete CSR, members of a joint submission can chose to submit an additional CSR, e.g. with uses specific to their company or its downstream users that are not covered by the CSR of the lead company.

Further evaluation of the extracted information also suggested that there are some cases, where the LEAD FULL registration did not contain a CSR, while MEMBER FULL registrations did. This was e.g. the case when the registration of the lead company was 'inactive' (see above). Other cases appeared to suggest that responsibilities are changing (e.g. a former member taking over as the lead company in a joint submission). As a result of these considerations, CSRs of lead and members were evaluated, whenever possible. However, the sheer number of CSRs submitted prevented such evaluations for a few chemical agents, most notably formaldehyde. In such cases, the CSR from the LEAD FULL registration was given preference. In some cases, different versions of almost identical CSRs were submitted by different companies. These appeared to reflect a different update status of the registrations and the most recent version of the CSR was evaluated. In a single case, the entire CSR was claimed confidential by the lead company and could not be evaluated. In this case, available member CSRs were evaluated.

This evaluation also showed that exposure of workers to formaldehyde was based on a separate report annexed to the CSR. This annex was not only submitted by the lead company, but also by many members of the joint submission. This annex formed the basis of the evaluations in the case of formaldehyde. As a consequence, the impossibility to evaluate all attachments submitted for formaldehyde is considered a minor issue.

The following table summarises the information on CSRs available for evaluation.

Table 35: Availability of CSRs for evaluation

Chemical agent	CAS No.	CSR availability (justification)
4,4'-methylenebis[2-chloroaniline]	101-14-4	2 CSRs
Beryllium oxide	1304-56-9	No CSR (≤ 10 tonnes per annum)
Beryllium	7440-41-7	No CSR (≤ 10 tonnes per annum)
Cadmium carbonate	513-78-0	2 CSRs
Cadmium oxide	1306-19-0	1 CSR
Cadmium sulphide	1306-23-6	1 CSR
Cadmium	7440-43-9	1 CSR
Cadmium chloride	10108-64-2	2 CSRs
Cadmium nitrate	10325-94-7	1 CSR
Cadmium hydroxide	21041-95-2	1 CSR
Lead, bullion	97808-88-3	1 CSR – not evaluated
Chromium trioxide	1308-38-9	2 CSRs (checked only for information on welding and associated operations)
Formaldehyde	50-00-0	Many CSRs (evaluation based on Annex on worker exposure)
Gallium arsenide	1303-00-0	2 CSRs
Diarsenictriselenide	1303-36-2	No CSR (≤ 10 tonnes per annum)
Diarsenic trioxide	1327-53-3	2 CSRs (checked for uses exempted from authorisation)
Arsenic acid	7778-39-4	1 CSR
Lead, antimonial, dross	69029-51-2	1 CSR – not evaluated
Flue dust, lead-refining	69029-67-0	1 CSR – not evaluated
Source: RPA (2018)		

Available CSRs were evaluated in detail for uses of the substance, occupational exposure associated with these uses as well as risk management measures and operational conditions. These data were used in the assessments of the chemicals agents documented in separate reports.

A detailed discussion is available in the RPA (2018) draft final report.

Annex 5: OELs and STELs in EU Member States for the substances subject to this report

Table 36: OELs for five substances / groups of substances for EU-Member States

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)][§]	MOCA [mg/m³ (ppm)][§]
Austria	0.03 (I) - manufacture of batteries, thermic extraction of zinc, lead and copper, welding of Cd containing alloys 0.015 (I) -other uses	5 (I) -whetting of Be metals and alloys, SKIN 2 (I) -other uses, SKIN	0.1 (I)	0.37 (0.3) -SKIN	0.02 (0.002) -SKIN
Belgium	0.01 (I) 0.002 (R)	2 (I)	0.01 (I)	-	0.11 (0.01) -SKIN
Bulgaria	0.05	2	0.05	1.0 (0.83)	-
Croatia**	0.03 (R) -CdS and CdS pigments 0.025 -CdF_2, CdO, $CdCl_2$	2 -except aluminium beryllium silicate	0.1 -SKIN notation only for AsO_3 and As_2O_3	2.5 (2.0)	0.005 (0.0005) -SKIN
Cyprus	0.05 (T) -metal powder and fumes, SKIN	2 -SKIN	0.01 -SKIN	3.0 (2.0) -SKIN	-
Czech Republic	0.05 -SKIN	1	0.1	0.5 (0.42) -SKIN	-
Denmark	0.005 –powder, dust, and smoke[+]	1 -powder and compounds, SKIN	1 -calcium arsenate 0.01 (T) -other inorganic As compounds	0.4 (0.3)	0.11 (0.01) -SKIN
Estonia	0.05 (T) 0.01 (I)	2	0.03	0.6 (0.5)	-
Finland**	0.004 (R)	0.1 (I) -SKIN	0.01 (I) [+]	0.37 (0.3)	0.11 (0.01) -SKIN
France[§§]	0.05 (I) [+]	2 (I) -SKIN	0.2 -As_2O_3[+]	0.6 (0.5)	0.22 (0.2) -SKIN
Germany	1.0 µg/m³ (I) –only for non-carcinogenic effects 1.6 µg/m³ (I) - "tolerable risk" * 0.16 µg/m³ (R) - "acceptable risk"	0.14 (I) –except aluminium beryllium silicate 0.06 (R) –except aluminium beryllium silicate	8.3 µg/m³ (I) - "tolerable risk"* 0.83 µg/m³ (I) - "acceptable risk"	0.37 (0.3)	-
Greece	0.025	5	0.1	2.5 (2.0)	0.22 (0.2) -SKIN
Hungary	0.05 -CdF_2, $CdCl_2$, CdO 0.015 -except CdF_2, $CdCl_2$, CdO[+]	2	0.03 -As_2O_5, SKIN 0.1 -As_2O_3, SKIN 0.01 -other inorganic	0.6 (0.5) -SKIN	-

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)][§]	MOCA [mg/m³ (ppm)][§]
			As compounds, SKIN		
Ireland	0.03 (R) -CdS and CdS pigments 0.01 (T) -except CdO fume and CdS pigments 0.025 (R) –CdO 0.002 (R) -except CdO fume and CdS pigments	0.2 -SKIN+	0.01 (T)	0.24 (0.2) +	0.005 (0.0005) -SKIN
Italy	-	-	-	-	-
Latvia	0.01	1 (I)	0.01 +	0.5 (0.42)	-
Lithuania	0.05 (I) 0.01 (R)	2 (I)	0.03	0.6 (0.5)	-
Luxembourg	-	-	-	-	-
Malta	-	-	-	-	-
Netherlands	0.005 (R) -CdO, CdS,$CdCl_2$+	-	0.0028 [Excess cancer risk: 4 x 10^{-4} – 0.0028 mg/m^3]2	0.15 (0.12)	0.02 (0.002) -SKIN
Poland	0.01 (I) 0.002 (R)	0.2 (I)	0.01 (I)	0.5 (0.42) -SKIN [0.37 (0.3)] – intended change~	0.02 (0.002) -SKIN
Portugal**	0.01 (I) 0.002 (R)	0.05 (I) -SKIN	0.01	0.37 (0.3)	0.11 (0.01) -SKIN
Romania	0.05	2	0.01	1.2 (1.0)	0.22 (0.2) -SKIN
Slovakia	0.15 (I)-others 0.03 (I) -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals	5 (I) -refers to whetting of Be metals and alloys, except aluminium beryllium silicate 2 (I) –refers to other uses, except aluminium beryllium silicate	0.1 (I)	0.37 (0.3) -SKIN	0.02 (0.002) -SKIN
Slovenia	0.03 (I) -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals 0.015 (I) -other uses	5 (I) –refers to grinding, except aluminium beryllium silicate 2 (I) –refers to other uses, except aluminium beryllium silicate	0.1 (I) -H_3AsO_4 plus salts	0.62 (0.5) -SKIN	0.02 (0.002) -SKIN
Spain	0.01 (I)	0.2 (I)	0.01 (T)	-	0.1 (0.01)

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts‡ [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)]§	MOCA [mg/m³ (ppm)]§
	0.002 (R)				
Sweden	0.02 (T) 0.002 (R)	2 (T)	0.01 (T)	0.37 (0.3) -SKIN	###
United Kingdom	0.025 -except CdS pigments, SKIN+ 0.03 -CdS and CdS pigments, SKIN+	2 -SKIN	0.1 (T) -SKIN	2.5 (2.0) -SKIN	0.005 (0.0005) -SKIN

‡ inorganic arsenic compounds including arsenic acid and its salts, arsine exempted, for all occupations, as As, if not stated otherwise in this column.
+ Contradictory data from questionnaire responses or GESTIS.
- not established/assigned
~ Intended change not implemented, yet.
§ Unit transformation according to specific country rounding or for formaldehyde according to 1 ppm = 1.2 mg/m³; 1 mg/m³ = 0.83 ppm and for MOCA according to 1 ppm = 10.9 mg/m³; 1 mg/m³ = 0.09 ppm.
SKIN: Skin notation assigned.

*** Limit values are indicative.*
§§ Limit values are recognised values with an indicative character – not according to decree modified on 30 June 2004 – thus not legally binding.
** In Germany, this concentration is not regarded as a fixed OEL (AGS; TRGS 910; https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=4), but as an upper limit, i.e. "tolerable risk level": usually 4:1000 excess risk. However, exposures below the "tolerable risk level" but above the "acceptable risk level" need to be minimised in order to avoid cancer risk.*
Handling of MOCA requires authorisation from the Swedish Work Environment Authority.

1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen.
2: HCN (2012) Health-Based Calculated Occupational Cancer Risk Values. Arsenic and inorganic arsenic compounds. Publication no. 2012/32.

Source: RPA (2018)

Table 37: Short-term Exposure Limits (STELs) for five substances / groups of substances for EU Member States

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)]§	MOCA [mg/m³ (ppm)]§
Austria	0.12 (I) -battery production, zinc-, lead- or copper winning, welding of cadmium	20 (I) -wetting of Be metals and alloys, SKIN 8 (I) other uses,	0.4 (I)	0.74 (0.6) -15 min, SKIN	0.08 (0.007) - 15 min, SKIN

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)][§]	MOCA [mg/m³ (ppm)][§]
	containing alloys 0.06 (I) -other uses	SKIN			
Belgium	-	10 (I) -SKIN	-	0.38 (0.3) – momentary, 15 min	-
Bulgaria	-	-	-	2.0 (1.7)	-
Croatia**	0.05 -CdO	-	-	2.5 (2.0)	-
Cyprus	-	-	-	-	-
Czech Republic	0.1 -ceiling	2 -ceiling	0.4 -ceiling	1.0 (0.8) –ceiling, SKIN	-
Denmark	-	-	-	0.4 (0.3) -ceiling	- [+]
Estonia	-	-	-	1.2 (1.0) –ceiling, 15 min	- [+]
Finland**	-	4 (I) -15 min, SKIN	-	1.2 (1.0) –ceiling, 15 min	-
France	0.05 -CdO, fume or respirable dust	2	-	1.2 (1.0)	-
Germany	0.008 (I)	0.14 (I) -except aluminium beryllium silicate 0.06 (R) -except aluminium beryllium silicate	-	0.74 (0.6) -15 min	-
Greece	0.1	-	-	2.5 (2.0)	-
Hungary	-	-	-	0.6 (0.5) -15 min, SKIN	-
Ireland	0.05 (R) -CdO, fume or respirable dust	-	-	0.5 (0.4) -15 min	-
Italy	-	-	-	-	-
Latvia	0.05	-	0.04 -15 min	-	-
Lithuania	-	-	-	1.2 (1.0) -ceiling	-
Luxembourg	-	-	-	-	-
Malta	-	-	-	-	-
Netherlands	-	-	-	0.5 (0.42) -15 min	-
Poland	-	-	-	1.0 (0.8) -15 min, SKIN 0.74 (0.6) - intended change[~]	-
Portugal**	-	-	-	-	-
Romania	-	-	0.1	3.0 (2.0)	-
Slovakia	-	-	-	0.74 (0.6) -15 min, SKIN	-
Slovenia	0.12 (I) - production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed	20 (I) –refers to grinding, except aluminium beryllium silicate 8 (I) –refers to other uses, except aluminium beryllium silicate	0.4 (I) -H_3AsO_4 plus salts	0.62 (0.5) -SKIN	0.08 (0.007) - SKIN

Member State / compound	Cadmium and inorganic compounds [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Beryllium and inorganic compounds [µg/m³] I=inhalable; R=respirable; T=total dust - fraction	Inorganic arsenic compounds including arsenic acid and its salts [mg/m³] I=inhalable; R=respirable; T=total dust - fraction	Formaldehyde [mg/m³ (ppm)][§]	MOCA [mg/m³ (ppm)][§]
	metals) 0.06 (I) -other uses				
Spain	-	-	-	0.37 (0.3)	-
Sweden	-	-	-	0.74 (0.6) - 15min, SKIN	-
United Kingdom	0.05 -CdO fume, SKIN	-	-	2.5 (2.0) -15 min, SKIN	-

+ Contradictory data from questionnaire responses or GESTIS.
- not established/assigned
~ Intended change not implemented, yet.
§ Unit transformation according to specific country rounding or for formaldehyde according to 1 ppm = 1.2 mg/m³; 1 mg/m³ = 0.83 ppm and for MOCA according to 1 ppm = 10.9 mg/m³; 1 mg/m³ = 0.09 ppm.
SKIN: Skin notation assigned.

***Limit values are indicative.*
§§ Limit values are recognised values with an indicative character – not according to decree modified on 30 June 2004 – thus not legally binding.
† Official Japanese values could not be identified. Therefore, recommendations from the Japan Society for Recommendation of Occupational Exposure Limits (JSOH), which are not mandatory, are stated.

References:
Questionnaire information (this project) or GESTIS (IFA, 2017), or country specific lists of OEL from web-search.

Source: RPA (2018)

Table 39(a): Member States with OELs higher than the proposed levels

Cadmium and its inorganic compounds under the scope of the CMD

MS with OELs higher than the proposed levels for Cadmium and its inorganic compounds			
OEL µg/m³	**Member States where current limits are higher**	**% of MSs above reference OELV**	**Notes regarding national limits**
1	AT, BE, BG, HR, CY, CZ, DE, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	80%	DE: Excess cancer risk (I): 2.5 x 10^{-3} (1.6 µg/m^3;"tolerable risk")
4	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL?, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	75%	BE: 5 µg/m^3 but not clear for what. EL: limit of 2.5 µg/m^3 but unclear if (I) or (R). If R, equiv. I is 6.25 µg/m^3
5	AT, BE, BG, HR, CY, CZ, DK?, FI, FR, EL?, HU, IE, LV, LT, NL, PL?, SI, ES?, SE, UK	70%	DK: limit of 5 µg/m^3 but unclear if (I) or (R). If R, equiv. I is 12.5 µg/m^3 EL: As above PL: 10 µg/m^3 based on (I) value and 5 µg/m^3 based on (R) value ES: 10 µg/m^3 based on (I) value and 5 µg/m^3 based on (R) value
10	AT, BG, HR, CY, CZ, DK?, FR, HU, IE, LV, LT, NL, SI, SE, UK	55%	AT: 15 µg/m^3 for welding of Cd containing alloys, other uses DK: as above FI: 10 µg/m^3 limit is indicative LV: limit of 10 µg/m^3 but unclear if (I) or (R). If R, equiv. I is 25 µg/m^3
25	AT, BG, HR, CY, CZ, FR, HU?, IE, LT?, SI, SE, UK?	45%	AT: 30 µg/m^3 for manufacture of batteries, thermic extraction of zinc, lead and copper HR: 75 µg/m^3 for CdS and pigments (indicative). Limit of 25 µg/m^3 covers Cd F, Cd O, Cd Cl HU: limit of 15 µg/m^3 but unclear if (I) or (R). If R, equiv. I is 37.5 µg/m^3 IE: limit of 62.5 µg/m^3 for "except CdO fume and CdS pigments". Other limits at 25 and 5 µg/m^3 LT: 50 µg/m^3 based on (I) value and 25 µg/m^3 based on (R) value UK: limits of 25 µg/m^3 and 30 µg/m^3 but unclear if (I) or (R). If R, equiv. I values are 62.5 µg/m^3 and 75 µg/m^3
(I) = inhalable, (R) = respirable (T) = total dust CY has limit of 50 µg/m^3 (T) Included in all OEL categories EE also has limit of 50 µg/m^3 (T) Included in all OEL categories SE also has limit of 5 µg/m^3 (T) Already included for (I) values			

Beryllium and inorganic beryllium compounds

MS with OELs higher than proposed levels		
OEL µg/m³	**Member States where current limits are higher**	**Notes regarding national limits**
0.02	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	
0.05	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	
0.1	AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE*, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	DE: 0.06 (R), except aluminium beryllium silicate; 0.14 (i) except aluminium beryllium silicate
0.2	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK	
0.35	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK	
0.6	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK	
1	AT, BE, BG, HR, CY, DK*, EE, FR, EL, HU, LT, RO, SK, SI, SE, UK	DK: Powders and compounds
2	AT*, HR*, EL, SK*, SI*	AT: Current limit of 2(i) for "other uses,"; 5 for "whetting of beryllium metals and alloys" HR: Except aluminium beryllium silicate SK: 5(i), except aluminium beryllium silicate, whetting of beryllium metals and alloys; 2(i), Except aluminium beryllium silicate, other uses SI: 5(i), except aluminium beryllium silicate, grinding; 2 (i), Except aluminium beryllium silicate, other uses

Source: RPA

i = inhalable, R = respirable

**Indicates that MS has more than one limit, at least one of which is higher than the proposed OEL, or that it is not clear if all uses are covered by the limit*

Arsenic acid and its salts, as well as inorganic arsenic compounds

MS with OELs higher than assessed OELVs			
OELV µg/m³	**Member States where current limits are higher or the MS does not have an OEL covering the compounds within the scope**	**% of MS above reference OELV or without OEL**	**Notes regarding national limits**
10	AT, BG, HR, CZ, EE, FR, EL, HU**, IT, LT, LU, MT, PT, SK, SI, UK	57%	
25	AT, BG, HR, CZ, EE, FR, EL, HU**, IT, LT, LU, MT, PT, SK, SI, UK	57%	
50	AT, HR, CZ, FR, EL, HU**, IT, LU, MT, PT, SK, SI***, UK	46%	Hungary has separate OELs for As_2O_5 and As_2O_3 at 30 and 100 µg/m³, respectively, whereas it is 10 µg/m³ for other inorganic arsenic compounds
Notes: Denmark has for calcium arsenate an OEL at 1,000 µg/m³. As no intentional use of calcium arsenate in Denmark has been identified it is estimated that establishing an OEL at the assessed levels in Denmark would not have any impact.			

Formaldehyde

Table 8-38: MS with OELs higher than proposed levels		
OEL mg/m³	**Member States where current limits are higher**	**Notes regarding national limits**
0.15	AT, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, PT, RO, SK, SI, SE, UK	
0.37	BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, PL, RO, SI, UK	FR: Intended change to 0.35 PL: intended change to 0.37
0.6	BG, HR, CY, EL, RO, SI, UK	

4,4'-Methylene-bis(2-chloroaniline) (MOCA)

MS with companies using MOCA and with OELs higher than assessed levels			
OELV µg/m³	**Companies located in MS where current limits are higher or the MS do not have an OEL covering the compounds within the scope**	**% of MS with companies using MOCA above reference OELV or without OEL**	**Notes regarding national limits**
5	BE, DK, FR, EL, NL, PT, ES HU, IT	82%	-
10	BE, DK, FR, EL, NL, PT, ES HU, IT	82%	-
20	BE, DK, FR, EL, NL, PT, ES HU, IT	82%	-

Annex 6: Selection procedure for priority compounds in substance groups

The Commission initiated work to amend or establish OELs for 25 priority chemicals agents in 2004. The selection was made on the basis of the views of stakeholders, in particular with MS during exchanges with the Commission, notably meetings of National Experts Working Group on OELs. These 25 chemical agents were considered a priority for protection of workers and the choice is in line with subsequent third party priority lists, for instance those put forward by the European Trade Unions or the Netherlands National Institute for Public Health and the Environment.

Further to exchange and in particular within the tripartite Advisory Committee on Safety and Health at Work, the five additional substances subject to this initiative were selected taking into account general considerations such as the following:

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

In particular, as regards three of the substances, refined prioritisation was needed in order to identify compounds that fall under the scope of the CMD. The following elements have been considered for such selection as regards each of them.

Cadmium and its inorganic compounds

Criteria for the determination of the relevant compounds

The following screening criteria have been applied to select the cadmium compounds:

- Does the compound pass the initial test of relevant (not an erroneous entry, not a reaction mass, not a UVCB[77])?
- Is there a CLH 1A or 1B for the compound? If the compound only has a self-classification as Carc. 1A or 1B, is the compound also registered?
- Where compounds also contain another carcinogen, is cadmium clearly the driver of the carcinogenic potency or the "mode of action" (MoA)?

[77] Substance of Unknown or Variable composition, Complex reaction products or Biological materials

- Is there any another reason for excluding any of the compounds, e.g. compound too far removed from the definition?

Final selection

The relevant substances following the screening process are summarised below.

Table 39: Cadmium – screening process

Step	Number of compounds
Total number of Cd compounds identified	364
Of which, pass the first test of relevance (not clearly erroneous, not a reaction mass, not a UVCB, etc.)	120
Of which, compounds with CLH Carc. 1A or 1B or self-classified as Carc. 1A or 1B and registered	16
Of which, Cd driver of carcinogenic potency or the mode of action	11
Source: RPA (2018)	

The relevant compounds to be assessed in the study are summarised below.

Table 40: Cadmium and inorganic Cd compounds – final selection

Compound	CAS No.
Cadmium oxide	1306-19-0
Cadmium sulphide	1306-23-6
Cadmium	7440-43-9
Cadmium fluoride	7790-79-6
Cadmium chloride	10108-64-2, 35658-65-2
Cadmium sulphate	7790-84-3, 10124-36-4, 31119-53-6
Cadmium nitrate	10022-68-1, 10325-94-7
Cadmium hydroxide	21041-95-2
Cadmium carbonate	513-78-0
Cadmium sulfate hydrate	15244-35-6
Cadmium(2+) ion bis(nitric acid)	10022-68-1
Source: RPA (2018)	

Arsenic acid and its salts under the scope of the CMD

Criteria for the determination of the relevant compounds

The following screening criteria have been applied to select the arsenic compounds that were prioritised:

a) Is there a harmonised classification as Carc. 1A or 1B for the compound? We have assumed that in line with the 'arsenic acid and its salts not listed elsewhere in this annex' all arsenic acid salts are CLH Carc. 1A but have checked this for all the other arsenic compounds.
b) If the compound only has a self-classification as Carc. 1A or 1B, is the compound also registered? We have assumed that more reliable data/information will be available for registered compounds.
c) Does the compound fit the definitions 'arsenic acid and its salts' or 'inorganic arsenic compound?
d) Where compounds also contain another carcinogen element: Is As the component driving carcinogenic potency or Mode of Action (MoA)?[78]
e) Is there any another reason for excluding any of the compounds? For example, we have excluded salts from arsine or complex compounds.

The relevant substances following the screening process are summarised below.

Table 41: As – screening process

Step	Number of compounds
Total number of As compounds	164
Of which, compounds with harmonised classification as Carc. 1A or self-classified as Carc. 1A and registered	11+46
Of which, inorganic arsenic compounds	53
Of which, As driver of carcinogenic potency or the mode of action	31
Source: RPA (2018)	

The relevant compounds assessed are summarised below.

Table 42: Inorganic arsenic compounds – final selection

Compound	CAS No.
Diarsenic pentaoxide	1303-28-2, 12044-50-7
Diarsenic trioxide	1327-53-3, 7440-38-2
Arsenic acid, sodium salt	7631-89-2
Arsenic acid	7778-39-4
Disodium hydrogenarsenate	7778-43-0
Calcium arsenate	7778-44-1
Arsenic trichloride	7784-34-1
Potassium dihydrogenarsenate	7784-41-0
Diammonium hydrogenarsenate	7784-44-3
Sodium dioxoarsenate	7784-46-5

[78] The compounds that will be considered are those where arsenic is clearly the driver of the carcinogenic potency or the "mode of action" (MoA). Existing OEL and cancer risk quantifications from SCOEL/RAC do not cover arsenic compounds with other MoA and potency. Therefore, the impact assessment is preferably to be linked to this demarcation criterion.

Compound	CAS No.
Iron arsenate	10102-49-5
Iron bis(arsenate)	10102-50-8
Arsenic acid, magnesium salt	10103-50-1
Arsenic acid, copper salt	10103-61-4
Arsenic acid, calcium salt	10103-62-5
Ammonium dihydrogenarsenate	13462-93-6
Trisodium arsenate	13464-38-5
Zinc arsenate	13464-44-3
Sodium metaarsenate	15120-17-9
Triammonium arsenate	24719-13-9
3-methyl-4-(pyrrolidin-1-yl)benzenediazoniumhexafluoroarsenate	27569-09-1
Arsenic acid, copper(2+) salt	29871-13-4
Vanadium(4+) diarsenate (1:1)	99035-51-5
Sodium hexafluoroarsenate(V)	12005-86-6
Calcium hydrogen arsenate	15195-00-3
Sodium arsenate dibasic heptahydrate	10048-95-0
Source: RPA (2018)	

Beryllium and its inorganic compounds

The beryllium compounds were screened as described below

Table 43: Beryllium – screening process

Step	Number of compounds
Total number of beryllium compounds	66+beryllium silicates
Of which, compounds that are also self-classified	12
Of which, inorganic beryllium compounds (or Be)	9
Source: RPA (2018)	

The relevant compounds assessed are summarised in the table below: two are definitely considered (shown in bold) and seven could potentially be relevant.

Table 44: Beryllium and inorganic beryllium compounds – final selection

Compound	CAS No.
Beryllium oxide	**1304-56-9**
Beryllium	**7440-41-7**
Beryllium chloride	7787-47-5
Beryllium fluoride	7787-49-7
Beryllium sulphate	13510-49-1
Beryllium nitrate	13597-99-4

Compound	CAS No.
Disodium tetrafluoroberyllate	13871-27-7
Beryllium(2+) ion tetrahydratedinitrate	13510-48-0
1000 mg/L Beryllium	-
Source: RPA (2018)	

In this assessment two compounds were ever considered: beryllium and beryllium oxide. Copper, aluminium, magnesium and nickel are widely alloyed with beryllium. These are a cause of worker exposure and are included in the assessment. Approximately 80% of all beryllium in EU is used in copper beryllium alloy (CuBe.)

Annex 7: Relevant sectors, uses and activities and estimations of EU workers exposed

Cadmium and its inorganic compounds

Cadmium

Cadmium is a rare element not found in its pure state in nature. Instead, it occurs mainly as cadmium sulphide (or 'greenockite') in deposits of zinc (National Toxicology Program, 2014).[79]

Today, most cadmium metal is produced as a by-product of the extraction, smelting and refining of zinc, lead and copper. In addition, cadmium is also produced from the recycling of spent nickel-cadmium batteries (its largest use), and secondary or recycled cadmium now accounts for about 23% of total cadmium supply (ICdA, 2016).[80] Cadmium is commercially available in purities ranging from 99 - 99.9999%, as powders, foils, ingots, slabs, sticks and crystals (National Toxicology Program, 2014).

Information on cadmium uses, as identified by the Cd REACH Consortium (2012a) is provided in the following figure[81].

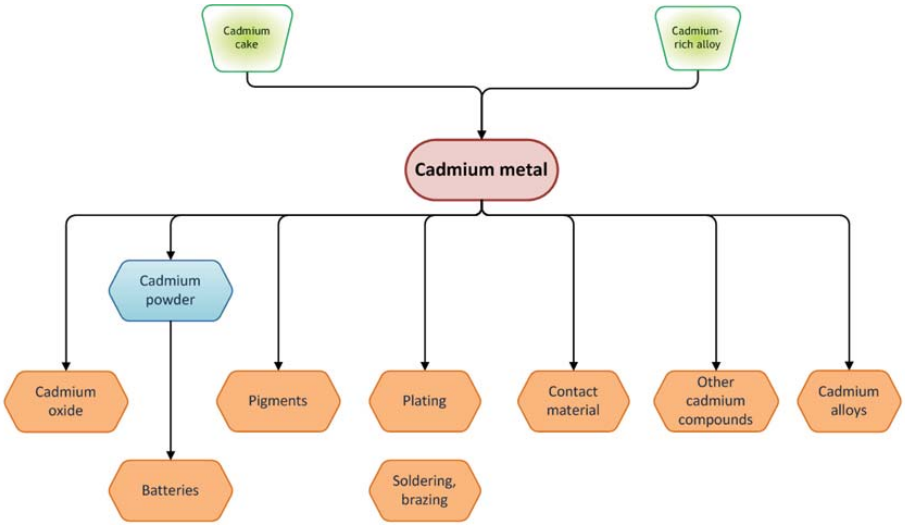

Figure 9: Initial overview of cadmium uses
Source: Cd REACH Consortium (2012a)

Cadmium alloys

The widespread use of cadmium in such alloys is of importance to a number of sectors[82]. For example, AIA in ECHA (2013b)[83] highlights the use of cadmium as an alloying

[79] US National Toxicology Program. (2014). Report on Carcinogens (13th Edition), from https://ntp.niehs.nih.gov/ntp/roc/content/profiles/cadmium.pdf

[80] ICdA. (2016). Cadmium - Introduction, from http://www.cadmium.org/introduction

[81] Cd REACH Consortium. (2012a). Cadmium - Identification of Uses, from http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-2311528

[82] International Cadmium Association. (undated). Cadmium in Alloys.International Cadmium Association. Retrieved July 29, 2016, from http://www.cadmium.org/cadmium-applications/cadmium-in-alloys

element in copper, tin, and zinc alloys used in the aerospace industry. In the same document the UK ADS notes that silver electric contacts (silver-cadmium oxide) incorporating 10 to 15% cadmium are useful in many heavy duty electrical applications such as relays, switches, circuit breakers and thermostats in the aerospace and defence sector. The presence of cadmium improves resistance to material transfer and electric erosion.

Cadmium chloride

Cadmium chloride is produced by reaction of molten cadmium and chlorine gas at 600 °C or by dissolving cadmium metal or the oxide in hydrochloric acid, subsequently vaporising the solution (Pubchem, undated).[84]

ICdA in ECHA (2014a)[85] provides more specific information, noting that the reported manufactured (or imported) tonnage of cadmium chloride in the EU fluctuates from year to year, depending on the demand of photovoltaic panels but is in the range of 5-8 t/y.

As well as photovoltaic applications, the Cd REACH consortium highlights that following uses of relevance associated with the substance[86]:

- Component for production of organic and inorganic cadmium compounds;
- Electro-galvanizing;
- Electroplating; and
- Chemical reagent.

Cadmium fluoride

ICdA in ECHA (2014b) notes that the compound is probably limited to minor laboratory reagent uses[87].

Cadmium sulphate

Anhydrous cadmium sulphate is prepared by oxidation of the sulphide or sulphite at elevated temperatures, or by the action of dimethyl sulphate on finely powdered cadmium nitrate, halides, oxide or carbonate. Solutions are prepared by dissolving cadmium metal, oxide, sulphide, hydroxide or carbonate in sulfuric acid. Anhydrous cadmium sulphate is also produced by melting cadmium with ammonium or sodium peroxodisulphate. Cadmium sulphate monohydrate, which is the form usually marketed, is produced by evaporating a cadmium sulphate solution above 41.5 °C

Despite the intermediate only registration, available literature does suggest that the compound may have a wider scale of uses to consider. For example, Rajadurai et al.

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83 ECHA. (2013b). Comments on an Annex XV dossier for indentification of a substance as SVHC and responses to those comments - Cadmium.fromhttps://echa.europa.eu/documents/10162/9731cc85-9740-47ac-a489-0142f38a6956

84 Pubchem. (undated). Compound summary for cadmium chloride, from https://pubchem.ncbi.nlm.nih.gov/compound/Cadmium_dichloride#section=Top

85 ECHA.(2014a). Comments on an Annex XV dossier for indentification of a substance as SVHC and responses to thse comments - Cadmium chloride.

86 See http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-chloride-2332967.

87 ECHA. (2014b). Comments on an Annex XV dossier for indentification of a substance as SVHC and responses to thse comments - Cadmium fluoride, from https://echa.europa.eu/documents/10162/6f01fd3c-e0e6-4f19-be18-855ad6851eb3

(2013)[88] highlights that cadmium sulphate is an important inorganic cadmium compound which is widely used in semiconductor industry with many excellent physical and chemical properties.

Cadmium sulphide

Cadmium sulphide (CdS) can be manufactured by passing hydrogen sulphide gas into cadmium chloride solution ($CdCl_2 + H_2S = CdS\downarrow + 2HCL$). Another method is to acidify a solution of cadmium sulphate with hydrochloric acid and to add a freshly made solution of sodium sulphide ($CdSO_4 + NA_2S = CdS\downarrow + NA_2SO_4$) (NIIR Board, 2003)[89]. Information within the Candidate List 'Response to Comments' (RCOM) document for the compound[90] suggests it is used mainly for the manufacture of photovoltaic panels and as an intermediate in the manufacture of other cadmium compounds, including pigments. It is also used in small quantities as intermediate in glass colouration.

Uses as identified by the Cd REACH Consortium[91] have been listed below:

- Component for production of inorganic cadmium compounds;
- Laboratory reagent;
- Cadmium production by pyrometallurgy;
- Component for production of organic cadmium compounds;
- Component for production of inorganic pigments;
- Additive for production of frits;
- Additive for production of glass;
- Additive in the manufacturing of electronic components;
- Use of CdS-containing catalysts; and
- Component for production of PV modules.

Cadmium oxide

The figure below presents a flow diagram for the production of cadmium oxide which includes the fusion of metal ingots at temperatures higher than 320°C, followed by oxidation on contact with air to produce cadmium oxide in a powder form which is subsequently collected in bag filters.

88 Rajadurai, G., Puhal Raj, A., &Pari, S. (2013). Growth and characterization of cadmium sulphate single crystal by gel growth. Archives of Applied Science Research, 5(3), 247-253, from http://scholarsresearchlibrary.com/aasr-vol5-iss3/AASR-2013-5-3-247-253.pdf

89 NIIR Board. (2003). The Complete Technology Book on Printing Inks. Asia Pacific Business Press.

90 See https://echa.europa.eu/documents/10162/5f847fab-5b4d-43da-a220-53ac8280464f

91 Seehttp://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-sulphide-2151478.

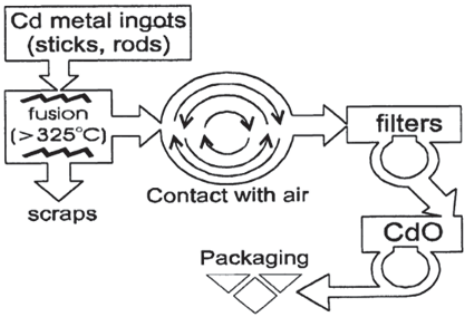

Figure 10: Flow diagram for the production of Cd oxide
Source: Cd REACH Consortium (2012b)

Information on cadmium oxide uses, as identified by the Cd REACH Consortium are provided in the following figure. The substance is one of the main precursors to other cadmium compounds.

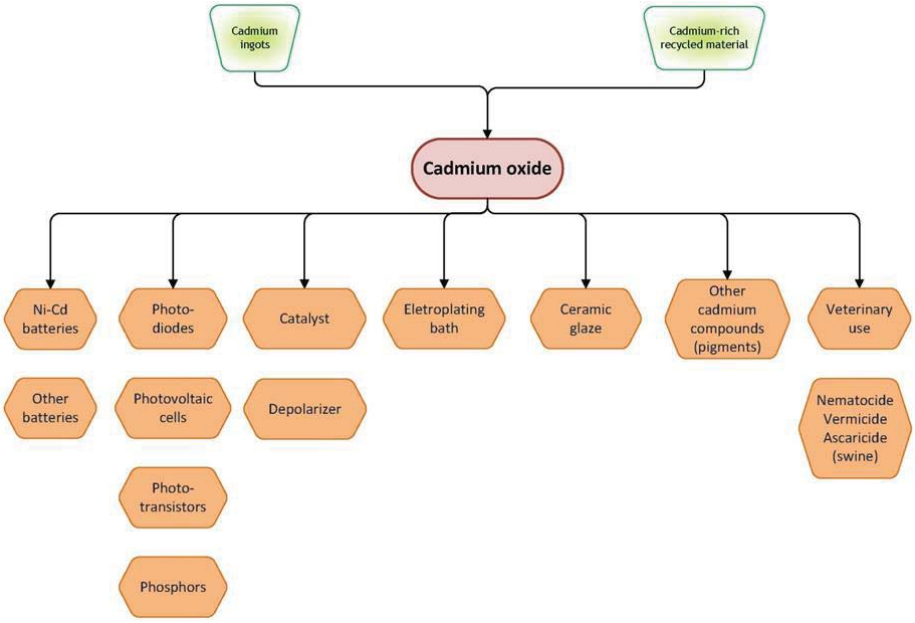

Figure 11: Initial overview of cadmium oxide uses

Source: Cd REACH Consortium (2012b)[92]

Cadmium carbonate

According to Considine (1995), cadmium carbonate is produced by the reaction of cadmium hydroxide and carbon dioxide or upon precipitation of a cadmium salt with ammonium carbonate. The Cd REACH Consortium[93] has identified the following uses of cadmium carbonate:

[92] REACH Consortium. (2012b). Cadmium Oxide (215-146-2), from http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-oxide-2151462

[93] Seehttp://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-carbonate-2081689.

- Lab reagent;
- Component for production of organic/inorganic cadmium compounds and salts;
- Component for production of inorganic pigments;
- Additive for production of glass;
- Component for polymer-matrices, plastics and related preparations;
- Use of CdCO3-containing polymers for cable protecting & isolating coatings;
- Use of CdCO3-containing polymers for tube & sheet articles;
- Use of CdCO3-containing polymers for moulded articles; and
- Use of CdCO3-containing catalysts.

Cadmium hydroxide

The Cadmium REACH Consortium[94] has identified the following uses of the compound:

- Component for production of organic and inorganic cadmium compounds;
- Electro-galvanizing;
- Electro-plating;
- Laboratory reagent;
- Cadmium production by pyrometallurgy;
- Component for production of Inorganic pigments; and
- Batteries/fuel cells.

Cadmium nitrate

The Cadmium REACH Consortium[95] has identified the following uses of the compound:

- Component for production of inorganic cadmium compounds;
- Component for production of organic cadmium compounds;
- Laboratory reagent;
- Component for production of inorganic pigments;
- Additive for production of glass;
- Additive for production of ceramics;
- Use of Cd(NO3)2-containing catalysts;
- Use of Cd(NO3)2-containing photographic emulsions; and

94 See http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-hydroxide-2441685.

95 See http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-nitrate-2151462.

- Batteries/fuel cells.

Relevant sectors, uses and activities

According to the RPA study, the sectors and uses where occupational exposure is expected to take place are summarised below.

Table 45: Sectors and uses where occupational exposure to cadmium is expected

Sector	Uses and/or activities	Notes
1: Zn & Cu smelting and Cd refining	Extraction and refining of Cd	
2: Speciality chemicals	Mechanical or chemical transformation of Cd metal into specialised compounds, mainly for the battery, PV panels and pigments sectors	
3: Ni-Cd batteries	Production of Ni-Cd batteries	
4: Pigments	Production of pigments	ICdA: Cd compounds not classified hazardous vs. SUMER 2010: Cadmium sulphide
5: Aerospace & defence	Parts[96], connectors and fasteners undergo Cd surface treatment	
	Brazing alloys	
6: Surface treatment contractors	Subcontracted surface treatment for Sector 5, includes repair & maintenance[97]	
7: Niche manufacturing	PV panels, low temperature infra-red detectors, high performance contact materials	
8: Recycling	Post-industrial waste, used batteries, treatment of ZnO dust captured in Zn smelters' bag houses, metals	
	WEEE (shredding of electronic waste)	Exposure to cadmium can be an effect of shredding older televisions, with cathode ray tubes, which are known to contain fluorescent powder that includes cadmium.
9: Mining of non-ferrous metal ores	A: Exposure at all stages of production processes (mining, beneficiation, haulage) B: Maintenance workers and process operators	CdS in ore, Cd in ore
10 Metals fabrication	Smelting (steel), foundries, refining	Cadmium is sometimes measured in foundry dust. Cd is a part of the amalgam of castings alloys, in low concentrations. Therefore, exposure to these substances through foundry activities is no source of concern to the companies. The exposure is

[96] Assumed to include landing gear.
[97] See http://dublinaerospace.com/landing-gear/

Sector	Uses and/or activities	Notes
		below the present OELs.
11 Glass	Production of frit	Cadmium carbonate
12 Cement	Cement & clinker production	
13 Other (ASA, excl. those already mentioned above and those with fewer than 20 exposed workers)	Real estate and landscaping Office and institutional detergents etc.; Agricultural and industrial machinery installers and repairers Laboratories Waste incineration and water treatment plants process managers Electrical, gas and heat supply, cooling business Scientific research and development Architectural and engineering services; technical testing and analysis Public administration and defence, compulsory social insurance Paper, paper and board products manufacturing Electronics and automation equipment installers and repairers Office cleaners in offices, hotels and other institutions Pipe fitters Paper pulp and paper and board manufacturing process workers Insulators	
14 Other (consultation)	Welding, Cement Energy generation Glass	
Source: RPA (2018)		

There are a number of sectors that have been identified from consultation or the Finnish Register of Workers Exposed to Carcinogens (ASA Register) but for which exposure could not be corroborated from other sources. In Finland, employers are obliged to provide data on the exposure of workers to certain carcinogens to the Finnish Institute of Occupational Health (FIOH)) so that it can be entered into the ASA register (EU-OSHA, 2014)[98]: Although this is an obligation for employers, Kauppinen et al. (2007) note that it is likely some do not submit data.[99]

Other sectors considered by the study team but not included in the table above include recycling of Cd-containing rigid PVC. Communication with EuPC suggests that the Cd compounds to which workers are exposed are outside the scope of the study.

The sectors in REACH registration CSRs (see below) overlap with the sectors in the table below.

[98] https://osha.europa.eu/en/tools-and-publications/publications/reports/report-soar-work-related-cancer
[99] https://academic.oup.com/annweh/article-lookup/doi/10.1093/annhyg/mem030

Table 46: Sectors in REACH registration CSRs that are relevant to cadmium metal, cadmiumoxide, cadmiumcarbonate

Cadmium metal production RLE
Cadmium metal production by pyrometallurgy
Storage of ingots-slabs in warehouses
Production of chemicals (pyro)
Production of chemicals (hydro)
Additive for production of inorganic catalysts
Melting, alloying and casting
Production of "targets" by (EB) PVD
Cadmium casting and rolling
Wire and rods manufacturing
Component for brazing products
Component for soldering products
Downstream use of Cadmium based brazing products
Downstream use of cadmium-based soldering products
Cadmium (alloyed) powder manufacturing
Powders for contact materials
Use of active powders for batteries
Use of fine powders for mechanical plating
Manufacturing of Cadmium containing-alloys
Use of cadmium containing Ag alloys
Electroplating
PVD / coating
Source: RPA (2018)

Estimated EU workers exposed

According to the draft final report of the external study[100] different sources compile estimates of the total number of exposed workers – which can differ by a factor of up to 125.

The consultant identified as the only multi-country estimate the CARcinogen EXposure (CAREX[101,102]) database, with further estimates being available for the Czech Republic, Finland, France, and the UK (although the data for the UK are also based on CAREX).

The different estimates are presented in the table below. The divergence in the estimates is representative for many problems confronted with in the analysis presented in this

[100] Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC – Interim report for cadmium and its inorganic compounds.

[101] See: http://oem.bmj.com/content/57/1/10;

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

report, starting with scarcely available information on exposure of workers as such, outdated information sources, different methodologies used by different authors, and concentration on one of few countries only.

Table 47: Published data – workforce exposed to cadmium and cadmium compounds

Study	Country	Year/period	No. of exposed workers
CAREX	EU-14	1990-1993 (mean)	207,000
	France	1990-1993	22,034
	Finland	1990-1993	1,040
	EU-5	1997	86,000
ICdA[103]	EU-28	2017	2,900
INRS[104]	France	2005	2,250-6,600
INRS (adjusted by ICdA)	France	2017	900-1,100
SUMER	France	2003[105]	27,700
		2010[106]	39,700
ASA[107]	Finland	2005	964
		2014	1,550
Regex[108]	Czech Republic	2009-2016	49*
Note: *Cadmium only			
Source: RPA (2018)			

The consultant has carried out extrapolations of the data above to the EU-28, summarised below.

[103] ICdA (2017a): Where and how many workers are occupationally exposed to Cd and Cd compounds in the EU? http://www.cadmium.org/

[104] See http://www.inrs.fr/publications/bdd/cmr.html

[105] http://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition-115982

[106] http://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition

[107] Finnish Register of Workers Exposed to Carcinogens.
See http://www.julkari.fi/bitstream/handle/10024/131073/ASA_2014.pdf?sequence=1

[108] Registry of Subjects Occupationally Exposed to Carcinogens (REGEX).

Table 48: Population occupationally exposed to cadmium and cadmium compounds in the EU-28

Source estimate	EU-28 extrapolation
SUMER 2010[109] exposed workers in FR	300,000
CAREX EU14+5 mid-1990s	
ASA 2014 exposed workers in FI	140,000
ASA 2005 exposed workers in FI	90,000
INRS 2005 FR exposed workers in FR	17,000-50,000
INRS 2005 adjusted by ICdA for 2017, exposed workers in FR	6,800 – 8,400
ICdA 2017 (EU-28 estimate, no extrapolation)	2,900
Regex 2009-16, exposed workers in CZ	2,400

Note: All extrapolations have been carried out on the basis of population.

Source: RPA (2018)

The International Cadmium Association (ICdA) is using data from its occupational exposure biomonitoring programme and estimates that approximately 2,900 workers are occupationally exposed to cadmium and cadmium compounds in the EU.

Occupations in which the highest potential exposures occur include cadmium production and refining, nickel-cadmium (Ni-Cd) battery manufacture, cadmium pigment manufacture and formulation, cadmium alloy production, mechanical plating, zinc smelting, brazing with a silver-cadmium-silver alloy solder, and polyvinylchloride compounding.[110] Recycling of scrap metal and Ni-Cd batteries may also involve some exposure.[111]

The major routes of occupational exposure are inhalation of dust and fumes and incidental ingestion of dust from contaminated hands, cigarettes or food.[112].

In industrial settings, airborne exposure levels typically have been reported to range from 0.005 to 0.05 mg/m³; with extreme values up to 0.4 mg/m³[113].

[109] http://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition

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

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

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

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

Beryllium and its inorganic compounds

Relevant sectors, uses and activities

The RPA (2018) study identified ten industrial sectors as using beryllium. The following sectors where occupational exposure is expected to take place are the following:

Table 49: Sectors in the EU affected by beryllium and associated NACE codes

Sector	Associated NACE codes
Foundries	C24
Metal fabrication (includes manufacture of injection moulds and stamping)	C25
Transportation	C29 & C30
Sector	**Associated NACE codes**
ICT	C26
Specialist manufacturers including defence, security, fire-fighting & rescue, oil gas and electricity, space and research	C27, C28, C33
Medical devices	C32.5
Glass	C23.1
Construction	F
Laboratories	M72
Recycling	E37.1
Source: RPA (2018)	

In these sectors, the uses presented in the next table were identified.

The list was provided by BeST and also gives an indication of whether or not they believe the process would be technically feasible and economically viable at different OELs (see explanation of the abbreviations used at the end of this table).

Table 50: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
Abrasive Blasting	A process for cleaning the surface of metals or ceramics which involves using compressed air to blow an abrasive material (i.e., sand) with considerable force through a hose against a surface.	C	C+	NF	NF	NF	Mechanical - machining
Abrasive Processing	Processes that involve cleaning or altering the surface of metals or ceramics by abrasive action, utilizing natural or manufactured abrasive materials.	C	C+	NF	NF	NF	Mechanical - machining
Abrasive Sawing	The process of sawing metals or ceramics by abrasive action.	C	C+	NF	NF	NF	Mechanical - machining
Adhesive Bonding	The process of joining two similar or non-similar materials (metals, plastics, composites, etc.) using an adhesive.	NA	NA	NA	NA	NA	Handling
Age Hardening (<950ºF)	The process of increasing the strength and hardness of a metallic material using a relatively low-temperature heat treatment.	NA	NA	C	C	C	Thermal
Annealing	The controlled heating and cooling of a metal to remove stresses and to make the material softer and easier to work with during subsequent operations such as rolling.	NA	NA	C	C	C	Thermal
Assembly	The fitting together of manufactured parts into a complete machine, structure or unit of a machine.	NA	NA	NA	NA	NA	Handling
Bending	The process in which metal is deformed by plastically deforming the material and changing its shape. The material is stressed beyond the yield strength, but below the ultimate tensile strength. The surface area of the material does not change much. Bending usually refers to deformation about one axis.	NA	NA	NA	NA	NA	Mechanical - shaping
Blanking	The process of cutting up a large sheet of stock into smaller pieces suitable for the next operation in stamping. Blanking can be as simple as a cookie cutter-type die to produce prototype parts, or high speed dies that run at 1000+ strokes per minute, running coil stock.	NA	NA	C	C	C	Mechanical - machining
Bonding	The process of joining two materials together by passing the metal between rolls which compress and bond the metals together.	NA	NA	NA	NA	NA	Handling
Boring	The formation of a cylindrical hole in a solid material cutting tool.	NA	NA	C	C	C	Mechanical -

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
							machining
Brazing	Joining metals by the fusion of alloys having a melting temperature above 800 degrees Fahrenheit, but below the melting temperature of the metals being joined. In ceramics, refers to the joining of a plated surface to another metal component at temperatures typically less than 1100 degrees Celsius.	NA	NA	C	C	C	Thermal
Bright Cleaning	A process in which metallic pieces are dipped into an acid solution in order to achieve a clean, bright surface.	C	C	C+	C+	NF	Chemical
Broaching	Multiple milling, accomplished by pushing a tool with stepped cutting edges along the part, usually through holes.	NA	NA	C	C	C	Mechanical - machining
Brushing	The process of cleaning the surface of metal using a brush. The bristles of the brush can be soft or hard; natural, synthetic or metallic.	C	C	C+	C+	NF	Mechanical - machining
Buffing	The smoothing of a metal surface by means of flexible wheels.	C	C	C+	C+	NF	Mechanical - machining
Burnishing	The process in which a smooth hard tool (using sufficient pressure) is rubbed on the metal surface to flatten the high spots by causing plastic flow of the metal.	C	C	C+	C+	NF	Mechanical - machining
Casting	The process of pouring a heated liquid metal into a mould. Once the metal solidifies, taking the shape inside the mould, it is removed, resulting in a cast shape.	C	C	NF	NF	NF	Melting
Centreless Grinding	A grinding process that differs from other cylindrical processes in that the work piece is not mechanically held in place at the centre.	C	C+	NF	NF	NF	Mechanical - machining
Chemical Cleaning	The process of removing oil, dirt and scale from the surface of metals using caustic chemicals.	C	C	C+	C+	NF	Chemical
Chemical Etching	Involves removing the surface of a metal chemically or electrochemically.	C	C	C+	C+	NF	Chemical
Chemical Milling	The process of controlled removal of metal using corrosive chemicals.	C	C	C+	C+	NF	Chemical
CNC Machining	Computerized Numerically Controlled (CNC) machining refers to the computer control of machine tools for the purpose of repeatedly manufacturing complex parts in metal.	NA	NA	C	C	C+	Mechanical - machining
Cold Forging	Involves the working of metal at normal atmospheric temperatures, to a predetermined shape by the process of hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Cold Heading	A cold forming process that involves applying force with a punch to the end of a metal blank contained in a die to redistribute metal to a particular area.	NA	NA	C	C	C+	Mechanical - shaping

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
Cold Pilger	The drawing technique employed to produce seamless tubing using a die and mandrel.	NA	NA	C	C	C+	Mechanical - shaping
Cold Rolling	The process of shaping and reducing metal in thickness by passing it between rolls which compress, shape and lengthen the metal, at a temperature below the softening point of the metal to create strain hardening.	NA	NA	C	C	C	Mechanical - shaping
Coolant Management	Involves the handling and management of the liquids used to quench metals in heat treating, to cool and lubricate cutting tools and workpieces in machining, or those applied to forming tools and workpieces to assist in forming operations.	NA	C	C	C	C+	Handling
Cutting	The process of mechanically shearing metal.	NA	NA	C	C	C+	Mechanical - machining
Deburring (grinding)	A finishing step involving the removal of burrs or surface imperfections from materials using abrasive activities such as sanding.	C	C	C+	C+	C+	Mechanical - machining
Deburring (non-grinding)	The removal of burrs, sharp edges or fins from metal parts by processes other than grinding, such as filing, machining or tumbling.	NA	NA	C	C	C+	Mechanical - machining
Deep Hole Drilling	To form deeply drilled holes with a rotary end cutting tool.	NA	NA	C	C	C+	Mechanical - machining
Destructive Testing	Refers to testing a workpiece for comparison to standards, where the testing results in the destruction of the work piece.	C	C	C	C	C+	Mechanical - machining
Drawing	A manufacturing process for producing a wire, bar or tube by pulling the material through a die to reduce the diameter and increase its length.	NA	NA	C	C	C+	Mechanical - shaping
Drilling	The process of using a drill bit in a drill to produce holes in a solid material.	NA	NA	C	C	C+	Mechanical - machining
Dross Handling	The process of physically handling dross produced by the melting of metals and alloys throughout manufacturing, packaging and shipping.	C	C	NF	NF	NF	Melting
Dry Tumbling	A process used to remove burrs, sharp edges or fins from metal parts by rolling the work in a barrel with other materials.	NA	C	C+	C+	NF	Mechanical - machining
Electrical Chemical Machining (ECM)	The process of removing material using electrical energy created in an electrolyte solution to erode metal from the workpiece.	C	C	C+	C+	NF	Chemical

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
Electrical Discharge Machining (EDM)	The process of removing material by a series of rapidly recurring electric arcing discharges between an electrode (the cutting tool) and the work piece, in the presence of an energetic electric field. This is sometimes referred to as spark machining or spark eroding.	C	C	C+	C+	NF	Melting
Electroless Plating	A process in which a layer of metal contained in an aqueous solution is deposited (coated) onto a surface without the use of external electrical power.	NA	NA	C	C	C+	Chemical
Electron Beam Welding (EBW)	A fusion joining process that produces a weld by impinging a beam of high energy electrons to heat the weld joint.	C	C	C+	C+	C+	Melting
Electroplating	A process in which a layer of metal contained in an aqueous solution is deposited (coated) onto an electrically conductive surface using an electrical current.	NA	NA	C	C	C+	Chemical
Etching (chemical)	A process which involves chemically or electrochemically removing the surface of a metal.	C	C	C+	C+	NF	Chemical
Extrusion	The process of shaping metal into a chosen continuous form by forcing it through a die of a desired shape.	NA	NA	C+	C+	C+	Mechanical - shaping
Filing by Hand	The non-mechanized process of using a metalworking hand tool (a file) to shape material.	NA	NA	C	C	C	Mechanical - machining
Forging	The process of working a heated metal to a predetermined shape by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Grinding	A process that uses friction with a rough surface, such as an abrasive wheel, on the workpiece to make very fine finishes or very light cuts.	C	C+	NF	NF	NF	Mechanical - machining
Gun Drilling	A process where a drill, usually with one or more flutes and with coolant passages through the drill body, is used to produce a deep-drilled hole.	NA	NA	C	C	C+	Mechanical - machining
Hand Solvent Cleaning	The non-mechanized process of cleaning the surface of a part using a solvent.	NA	NA	NA	NA	NA	Handling
Handling	The process of physically handling materials or products throughout manufacturing, packaging, distribution and shipping.	NA	NA	NA	NA	NA	Handling
Heading	A cold forming process that essentially involves applying force with a punch to the end of a metal blank contained in a die. Heading, which includes upsetting and extruding, is often performed in conjunction with other cold forming operations such as sizing,	NA	NA	C	C	C+	Mechanical - shaping

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
	piercing, trimming, thread rolling, blank rolling and pointing.						
Heat Treating (inert atmosphere)	The process of heating and cooling solid metals, alloys or ceramics in an inert atmosphere, such as nitrogen gas, to obtain certain desired properties or characteristics. The inert atmosphere excludes oxygen and reduces the generation of oxides on the surface of the metal or alloy.	NA	NA	C	C	C	Thermal
Heat Treating (in air)	The process of heating and cooling solid metals, alloys or ceramics in normal atmosphere to obtain certain desired properties or characteristics.	C	C	C	C	C+	Thermal
High Speed Machining (>10,000 rpm)	Material-working processes that involve using a power-driven machine tool, such as a router or drill, at speeds in excess of 10,000 rpm to shape metal.	C	C	C+	C+	NF	Mechanical - machining
Honing	The process of finishing ground surfaces to a high degree of accuracy and smoothness with abrasive blocks applied to the surface under a light controlled pressure, with a combination of rotary and reciprocating motions.	NA	C	C+	C+	NF	Mechanical - machining
Hot Forging	The process of working a heated metal to a predetermined shape by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Hot Rolling	A metallurgical process in which the metal is passed through a pair of rolls while the metal is above its recrystallization temperature.	NA	C	C+	C+	NF	Mechanical - shaping
Inspection	The evaluation of a part for defects, imperfections and preferred characteristics and specifications.	NA	NA	NA	NA	NA	Handling
Investment Casting	The process of producing castings of a part using ceramic moulds produced by injection moulding.	C	C	NF	NF	NF	Melting
Lapping	An abrasive machining operation that scours the surface of the work piece with an abrasive in fluid.	C	C	C+	C+	NF	Mechanical - machining
Laser Cutting	A process which uses a laser to cut materials. The material to be cut either melts, burns or vaporizes away.	C	C	C+	C+	NF	Melting
Laser Machining	A process which uses a laser to machine materials. The material either melts, burns or vaporizes away.	C	C	C+	C+	NF	Melting
Laser Scribing	A process that uses a laser to cut grooves into the surface of thin material to facilitate mechanical breaking.	C	C	C+	C+	NF	Melting

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
Laser Marking	A process that uses a laser to mark the surface of a material for identification purposes.	C	C	C+	C+	NF	Melting
Laser Welding	A process that uses a laser to weld metals.	C	C	C+	C+	NF	Melting
Laundering	The washing and drying of work clothing, rags, etc.	C	C	C+	C+	NF	Handling
Machining	Material-working processes that involve using a power-driven machine tool such as a lathe, milling machine or drill to shape metal.	NA	NA	C	C	C+	Mechanical - machining
Melting	The processes of heating a solid substance to a point where it turns liquid.	C	C	NF	NF	NF	Melting
Metallography	The process of preparing a metal surface for analysis by grinding, polishing, and etching to reveal micro structural constituents.	NA	NA	C	C	C	Mechanical - machining
Milling	The machining or cutting of metal products with revolving cutters.	NA	NA	C	C	C+	Mechanical - machining
Packaging	The process of placing finished and/or semi-finished products into a container for shipping.	NA	NA	NA	NA	NA	Handling
Painting	The process of applying paint to the surface of a finished or semi-finished part.	NA	NA	NA	NA	NA	Handling
Physical Testing	An examination or formal evaluation process whereby a material, semi-finished or finished product, is tested and the results typically compared to specified requirements and standards. Can be destructive or non-destructive in nature.	NA	NA	C	C	C+	Mechanical - machining
Photo-Etching	A chemical etching process that dissolves material from unmasked areas of metallic parts. The design is photographically exposed on the workpiece using ultraviolet light.	C	C	C+	C+	NF	Chemical
Pickling	The process of chemically removing oxides and scale from the surface of metal using inorganic acids.	C	C	C+	C+	NF	Chemical
Piercing	The process of cutting internal features (holes or slots) in stock.	NA	NA	C	C	C+	Mechanical - shaping
Pilger	The process employed to produce seamless tubing using a die and mandrel.	NA	NA	C	C	C	Mechanical - shaping
Plating	The process of applying a thin coating of metal onto another metal.	NA	NA	C	C	C+	Chemical
Point and Chamfer	A process used to grind or machine a point or bevel on the end of a rod or wire which facilitates insertion into a drawing machine.	C	C	C+	C+	NF	Mechanical - machining
Polishing	The process of creating a smooth and shiny surface by rubbing the surface with a fine abrasive material.	C	C	C+	C+	NF	Mechanical - machining
Pressing	The process in which metal is deformed by plastically deforming the material and	NA	NA	C	C	C	Mechanical - shaping

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
	changing its shape. The material is stressed beyond the yield strength, but below the ultimate tensile strength. The surface area of the material does not change much.						
Process Ventilation Maintenance	The preventive or reactive repair, maintenance or restoration of general or local exhaust ventilation systems. Process ventilation refers to ventilation systems designed to reduce exposure to contaminants.	C	C+	NF	NF	NF	Handling & Machining
Radiography/X-ray	A method of non-destructive testing. Internal examination of a metallic structure or component with X-ray or gamma radiation. Internal defects can be seen on a screen or recorded on film.	NA	NA	NA	NA	NA	Handling
Reaming	To enlarge or dress out a hole in metal with a reamer.	NA	NA	C	C	C+	Mechanical - machining
Resistance Welding	A process where heat to form the weld is generated by the electrical resistance of current through the workpieces.	C	C	C+	C+	NF	Melting
Ring Forging	The process performed by punching a hole in a thick, round piece of metal, and then rolling and squeezing (or in some cases, pounding) the seamless shape to a thin ring.	NA	C	C+	C+	NF	Mechanical - shaping
Ring Rolling	The process of forming seamless rings from pierced discs or thick-walled, ring-shaped blanks between rolls that control wall thickness, ring diameter, height and contour.	NA	C	C+	C+	NF	Mechanical - shaping
Roll Bonding	The process of bonding two metals together by passing the metal between rolls which compress and bond the metals together.	NA	NA	C	C	C	Mechanical - shaping
Roller Burnishing	The process in which a smooth hard roller tool (using sufficient pressure) is rubbed on the metal surface to flatten the high spots by causing plastic flow of the metal.	C	C	C+	C+	NF	Mechanical - shaping
Rolling	A term applied to the operation of shaping and reducing metal in thickness by passing the metal between rolls which compress, shape and lengthen the metal.	NA	NA	C	C	C	Mechanical - shaping
Rotary forging	A process designed to efficiently forge round (cylindrical) shapes by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Sand Blasting	A process for cleaning the surface of metals or ceramics which involves using compressed air to blow sand with considerable force through a hose against a surface. In ceramics, commonly used to remove metallization as a rework operation.	C	C+	NF	NF	NF	Mechanical - machining
Sand Casting	The production of a metal casting made in a sand mould	C	C+	NF	NF	NF	Melting
Sanding	A process used to smooth or dress the surface of a workpiece using an abrasive surface.	C	C+	NF	NF	NF	Mechanical -

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
							machining
Sawing (tooth blade)	A manufacturing process that involves cutting or severing of metal or other materials with a serrated blade.	NA	NA	C	C	C+	Mechanical - machining
Scrap Management (Clean)	Refers to the routine handling, transfer, segregating or transport of scrap materials.	C	C	C+	C+	NF	Handling
Sectioning	The process of obtaining a smaller piece of material from a larger sample of the material. The process can involve fracturing, sawing and/or abrasive cutting.	NA	NA	C	C	C+	Mechanical - machining
Shearing	The process of severing of metal, usually cold, between sharpened blades, as in a shear; to severe or rupture a part as a result of forces in parallel planes that slide across each other at right angles to a major axis of the part.	NA	NA	C	C	C+	Mechanical - shaping
Shipping	The process of transporting a finished and/or semi-finished product to a destination using various modes of transportation.	NA	NA	NA	NA	NA	Handling & Machining
Sizing	Refers to the various mechanical processes to bring a work piece to the proper shape and dimensions.	NA	NA	C	C	C	Mechanical - shaping
Skiving	A continuous shaving process which results in a smoother surface finish than is possible with milling.	NA	NA	C	C	C+	Mechanical - shaping
Slab Milling	The milling process used to remove large amounts of material, leaving a flat finished surface.	NA	NA	C	C	NF	Mechanical - machining
Slitting	The operation of cutting wide sheets of metal into narrower strips by passing them through rotary shears that cut it to finished width.	NA	NA	C	C	C+	Mechanical - shaping
Soldering	Joining metals by fusion of alloys that have relatively low melting points.	NA	NA	NA	NA	NA	Thermal
Solution Management	Refers to routine handling, transfer, transport or processing of beryllium-containing solutions, such as coolants, oils and other liquids containing beryllium, beryllium oxide or alloys of beryllium.	NA	NA	C	C	C+	Handling
Spot Welding	The process of welding two or more thin pieces of metal together using electrical resistance to heat the metal at the spot of the weld.	C	C	C+	C+	NF	Melting
Sputtering	The physical process where atoms of a solid target material are ejected into the gas phase due to bombardment of the material by energetic ions and deposited on a substrate.	NA	NA	C	C	c+	Melting

Process	Detail	2 µg /m³	0.6 µg /m³	0.2 µg /m³	0.1µg /m³	0.02µg /m³	Process group
Stamping	The formation of light metal parts from metal sheet, strip or thin plate, using dies.	NA	NA	C	C	c+	Mechanical - machining
Straightening	Metal forming in which a bend is removed from a piece of metal by applying a force.	NA	NA	C	C	c	Mechanical - shaping
Stretch Bend Levelling	The process of making metal sheet or strip flat by stretching.	NA	NA	C	C	c	Mechanical - shaping
Stretcher Levelling	The process of making metal sheet or strip flat by stretching.	NA	NA	C	C	c	Mechanical - shaping
Swaging	The process of using a die and mandrel along with hammering to change the size and shape of the outer and inter diameters of tubes and/or rods.	NA	NA	C+	C+	NF	Mechanical - shaping
Tapping	The process of cutting screw threads in a round hole with a tap (an internal thread cutting tool).	NA	NA	C	C	C	Mechanical - machining
Tensile Testing	A standard test piece is gripped at either end in a testing machine, which slowly exerts an axial pull so that the metal is stretched until it breaks.	NA	NA	C	C	C	Mechanical - machining
Thread Rolling	The process used for making external threads in round stock by pressing the rotating workpiece against a die containing the thread profile.	NA	NA	C	C	C	Mechanical - shaping
Torch cutting (i.e., oxy-acetylene)	The process of cutting metals by using an oxygen/fuel mixture to heat the metal above the melting point.	C	C+	C+	C+	NF	Melting
Trepanning	A type of boring where an annular cut is made into a solid material with the coincidental formation of a plug or solid cylinder.	NA	NA	C	C	c+	Mechanical - machining
Tumbling	A deburring operation that involves rolling the work in a barrel containing abrasives suspended in a liquid medium.	NA	C	C+	C+	NF	Mechanical - machining
Turning	The process used to produce cylindrical components in a lathe. A cylindrical piece of stock is rotated and a cutting tool is traversed along 2 axes of motion to produce precise diameters and depths.	NA	NA	C	C	c+	Mechanical - machining
Ultrasonic Cleaning	The process of cleaning the surface of materials using ultrasound (usually from 15-400 kHz) in an aqueous solution.	NA	NA	NA	NA	NA	Handling
Ultrasonic Testing	The process of using ultrasound to detect flaws or characterize materials.	NA	NA	NA	NA	NA	Handling

Process	Detail	2 µg /m^3	0.6 µg /m^3	0.2 µg /m^3	0.1µg /m^3	0.02µg /m^3	Process group
Upsetting	A cold forming process that involves applying force with a punch to the end of a metal blank contained in a die.	NA	C	C+	C+	NF	Mechanical - shaping
Water-jet Cutting	A process to cut metal parts using a very high-pressure stream of water.	C	C	C+	C+	NF	Mechanical - machining
Welding (ARC, TIG, MIG, etc.)	A process used to join metals by the application of heat.	C	C	C+	C+	NF	Melting
Wire Electrical Discharge Machining	The process of removing material by a series of rapidly recurring electric arcing discharges from a thin single-strand metal wire fed through the workpiece.	C	C	C+	C+	NF	Melting

Source: RPA and BeST
NA = No additional controls required beyond normal operating controls
C = Controls required including engineering work and best practice
C+ = Additional advanced controls are necessary but not likely to be economically feasible
NF = Not technically feasible

The processes are grouped into a smaller set of higher level processes to make analysis easier. The process groups are:

- Mechanical – shaping
- Mechanical – machining
- Melting
- Thermal
- Chemical
- Handling

The sectors were then linked to the appropriate process groups and these are described in the table below. Mechanical - machining and mechanical - shaping were found to always appear together: they are amalgamated in mechanical. Handling is found in every sector and has little bearing on costs, so it is omitted. This information helped in the development of risk management measures (RMMs) for the cost model.

Table 51: Sectors, and the group processes predominantly used

Sector	Chemical	Thermal	Mechanical	Melt	Alloys
Foundries	N	N	N	Y	
Metal fabrication	N	N	Y	N	
Transportation	Y	Y	Y	Y	Cu-Be alloys BeO Al-Be alloys
ICT	Y	Y	Y	N	Cu-Be alloys (typically 0.2-2% Be metal)
Specialist manufacturers	Y	Y	Y	Y	Cu-Be alloys Ni-Be alloys BeO Be Al-Be
Medical devices	Y	Y	Y	N	Be metal Cu-Be alloys Be foil BeO
Glass	Y	Y	Y	Y	?
Construction	N	N	Y	N	?
Laboratories	Y	N	N	N	?
Recycling	N	N	Y	Y	ALL
Source: RPA and BeST					

Estimated EU workers exposed

According to the consultant, ten industrial sectors were identified in which beryllium and its compounds are used, and in which workers are at risk of exposure to beryllium:

Table 52: Sectors in the EU affected by beryllium and associated NACE codes

Sector	Associated NACE codes
Foundries	C24
Metal fabrication (includes manufacture of injection moulds and stamping)	C25
Transportation	C29 & C30
ICT	C26
Specialist manufacturers including defence, security, fire-fighting & rescue, oil gas and electricity, space and research	C27, C28, C33
Medical devices	C32.5
Glass	C23.1
Construction	F
Laboratories	M72
Recycling	E37.1
Source: RPA (2018)	

The following average exposure concentrations were calculated based on the information sources provided at the end of the following table:

Table 53:Sectors in the EU affected by beryllium and any available average exposure concentrations in µg/m^3

Sector	MEGA [114] 95th percentile[115]	France[116] 90th percentile[117]
Foundries	1.05 (n=101)	16.06 (n=159)
Metal fabrication	0.228 (n=79)	0.6 (n=76)
Transportation	0.554 (n=14)	0.015 (n=14)
ICT	0.512 (n=33) *	10.44 (n=29)
Specialist manufacturers	0.512 (n=33) *	-
Medical devices	0.512 (n=33) *	0.5 (n=74)
Glass	2.78 (n=16)	-
Construction	2.52 (n=10)	-
Laboratories	0.512 (n=33) *	-
Recycling	0.19 (n=116)	0.1 (n=30)
Source: RPA, MEGA, France 2004-2006 - Vincent et al. *Note: * The value has been taken from the category 'other sectors' in the database*		

Three different methods were used to arrive at estimates of the number of EU workers exposed to beryllium. All three methods use US-OSHA Table IX-2[118] – "Characteristics of industries affected by US-OSHA's proposed standard for beryllium". This provides

[114] BAuA.Substance Evaluation Report- Beryllium. http://echa.europa.eu/documents/10162/a99d2dc4-c217-4024-b6ed-9c7262e2ba56 IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien für Beryllium und seine Verbindungen. 2014.

[115] A percentile is a measure used in statistics indicating the valuebelow which a given percentage of observations fall. For example, the 95th percentile is the value below which 95% of the observations may be found.

[116] Vincent et al.Occupational exposure to beryllium in French enterprises 2009 https://www.ncbi.nlm.nih.gov/pubmed/19372137

[117] A percentile is a measure used in statistics indicating the value below which a given percentage of observations fall. For example, the 90th percentile is the value below which 90% of the observations may be found.

[118] US-OSHA, Occupational Safety and Health Administration.Occupational Exposure to Beryllium and Beryllium Compounds 2015. Available at: www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=25346

the number of USA workers exposed to beryllium for each relevant NAIC code, which is mapped to the relevant NACE code(s). This data is available for seven of the sectors identified by the study, all except construction, laboratories and recycling. The three methods are referred to throughout the remainder of this report as Beryllium Science and Technology Association (BeST), EU/USA and US-OSHA. They are:

- **BeST** - BeST say that the total number of workers exposed to beryllium in the EU is 12,000 to 13,000. The higher number, 13,000, was split across the seven sectors according to the proportions of exposed workers. The higher number was taken as this number is more likely to be an understatement rather than an overstatement
- **EU/USA** - The number of exposed workers in each of the seven sectors is multiplied by 1.5, which is the proportion of EU population (510 million) to USA population (326 million)
- **US-OSHA** - The number of exposed workers in each of the seven sectors is divided by the total number of USA workers corresponding to the NACE[119] code, which gives the percentage of exposed workers in this industry. This is multiplied by the total number of EU workers for this NACE code

The key information for exposed workers in each sector is given in following table.

Table 54: USA and EU data on workers by sector

Sector	USA workers in associated NAIC sectors (US-OSHA)	USA workers in associated NAIC sectors affected by beryllium	% USA workers affected by beryllium	Total workers in EU (Eurostat**)
Foundries	297,333	3,262	1.10%	930,187
Metal fabrication	1,530,220	12,469	0.81%	3,341,115
Transportation	1,557,729	2,048	0.13%	3,155,749
ICT	778,433	1,042	0.13%	1,035,484
Specialist manufacturers	2,052,363	5,808	0.28%	5,368,786
Medical devices	297,762	8,148	2.74%	413,783
Glass	652,489	453	0.07%	287,788
Construction	9,784,621	-	0.42% *	9,789,969
Laboratories	710,059	-	0.42% *	606,352
Recycling	22,685	-	0.42% *	180,164
*Source: RPA Note: *Based on estimated percentages of workers affected by beryllium ** Eurostat (2015): Structural Business Statistics. Available at: http://ec.europa.eu/eurostat/web/structural-business-statistics/data/database.*				

The predicted workers affected by beryllium using each of the three methods are given in the next table. The relevant figures from the CAREX EU data are also displayed in that table.

[119] Eurostat.*NACE Rev. 2 - US NAICS 2007 correspondence table* http://ec.europa.eu/eurostat/ramon/documents/nace_2_us_naics_2007/NACE_Rev_2-US_NAICS_2007-as_per_October_1st_2010.zip. 2007.

Table 55: Predicted workers affected by beryllium by sector

Sector	Predicted number of EU workers affected by Be (BeST)	Predicted number of EU workers affected by Be (EU/USA)	Predicted number of EU workers affected by Be (US-OSHA)	CAREX estimate of EU workers affected by Be
Foundries	1,276	5,099	10,205	2,620
Metal fabrication	4,878	19,491	27,225	5,743
Transportation	801	3,202	4,149	4,394
ICT	408	1,628	1,386	3,798
Specialist manufacturers	2,272	9,079	15,193	46,265
Medical devices	3,188	12,737	11,323	1,040
Glass	177	709	783	2,129
Laboratories	410*	1,639*	2,556*	N/A
Recycling	122*	487*	760*	N/A
Total excluding construction	**13,532**	**54,071**	**73,580**	**65,989**
Construction	6,624*	26,469*	41,276*	490
Total	**20,156**	**80,540**	**114,856**	**66,479**

*Source: RPA (2018) Note: *Based on estimated percentages of workers affected by beryllium*

Examining the figures produced by the three methods, those using the BeST data appear to be too low: it seems likely that BeST has included the companies that it supplies and their workers, but has not allowed for the companies that are further down the supply chain.

CAREX EU[120,121] and the IOM report[122] predicted approximately 65,000 workers exposed in the EU. The estimate using the EU/USA method arrives at a figure of 54,071 excluding construction, higher than the 13,000 of BeST and lower than the CAREX/IOM figure. Examining the data from the USA, and the number of workers in the EU in each of the sectors, the EU/USA figures are the most plausible. Throughout the remainder of the analysis, the EU/USA figures will be used, and sensitivity analysis is made using the BeST and US-OSHA data.

The estimated numbers of workers exposed to different concentrations of beryllium in each sector are shown in the tables below. These are based upon the EU/USA data set described before.

The first table shows the estimates using the BeST survey data; the percentage split of the exposure concentration range is the same for every sector, while the second table shows the estimates using US-OSHA data for the seven sectors covered by its worker data. The percentage split of the exposure concentration range is different for each of the seven sectors. The first table also shows the each sector's 95% exposure concentration (MEGA)

[120] See: http://oem.bmj.com/content/57/1/10;

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

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

measured by BAuA 2014[123] and 90% exposure concentration measured in France from 2004 – 2006[124].

Table 56: Estimated EU workers exposed to different exposure concentrations of beryllium: EU/USA data set and BeST exposure concentrations

Sector	< 0.06 µg/m³	0.06 µg/m³ – 0.2 µg/m³	0.2 µg/m³ – 1 µg/m³	1 µg/m³ – 2 µg/m³	Total workers exposed in sector	Exposure 95 percentile MEGA	Exposure 90 percentile France
Foundries	1,043	2,820	817	418	5,099	1.05	16.06
Metal fabrication	3,989	10,780	3,123	1,599	19,491	0.228	0.6
Transportation	655	1,771	513	263	3,202	0.554	0.015
ICT	333	901	261	134	1,628	0.512	10.44
Specialist manufacturers	1,858	5,021	1,455	745	9,079	0.512	-
Medical devices	2,606	7,044	2,041	1,045	12,737	0.512	0.5
Glass	145	392	114	58	709	2.78	-
Total (seven sectors)	**10,629**	**28,729**	**8,324**	**4,262**	**51,945**	-	-
Laboratories	335	907	263	135	1,639	0.512	-
Recycling	100	269	78	40	487	0.19	0.1
Total excl construction	**11,064**	**29,905**	**8,665**	**4,437**	**54,071**	**-**	**-**
Construction	5,416	14,639	4,241	2,172	26,469	2.52	-
Total incl construction	**16,480**	**44,544**	**12,906**	**6,609**	**80,540**	**-**	**-**
% (same for all sectors)	20.5%	55.3%	16.0%	8.2%	100%	-	-
Source: RPA, BAuA MEGA data[125], Vincent et al (2009)[126]							

Table 57: Estimated EU workers exposed to different exposure concentrations of beryllium: EU/USA data set and US-OSHA exposure concentrations

Sector	< 0.2 µg/m³	0.2 µg /m³ - 0.4 µg/m³	0.4 µg/m³ – 1 µg/m³	1 µg/m³ – 2 µg/m³	2 µg/m³ – 4 µg/m³	> 4 µg/m³	Total workers exposed in sector	Exposure 95% MEGA	Exposure 90% France
Foundries	2,052 (40%)	839 (16%)	1,039 (20%)	497 (10%)	249 (5%)	423 (8%)	5,099 (100%)	1.05	16.06
Metal	15,540	1,640	1,382	405	159	365	19,491	0.228	0.6

123 BAuA.Substance Evaluation Report- Beryllium. http://echa.europa.eu/documents/10162/a99d2dc4-c217-4024-b6ed-9c7262e2ba56

124 Vincent et al.Occupational exposure to beryllium in French enterprises 2009 https://www.ncbi.nlm.nih.gov/pubmed/19372137

125 BAuA. SubstanceEvaluation Report- Beryllium. http://echa.europa.eu/documents/10162/a99d2dc4-c217-4024-b6ed-9c7262e2ba56 IFA (2013): MEGA-Auswertungen zur Erstellung von REACH-Expositionsszenarien für Beryllium und seine Verbindungen. 2014

126 Vincent et al. Occupational exposure to beryllium in French enterprises 2009 https://www.ncbi.nlm.nih.gov/pubmed/19372137

fabrication	(80%)	(8%)	(7%)	(2%)	(1%)	(2%)	(100%)		
Transportation	1,948 (61%)	429 (13%)	472 (15%)	271 (8%)	19 (1%)	62 (2%)	3,202 (100%)	0.554	0.015
ICT	1,213 (75%)	162 (10%)	172 (11%)	54 (3%)	16 (1%)	12 (1%)	1,628 (100%)	0.512	10.44
Specialist manufacturers	8,133 (90%)	398 (4%)	332 (4%)	111 (1%)	40 (0%)	65 (1%)	9,079 (100%)	0.512	NA
Medical devices	7,176 (56%)	1,794 (14%)	1,973 (15%)	1,435 (11%)	0 (0%)	359 (3%)	12,737 (100%)	0.512	0.5
Glass	378 (53%)	104 (15%)	161 (23%)	42 (6%)	14 (2%)	8 (1%)	709 (100%)	2.78	NA
Total (seven sectors)	**36,440 (70%)**	**5,366 (10%)**	**5,531 (11%)**	**2,815 (5%)**	**497 (1%)**	**1,294 (2%)**	**51,945 (100%)**	-	-
Laboratories	1,150 (70%)	169 (10%)	175 (11%)	89 (5%)	16 (1%)	41 (2%)	1,639	NA	NA
Recycling	342 (70%)	50 (10%)	52 (11%)	26 (5%)	5 (1%)	12 (2%)	487	NA	NA
Total excluding construction	**37,931 (70%)**	**5,586 (10%)**	**5,757 (11%)**	**2,930 (5%)**	**517 (1%)**	**1,347 (2%)**	**54,071**	-	-
Construction	18,568 (70%)	2,734 (10%)	2,818 (11%)	1,434 (5%)	253 (1%)	659 (2%)	26,469	NA	NA
Source: RPA (2018)									

The data in the tables above have different exposure ranges. The following comparisons between the two can only be made for the first seven sectors as the US-OSHA data only covers seven sectors, however, construction would need to be excluded as the numbers distort the analysis and the figures for laboratories and recycling are small. The BeST distribution predicts that 4,262 are exposed to over 1 μg/m^3 in the EU compared with the US-OSHA distribution which predicts 4,606 are exposed. Given the totally different methods of achieving these numbers, this is remarkably similar. The US-OSHA distribution also predicts that 1,791 workers are exposed to over 2 μg/m^3, which is at or above the OEL for nearly all Member States. These figures are similar to the IOM report predictions of 3,000 workers exposed to higher levels of beryllium and under 10% exposed to 2 μg/m^3 or more. Both the BeST and US-OSHA predictions are for 8% of workers being exposed to 2 μg/m^3 or more.

At the lower end of the scale, the numbers of workers exposed to less than 0.2 μg/m^3 are 39,358 (66%) for the BeST predictions and 36,440 (70%) for the US-OSHA predictions, again they are similar.

The different distributions (BeST and US-OSHA) applied to the predictions for all three methods are plotted for each sector in turn in the tables above. They show that foundries are the sector where workers are exposed to the highest levels of beryllium: 13% are predicted to be working at over 2 μg/m^3.

Arsenic acid and its salts, as well as inorganic arsenic compounds in the scope of the CMD

Relevant sectors, uses and activities

This section provides an overview of the sectors, uses, and activities in which occupational exposure to arsenic acid, its salts and inorganic arsenic compounds is likely to take place.

Occupational exposure to inorganic arsenic compounds may take place in a number of processes including production and intentional use of the substances within the scope; formation of the substances by processes involving alloys with arsenic metal and thermal processes where arsenic is present as unintentional impurity in raw materials. Arsenic is naturally present as impurity in ores, fossil fuels, soil, plant material, etc. and may be released to the air by thermal processing/combustion of these materials.

Furthermore, arsenic compounds would be present in dust formed by the processes. The number of workers potentially exposed to inorganic arsenic in the workplace is high. For the study no comprehensive datasets with exposure concentration data across sectors has been available. Data have mainly been obtained by stakeholder consultation and from the literature.

For further details on processes for the manufacture of products and other intentional and un-intentional uses of arsenic compounds and the resulting exposures refer to the RPA (2018) draft final report. The table below includes a general description for each sector.

Table 58: Inorganic arsenic compounds – sectors and uses

Sector	Use or activity	Intentional use of substances
1: Glass sector	Production of special glass	Arsenic acid, diarsenic trioxide
	Production of domestic glass	Diarsenic trioxide
	Recycling of glass	Unintentional, from former use in glass
2: Electronics sector	Manufacture of copper foil for printed circuit boards	Arsenic acid
	Gold plating of circuit boards	Diarsenic trioxide
	Manufacture and use of gallium arsenide wafers and semiconductors	Diarsenic trioxide, arsenic metal
3: Chemicals sector	Manufacture of arsenic compounds	Diarsenic trioxide, various compounds
	Production of sulphuric acid from pyrites and residues from non-ferrous production	Unintentional
4: Copper sector	Primary copper smelters	Unintentional
	Secondary copper smelters, recycling of copper alloys	Unintentional (dross, slags, etc.); arsenic metal in alloys
	Production of copper-arsenic alloys, production of articles of brass and other alloys	Arsenic metal in alloys
5: Zinc production using diarsenic trioxide	Use in the electrowinning process	Diarsenic trioxide
6: Other non-ferrous metals	Nickel, zinc, lead, precious metal smelters	Unintentional
	Production of alloys of lead and tin with arsenic Use of lead-arsenic alloys to produce batteries, ammunition, etc.	Arsenic metal in alloys
	Manufacture of ultrapure arsenic metal	Diarsenic trioxide
7: Cross-sector	Various welding processes. Plasma cutting and other thermal cutting processes.	Arsenic metal in alloys; unintentional

Sector	Use or activity	Intentional use of substances
8: Ferrous metals	Pig iron production (sinter plants and pelletization plants)	Unintentional
9: Power sector	Maintenance of boilers and equipment for flue gas treatment	Unintentional
10: Other	Mining operations and production of concentrates	Unintentional
	Other metalworking processes	Arsenic metal in alloys; unintentional
	Shredding and dismantling of WEEE	Gallium arsenide, various As compounds in semiconductors
	Maintenance and recycling of wood treated with arsenic compounds	Various arsenic compounds use in CCA treated wood
	Various uses as analytical standards in laboratories	Various compounds
	Reclamation of CCA wood	Former use of arsenic compounds
Source: RPA (2018)		

- **Glass sector**

Production of glass is together with the electrowinning of zinc the major application of arsenic compounds. Two arsenic compounds are used in significant quantities: arsenic acid and diarsenic trioxide. Both substances are used as fining agents in the production of glass. The substances can, according to Glass Alliance Europe, be used interchangeably in the glass sector. A detailed description of the processes and uses of arsenic compounds in the manufacture of special glass, domestic glass and glass insulation materials and recycling of glass is available in RPA (2018).

- **Electronics sector**

Arsenic compounds are used for various applications in the manufacture of electronic components and printed circuit boards. Exposure by inhalation may take place by the use of the substances for the manufacture of the components, whereas the exposure by the later use of the components and printed circuit boards for production of electronics is considered insignificant.

For the detailed description of the processes and uses of arsenic compounds in the manufacture of copper foils, gold plating of circuit boards and the description of the supply chain and processes in the manufacture of semiconductors (RPA (2018)).

- **Chemicals sector**

Diarsenic trioxide and arsenic acid is manufactured as a by-product by two EU companies by recovery from waste products from the production of non-ferrous metals.

About 60 tonnes was used in the chemicals sector for production of other arsenic chemicals and the ultra-pure arsenic metal (ECHA, 2016). The available information indicates that the majority is used for the manufacture of ultra-pure arsenic metal. As this application is a use as intermediate, it is not subject to authorisation under REACH.

No detailed information on exposure to arsenic from the production of other arsenic compounds is available. Some production of arsenic compounds in volumes below the 1 t/year probably takes place by some manufacturers of laboratory standards and specialty chemicals.

Two arsenic salts, calcium arsenate and trileaddiarsenate are used as intermediates in the "manufacture of basic metals, including alloys" according to their REACH registrations. The same substances may be present in flue gas treatment residues from pig-iron production or non-ferrous metal production (see description below) - the majority of these residues seem to be disposed of to landfill, but a part is used as intermediate in the production of arsenic compounds or arsenic metal in the non-ferrous industry. The possible exposure by use of the substances as intermediates is covered by "other non-ferrous metals".

The industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide was granted authorisation and approved by RAC in 2015 for a period of 22 months. Within this period, the use of diarsenic trioxide for this particular process should have been phased out and replaced by an alternative (vanadium pentaoxide).

Available information indicates that occupational exposure to arsenic would potentially take place when sulphuric acid is produced in the non-ferrous metal sector, and in particular in the copper sector, and when it is produced from pyrite. For more details see RPA (2018).

- **Copper sector**

The copper sector has been identified by the stakeholder consultation as a sector where exposure to arsenic is of major concern and a sector that could be impacted by establishing an OEL.

Exposure to arsenic in the copper sector could basically take place by three activities, which will be described separately:

- Primary copper production;
- Secondary copper production where arsenic may originate from recycled copper-arsenic alloys or arsenic impurities in the recycled materials;
- Production and casting of copper-arsenic alloys.

As metallic arsenic is not within the scope of the assessed OEL, exposure to dust of pure metallic arsenic or arsenic in alloys would not lead to exposure within the scope, and the assessment focuses on processes where inorganic arsenic compounds are formed which could lead to exposure.

Many of the processes described below for the primary copper sector where exposure could take place would be quite the same for other non-ferrous metals, but the exposure levels would in general be lower as the arsenic content of such ores and concentrates is generally lower.

Primary copper production

The main sector affected by arsenic in raw materials is the primary copper sector, where arsenic in the ores is a major issue both with regard to occupational exposure and environmental releases.

Arsenic in mined copper concentrates is increasing, which is a major concern for the copper sector. According to Rohner et al. (2017) from 2000 to 2017 the average arsenic content in world copper concentrates increased from 0.13 to 0.22 %.

Based on information obtained from the stakeholder consultation it is estimated that the total content of arsenic in concentrates used in primary copper production in the EU is likely in the range of 3 000-6 000 t/year. The turnover of arsenic in copper production is thus several times the total intentional consumption of arsenic compounds for all applications in the EU. The range indicated would correspond to an average content of the concentrate of 0.05 to 0.10% if it is assumed that the copper content of the concentrates is 30% (typical content). Primary nickel production, with the potential exposure of arsenic compounds to workers, takes place in one facility in the EU in the same building and workers involved in nickel smelting are consequently included in the exposed workforce for primary copper smelting.

A schematic overview and a detailed description of primary copper smelter operations is available in RPA (2018).

Secondary copper production

In secondary smelting, the feed material is scrap either loaded into a smelting furnace, for example loaded through a vertical shaft into a blast furnace below, or, if sufficiently pure, loaded directly into a converter or anode furnace.

The sources of arsenic from the secondary copper production are different as in primary copper production: mainly arsenic present as alloying element in some copper alloys and arsenic in some residues from other industrial processes.

Copper alloys

It is estimated that about 300 t/year of metallic arsenic is used for production of copper alloys. Arsenic metal is not within the scope of the assessed OEL, but arsenic oxides may be formed by the melting of the alloys. In the process, the arsenics can be released e.g. in fumes, dusts and skimmings.

The first step in the manufacture of the alloys is the manufacture of copper-based master alloys, produced by a limited number of companies specialised in the manufacture of such alloys. A copper-arsenic master alloy typically contain 30% arsenic and 70% copper (CuAs30).

The master alloys are used by a large number of manufacturers of copper alloys where the master alloy is melted with the other alloying components. As an example, a brass alloy suited for the use in drinking water applications could typically contain 63% copper, 0.2% lead, 0.1% arsenic and the remaining part zinc. A large number of workers may be exposed to low levels of arsenic by the further machining of the alloys, but as this exposure would be to metallic arsenic, it is not considered to be within the scope of this assessment. RPA (2018)

- **Zinc production using diarsenic trioxide**

Exposure to inorganic arsenic compounds in the zinc industry can either be due to the intentional use of arsenic compounds in the electrowinning process or due to low levels of arsenic in the raw materials for the production. The exposure from the intentional use of arsenic compounds taking place in two facilities is described in this section whilst the exposure to arsenic in the ores, potentially taking place in more facilities, is described together with exposure to arsenic in ores used in the manufacture of other nonferrous metals.

The production of zinc is together with the manufacture of glass the major application area for arsenic compounds. The application is subject to authorisation under REACH. Details on the two application documents and RAC decisions are presented in RPA (2018).

- **Other non-ferrous metals**

Occupational exposure to arsenic may take place by a number of processes in the non-ferrous sector. The detailed assessment of the effects of the proposed OEL for the sectors 'Manufacture of ultrapure arsenic metal,' lead alloys with arsenic' (with its main uses in battery grids where trace quantities of arsenic are added to lead/antimony grid alloys used in lead-acid batteries, ammunition, where the addition of arsenic (0.5–2%) improves the sphericity of lead shot and cable sheathing (not confirmed information from literature). RPA (2018).

Primary lead, zinc and cadmium production

Arsenic is naturally present as impurity in ores, fossil fuels, soil, plant material, etc. and may be released to the air by thermal processing/combustion of these materials. Furthermore, arsenic compounds would be present in dust formed by the processes.

Compared to primary copper production, arsenic is less an issue in primary lead and zinc production because the arsenic content of the concentrates is lower.

Precious metals and other non-ferrous metals

Gold, silver and platinum group metals and other metals such as selenium, cobalt, and germanium are produced either from ore concentrates, from waste products from other non-ferrous metal production or from scrap e.g. from electronic products. Arsenic may be present in all the raw materials e.g. in the form of nickel arsenide, but in particular large quantities are processed with waste products from other non-ferrous metal production. Some of these activities are undertaken at sites manufacturing primary copper and are in these instances included in the description for this sector.

Processes differ between the companies, but the following worker exposure scenarios have been indicated in responses to the stakeholder consultation:

- Transportation and unloading of raw materials
- Sampling of raw materials
- Sampling as part of process control
- Smelting of raw materials
- Refining of final products
- Packaging final products (if the end products include arsenic compounds)
- Maintenance operations

- **Welding, plasma cutting and similar processes**

Exposure to arsenic by welding are often mentioned in general introductions to exposure to hazardous substances in welding. Very limited data, however, has been identified describing the sources of arsenic in the welding processes and the differences in exposure

levels between different processes. Data from the German MEGA database demonstrates exposure to arsenic in different welding and thermal cutting processes.

- **Ferrous basic metal production**

The CAREX Canada (2017) estimates that <5% of the workers in the "Iron and steel mills and ferroalloy manufacturing" are potentially exposed to arsenic. Likewise, the European CAREX database (form 1997) estimates that some 7 000 workers may be exposed in the iron and steel basic industries. None of the databases include actual data on exposure levels.

The BAT document for iron and steel production (JRC, 2013b) describes that bleed water from scrubbers from palletisation plants (first step in the pig iron production in some plants; in others the first step is sinter plants) in some cases is treated in an "arsenic removal plant". Some exposure could take place by maintenance of the arsenic removal plant and by handling the filter cake. Furthermore, maintenance and cleaning works on electrostatic precipitators and bag filters on sinter plants, palletisation plants and blast furnaces may likely lead to some exposure to arsenic as has been demonstrated by maintenance of similar filters in some coal power plants.

- **Power sector**

Workers in coal and oil-shale powered power plants may be exposed to arsenic in fly ash during cleaning. Fly ash contains arsenic and a number of other heavy metals which the workers are exposed to e.g. by cleaning and maintenance.

During coal combustion, arsenic readily oxidizes to form arsenic oxide vapour which combines with calcium oxide and condenses on the surface of fly ash (RAC, 2017). Solid by-products of the combustion process, including fly ash and bottom ash, are major sinks for arsenic. Workers in power plants may first of all be exposed to arsenic found in the fly ash during cleaning of fabric filters and boilers. Arsenic in coals are analysed periodically together with other element and the arsenic content varies considerably. Occupational exposure to arsenic has not been measured and is not considered to be of specific concern. Workers involved in cleaning and maintenance in any case wear full-face respirators.

- **Other sectors**

Mining sector

The main activity where exposure to arsenic may take place is expected to be mining of copper because copper concentrates compared to other concentrates contain relatively high concentrations of arsenic. By handling of copper concentrates in the primary copper smelters, significant workplace concentrations, e.g. by sampling of raw materials and by maintenance procedures, are reported and workers would typically use RPE for these processes. Similar work processes may be expected to take place by the manufacture of arsenic-containing concentrates in mining sites.

Other processes in the metal industry

Data from the German MEGA database indicates that exposure to arsenic may take place by various processes in the metal industry such as soldering, casting/melting and similar process, dry sanding, and various machining processes. As details are not provided it is not clear if the exposure is due to intentional use of arsenic in e.g. copper alloys or due to

low levels of arsenic as unintentional trace element in e.g. sandblasting and abrasive materials.

Wood preservatives and preserved wood

Historically, diarsenicpentaoxide was used in chromated copper arsenate (CCA) wood preservatives. The substance is subject to authorisation, but no companies have applied for authorisation.

The use of CCA solutions in the preservation of timber and import of CCA treated timber is regulated by the Biocidal Product Regulation and is no longer permitted, its use is further restricted under Annex XVII to the REACH Regulation. In practice the Regulation applies to reclaimed timber and included some derogations for wood treated with CCA solution placed on the market for professional and industrial use, provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely. RAC (2017) notes that the use of CCA to preserve wood has effectively ceased in the EU, as has the import of CCA treated timber. However, this leaves a considerable legacy of treated timber still in use with implications for occupational exposure in relation to waste treatment and recycling for the future (RAC, 2017). Workers may be exposed to arsenic by recycling of wood for exempted purposes. Potentially, a large number of workers may occasionally be exposed to low levels of arsenic in dust from the wood.

Taxidermists and preservators

Traditionally diarsenic trioxide has been used by taxidermists for the preservation of animals. Diarsenic trioxide was the most used biocidal product for 'dry' preservation. The exposure for e.g. museum workers today are considered low and are not further assessed.

Dismantling and recycling of waste of electrical and electronic equipment

Arsenic is intentionally used in some electronic components and some exposure to arsenic by dismantling and recycling of electronics may take place, e.g. exposure to cadmium and arsenic compounds is to be expected, in particular with recycling of not silicon based photovoltaic modules.

Laboratory use

Various arsenic compounds are applied for laboratory use. Besides the use of the compounds as analytical standards, apparently mainly organic arsenic compounds have specific applications in chromatography, separations, and environmental chemistry, materials science in polymers, proton-exchange membranes, and optical materials. The exposure in laboratories by use of inorganic arsenic compounds as analytical standards is considered insignificant.

Estimated EU workers exposed

The estimated number of workers exposed to inorganic arsenic compounds by sector is summarised in Table 9. The table distinguishes between two groups:

- Workers for which available data shows that they are exposed at higher levels as demonstrated by measurements, modelling or from comparison to similar processes.

- Other workers which may potentially be occupationally exposed. The latter group either works in sectors and with processes where arsenic may be present in raw materials at considered relatively low levels, or they work in high-exposure sectors (as the copper sector), but likely are not routinely working with the high-exposure processes covered by the monitoring of workplace concentrations.

The estimated total for the EU28 for the two groups of exposed workers is 25,300 – 116,200. For comparison the total of 86,000 is estimated for the mid 1990's for the EU15 in the CAREX database (when applications phased out or beyond the scope of the current study is subtracted the total in the CAREX database).

There is a probability that the numbers of the first group are significantly underestimated as they include only a group of workers for which data is available. There can be more workers exposed at higher levels for whom data is not available.

Table 59: Inorganic arsenic compounds – exposed workforce

Sector	Use/operation	At exposure level as demonstrated by measurements or modelling		No of workers potentially exposed at lower levels **
		Sites	Exposed workers *	
1: Glass sector	Fining agent in special glass	10-20	300-500	1,000-3,500
	Fining agent in domestic glass	0-20	0-200 no use confirmed	
	Recycling of glass	30-50	-	1,000-3,000
2: Electronics sector	Manufacture of copper foils	1	48	-
	Gold plating of circuit boards	1	25	-
	Manufacture and use of gallium arsenide wafers and semiconductors	18-25	150-300	1,000-5,000
3: Chemicals sector	Manufacture of arsenic compounds, not included elsewhere	2-10	-	20-200
	Production of sulphuric acid (from pyrite and by-product from other than copper production)	15	30-170	200-600
4: Copper sector	Primary copper smelters (incl. prod of sulphuric acid)	7	3,200	2,000-4,000
	Secondary copper smelters	8	2,000-3,000	
	Production and use of copper-arsenic alloys	10-30	50-200 (masters alloy)	
5: Zinc production using diarsenic trioxide	Purification in zinc electrowinning	2	90	-
6: Other non-ferrous metals	Primary production of lead, zinc, precious metals, ultrapure arsenic	50-200	300-1,000	5,000-20,000
	Production of alloys of lead and tin with arsenic	-	-	
	Use of lead-arsenic alloys to produce batteries, ammunition, etc.			
7: Cross-sector	Various welding processes. Plasma cutting and other thermal cutting processes.	>500	1,000-4,000	-
8: Ferrous base metals production	Pig iron production (sinter plants and palletisation plants)	40	500-1,500	600-6,000
9: Power sector	Maintenance operations in coal and oil-shale power plants	93	50-500	500-2,500
10: Other	Mining operations and production of concentrates	10-30	200-600 (copper)	500-2,000
	Other metalworking processes	>500	-	5,000-50,000
	Shredding and dismantling of WEEE	20	-	1,000-3,000
	Reclamation of CCA wood	-	-	20-2,000
	Laboratory use	-	-	Insignificant
TOTAL (rounded)			**7,900-15,300**	**18,000-102,000**

Source: RPA (2018)

Formaldehyde

Relevant sectors, uses and activities

In its pure monomeric form, formaldehyde is somewhat unstable and, as such, it is usually converted into a variety of forms for consumer or commercial use, for example into formaldehyde-based resins and polymeric materials, such as polyurethane (RPA, 2006).

Formaldehyde is used in a wide variety of sectors. According to the ECHA substance information portal, formaldehyde is used in: adhesives and sealants; coating products; polymers; biocides; laboratory chemicals; polishes and waxes; fuels; washing and cleaning products; cosmetics and personal care products. Formaldehyde is also used in the manufacturing of leather and fur, pulp, paper and paper products, textile and wood and wood products and is used in building and construction work (ECHA, 2017a).

Formaldehyde is used for tissue preservation in embalming fluids and as a disinfectant in pathology departments and autopsy rooms, usually in the form of formalin (i.e. mixture of formaldehyde, water, and methyl alcohol). Formaldehyde can also be used in the form of a polymerized solid - paraformaldehyde, which tends to be favoured in industrial applications in plants that are located at long distances from formaldehyde manufacturing plants due to its lighter weight and lower shipping costs (IARC, 2012).

The breakdown of formaldehyde use in the EU is as follows from information supplied by Formacare:

41% is used in urea formaldehyde;

9% is used in phenolic resins;

7% is used for melamine formaldehyde;

11% is used in polyols;

8% is used for methylene dianiline (MDA);

7% is used in polyacetal resins; and

17% for other uses.

The most relevant sectors/uses of formaldehyde from literature review and consultation are discussed in the following sectors.

- ***Agriculture, Forestry and Fishing (NACE Code A)***

Formaldehyde is used in slow release fertilisers and in urea treated with formaldehyde as a stabiliser in fertiliser manufacturing. Further information about this use is discussed in the manufacturing of chemicals and chemical products section.

Formaldehyde has been identified as being used in fish farms which are stocked with brown and rainbow trout. It used in the form of formalin with a concentration of 200 ppm and is mainly used in ponds on an infrequent basis dependent on weather conditions (<10 times per year from consultation). It is used to treat fungal infection and growth in ponds stocked with brown and rainbow trout and may be used to some extent in all trout fish farms in Ireland. From consultation, a limited number of people are involved in the formaldehyde treatment.

Manufacturing of food products (NACE Code C10)

Formaldehyde is used in the manufacturing of food products as a bacteriostatic agent, for example in foods such as cheese, in the preservation of dried foods, for disinfecting containers, in the preservation of fish and certain oils and foods, and in the modification of starch for cold swelling (OECD, 2017).

Formaldehyde is also used in sugar beet processing, where it is used as a biocidal agent in saccharose extraction from beetroots (ANSES, 2016).

- ***Manufacture of textiles (NACE Code C13)***

In the manufacture of textiles, formaldehyde based resins are used. These resins are used to bind dyes and pigments to fabrics and also to prevent colours from running when clothes are washed. Urea formaldehyde (UF) and melamine formaldehyde (MF) resins can also be used in textile manufacturing for making clothes stain and wrinkle resistance (Formacare, 2014a).

Operations where exposure could occur are during the manufacturing process, which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding. This is further discussed in Section 3.5.

- ***Manufacture of leather and related products (NACE Code C15)***

In the REACH dossier, the use of formaldehyde in leather tanning is listed (ECHA, 2017b). Operations where exposure could occur are during the manufacturing process which includes spraying, processing, mixing/blending, assembly, dipping/pouring and cutting/sanding. This is discussed in more detail in Section 3.5.

- ***Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)***

The majority of formaldehyde produced in the EU is used to manufacture resins. The primary use of is in the production of urea-formaldehyde resins (50% of EU consumption), melamine formaldehyde resins (10% of EU consumption) and phenol formaldehyde resins (12% of EU consumption). Polyacetyl resins (POM) account for 8% of the EU formaldehyde market and is a growing market as POMs are self-lubricating thermoplastics for replacing metal components and are used in a variety of sectors such as gears, housings and bearings.

The primary use of formaldehyde based resins is in the manufacture of wood based panels (TNO Triskelion B.V. and RPA, 2013). In particular, urea-formaldehyde (UF) resin and phenol formaldehyde (PF) resin are used in the manufacture of wood and products of wood and cork. The primary application of the resins is as a "glue resin" in wood panels and wooden plates.

For these uses, emission standards are in place in the EU to limit formaldehyde exposure. Two standards exist for wood-based products: emission class E1 and emission class E2. In E1 boards, formaldehyde emissions are less than 0.1 ppm; and for E2 boards formaldehyde emissions are between 0.1 and 0.3 ppm (Health and Safety Executive, undated).

Emission class E1 is the class that applies to panel production (ANSES, 2016). Operations where exposure could occur are during panel production (which includes

loading/unloading; process operations; line operations; sorting/packing; testing; weighing; mixing and filling) and also during *in situ* use downstream users.

- ***Manufacture of paper and paper products (NACE Code C17)***

Formaldehyde is used in the manufacture of paper and paper products. Urea formaldehyde resin is used for producing printer paper, craft paper, packaging paper, hygienic paper and also paper that requires special security features such as bank notes and passports (ANSES, 2016).

- ***Manufacture of chemicals and chemical products (NACE Code C20)***

Formaldehyde is also used in the manufacturing of the following chemical products:

- Fertilisers (NACE Code C20.1): In slow release fertilisers, formaldehyde is used in the preparation of the polymer nutrient but is not present in the final product (consultation with Fertilizer Europe). In urea, formaldehyde is added as a stabiliser which improves the physical characteristics of the granules and also avoids caking phenomenon further down the supply chain (from consultation). Exposure could occur during fertiliser production (during cleaning/maintenance, sampling and general operation) and in some cases, where formaldehyde is used as a stabiliser as this may be partially sprayed over the final product;
- Methylene dianiline (MDA) and diphenyl methane diisocyanate (MDI), where its use is as an intermediate. MDA is used in the manufacture of MDI which is used in insulation foams, paints and coatings, adhesives for wood panels, automotive seats, bedding and mattresses (8% of formaldehyde in the EU is used for this purpose);
- Paints, varnishes and similar coatings, printing inks and mastics (NACE Code C20.3): Urea formaldehyde resins, melamine formaldehyde resins and phenol formaldehyde resins) are used as binding agents. The applications of adhesives and coatings is also listed as a use for professional workers in the REACH registration dossier (ECHA, 2017b);
- Soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations (NACE Code C20.4): Formaldehyde can be used for preservation applications, household cleaning agents and in nail hardeners amongst others and is present in low concentrations (Denmark Environmental Protection Agency, 2014 and Boyer, 2013); and
- Explosives (NACE Code C20.51): Formaldehyde can also be used in the manufacture of explosives such as RDX. In this application, formaldehyde is reacted with ammonia to produce hexamine (which can then be used in explosives) (Maxwell, 2004).

Exposure to formaldehyde during manufacturing of chemicals and chemical products can occur during process control and sampling, cleaning/service/repairs and filter changing amongst others.

- ***Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)***

In pharmaceutical sector, formaldehyde is used in the manufacture of gelatin capsules. It is also used as an inactivating agent in vaccines (Pina and Sousa, 2002), where it is used

to inactivate toxins from bacteria and viruses. There may be traces of formaldehyde in the final vaccine, however, this is broken down in water (and most of the vaccine is water - Oxford Vaccine Group, 2015).

- ***Manufacture of rubber and plastic products (NACE Code C22)***

Formaldehyde has been identified as being used in the manufacture of rubber and plastic products in the ANSES (2016) draft document with hexamine (formaldehyde is used as a starting material) used as a rubber accelerator (ANSES, 2016). In the study by Clerc*et al*, exposure to formaldehyde has been observed in France and Germany in the manufacture of rubber and plastic products (Clerc*et al*, 2015). Phenol formaldehyde and urea formaldehyde resins are also used in plastic fuse boxes, knobs and switches (British Plastics Federation, 2015).

Operations where formaldehyde exposure in this sector could occur include in weighing and loading; mixing; shaping; vulcanisation/curing; and finishing.

- ***Manufacture of fabricated metals, except machinery and equipment (NACE Code C25)***

Formaldehyde can be used as a preservative in metal remover fluids, anticorrosive agents and metalworking agents; these products may also release formaldehyde. The use of formaldehyde releasers for metal working fluids is covered in PT 13 of the biocidal products regulation (RIVM, 2015). Exposure can occur during metal finishing and plating. Exposure can also occur in foundries, as when sand is hardened, formaldehyde based resins are used.

- ***Manufacture of electrical equipment (NACE Code C27)***

Polyoxymethylene (also called Polyacetal) resins are formaldehyde polymers which are used in powder injection moulding technology (Antoun et al, 2013). POM resins are also used in the manufacture of electrical and electronic appliance parts (moulding).

- ***Manufacture of machinery and equipment (NACE Code C28)***

Phenol formaldehyde resin is used in the production of abrasive wheels.

- ***Manufacture of motor vehicles, trailers and semi-trailers (NACE Code C29)***

Formaldehyde based resins are used in many automotive applications and these are described in the below table.

Table 60: Formaldehyde resins used in automotive applications

Formaldehyde resin	Properties for application	Application
Phenol formaldehyde	High moisture resistance, high chemical resistance, and high thermal resistance	Engine parts, transmission parts, brake parts, brake pads, clutches, and decorative laminates
Melamine formaldehyde	Withstand high temperatures, fast curing, and excellent chemical resistance	Surface coatings and decorative laminates
Polyoxymethylene	Gasoline resistance and lubricant properties (main use in the manufacture of fuel pumps)	Automatic transmission parts, car heater plates, gear selectors, steering column shear pin parts, suspension links, tyre valve stems, electrical switch parts, light sockets, fuel system components, fan parts, car ventilation grille, truck release levers, door handles, door catches, window cranks, control switches and instrument knobs, gear selectors, plastic component of seat belt systems, and locks, hooks, fasteners, clips and mirrors
Source: Formacare (2014): Formaldehyde in Automotive Applications. Available at: http://www.formacare.org/automotive/		

Methylene bis (dephenyl di-isocyanate) (MDI), 1,4-Butanediol (BDO) and Pentaerythritol (Penta), in which formaldehyde is used as a starting material, are also used in automotive applications (Formacare, 2014b).

- ***Manufacture of air and spacecraft and related machinery (NACE Code C30.3)***

According to Formacare, formaldehyde based resins are used in the following aircraft applications (Formacare, 2014c):

Phenol formaldehyde resins are used in the panelling of aircraft interiors;

Polyoxymethylene is used in the manufacture of seatbelt plastic components;

Hexamine is used as an accelerator in rubber tyres;

Pentaerythritol is used as a lubricant for turbines; and

MDI is used in aircraft seats.

- ***Manufacture of furniture (NACE Code C31)***

Urea formaldehyde and phenol formaldehyde resins are used as "glue resins" in furniture manufacturing, which is further discussed in the "Manufacture of wood and products of wood and cork; except furniture" section above.

- ***Construction of buildings (NACE Code F41)***

Formaldehyde based foams (urea-formaldehyde and phenol formaldehyde) are used as building materials, insulator materials, and can also be used as an adhesive in mineral wools which have applications as thermal insulators. ECHA lists the use of formaldehyde in outdoor use in long life materials with low release rates such as building

materials and in indoor use in long life materials with low release rates such as construction materials (ECHA, 2017a).

- ***Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)***

Formaldehyde is used in the electrophoresis (method to separate mixtures by size) of RNA (ThermoFisher Scientific, undated and Bryant, 1998). In the formaldehyde gel used, formamide (30-60 wt. %) and formaldehyde (10-30 wt. %) is used (ThermoFisher Scientific, 2013). ANSES (2016) also reports that formaldehyde is used as a laboratory reagent in control laboratories (ANSES, 2016).

Formaldehyde is also used in the synthesis of chelating agents and pyridines and is used for health research which is further discussed in the higher education sector.

- ***Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)***

Formaldehyde is used as a veterinary biocidal agent in the poultry sector and is used as a fumigant due to its capability to destroy microorganisms on eggs, egg cases, chick boxes and hatchery equipment; it is also used as a disinfectant for poultry houses (Association of Poultry Processors and Poultry Trade in the EU Countries, 2015). In a submission to an ECHA consultation regarding formaldehyde as a potential candidate for substitution under the BPR regulation, the British Poultry Council stated that formaldehyde is used in the poultry industry for the following reasons: (British Poultry Council, 2015):

Formaldehyde is used in hatcheries to stop bacterial contamination in fluff and hatching eggs;

Formaldehyde vapour is easily generated from formalin or paraformaldehyde for use as a disinfectant;

Formaldehyde is efficient for treating buildings;

There is more penetration power down the pores of eggshells (gas-phase disinfectant) undergoing fumigation and this process does not damage the eggs or embryos; and

The use of formaldehyde decreases chick mortality.

Formaldehyde is also used as a disinfectant in greenhouses between crop cycles and in foot baths for treating mortellaro disease in dairy cows (LTO Netherlands, undated). The use of formaldehyde in fish farms is discussed in the agricultural uses section.

- ***Education (NACE Code P85- P85.4. Higher Education)***

Formaldehyde is used as a used as a preservative for specimen and tissue samples which is discussed in more detail in the following section. Formaldehyde is used in the following activities (consultation):

Preparation of fixation solutions (3-4% formaldehyde);

Fixation of human bodies;

Storage (preservation of bodies); and

Teaching for student courses, for example dissection activities.

- ***Human health and social work activities: Human health activities (NACE Code Q86)***

Formaldehyde is used for the following applications in the healthcare sector:

> *Health services:* Cleaning medical equipment, surfaces and environments; used to fix and maintain specimens and tissue samples; used as a tissue preservative (typically 10% concentration) and as an embalming agent;
>
> *Dentistry:* Antiseptics and disinfectants, e.g. composite resins replacing amalgam and root canal fillings; and
>
> *Schools and universities:* Used as a preservative for specimen and tissue samples.

Operations where formaldehyde exposure could occur include in operating rooms and pathology laboratories and for the uses listed above.

- ***Funeral and related activities (NACE S96.03)***

Formaldehyde is used for embalming in funeral homes. From consultation, formaldehyde is used as it cross-links to protein to stop bacteria nourishment. Exposure could occur during the embalming process.

- ***Other Biocidal Uses***

Formaldehyde is also reportedly used in the hot water treatment of flower bulbs to destroy nematodes in a submission from the Royal General Bulb Growers Association; as hot water treatment can lead to basal rot and Legionella Pneumophila, formaldehyde (0.5% solution of formalin) is added to the bath (Royal General Bulb Growers Association, undated) to prevent this from occurring.

The relevant sectors and uses in which occupational exposure to formaldehyde could occur are summarised in the following table.

Table 61: Formaldehyde exposure sectors

Sector	Form	Applications
Agriculture, Forestry and Fishing (NACE Code A)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Biocide	Used as a preservative and biocide in: Pesticides, fungicides, herbicides, etc.
Manufacturing of food products (NACE Code C10)		Used in the manufacturer of sugar (saccharose extraction from beetroots); as a preservative agent for food additives; as a synthetic reactive substance for food contact materials and as a surface cleaning agent
Manufacture of textiles (NACE Code C13)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Phenol formaldehyde (PF) resin	Used as a crease-proof (or anti-wrinkle) agent for: clothes and household linen products, curtains, carpets, fabric softeners, textile processing (dyes) and finishing (permanent press); used as an antimicrobial in medical textiles and also used in textile processing (formaldehyde-based resins)
Manufacture of leather and related products (NACE Code C15)	Urea-formaldehyde (UF) resin	Used in tanneries Used as a preservative for preventing hides from decomposing
Manufacture of wood and products of wood and cork; except furniture (NACE Code C16)	Urea-formaldehyde (UF) resin Phenolformaldehyde (PF) resin	Used as a “glue resin” in wood panels and wooden plates
Manufacture of paper and paper products (NACE Code C17)	Urea-formaldehyde (UF) resin	Used in towel products, kitchen rolls, napkins, sack papers, labels, currency, maps and filter papers
Manufacture of chemicals and chemical products (NACE Code C20: C20.1, 20.2 and 20.4))	Formaldehyde, 37% solution, 49%, 50-55%	Production of formaldehyde; used in fertiliser synthesis; used as a startingmaterial in the production of polyacetalresins (polyoxymethylene-POM) and paraformaldehyde; used as a starting material in the production of condensed resins: Urea-formaldehyde (UF); melamine-formaldehyderesins; phenol-formaldehyderesins; used as an intermediate in the synthesis of methylene dianiline (MDA), diphenylmethanediisocyanate (MDI), hexamethylenetetramine; used in HTMA which is used as a curing agent, rubber accelerator and in the manufacture of explosives, trimethylolpropane, neopentylglycol, pentaerythritol, butanediol (BDO) and acetylenic agents Used in adhesives and used in biocidal applications
Manufacture of paints, varnishes and similar coatings, printing inks and mastics (NACE Code C20.3)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin Phenolformaldehyde (PF) resin	Used as a binding agent in: paints, polishes, varnishes, lacquers, wax for furniture and floors, furniture polish, shoe shine, printing inks, external coating for cars and in external coatings

Sector	Form	Applications
		for building claddings and for white goods etc.
Manufacture of soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations (NACE Code C20.4)	Preservatives Nail hardening agents Disinfectants	Used in the preservation of cosmetic products and raw materials against microbial contamination; use in certain cosmetic treatments, such as hardening of fingernails; and plant and equipment hygiene. Used in shower gels, shampoos, deodorants, nail hardeners, etc.
Manufacture of explosives (NACE Code C20.51)	Urea-formaldehyde (UF) resin Melamine formaldehyde (MF) resin	Used in the form of foam resin and other in: Household cleaning products, carpet cleaning agents, car cleaning agents, swimming pool cleaning products, etc. Used as an antimicrobial preservative in household and industrial products; and used to clean surfaces and equipment Used in the manufacture of explosives such as RDX
Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE Code C21)	Polyacetal (POM) resin	Used as an inactivating agent in vaccines: e.g. human vaccines and medicines; and used in the manufacture of gelatin capsules
Manufacture of rubber and plastic products (NACE Code C22)		Used in tyre and rubber manufacturing
Manufacture of fabricated metals, except machinery and equipment (NACE Code C25)	Preservatives Formaldehyde resins	Uses as metal remover fluids, as anti-corrosive agent, as an oxidising and reducing agent, used in electroless plating, used in coatings and used to harden sand in foundries. Metalworking fluids can also be formaldehyde releasing agents, such as triazine; used in paints and coatings to extend shelf life
Manufacture of electrical equipment (NACE Code C27)	Polyacetal (POM) resin	Electrical/electronic appliances parts
Manufacture of machinery and equipment n.e.c. (NACE Code C28)	Phenol formaldehyde resin	Production of abrasive wheels
Manufacture of motor vehicles, trailers and semi-trailers (NACE Code C29)	Polyacetal (POM) resin Phenolformaldehyde (PF) resin	Used for safety belt components, fuel system components and engine components
Manufacture of furniture (NACE Code C31)	Urea-formaldehyde (UF) resin Phenolformaldehyde (PF) resin	Used as a “glue resin” in the furniture manufacturing industry
Water collection, treatment and supply (NACE Code E36)		Used in water control (laboratories) and water purification

Sector	Form	Applications
Waste collection, treatment and disposal activities; materials recovery (NACE Code E38)		Precious metals recycling
Construction of buildings (NACE Code F41)	UF foam; PF foam	Used in building and insulating materials; and used as an adhesive in mineral wools that are used as thermal insulators
Professional, Scientific and Technical Activities: Photographic activities (NACE Code M74.2)	Stabilising agents in photographic colour processing Hardener/crosslinking agents Binding agent	Photographic materials (plates and papers) and processes
Professional, Scientific and Technical Activities: Scientific research and development (NACE Code M72)		Used as a laboratory reagent; used in electrophoresis of RNA; and used in the synthesis of chelating agents and pyridines
Professional, Scientific and Technical Activities: Veterinary activities (NACE Code M75)	Antiseptic, antimicrobial food additive, disinfectant	Used in animal feed, fish vaccines, etc.
Education (NACE Code P85.4):		**Schools and universities**: Used as a preservative for specimen and tissue samples; used for fixation; and used in teaching courses
Human health and social work activities: Human health activities (NACE Code Q86)		**Health services**: Used for cleaning medical equipment, surfaces and environments; used to maintain specimens and tissue samples; and is also used as a tissue preservative (typically 10% concentration **Dentistry**: Used for antiseptic and disinfectants e.g. composite resins replacing amalgam and root canal fillings
Funeral and related activities (NACE Code S96.0.3)	Formalin	Used as an embalming agent
Sources: ANSES (2016): Analysis of the most appropriate risk management option (RMOA) - formaldehyde. Available at http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_Formaldehyde_040716.pdf Consultation Responses Formacare (2014): About formaldehyde. Available at: http://www.formacare.org/about-formaldehyde/ IPCS (1991): Formaldehyde Health and Safety Guide. Available at: http://www.inchem.org/documents/hsg/hsg/hsg057.htm#SectionNumber:1.5 RPA (2006): Comparative Assessment of Alternatives in Formaldehyde in Consumer and Non-Consumer Products and Applications. Report for AFSSET		

Estimated EU workers exposed

This section first summarises the estimates at the EU-28 level of exposed workers and then provides a breakdown by sector. It is of note that there are differences in estimates between different sources.

The starting point for estimating the occupationally exposed population to formaldehyde is the CAREX database[127,128], with further estimates being available from SUMER (France in 2003[129] and 2010[130]), FinJem (Finland, reproduced in Santonen, 2013[131]), Regex (Czech Republic)[132], and Siew *et al*[133]. These estimates are summarised below.

Table 62: Published data – workforce exposed to formaldehyde

Study	Country	Year/period	No. of exposed workers	% of exposed workforce	Notes
CAREX	EU15	1990-1993 (mean)	971,402		
	France	1990-1993 (mean)	307,025		
	Finland	1990-1993 (mean)	10,530		
	Czech Republic	1997	43,669		
	UK	1990-1993 (mean)	93,807		
SUMER	France	2003	153,600 (66,800 men and 86,800 women)	0.9% (0.7% men and 1.2% women)	
		2010	139,400 (66,100 men and 73,300 women)	0.6% (0.6% men and 0.7% women)	
FinJem	Finland	2006	10,700		Woodworking & furniture industry, foundries
Siew *et al*	Global	Not specified		1%	

127 See: http://oem.bmj.com/content/57/1/10;

128 Kauppinen et al. (2000): Occupational exposure to carcinogens in the European Union. Occ Environ Med 57, p. 10–18.

129 http://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition-115982

130 http://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition

131 Santonen (2013): Well-being through work, available at http://ec.europa.eu/social/BlobServlet?docId=11305&langId=en

132 Regex (2016): Registry of Subjects Occupationally Exposed to Carcinogens, National Health Institute (2016), available at http://www.szu.cz/uploads/documents/chzp/odborne_zpravy/OZ_16/Prace_2016.pdf

133 Siew et al (2012): Occupational exposure to wood dust and formaldehyde and risk of nasal, nasopharyngeal, and lung cancer among Finnish men, In: Cancer Management and Research August 2012, available at: https://www.researchgate.net/profile/Pentti_Kyyroenen/publication/230699498_Occupational_exposure_to_wood_dust_and_formaldehyde_and_risk_of_nasal_nasopharyngeal_and_lung_cancer_among_Finnish_men/links/00b7d5229fa1e27a67000000.pdf

Study	Country	Year/period	No. of exposed workers	% of exposed workforce	Notes
Regex	Czech Republic	2009-2016	173		

In addition, the total number of potentially exposed workers, as well as figures by sector, were estimated based on data obtained through consultation and for some sectors by estimating the share of exposed workers based on the extent of formaldehyde application within the relevant sectors.

In order to be able to compare the results from different sources, the published data have been extrapolated to EU28 and the year 2015 based on the number of persons employed in each country and based on the changing trends in employment during the time period concerned. According to Eurostat, the total number of people in employment or self-employment in the EU-28 was 220 million in 2015. Applying the estimates of the proportion of the exposed workforce in the table above suggests an occupationally exposed population between 1.3 million and 2.2 million. A comparison of the number of workers exposed to formaldehyde identified through different sources is presented below.

Table 63: Comparison of the number of workers exposed to formaldehyde identified through different sources

Source of data	Number of exposed workers in the EU28 in 2015
Consultation/share of workforce using Eurostat data	0.99 million
Carex database*	1.4 million
FinJem database*	0.99 million
Sumer	1.6 million
Siew et al	2.2 million
*data have been extrapolated based on employment shares from Eurostat (2015): Structural Business Statistics. Available at: http://ec.europa.eu/eurostat/web/structural-business-statistics/data/database.	
Source: RPA (2018)	

The lowest estimate is 990 000 which was obtained through consultation and estimation of workers using Eurostat data. It corresponds with another estimate which relies on extrapolation to the EU-28 of the FinJem data (the Regex data for the Czech Republic are considered to be an outlier). The highest estimate can be derived on the basis of applying the 1% estimate in Siew *et al*[134]to the total EU workforce which yields an estimate of 2.2 million. All other estimates and extrapolations (CAREX, SUMER) fall between these two values.

[134] Siew et al (2012): Occupational exposure to wood dust and formaldehyde and risk of nasal, nasopharyngeal, and lung cancer among Finnish men, In: Cancer Management and Research August 2012, available at: https://www.researchgate.net/profile/Pentti_Kyyroenen/publication/230699498_Occupational_exposure_to_wood_dust_and_formaldehyde_and_risk_of_nasal_nasopharyngeal_and_lung_cancer_among_Finnish_men/links/00b7d5229fa1e27a67000000.pdf

4,4'-Methylene-bis(2-chloroaniline) - MOCA

Relevant sectors, uses and activities

The relevant sectors and uses where occupational exposure is expected to take place are summarised below.

Table 64: Relevant sectors and uses – MOCA

Sector	Group	Use/activity	Number of companies
Plastics industry, chemicals sector	Suppliers of the polyurethane sector	Providing MOCA and MOCA containing polyurethane systems	5
Plastics industry	Polyurethane moulders	Catalyst and chain extender by manufacture of polyurethane	89 (best estimate but it is noted that the maximum is less than 120)
Laboratories	Research and commercial laboratories	Analysis of MOCA in biological samples and workplace air	Not investigated
Source: based on REACH Law (2016a)			

The most relevant sectors/uses

According to the application for authorisation, the supply chain for MOCA is as illustrated below:

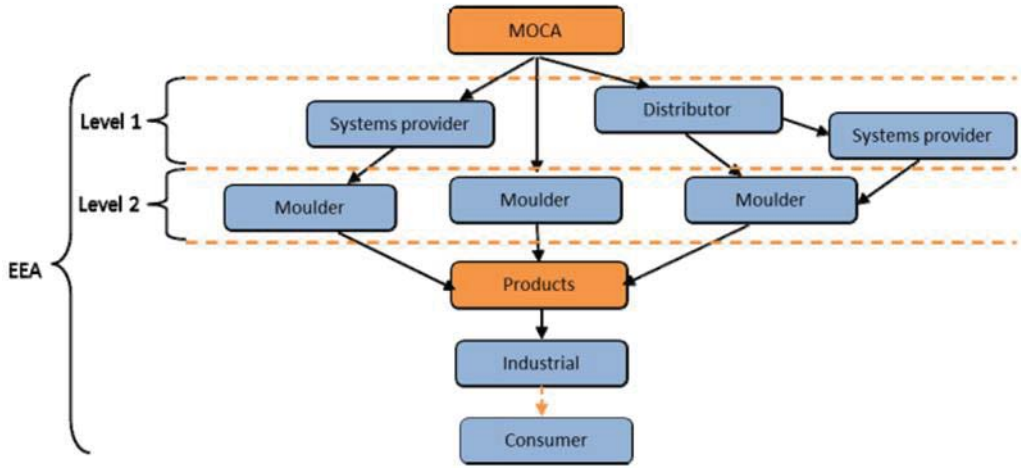

Figure 12: Supply chain for MOCA (reproduced from Reach Law, 2016b)

The scope of possible occupational exposure is limited to the importers of MOCA into the EEA (distributors and system providers) and their direct customers designated Level 1 (system providers) and Level 2 (moulders) in the figure. The following is extracted from the documents for the application for authorisation (REACH Law, 2016b).

Level 1: System providers sell cast polyurethane systems (e.g. prepolymers, curatives, additives, and also machinery) to moulders. There are 5 companies on this level of the supply chain and these are spread across Europe. The companies generally supply both machines and reagents to their customers and the systems they have available to moulders cover a wide spectrum of castable polyurethane formulations combining most diisocyanates and polyols available.

Level 2: Moulders produce polyurethane articles. The application for authorisation contains information on moulders based on questionnaire responses representing about 66% of the EU tonnage within this supply chain. The document distinguishes between three categories of moulders and their relative percentage in the supply chain is given below:

- Generalised moulders (60 %) who produce make-to-order products, low quantity per products, serving a large number of industries. MOCA range from a few percent to 100% of production. Typically quantities: 0.1-12 t/year.
- Specialised moulders (15 %) who produce a large quantity of specific products, serving specific industries. MOCA used in 80-100% of production. Typical quantities: 7-80 t/year.
- Mixed moulders (25%) who have mixed characteristics. MOCA used in 30-95% of production. Typical quantities: 6-40 t/year.

It is in the application estimated that about 89 companies operate at this level across the entire EU. The information on the amount of moulders in the supply chain comes directly from the system providers that supply MOCA to them and it is concluded in the application that there is a defined number of moulding companies that does not exceed 120 businesses. The average consumption of MOCA in the companies can be estimated at approximately 5.6 t/year if the number of 89 is used.

All moulders are in the application for authorisation surveyed as micro- (< 10 worker; 20%), small- (10-50 worker; 65%) or medium- (50-250 worker; 15%) sized enterprises as defined by the European Commission.

As part of the preparation of the application, a questionnaire was undertaken by the applicant in order to gather information about use conditions, company size and exposure. The application estimates in the socioeconomic analysis (of the application) that moulders have a median number of 23 workers with 1 worker as minimum. The mean number is not provided. The companies answering the questionnaire survey in total had 892 workers and represented 65% of the total volume of MOCA. If this number is extrapolated on a number of worker's per tonne basis, the total number of workers would be 1,526, which is considered the best estimate.

Chemtura, which until recently has been supplier of MOCA for the EU market, performed another market survey in 2015. They identified a total of around 50 MOCA users who collectively used some 350 tonnes of MOCA per year (Corden and Tyrer, 2017) i.e. on average the consumption of MOCA in these companies was 7 t/year. The same data showed that the maximum MOCA usage in one company within these 50 companies was around 50 tonnes per year and the smallest amount used was 1 tonne. This survey indicated that the largest producers employ some 60 workers; the smallest around 5 and the average company employed 12 people (Corden and Tyrer, 2017). Even the average is somewhat lower in this survey as compared to the number indicated in the

application for authorisation, the data are quite well in accordance with those provided in the application and support that the majority of the users are micro and small- sized companies.

According to the Annex XV report (ECHA, 2011a), based on the information from the industry, the supply chain around year 2010 consisted of importers, distributors and industrial users with a total of more than 200 use sites within the EU. MOCA was supplied as substance of its own or in mixtures containing the substance. A decrease from 200 sites to less than 100 in 2017 is well in accordance with general information from the sector indicating a decline in the use of MOCA.

According to Cocker et al. (2009), in late 2005/2006 around 25 companies in the UK were using MOCA in the manufacture of polyurethane elastomers. Twenty of the 25 companies visited in a survey ranged from micro companies (<10 workers) to small–medium enterprises (10–250 workers). The average number of workers per site is not reported but it is indicated that ~300 workers are directly exposed to MOCA during polyurethane elastomer production and ~1000 workers are indirectly exposed i.e. around 12 workers per company are directly exposed and 40 indirectly exposed. This could indicate that the average size of UK companies using MOCA at that time were somewhat larger than the average within the supply chain of the applicant. This will be discussed further in the use of the data from the UK surveys to extrapolate to the EU level.

Manual vs. automatic processing

As indicated in the application for authorisation, the users of MOCA "*either perform their tasks in manual processes or using machines. The exposure potential of the hot casting processes can, consequently, be divided into automated and manual processes. In the automated process the substance handling, melting and mixing are performed inside an enclosed machine, whereas in manual process these steps are performed manually. The highest potential for exposure during the casting processes is the manual handling, mixing steps and maintenance tasks."*

According to the survey undertaken by the applicant most of the moulding shops use automated moulding machines, but some still use manual moulding e.g. when producing smaller articles. As discussed later, the application provides risk estimates for the manual and automatic processes separately.

As the data from the UK surveys of worker exposure will be extensively used on the description of exposure levels, it is relevant to discuss to what extent the UK survey results also represent manual processes. According to Cocker et al. (2009), manual methods were used in 15 of the 20 visited sites. It is reported that the handling of MOCA during polyurethane elastomer production was essentially the same in all firms using the manual method. "*MOCA pellets or granules were scooped from a keg and placed in a container (pan or beaker). Then, under an LEV system, the container was heated on a hot plate to 98–110 ˚C and stored until mixed with a liquid pre-polymer resin, at 60–80 ˚C, containing TDI or HDI. Colourants may be added at this stage and then mixed. The ratio of MbOCA to resin is generally 1:10 but may be up to 3:10*" (Cocker et al., 2009). Five companies used automated methods to process MOCA but according to the authors there was still potential for spillage and exposure during the filling, dispensing, and mixing stages. "*The mixed polyurethane was de-gassed and poured into moulds preheated to 90–95 ˚C. Following casting, the moulds were cured in ovens at 100–120*

˚C for 4–24 h. After curing, the products were released from the moulds and excess ash and spurs were removed by trimming with a knife or scissors."

- **Downstream uses**

The polyurethane parts are used by a wide array of industries for many different applications. Occupational exposure to MOCA in the workplace air, by downstream users of the cured polyurethane parts, is considered low or insignificant and not further assessed.

- **Laboratories**

Small amounts of analytical standards for MOCA are used in laboratories for analysis of MOCA in biological samples and in workplace air. The occupational exposure by the analysis is considered insignificant. MOCA is not used as analytical reagent for any known laboratory analysis.

Applications

MOCA is used as a curing agent/chain extender in cast polyurethane elastomer production. Castable polyurethanes form a part of the overall polyurethane industry. They are prepared by mixing 3 main constituents: the polyol, the diisocyanate (which together form the prepolymer) and a curing agent/chain extender such as MOCA. Before mixing with the prepolymer, MOCA is first melted at ca. 120°C. The resulting molten polyurethane is then moved to a moulding area and poured into the moulds. The moulding process can be performed either manually or in an automated system. Finally, when the moulds are cast they are cured at 70-80 °C.

MOCA is used in the production of polyurethane elastomers to give specific properties (such as heat, fuel, and solvent resistance, high abrasion properties, and high load-bearing and favourable mechanical and dynamic properties) to the polyurethane products.

According to Corden and Tyrer (2017) in a report prepared for Chemtura (a previous provider of MOCA and now provider of alternatives), typical products in which MOCA-based cast polyurethanes are used a*re:*

- Rolls;
- Wheels;
- Hydrocyclones;
- Dynamic bend stiffeners;
- Power transmission belts;
- Vibratory bowls for metal finishing;
- Gaskets;
- Pump impellers;
- Pipeline pigs;
- Belt scrapers;
- Snow plough blades;
- Internal pipe liners;
- Die pads;
- Railway components; and
- Bushings.

According to the application for authorisation "*Products made with a MOCA cured system include wheels and rollers covered by polyurethane; technical machine parts; timing and other types of belts used in many applications e.g. printers, money sorting machines security cameras, sprinkler systems etc.; textile and paper manufacturing; and general machinery uses. MOCA cured systems are used for roller coating for any industrial sector, cone separators for paper industry, roller covers for steel industry, street furniture, sheets and scrapers. Polyurethane covered rollers are used especially in the steel, aluminium, paper, carton, wood and textile industry.*"

Estimated EU workers exposed

After the REACH Annex XIV sunset date of 22 November 2017, MOCA can only be used by the downstream users in the supply chain of the only applicant for authorisation. The authorisation has not yet been granted.

The application for authorisation estimates the total number of exposed workers by the moulders at 89 sites across the EU to be 213. This figure was derived from the number of potentially exposed workers reported in survey responses, giving a potential exposure worker per tonne ratio of 0.41. The total was then calculated by extrapolating to the total MOCA use of 516 t/year.

This figure would correspond to less than 3 workers per site. The total number of workers by the users of MOCA in the supply chain of the applicant can be estimated at 1,526. Consequently, the percentage of the total workforce in the companies which is exposed to MOCA would be 14%. This seems to be relatively low as compared with information from a UK survey.

The Health and Safety Executive (HSE) in the UK estimated that in the years 2005/2006, 300 workers in the UK were directly exposed to MOCA during polyurethane-elastomer production, and more than 1,000 workers, such as office staff, were indirectly exposed (Cocker *et al.*)[135]. The directly exposed workers represent 23% of all exposed workers, which is assumed to be identical to the total number of workers of the companies. Indirect exposure would be by the dermal route by touching surfaces with MOCA contaminated by workers directly exposed by production work processes. The total use of MOCA in the UK is reported at >200 tonnes in 2006 which is an increase from a level of 90-120 tonnes in 1995. The consumption of MOCA per worker was significantly lower in the UK in 2005/2006 as compared to the data from the supply chain of the application which presumably reflects an increase in the efficiency in the companies with larger production output per worker due to increased automation.

As the data from the UK is based on a systematic survey of 20 out of 25 companies in the industry with extensive measurements of workplace exposure concentration and urinary MOCA concentration, the results are considered to better reflect the actual exposure situation in the industry than the results of the survey of the applicant of the REACH authorisation. Consequently, it is assumed that 23% of the total number of 1,526 workers, corresponding to 350 workers would be the exposed. The remaining approximately 1,200 workers may potentially be indirectly exposed. The estimated 350 workers is only slightly higher than the 300 workers in the UK alone in 2005/2006,

[135] Cocker,J., Cain, J.R., Baldwin, P., McNally, K., Jones, K. (2009): A Survey of Occupational Exposure to 4,4'-methylene-bis (2-chloroaniline) (MbOCA) in the UK. *Ann. Occup. Hyg*., 53: 499–507.

where the total consumption was reported at >200 t/year. This indicates that the number of workers per tonne used was higher in the UK in 2005/2006 than in the supply chain of the applicant today, but this is considered to be in accordance with the higher share of automatic processes in the supply chain of the applicant.

Regional distribution. According to the survey undertaken for the application for authorisation, moulders within the supply chain of the applicant are located in Belgium, Denmark, France, Italy, Ireland, Greece, Hungary, Portugal, Spain, the Netherlands, and the United Kingdom. In addition, some moulders not responding to the survey may be located in other MS. The distribution of the consumption by MS is not provided.

Suppliers. Suppliers do not handle MOCA directly but supply filled drums as delivered by the manufacturer. Cooker et al. (2009) took samples from two UK importers/suppliers of MOCA in 2005/2006. At the two suppliers, samples (n =28) were collected from the outside surfaces of recently imported kegs, pallets, and the floor around kegs. Six samples had detectable levels and four of these were from the floor and pallets in both suppliers. Samples were also taken of staff of suppliers but the results are not reported separately. The application for authorisation does not address exposure by the suppliers. According to information obtained from ReachLaw[136] for this study, the MOCA is packed in drums in China. The MOCA drums are inspected with Swype tests in the factory in China before shipping to ensure that there is no contamination on the surface of the drums. Any exposure by the suppliers would be by the dermal route to contaminants on the surface of the packaging and not further assessed.

Historical exposure

CAREX (1999) estimated the numbers of workers potentially occupationally exposed to MOCA in the EU at 3,300 distributed within the following sectors:

- Manufacture of plastic products not elsewhere classified: 1,390
- Manufacture of rubber products: 1,360
- Manufacture of industrial chemicals: 100
- Manufacture of miscellaneous products from petroleum and coal: 10
- Research and scientific institutes: 430

Polyurethane elastomer are by some considered "rubber" whereas by others as "plastic", and the figures for manufacture of the two materials probably both represent the manufacture of polyurethane elastomers, so the total for this sector is 2,750 exposed workers. MOCA was at that time manufactured within the EU, but has for more than 10 years only been imported.

The CAREX data was used by IOM[137] in a previous study where it was estimated that 2,500 workers were exposed to MOCA in the EU, of which about 1,400 were estimated to potentially be exposed in high-exposure industries (manufacture of rubber and plastics products).

[136] REACHLaw (2017): personal communication with RuaidríMacDomhnaill, REACHLaw Oy.

[137] Health, socio-economic impact and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risk related to carcinogens and mutagens at work. 4,4'-methylene-bis-ortho-chloroaniline (MbOCA). IOM and partners.

Trend in number of exposed workers

No data exist on the trend in number of exposed workers. An indication of the trend in number of exposed workforce could be derived from the trend in the consumption of MOCA in the EU, but detailed data on this trend is not available. Furthermore, it could be expected that more workers were exposed in the past because manual processes were more widespread.

The available data on number of exposed worker is summarised in the table below. A distribution by Member State is not available.

Table 65: Number of workers exposed to MOCA

Sector	Country/Region	Number of sites	No. of exposed workers
Plastics sector Moulding of polyurethane elastomer parts	EU 28	89 (best estimate)	350 directly exposed Indirectly exposed workers by the dermal route ~ 1,200
Source: RPA (2018)			

Exposure concentrations

The only comprehensive dataset available on exposure concentrations in the workplace air is the data obtained in the UK in 2005/2006.

The highest levels were found for workers undertaking manual processes which are supported by modelling results from the application for authorisation. The dataset is 12 years old and most of the companies used at that time manual processes. According to the application today most companies use the automatic process. On the other hand most MS have higher OELs than applied in the UK and the companies would be less forced to reduce the exposure levels. New data from Australia shows significantly lower levels than reported in the UK 2005/2006 survey.

Table 66: Distribution of workers by exposure concentration

	< 1 µg/m^3	1-1.5 µg/m^3	1.5-5 µg/m^3	5-10 µg/m^3	10-15 µg/m^3
Number of workers - UK survey	183	12	11	0	2
Percentage	88%	6%	5%	0%	1%
Number of workers at EU level	308	20	19	0	3
Source: RPA (2018)					

Urinary concentrations

For the subsequent estimation of the current, past and future current burden of disease based on urinary concentration an arithmetic mean value of urinary levels in mol/mol creatinine is used. As the exposure risk relationship (ERR) is linear without threshold, only the mean value is needed for calculation of the burden.

As for the exposure concentrations, the best dataset is available from the UK, and as mentioned above, these data are considered to be representative for the companies in the supply chain of the applicant for authorisation.

For the 2005/2006 survey, a mean value for the 40 out of 78 samples above the detection limit is reported to be 3.2 µmol/mol creatinine. If the analyses below the detection limit is set at half the detection limit (0.4/2 µmol/mol creatinine) a geometric mean value for entire dataset can be estimated at 1.8 µmol/mol creatinine. IOM[138] estimated, on the basis of the same dataset using Monte Carlo modelling for the data below the detection limit, a mean value for the dataset at 2.3 µmol/mol creatinine. The median is reported to be 3.2 µmol/mol creatinine.

For the surveys from 2008 and 2011 no mean value were reported but the median values were in both surveys reported at 1.6 µmol/mol creatinine i.e. about half the value in the 2005/2006 survey and the mean value is likely also significantly lower. The median values reported for the application for authorisation for the 9 companies reporting on the median, it range from 0 to 10.3 µmol/mol creatinine with an average value of 3.2 (not a mathematically correctly derived median but a simple average of reported median µmol/mol creatinine).

Based on the available data a mean value of 2 µmol/mol creatinine (range 1 - 3 µmol/mol creatinine) is set as the most likely value and used for the calculation of the current burden of disease.

[138] Health, socio-economic impact and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risk related to carcinogens and mutagens at work. 4,4'-methylene-bis-ortho-chloroaniline (MbOCA). IOM and partners.

Annex 8: route(s) of exposure, adverse health effects

Cadmium and its inorganic compounds

Occupations in which the highest potential exposures occur include cadmium production and refining, nickel-cadmium (Ni-Cd) battery manufacture, cadmium pigment manufacture and formulation, cadmium alloy production, mechanical plating, zinc smelting, brazing with a silver-cadmium-silver alloy solder, and polyvinylchloride compounding.[139] Recycling of scrap metal and Ni-Cd batteries may also involve some exposure. [140]

Route of exposure

The major route of occupational exposure is inhalation of cadmium-containing dust and fumes. Additional uptake can occur through incidental ingestion of dust from contaminated hands, cigarettes or food.

Adverse health effects

Cadmium is an established human carcinogen. Most evidence is available for elevated risk for lung cancer after occupational exposure; however, associations between cadmium exposure and tumours at other locations including kidney, breast, and prostate may be relevant as well.

Different and a priori non-mutually exclusive mechanisms for the carcinogenicity of cadmium have been identified. All these mechanisms are non-stochastic and are characterised by a threshold below which no effect is expected. Cadmium can therefore be considered as a genotoxic carcinogen for which a practical threshold can be identified.

Major target organs for non-cancer effects of cadmium and inorganic cadmium compounds are

- The kidneys;
- The bones;
- The respiratory tract (from inhalation exposure).

Cadmium and inorganic cadmium compounds are also classified as reproductive toxicants.

Kidney toxicity is often regarded as critical toxicity. Tubular proteinuria is the first sign of renal toxicity (ECHA, 2013d; EFSA, 2011; SCOEL, 2017). However, some authors question that minor proteinuria is already indicative of an adverse effect induced by cadmium (e.g., Byber et al., 2016; Byber et al., 2017).

Osteoporosis can also be enhanced by cadmium. Some studies indicate effects associated with similar cadmium exposures as for first kidney effects (Åkesson et al., 2014;

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

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

Buhaund Matovic, 2016; Suwazono et al., 2010; Wallin et al., 2016) and may not be secondary to kidney impairment (Engström et al., 2009).

Respiratory effects (including but not limited to carcinogenicity) are a very important endpoint from inhalation of cadmium particles, often regarded as the critical effects or occurring an only slightly higher exposures compared to systemic effects.

Even though, cadmium and inorganic cadmium compounds are classified reproductive toxicants, this endpoint is currently not in focus, when OELs are derived. Apparently, effect concentrations are above those relevant for the other mentioned effects.

There are contradictory data on dermal sensitisation and no data on sensitisation of the respiratory tract from cadmium exposure.

Beryllium and inorganic beryllium compounds

Occupational exposure to beryllium occurs in various industries, the majority during production of beryllium metal and beryllium containing alloys. Processes most likely to generate airborne beryllium are related to melting, casting, hot working, or abrasion of beryllium containing alloy, accordingly the workers with the highest exposure potential are employed in processes of mining, production of beryllium alloys, phosphorus manufactures, ceramic production, nuclear reactors, production of electric and electronic equipment, missile technicians and jewellers.[141]

Route of exposure

Exposure to beryllium and its compounds at the workplace occurs mainly via inhalation, with only minor skin absorption for the less soluble beryllium compounds.

Adverse health effects

Beryllium is a classified local carcinogen in the respiratory tract (Cat. 1B carcinogen, H350i), however, probably with a low potency. The mode of action for the carcinogenic effects is not fully understood, but, in most recent assessments, the substance is regarded to act via indirect genotoxicity and epigenetic mechanisms and therefore considered a threshold carcinogen.

The main non-carcinogenic health effects are:

- Chronic beryllium disease (CBD)
- Beryllium respiratory sensitisation (BeS)

CBD is a cell-mediated immunological reaction of delayed type, usually observed after a long latent period. BeS precedes CBD, but the progression from sensitisation to disease is not fully understood.

Dermal exposure to beryllium and beryllium compounds can cause allergic contact dermatitis or a granulomatous skin reaction. In addition, with regard to non-cancer effects, skin sensitisation has to be considered. Systemic effects (cardiovascular, renal, hepatic and haematological effects) are assumed to be induced secondary to functional

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

respiratory effects and therefore do not represent critical endpoints. Information on reproductive toxicity is largely lacking, but the sparse data available do not indicate effects on fertility or developmental toxicity.[142]

Arsenic acid and its salts, as well as inorganic arsenic compounds

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

Occupational exposure to arsenic may also be significant in other industries, such as arsenic production, electronics (gallium arsenide semiconductors), glass manufacturing and in the pharmaceutical industry.

Route of exposure

Occupational exposure to arsenic acid and its inorganic salts is primarily through inhalation of arsenic-containing particulates, but ingestion (skin-to-mouth) exposure may be significant in particular situations (e.g. CCA-treated timber); dermal absorption is considered to be limited.[143] It is extremely rare for workers to be exposed to arsenic alone; the exposure is usually to arsenic in combination with other elements[144].

Adverse health effects

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

Inorganic arsenic compounds produce lung tumours in humans, following inhalation, oral or parenteral exposures. Exposure to high levels of inorganic arsenic compounds in drinking water has been associated with skin, and urinary tract or bladder cancer or both in humans. Tumours at other sites including the adrenal glands, bladder and liver have also been reported in some animal studies.

Relevant non-carcinogenic endpoints of occupational exposure are neurotoxicity and cardiovascular effects. Immunotoxicity, reproductive and developmental effects have

[142] RPA (2018) draft final report. Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC.

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

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

been observed in animal studies with inhalation exposure, but to date there is no evidence for such endpoints in humans exposed by inhalation.[145]

Formaldehyde

Formaldehyde is used in a wide variety of sectors. According to the ECHA substance information portal, formaldehyde is used in: adhesives and sealants; coating products; polymers; biocides; laboratory chemicals; polishes and waxes; fuels; washing and cleaning products; cosmetics and personal care products. Formaldehyde is used in the manufacturing of leather or fur, pulp, paper and paper products, textile and wood and wood products and is also used in building and construction work.[146]

Formaldehyde is also used for tissue preservation, in embalming fluids and as a disinfectant in pathology departments and autopsy rooms usually in the form of formalin (i.e. mixture of formaldehyde, water, and methyl alcohol). Formaldehyde can also be used in the form of a polymerized solid - paraformaldehyde, which tends to be favoured in industrial applications in plants that are located at long distances from formaldehyde manufacturing plants, due to its lighter weight and lower shipping costs (IARC, 2012; RPA, 2006).

Route of exposure

Formaldehyde can be inhaled, ingested and absorbed through the skin. Inhalation is considered to be the main route of exposure of exogenous formaldehyde. As critical effects associated with formaldehyde exposure are directly linked to the contact surface, the oral pathway may not be negligible.[147]

Adverse health effects

As a result of its reactivity in target tissues with direct contact with the substance, formaldehyde causes local irritation, acute and chronic toxicity and has genotoxic and cytotoxic properties. It is classified, based on the CLP Regulation, as a Cat.1B carcinogen (H350 "May cause cancer").

According to RAC, formaldehyde is a local acting genotoxic carcinogen. RAC states that there is limited evidence of carcinogenicity in humans mainly from the positive association of nasopharyngeal tumours in one industrial cohort, but that there is sufficient evidence of carcinogenicity from animal studies[148].

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

In addition, skin-sensitising properties are relevant in case of dermal exposure.

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145 See footnote 143.

146 ECHA (2017): Formaldehyde Substance Information. Available at https://echa.europa.eu/substance-information/-/substanceinfo/100.000.002

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

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

4,4'-Methylene-bis(2-chloroaniline) (MOCA)

MOCA is used primarily in the polyurethane industry (manufacture of polyurethane and plastic products. Typical products made with MOCA-based cast polyurethanes include wheels, power transmission belts, gaskets or pump impellers.

Route of exposure

The most important occupational exposure route for MOCA is via dermal exposure after contact with contaminated surfaces. Inhalation and ingestion represent minor routes of occupational exposure.

The substance is easily absorbed via the skin. Therefore a "skin" notation[149] is warranted.

Adverse health effects

MOCA is classified, based on the CLP Regulation, as a Cat. 1B carcinogen (H350 "May cause cancer") and has been classified by IARC as a Group 1- carcinogen to humans, taking also into account mechanistic and other relevant data[150]. As an aromatic amine, the reasonable human target of carcinogenicity is the urothelium. This is supported by limited data in humans and by the induction by MOCA of urothelial carcinomas in the dog, which is known from experiments with other aromatic amines, which are clear human carcinogens (benzidine, 2-naphthylamine), to respond in this respect similar to humans.

Very few data are available regarding non-carcinogenic toxic effects of MOCA. In occupationally exposed humans, haematuria has been described with no further details, but otherwise, even after long-term occupational exposure, no non-neoplastic chronic effects.

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

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

Annex 9 - Process for setting binding OELs and associated provisions under the CMD

Step 1: Social partners consultation

TFEU Article 154 requires a formal two-stage consultation of the social partners at EU level (management and labour) prior to submitting proposals in the social policy field. As regards the present initiative this consultation took place in 2017 and addressed the third and fourth amendment for the establishment and/or revision of binding occupational limit values in Annex III of the Carcinogens and Mutagens Directive. Annex 2 provides further information on the outcomes of the consultation.

Step 2: Priority setting

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

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

- Potential to cause adverse health effects resulting from occupational exposure.
- Processes resulting in exposure or combined exposures to chemicals with the potential to cause adverse health effects resulting from a work activity for which markers of exposure are needed.
- Emerging specific issues on a basis of reported evidence and expert judgment.
- Degree of evidence for adverse effects.
- Characteristics of the adverse effects (severity, potency, reversibility, specificity).
- Estimated number of workers exposed.
- Identified exposure patterns that pose difficulties for the control of exposures.

Policy considerations, such as problematic disparities with or between other relevant threshold values, degree of stakeholders' interest in having an EU OELV, or other institutional priorities.Considering the occupational cancer burden, it is important to note that when identifying a priority substance, stakeholders look at the whole range of potential negative health effects (carcinogenic and non-carcinogenic) which could be prevented by establishing an EU level OEL. In this proposal for example, concerning formaldehyde although an impact on cancer prevention is somewhat limited, it will have a major impact on prevention of other relevant non-cancer health problems such as sensory irritation (preventing around 19 200 cases) which otherwise would cause sufferings to these workers and compromise their quality of life. As formaldehyde (and the other four substances) falls under CMD, in order to prevent the whole range of health problems, an OEL can only be established under this directive.

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

Step 3: Scientific evaluation and public consultation

Article 16 of the CMD, 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. With a view to mainstream scientific advice and in line with the Commission Communication on "Safer and Healthier Work for All" of 10 January 2017, the Commission seeks advice from both the Scientific Committee on Occupational Exposure Limits (SCOEL) or the Committee for Risk Assessment (RAC) of the European Chemical Agency (ECHA). Scientific information from other sources can also be used as part of the scientific evaluation process as long as the data is adequately robust and is in the public domain (e.g. IARC monographs or conclusions of national OELV-setting science committees).

SCOEL or RAC carry out a scientific evaluation at EU level and as a result publish a single evaluation document (respectively a Recommendation or Opinion) for hazardous chemicals where there is priority concern for worker protection.

SCOEL and RAC procedures for the adoption of a Recommendation/Opinion include an external consultation of relevant stakeholders with identified contact points in all of the Member States; this ensures scrutiny of the scientific evidence and methodological approach and ensures transparency of the process.

Further Information on the SCOEL methodology is available at:

http://ec.europa.eu/social/main.jsp?catId=148&intPageId=684&langId=en

More information on the ECHA methodology used by RAC can be found on the ECHA website: https://echa.europa.eu/en/about-us/who-we-are/committee-for-risk-assessment

In the case of the carcinogens considered in this report, SCOEL concluded scientific evaluations (recommendations) on the following 3 substances: formaldehyde, cadmium and beryllium, while RAC provided scientific evaluations (opinions) on arsenic acid and its salts and MOCA- further details are provided in Annex 1.

Step 4: Tripartite consultation of Member States and social partners

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

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

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

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

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

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

The 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.

The ACSH has adopted opinions for all priority substances foreseen for the third amendment of the CMD[151], proposing a binding OEL for all of them and in addition a skin notation for MOCA as possible approaches for these chemicals.

In practice an OEL emerging from this process reflects a deep technical, socioeconomic, and political consideration of what is achievable by employers across the EU and also ensures that workers' health is adequately protected. These Opinions are also adopted taking into account that OELs for carcinogens exist within the broader context of the CMD elimination/minimisation obligation, which establishes an appropriate and exceptionally high legal standard for workplace- and process-specific risk control.

Step 5: Impact assessment

In 2017 an external contractor evaluated, on behalf of the Commission, health, socio-economic and environmental aspects of the proposed amendments to CMD in order to perform an impact assessment according to the regulatory procedures in place.

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

The options for action proposed by the ACSH are established through a thorough scientific, technical and socioeconomic discussion and in general the tripartite

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

agreements reached in the Advisory Committee would be put forward in the eventual Commission's proposal. However, in line with the Better Regulation guidelines, an IA is conducted before presenting the proposal. In the IA the Commission verifies the ACSH opinions on the basis of a dedicated study. Other sources of information and data are duly taken into account at this stage.

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

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

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

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

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

After completion of these steps the Commission prepares and adopts the legislative procedure which then follows the ordinary legislative procedure for adoption.

The adopted Directive will be published in the EU Official Journal and Member Stages will then transpose the limit values and any associated notation into their national legislation by the date set in the Directive.The OELs adopted will then ensure a consistent level of minimum protection for all workers in the EU, while leaving the Member States the option of keeping or setting more favourable standards by introducing more stringent OELs

Within the CMD there is an obligation for employers to apply the appropiate measures at the workplace to ensurethat the exposure of workers to these substances do not exceed the OEL. The monitoring and of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

Annex 10 - Consistency and synergies with the REACH Regulation [152]

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

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

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

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

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

The REACH Regulation 'authorisation' and 'restrictions' also establishes, for a given chemical agent, a clear and renewed pressure to substitute it with safer alternatives, and can drive industry to improve the risk management measures and operational conditions at the workplace in order to improve the safety and the protection of workers. At the same time existing OELs and/or the underlying information used for setting the OEL can be used to derive DNELs under the REACH Regulation.[153]

An authorisation under the REACH Regulation may only be granted for specific uses and operators who have demonstrated that the risks are either adequately controlled (the 'adequate control route') or when the socio-economic benefits outweigh the risk arising from the use (the 'socio-economic route') and there are no suitable alternative substances or technologies.

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

[152] 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.

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

substances restrictions in marketing and use are important risk management measures under REACH, to be applied at EU level by all companies.

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

However, some uses of substances are not covered by the authorisation requirement, namely intermediates[154] and unintended process generated substances. The former is for example very relevant for formaldehyde, which is predominantly used as a chemical intermediate.

Intermediates as defined by the REACH Regulation are chemical substances which are manufactured for and consumed in or used for chemical processing in order to be transformed into another substance[155]. Occupational exposure to intermediates may nevertheless occur for example during cleaning, maintenance, etc, where residues may be present and/or where process-streams are interrupted and containment may be compromised.

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

- CMD applies to all potential worker exposures – including those associated with intermediates, and process-generated substances, or resulting from unintended or misuse-related release.
- For so-called non-threshold carcinogens the OEL-setting process provides a thorough and robust process for establishing minimum standard exposure levels – ultimately passing through the co-legislator for adoption – based on a science and stakeholder consultation based process. The overall relationship between the REACH Regulation and the OSH Directives (including some references specific to the CMD) has been subject of an opinion of the 'REFIT Platform'[156] adopted on 27-28 June 2016.[157]

In their document the REFIT Platform recognises that the two sets of legislation are mutually reinforcing but points out that the interface between the REACH Regulation and OSH legislation is complex and that further clarification is needed. Furthermore, the

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

[155] Article 3(15) of REACH.

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

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

ongoing review of the REACH Regulation revealed areas where improvements in the interaction of both areas can be made.

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

Status of the substances under the REACH Regulation

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

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

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

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

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

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

Name of agents in Annex XIV	CAS No.	EC No.	Sunset date[158]
Arsenic acid	7778-39-4	231-901-9	22/08/2017
Diarsenicpentaoxide	1303-28-2	215-116-9	21/05/2015
Diarsenic trioxide	1327-53-3	215-481-4	21/05/2015

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

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

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

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

Beryllium and inorganic beryllium compounds and **formaldehyde** are currently not identified as SVHC or subject to restrictions under the REACH Regulation.

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