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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa

{COM(2025) 418 final} - {SEC(2025) 217 final} - {SWD(2025) 191 final} - {SWD(2025) 193 final}

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Glossary

Term or acronym	Meaning or definition
ACSH	Advisory Committee on Safety and Health at work
AM	Arithmetic mean
BLV	Biological limit value
BaP	Benzo[a]pyrene
C/B	Costs/benefits
CAD	Chemical Agents Directive 98/24/EC
CAS	Chemical Abstracts Service
CDB	Current disease burden
CLP	Classification, labelling and Packaging
CSRs	Chemical Safety Reports
CVD	Cardiovascular diseases
CMRD	Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EC
DALYs	Disability-adjusted life years
DG	Directorate-General
DRR	Dose-response relationship
ECHA	European Chemicals Agency
EPRS	European Pillar of Social Rights
ERR	Exposure-risk relationship
ETUC	European Trade Union Confederation
EU	European Union
FDB	Future disease burden
GM	Geometric mean
HMPs	Hazardous medicinal products
IARC	International Agency for Research on Cancer
ISG	Inter-service Steering Group
OEL(s)	Occupational exposure limit(s)
OSH	Occupational safety and health
PAHs	Polycyclic aromatic hydrocarbons
PGS	Process-generated substance
PO	Policy option
PPM	Parts per million
PV	Present value
R&D	Research and development
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory fitness and performance programme
RMMs	Risk Management Measures
RPA	Risk & Policy Analysts Ltd
RPE	Respiratory protective equipment
RSB	Regulatory Scrutiny Board
SDGs	Sustainable Development Goals
SLA	Service-level agreement

SLIC	Senior Labour Inspectors' Committee
SMEs	Small and medium-sized enterprises
STEL	Short-term limit value
SVHC	Substance of very high concern
SWD	Staff Working Document
TFEU	Treaty on the Functioning of the European Union
TWA	Time-weighted average
WPC	Working Party on Chemicals
WTP	Willingness to pay

1. Introduction: Political and legal context

1.1. Political context

In June 2021, the Commission presented the EU strategic framework on health and safety at work 2021-2027[1] ('EU OSH strategic framework'). This strategic framework aims to turn into concrete actions principle 10 enshrined in the European Pillar of Social Rights[2] ('EPSR') related to workers' right to a high level of protection of their health and safety at work. In particular, it strengthens prevention culture, both in organisations and among individual workers to reduce work-related deaths as much as possible, in line with a Vision Zero approach to work-related deaths in the EU.

One of the objectives of the strategic framework is the prevention of workplace accidents and illnesses, which can cause serious adverse health effects on workers, including fatalities, and which lead to an estimated annual loss of around 3.3% of gross domestic product in the EU.

As shown in figure 1, cancer remains the first cause of work-related death in the EU, followed by cardiovascular diseases (CVD). Every year, according to estimates, about 80,000 people in the EU lose their lives due to exposure to carcinogens at the place of work.

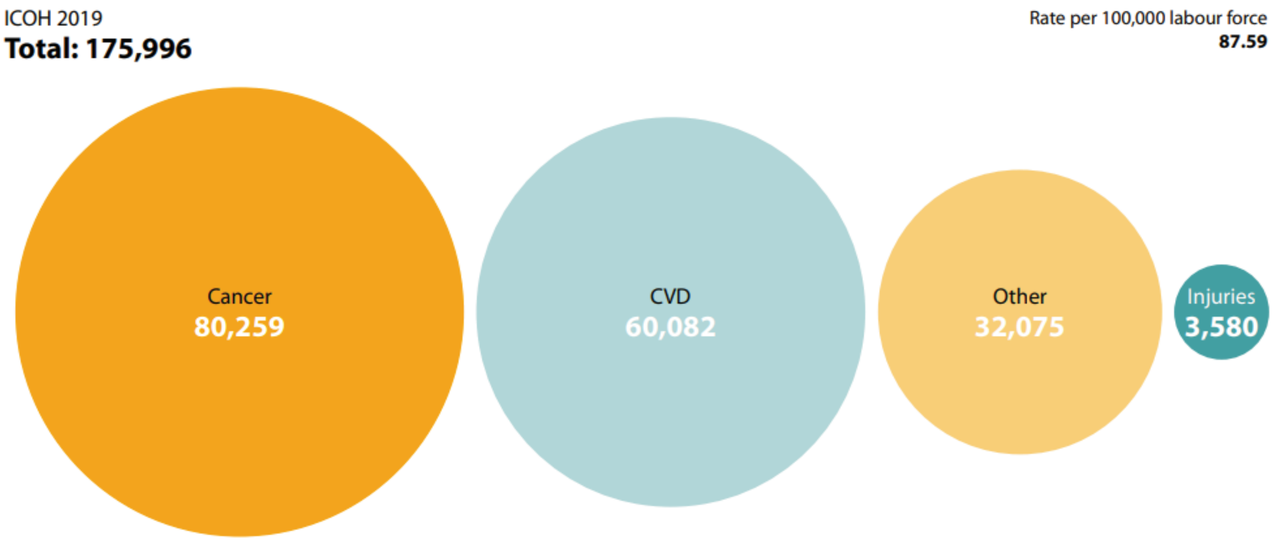

Figure 1: work-related deaths in the EU, ICOH 2019[3]

Exposure to reprotoxic substances at the place of work can also lead to serious adverse health effects, by affecting sexual function and fertility. It might also cause adverse effects on the development of workers' offspring. Up to 1,274 reproductive ill-health cases in the EU could occur

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[1] Communication from the Commission on EU strategic framework on health and safety at work 2021-2027 Occupational safety and health in a changing world of work, COM/2021/323 final

[2] Communication from the Commission on establishing a European Pillar of Social Rights, COM/2017/0250 final

[3] EU-OSHA (2023), Occupational safety and health in Europe: state and trends 2023 – Summary, based on International Commission on Occupational Health's figures

every year following exposure to reprotoxic substances that are not classified as carcinogenic or mutagenic[4].

To improve the prevention of work-related diseases in the EU, the Commission is pursuing a continuous update of the Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EC[5] ('CMRD'). This revision process is in line with the obligation laid down in the CMRD to set out limit values for all those carcinogens, mutagens or reprotoxic substances for which this is possible. It also responds to requests made notably by:

- stakeholders for considering the need to adopt limit values for more substances, as highlighted in the REFIT occupational safety and health ('OSH') evaluation[6] ('REFIT OSH evaluation'); and
- the European Parliament and the Council as part of the fourth revision of the CMRD[7] ('CMRD 4') to achieve new or revised occupational exposure limit values ('OELs') for at least 25 substances; and
- 14 Member States[8] in a letter dated 6 March 2024 and sent to the Commission to request limit values for more substances in the future.

Since the initiation of this continuous process in 2016, the EU has already adopted five revisions of the CMRD, addressing more than 40 key hazardous chemicals and contributing to saving the life of more than 100,000 workers over the next 50 years. The fifth legislative proposal for a revision of the CMRD[9], addressing lead, a key reprotoxic substance, was formally adopted in February 2024 and entered into force on 8 April 2024. The initiative subject to this impact assessment is therefore the sixth revision of the CMRD. It aims to further improve workers' protection and save lives in the future.

This continuous revision process relies on an inclusive approach where the Commission involves scientists from the European Chemicals Agency's ('ECHA') Risk Assessment Committee ('RAC'), Member States and social partners represented in the Advisory Committee on Safety and Health at Work ('ACSH'), and the social partners through the formal consultation provided by Article 154 of the Treaty on the Functioning of the European Union ('TFEU'). The ACSH is composed of three full members (and six alternates) per Member States, representing national governments, trade unions and employers' organisations. Its composition reflects the various economic sectors concerned (e.g. construction, industry, etc.) and the different sizes of companies (incl. SMEs), so that its opinions are based on the realities on the ground of the different sectors and companies.

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[4] European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Cary, E., Holmes, P., Vencovsky, D. et al., *Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC – Final report. Report 1, Baseline assessment*, Publications Office, 2019, https://data.europa.eu/doi/10.2767/964906

[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, *OJ L 158, 30.4.2004, p. 50-76*

[6] Ex-post evaluation of the EU occupational safety and health Directives (REFIT evaluation) – SWD (2017) 10 final

[7] Directive (EU) 2022/431 of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, *OJ L 88, 16.3.2022, p. 1-14*

[8] CY, CZ, DK, ES, FI, FR, DE, IT, LT, LU, NL, PT, SI and SE

[9] Directive (EU) 2024/869 of the European Parliament and of the Council of 13 March 2024 amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for diisocyanates, *OJ L, 2024/869, 19.03.2024.*

Furthermore, as it also include one full member (and two alternates) from each Member States, its opinions also take account of the economic and social specificities of each country.

As part of the 2nd stage consultation of social partners, BusinessEurope and the European Trade Union Confederation ('ETUC') supported the ACSH opinions while SMEunited called on the Commission not to go beyond what was agreed by the ACSH. This inclusive process allows for revisions of the CMRD which provide a high level of protection of workers' health while being socio-economically viable and technically feasible for businesses. More information on the evidence-based procedure supporting the continuous revision of the CMRD is available in section 1.3 and annex 8.

The planned sixth revision of the CMRD ('CMRD 6'), subject to this impact assessment, fits into this continuous revision process and contributes to the European Health Union. It also delivers on the European Parliament's and the Council's request through CMRD 4 to set an OEL for cobalt and inorganic cobalt compounds[10], and the substances identified for this revision are based on the Commission Staff Working Document (SWD) listing the priority substances to be scientifically assessed[11].

Importantly, hazardous substances are not limited to carcinogens, mutagens and reprotoxins. There are other types of substances that fall under EU OSH legislation, in particular the Chemical Agents Directive[12] ('CAD'), that cause other types of ill-health effects (e.g. respiratory ill-health) and should be tackled.

By improving the prevention of work-related diseases, the CMRD 6 will also contribute to the United Nations 2030 Agenda for a Sustainable Development[13], in particular its goal 3[14] ("Ensuring healthy lives and promote well-being for all at all ages") and goal 8[15] ("Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all").

In order to collect more recent information to support this impact assessment, the Commission contracted an external study[16]. This study was scrutinised by the relevant Commission services and members of the ACSH's Working Party on Chemicals (WPC).

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[10] Article 1 (15) of Directive (EU) 2022/431: "*No later than 31 December 2024, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation of relevant stakeholders, propose, where appropriate, a limit value for cobalt and inorganic cobal compounds*"

[11] Commission Staff Working Document List of substances to be scientifically assessed for the purposes of Article 18a, third paragraph, of Directive (EU) 2004/37/EC on presenting an action plan to achieve new or revised occupational exposure limit values for at least 25 substances, groups of substances or process-generated substances, SWD (2022) 438 final

[12] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, *OJ L 131, 5.5.1998, p. 11-23*

[13] United Nations resolution entitled 'Transforming our World: the 2030 Agenda for Sustainable Development, adopted at the UN Sustainable Development Summit on 25 September 2015 in New York

[14] In particular, target 3.4 ("by 2030, reducing by one third premature mortality from non-communicable diseases through prevention") and target 3.9 ("by 2030, substantially reducing the number of deaths and illnesses from hazardous chemicals")

[15] In particular, target 8.8 ("promoting safe and securing working environments for all workers")

[16] RPA (2024), *Study on collecting the most recent information on substances to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work*

1.2. Legal context

The main legislative instrument to ensure workers' protection against risks related to carcinogenic, mutagenic or reprotoxic chemicals is the CMRD, an individual directive under the OSH Framework Directive[17].

Whether a substance or mixture is under the scope of the CMRD is primarily based on its classification as a carcinogen, mutagen and/or reprotoxic substance (category 1A or 1B) according to the criteria established under the CLP (classification, labelling and packaging of substances and mixtures) Regulation[18].

There is also a possibility to bring a substance/mixture under the scope of the CMRD by including it in Annex I to the CMRD. This Annex covers substances, mixtures or processes (or substances/mixtures released by a process referred to in that Annex) which are not classified according to the CLP Regulation as carcinogens, mutagens or reprotoxic substances but are for example recognised by other international bodies (e.g. the International Agency for Research on Cancer - IARC) as substances, mixtures or processes of equal concern. These substances are often referred to as Process-Generated Substances (PGS). Annex I currently contains 8 entries.

To reduce the occupational exposure to these substances or mixtures, the CMRD provides for a hierarchy of preventive and protective measures. The employer has the obligation to substitute these chemicals by less or non-hazardous substances, mixtures or processes as far as technically possible. If substitution is not technically possible, other measures to prevent exposure have to be put in place by the employer, such as working in a closed system or reducing the number of workers potentially exposed.

Another obligation of the employer is to ensure that binding OELs and biological limit values (BLVs) set out in Annex III and Annex IIIb to the CMRD respectively shall not be exceeded. For binding EU OELs and BLVs adopted under the CMRD, Member States must establish a corresponding national limit value at least at the EU level or lower value (more protective).

1.3. Evidence-based procedure supporting the continuous revision of the CMRD

Setting new or revised limit values for carcinogens, mutagens or reprotoxic substances, or enlarging the list of substances, mixtures and processes in Annex I, requires a revision of the CMRD. To support this revision process, the Commission relies on a sound, comprehensive and evidence-based procedure, during which the consultation of the relevant stakeholders is key. This procedure ensures that the revisions of the CMRD are based on scientific evidence, while technically and socio-economic feasible for businesses of all sizes.

The figure below summarises this stepwise procedure starting with the prioritisation of the substances to be addressed and ending with the publication of the Directive adopted by the European Parliament and the Council, based on the legal proposal by the Commission, in the

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[17] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L 183, 29.6.1989, p. 1-8

[18] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, *OJ L 353, 31.12.2008, p. 1–1355*. The CLP Regulation is the core piece of legislation used in the EU to identify and communicate the hazardous properties of chemicals.

Official Journal of the EU. The figure 2 includes a brief description of each step. The procedure is explained in more detail in annex 8.

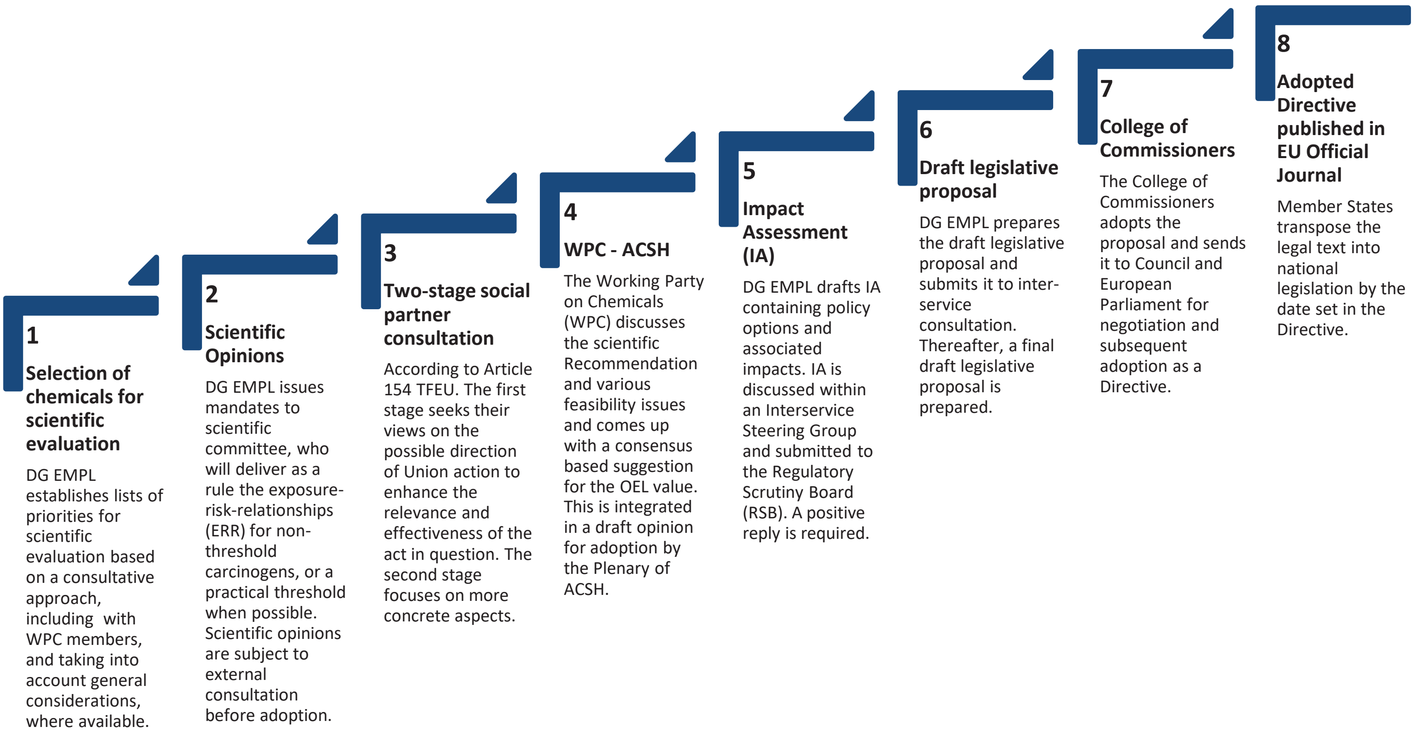

Figure 2 : evidence-based procedure supporting legislative initiatives in the area of OSH

The social partners and Member States play an important role throughout this procedure. In particular, they are involved in the following steps:

- *Selection of chemicals for scientific evaluation:* the members of the tripartite ACSH's Working Party on Chemicals make recommendations to the Commission on the substances that should be prioritised in the subsequent revisions of the CMRD;

- *Scientific opinions:* stakeholders, including businesses and trade unions, are given the possibility to express their views and concerns in the early phases of developing a scientific report on limit values on a substance at the workplace;

- *Two-stage social partners consultation:* EU social partners are consulted on the possible direction of each initiative and on its content. As part of this two-stage consultation, social partners share among other their views on the prioritised substances, the suggested approaches to address them and the opinions of the ACSH;

- *ACSH opinions:* the ACSH is composed of three full members per Member States, representing national governments, trade unions and employers' organisations. It adopts opinions for each substance, in which it recommends limit values or other measures (e.g. inclusion of a process-generated substance in Annex 1 to the CMRD). In its opinions, the ACSH may recommend transitional measures aiming at giving sufficient time to businesses to find technical solutions enabling them to comply with the new limit values or measures. The broad composition of the ACSH allows for the covering a large number of sectors and activities. This also ensures that its opinions reflect the current situation of each sector on the ground, including in terms of technical and socio-economic feasibility;

- *External study supporting impact assessment:* some members of the ACSH's Working Party on Chemicals representing the three interest groups are actively involved in the steering committees for the external studies supporting impact assessments. Their practical expertise contributes to the quality of the studies and their estimates, including the setting of thorough and realistic assumptions.

This extensive consultation and involvement of relevant stakeholders, in particular the ACSH and its Working Party on Chemicals, allows for effective, feasible and proportionate regulatory measures. It also enables to identify whether transitional measures are necessary for the development of technical solutions allowing for compliance with these new regulatory measures. Annex 2 provides a summary of stakeholder consultation and their feedback that informed the development of the policy options outlined in this report.

2. PROBLEM DEFINITION

2.1. What is/are the problems?

The REFIT OSH evaluation[19] concluded that the OSH directives, including the CMRD, remain highly relevant and effective according to the available evidence. They contributed to the decrease in the incidence and number of accidents at work.

Despite the protective EU legal framework and progress achieved over the last decades, according to estimates, more than 170,000 workers still lose their lives each year due to work-related illnesses. This shows the need to further improve prevention of work-related diseases in the EU[20], which has consequences for workers and their families, businesses and public authorities.

To address this problem, the Commission is continuously updating the CMRD to improve the protection of workers from the exposure to hazardous substances, in particular the 28 carcinogens, mutagens or reprotoxic substances to be scientifically assessed identified in the Commission's SWD[21] published in 2022. These scientific assessments to be carried out by ECHA's RAC are key as they provide most recent scientific data on the hazards of a substance and contribute to the decision of whether further legislative actions are required.

Providing scientific assessment requires time and resources. It is therefore not possible to address these 28 substances through one single initiative. Therefore, the Commission has prioritised 5 substances, groups of substances or process-generated substances (hereafter 'substances')[22], namely cobalt and its inorganic compounds, polycyclic aromatic hydrocarbons ('PAHs'), isoprene, 1,4-dioxane and welding fumes. The selection of these 5 substances was based on a consultative approach including social partners and Member States represented in the WPC, and taking into account other considerations, such as

[19] SWD (2017) 10 final, op. cit.
[20] COM/2021/323 final, op. cit., improving prevention of workplace accidents and illnesses is one of the three crosscutting key objectives identified in the EU OSH strategic framework
[21] SWD (2022) 438 final, op. cit.
[22] More information on the selection of the substances considered in this impact assessment is available in annex 9.

- *Cobalt and its inorganic compounds:* legal obligation[23] under CMRD 4 to set limit values for cobalt and importance to improve workers' protection from a substance whose consumption is expected to increase by 330% by 2050 with the green transition.
- *PAHs:* high number of workers potentially exposed to this group of substances.
- *1,4-dioxane:* recent classification as carcinogen 1b in the CLP Regulation.
- *Isoprene:* high number of Member States with no national limit value.
- *Welding fumes:* high number of workers potentially exposed to these process-generated substances and absence of classification at EU-level in the CLP Regulation despite the IARC classification from 2018, see section 2.2.2.

According to the evidence gathered, including scientific and socioeconomic data, workers, businesses and Member States are impacted by the insufficient prevention of occupational exposure to cobalt and its inorganic compounds, PAHs, 1,4-dioxane and welding fumes. Conversely, the evidence gathered indicates that workers are exposed to levels of isoprene which are lower than the health-based limit value[24] derived by RAC in its opinion[25], suggesting that the current prevention of occupational exposure to isoprene is sufficient.

For workers, the insufficient prevention may lead to serious health problems, including cancer. The table 1 below presents estimates of the number of cancer and other ill-health cases occurring in 2023 due to past workers' exposure (current disease burden) and over the next 40 years due to future exposure (future disease burden). For cancer cases, welding fumes, PAHs and cobalt and its inorganic compounds are the most problematic. For example, workers' exposure to welding fumes alone would lead to close to 30,000 lung cancer cases over the next 40 years. Although no cancer case is expected for 1,4-dioxane, workers' exposure to this substance causes other diseases as shown in table 1. More information on trends used for estimates is provided in section 5.

Table 1: estimates on number of workers exposed in the EU and estimated current and future burden of disease

Substance	Estimated number of workers exposed in the EU	Most critical adverse health effects	Estimated current burden of disease (number of cases/year in 2023)	Estimated future burden of disease (number of cases over the next 40 years)
Cobalt and inorganic cobalt compounds	111,300	Lung cancer	12	76
		Restrictive lung disease	100	4,365
		Upper airway irritation	350	14,152
Polycyclic aromatic hydrocarbons	1,284,052	Lung cancer	5	160
		Developmental toxicity	1	38
		Male fertility	78	3,157

[23] As part of the fourth revision of the CMRD, the European Parliament and the Council requested that "*no later than 31 December 2024, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation of relevant stakeholders, where appropriate, a limit value for cobalt and inorganic cobalt compounds*".
[24] Level of exposure that is considered to be safe (health-based) for a chemical substance in the air of a workplace.
[25] RAC (2022), op. cit.

1,4-Dioxane	31,150	Liver cancer	0	0
		Liver effects	16	633
		Kidney effects	12	497
		Local respiratory effects	110	4,382
Isoprene	10,539	Liver cancer	0.007	0.03
		Degeneration of olfactory epithelium	0	0
		Degeneration of spinal cord white matter	0	0
Welding fumes	1,200,000	Lung cancer	879	28,821
		Respiratory tract toxicity (incl. acute pneumonia and asthma)	No data available	No data available
Source: RPA (2024)				

For **businesses**, work-related diseases (cancer and other diseases) imply costs, including in terms of reduced productivity. Given the often-long time lag between exposure and illness and the probability of workers changing employers during their work career, the risk of future productivity losses is unlikely to be internalised by companies, and therefore not factored into present businesses' decisions. The table below includes an estimate of the costs to employers for the 5 substances subject to this impact assessment, which includes the cost due to insurance payments and absence from work, and the productivity loss due to mortality.

In addition to significant social and financial burden to those affected by work-related diseases and deaths, the diseases are also associated with significant costs to society. For **public authorities**, work-related diseases lead to increased healthcare costs related to treatment and rehabilitation, as well as to higher expenditure on associated inactivity and early retirement and compensation for recognised occupational diseases. According to estimates[26], direct costs of work-related cancer in terms of healthcare and productivity losses at the EU level are between €4 – 7 billion per year; and the indirect costs may reach between €242 and €440 billion each year. The table below includes an estimate of the costs to public authorities for the 5 substances subject to this impact assessment, which includes healthcare costs and loss of tax revenues.

Table 2: costs of ill-health for businesses and public administration (in € million, over 40 years)

	Businesses	**Public administration**
Cobalt and its inorganic compounds	€1.60	€8.12
Polycyclic aromatic hydrocarbons	€0.61	€5.51
1,4-dioxane	€1.58	€1.98

[26] The Netherlands' National Institute for Public health and the Environment (2016), Work-related cancer in the European Union, RVIM Letter report 2016-0010.

Isoprene	€0.00	€0.00
Welding fumes	€103	€363
TOTAL	€106.79	€378.61
Note: 3% static discount rate		

The problem tree below presents the identified problem, as well as its drivers and consequences. The problem and its drivers are further described above. More detailed information on the four identified drivers is provided in the next section.

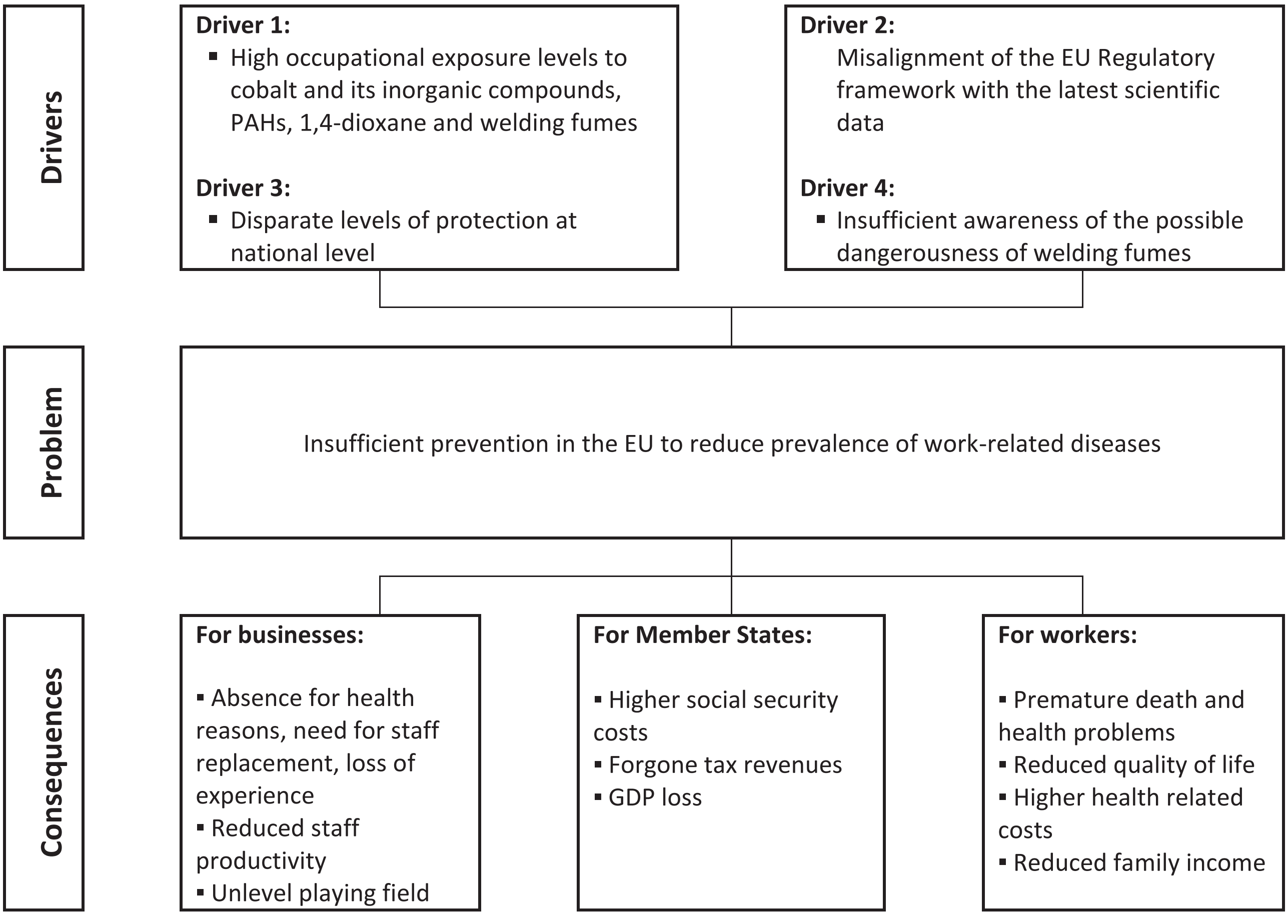

Figure 3: problem tree

2.2. What are the problem drivers?

2.2.1. Driver 1: high exposure levels to cancer-causing substances

As shown in section 1, cancer is the main cause of work-related diseases and deaths in the EU. Substances classified as carcinogenic can also cause other diseases. For instance, exposure to PAHs can lead to male infertility and developmental toxicity.

According to the evidence gathered[27], more than 2.6 million workers in the EU are exposed today to the 5 substances considered in this impact assessment. In order to adequately protect their workers, employers have to perform a risk assessment and implement the necessary risk management measures (RMMs). The type of RMMs required depends on several factors such as the nature of the work, the levels of exposure or the duration of exposure.

Today, some workers are still exposed to levels of substances that are too high and might lead to hazardous health problems, including cancer, as summarised in table 1. For instance, the evidence gathered indicates that workers operating in the manufacture of tools sector are exposed on average to 4.8 µg cobalt/m³ (inhalable fraction), while in 1% of these workers are exposed to levels higher than 27.9 µg cobalt/m³ (inhalable fraction). These levels are higher than the health-based limit value of 1 µg/m³ (inhalable fraction) derived by RAC in its opinion[28], which corresponds to the value below which the health risk for workers is nonexistent.

Conversely, the evidence gathered[29] indicates that the current levels of workers' exposure to isoprene are lower than the threshold limit value derived by RAC in its opinion[30]. Therefore, workers exposed to isoprene in the EU are not expected to experience adverse health effects. More information on the current exposure levels of workers to cobalt, PAHs, 1,4-dioxane and isoprene are available in annex 6.

These estimates of cancer and non-cancer cases reflect the insufficient RMMs currently in place in some sectors or companies resulting in some workers being exposed to hazardous levels. Following a survey[31] conducted for the purpose of this impact assessment, businesses indicated if additional RMMs would be necessary to comply with certain limit values.

To continue with the example of manufacturing of tools sectors, 30% of the respondents indicated that 30% of processes are fully enclosed, 20% partially enclosed, 20% have open hood systems, 10% have high efficiency particulate air (HEPA) filters and for the remaining 20%, workers wear simple masks. According to these respondents, complying with the health-based limit value for cobalt would require additional RMMs, in particular fully enclosed systems (33%). Only 10% of the processes would not require any additional RMMs. More information on the current and required RMMs for complying with certain limit values is provided in Annex 6.

In conclusion, the insufficient take-up of the relevant RMMs results in workers exposed to hazardous levels of carcinogenic substances.

2.2.2. *Driver 2: misalignment of the EU Regulatory framework with the latest scientific data*

Article 16 of the CMRD provides that EU-wide limit values should be established for all those carcinogens, mutagens or reprotoxic substances for which the available information makes this possible. Indeed, EU-wide limit values must be regarded as an important component of the general

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[27] RPA (2024), op. cit.
[28] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for cobalt and inorganic cobalt compounds, available at: https://echa.europa.eu/documents/10162/7937606/final_rac_oel_opinion_cobalt_en.pdf/d96755b2-8bd0-afe7-ab94-0a2f263fc593?t=1675065309296
[29] RPA (2024), isoprene report, section 3.12
[30] RAC (2022), op. cit.
[31] RPA (2022), op. cit., stakeholder

arrangements for the protection of workers. They provide clear benchmark for employers when implementing RMMs so workers' exposure cannot exceed limit values.

Despite the existence of EU-wide limit values for 39 hazardous substances within the CMRD, the following three substances subject to this assessment do not have yet a binding EU limit value although scientific data are available: cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons, 1,4-dioxane.

The necessary scientific data was provided by RAC in substance-related opinions in 2022. A summary of this scientific information is provided in annex 2. These opinions provide all the necessary information to establish limit values in the CMRD, as required by Article 16 of the CMRD.

The misalignment of the CMRD with the latest available scientific data may affect its effectiveness with insufficient RMMs in place in some sectors. As a result, workers are more likely to be exposed to too high levels of these 4 substances. More details on exposure levels are provided in section 5.

2.2.3. *Driver 3: disparate or inexistant limit value at national level*

While employers must comply with their minimisation obligations stemming from Articles 4 and 5 of the CMRD in all cases, limit values provide very relevant benchmarks enabling them to know exactly the levels above which exposure cannot occur. Limit values also allow employers to determine the level below which their RMMs should ensure compliance with the obligation to reduce the exposure to as low a level as it is technically possible. Likewise, limit values support enforcement authorities in controlling that employers are putting in place the relevant RMMs, including those that could contribute to lower the exposure below the limit values.

The absence of EU-wide binding limit values for the three substances does not prevent Member States to establish their own national limit values. According to the evidence gathered[32], several Member States have already set binding limit values for one or several of these substances. The table below includes the lowest and highest existing binding OELs in Member States for each substance, as well as the number of Member States with no binding OEL. More information on the current national OELs is available in Annex 6.

Table 3: national binding limit values in EU Member States

Hazardous substance	Lowest (strictest) national binding OEL	Highest (least strict) national binding OEL	Member States with no binding OEL
Cobalt and inorganic cobalt compounds	10 µg/m^3 DK	500 µg/m^3 LV	5 IT, LU, MT, PT, SI
PAHs	70 ng/ m^3 DE	200,000 ng/m3 DK, ES, RO	9[33] BE, CY, FI, FR, IE, IT, LU, MT, PT
1,4-Dioxane	20 mg/m^3 LV, NL	73 mg/m^3 AT, BE, BG, CY, DE, EE, EL, ES, FR, HR,	3[34] FI, IE, PT

[32] RPA (2024), op. cit.
[33] The evidence gathered does not indicate if the OEL set in Austria is binding or indicative.
[34] The evidence gathered does not indicate if the OEL set in Malta is binding or indicative. FI, IE and PT have an indicative limit value for 1,4-dioxane.

		HU, IT, LU, RO, SI, SK	
Source: RPA (2024)			

A high number of Member States have currently no binding OEL for PAHs. With regard to cobalt and inorganic cobalt compounds and 1,4-dioxane, a significant number of Member States already have an OEL. However, the OELs currently in place in most of the Member States are much higher than the values recommended by RAC and hence likely not sufficiently effective for protecting workers' health. Furthermore, diverging limit values across the EU result in an unlevel playing field within the single market. Indeed, businesses operating in Member States with more stringent limit values will have to bear higher costs than their competitors subject to less strict rules. Aside from improving workers' protection to exposure to hazardous substances at the workplace, employers' representatives are of the opinion that setting binding limit values at EU level helps to provide a level playing field for industry[35].

An inadequate OEL creates no incentive for the implementation of the most modern production technologies and RMMs allowing for a reduction of the occupational exposure to hazardous substances.

The evidence gathered[36] suggests that some companies would invest in more effective RMMs if they would have to operate under stricter OELs.

2.2.4. Driver 4: insufficient awarness of the possible dangerousness of welding fumes

In 2018, IARC classified welding fumes and UV radiation from welding as "carcinogenic to humans" (Group 1). Exposure to welding fumes may lead to lung damage and various types of cancer, including of the lung, larynx and urinary tract. As process-generated substances and despite the IARC classification, welding fumes are not classified according to the CLP Regulation.

As mentioned by ECHA in its scoping study[37], welding fumes are complex and have variable compositions. The content of welding fumes depends largely upon the materials being welded. The majority (95%) of the components of welding fumes are emitted from the fillet or consumables used and only 5% from the base material[38].

The dangerousness of welding fumes depends also on the process used, as shown in the ECHA scoping study. For instance, beam welding[39] is unlikely to lead to workers' exposure as it is almost completely automated while arc welding[40] workers are likely to be exposed to carcinogens,

[35] BusinessEurope (2017), Seconde phase consultation of social partners under Article 154 TFEU on revisions of Directive 2004/37/3EC to include binding occupational exposure limit values for additional carcinogens and mutagens, available at: https://www.businesseurope.eu/sites/buseur/files/media/position_papers/social/2017-12-20_carcinogens_and_mutagens_-_2nd_phase_social_partner_consultation_final_response.pdf.

[36] RPA (2024), op. cit.

[37] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)

[38] ANSES, Agence national de sécurité sanitaire de l'alimentation, de l'environnement et du travail (2022), Collective expert appraisal : summary and conslusions – Identification of works or processes to be included in the Order establishing the list of carcinogenic substances, mixtures or processes work involving exposure to welding fumes.

[39] Beam welding can be divided in two categories: laser bearm and electron beam. Laser welding is a process used to join together metals using a laser beam to form a weld. Electron beam (EB) welding is a fusion welding process whereby electrons are generated by an electron gun and accelerated to high speeds using electrical fields.

[40] This type of welding process uses an electric arc to create heat to melt and join metals.

particularly in the craft sector where automated process is less prevalent. A summary of the welding processes, the generated substances, the indication of the presence of carcinogens, mutagens or reprotoxic substances, and the workers' exposure is available in Annex 6.

Due to the complexity and heterogeneity of the composition of welding fumes, as well as the absence of harmonised classification in the CLP Regulation, employers might ignore that the fumes generated by their welding activities might include carcinogens, mutagens or reprotoxic substances. Consequently, those employers might not carry out the mandatory risk assessment provided in the CMRD when workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work. In the absence of such a risk assessment, employers might not implement all necessary risk management measures to comply with the CMRD and adequately protect their workers.

The evidence gathered[41] confirms that some employers are not aware that welding fumes may contain carcinogens, mutagens or reprotoxic substances (such as chromium (VI) compounds, nickel compounds, cadmium and its inorganic compounds, and beryllium and its inorganic compounds) and lead to health risks. Further, according to the evidence gathered, this lack of awareness is considered as an important driver by stakeholders[42].

These employers may therefore ignore to what extent exposure to their welding processes and materials used can be carcinogenic, mutagenic or reprotoxicant for their workers and do not apply the measures prescribed by the CMRD to protect workers. According to the evidence gathered[43], the improvement of risk management measures following the introduction of welding fumes in Annex I to the CMRD will concern about 1% of workers involved in welding activities[44].

As a consequence of the legal unclarity, and despite the fact that welding can be a relatively safe activity if all the safety and exposure control measures are in place, it remains a prominent concern that welders are at high risk from various diseases, including cancers[45] (see Table 1). In the absence of sufficient data, the geographical distribution of the level of compliance with the CMRD in individual Member States cannot be provided.

2.2.5. Driver 5: lack of inspections for non-compliance with the CMRD

The lack of inspections was also identified as a driver of the insufficient prevention in the EU to reduce prevalence of work-related diseases due to welding fumes-related activities[46]. However, as

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[41] RPA(2024), op. cit., views collected from six key stakeholders representing a large number of welders in the EU. All stakeholders were granted anonymity to share information.
[42] RPA(2024), op. cit., interview carried out with key stakeholders (interviews with three key EU level and three key national stakeholders (from Germany, Greece and Italy). The results of another survey conducted with twelve national stakeholders (from Croatia, Estonia, France, the Netherlands and Slovenia), comprising one company, two trade unions, three OSH experts and six training/trade associations, indicate that the estimated level of awareness of CMRs in welding fumes in their members, employees, or students ranged widely from 20-100%. All stakeholders were granted anonymity to share information.
[43] RPA (2024), op. cit.
[44] RPA(2024), op. cit., this estimate was not contradicted by key stakeholders following their interviews carried out as part of data collection activities. It assumes that some organisations (such as larger enterprises) will already be applying best practice measures and will not need to change their practices. Other organisations will not be applying best practice measures, but of these some might not be aware of a policy change.
[45] ECHA (2022), op. cit.
[46] RPA(2024), op. cit., a report on inspections undertaken in the Netherlands from 2009 to 2015 found 217 infringements of the OSH risk of exposure to welding fumes.

labour inspection is a prerogative of Member States and cannot be addressed by the CMRD, this driver was not reflected in the intervention logic.

2.3. How likely is the problem to persist?

In the absence of action at EU level, workers exposed to cobalt and its inorganic compounds, PAHs, 1,4-dioxane or welding fumes are expected to continue to be at risk of contracting work-related cancer and other adverse health effects. Estimates on the number of future ill-health cases are provided in table 4. Additional information, including the monetised health costs in case of no EU action (baseline scenario), are provided in section 5.

The general obligations set by the CMRD, employers' actions and the corresponding implementing measures adopted by Member States contribute overall to lowering exposures. According to the evidence gathered[47], exposure levels to the five substances have generally been decreasing in the past years and this positive trend is expected to continue in the future for PAHs and welding fumes[48]. Substitution may be possible for some chemicals and uses in the future and technological developments could lower exposure concentrations. Furthermore, the number of workers employed in the industries using these carcinogens may change, as further described in section 5. Despite these trends, the insufficient prevention of work-related diseases occurring from the exposure to these 4 substances is expected to persist.

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, the existing employers' practices as well as protective measures at Member State level do not always reflect the most recent scientific and technological knowledge. For that reason, the retained assumptions are based on the legal provisions contained in the CMRD, including the minimisation requirements, on information gathered from the stakeholders (via targeted consultations), as well as on the expertise of the employers, workers and government representatives that steered the supporting study (RPA 2024) analysis. The objective has been to define a baseline scenario as close as possible to the future situation. More information about the past and future trends that would influence the future burden of disease is available in section 5.1.

Member States usually do not inform the Commission on their intentions to revise existing or determine new OELs in their national legislation. However, 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.

Table 4: estimated future burden of disease over 40 years

Hazardous substance	Estimated cancer cases	Estimated cases of other adverse health effects
Cobalt and inorganic cobalt compounds	• Lung cancer: 76	• Restrictive lung disease: 4,365 • Upper airway irritation: 14,152
Polycyclic aromatic hydrocarbons	• Lung cancer: 160	• Developmental toxicity: 38 • Male infertility: 3,157

[47] RPA (2024), op. cit.
[48] More information on future trends is available in section 5 of this impact assessment.

1,4-dioxane	• Liver cancer: 0	• Liver effects: 633 • Kidney effects: 497 • Effects in nasal cavity: 4,381
Welding fumes	• Lung cancer: 28,821	No data available
Source: RPA (2024) *Note: key trends supporting the above estimates are provided in section 5.*		

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

Article 153 of TFEU[49] 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 of the CMRD sets out that limit values are to be adopted in respect of those carcinogens, mutagens or reprotoxic substances for which this is possible, having regard to the available information, including scientific and technical data.

3.2. Subsidiarity: Necessity of EU action

Cancer can affect every citizen in one way or another, regardless of their country of origin or residence. Faced with this issue, the Commission adopted in 2021 its Europe’s Beating Cancer Plan[50]. In this plan, the Commission recognises the need to mobilise the collective power of the EU to drive change to the benefit of the EU citizens.

As part of this plan, the Commission highlighted the need to reduce the exposure to carcinogens at the workplace, through the revision of the CMRD. It is in line with the REFIT OSH evaluation[51] which considers the CMRD of high relevance to protect workers at the EU level. According to contributions received from national and EU stakeholders during that evaluation process, further occupational limit values should be established at the EU level.

A consistent level of protection from the risks related to carcinogens, mutagens or reprotoxic substances must be established for the EU as a whole by a framework of general principles to enable Member States to apply the minimum requirements consistently. Action at EU level ensures that all workers within the EU will benefit from a similar high level of protection, in line with the latest scientific evidence.

EU-wide limit values must be regarded as an important component of the general arrangements for the protection of workers. Article 16 of the CMRD provides that EU-wide limit values should be established for all those carcinogens, mutagens of reprotoxic substances for which the available

[49] OJ C 326, 26.10.2012, p. 47-390
[50] Communication from the Commission to the European Parliament and the Council Europe’s Beating Cancer Plan, COM/2021/44 final
[51] SWD (2017) 10 final, op. cit.

information makes this possible. Following the request from the European Parliament and the Council made as part of the fourth revision of the CMRD, the Commission published in 2022 a SWD[52] listing 28 priority chemicals for scientific assessment in view of the subsequent revisions of the CMRD. Among them are the 5 substances subject to this impact assessment.

As shown in table 4 above, future occupational exposure to cobalt and its inorganic cobalt compounds, PAHs and welding fumes is expected to result in more than 30,000 cancer cases over 40 years. Therefore, it is urgent to improver workers' protection from the exposure to these 4 substances, in line with the Europe's Beating Cancer Plan. With regard to 1,4-dioxane, no cancer cases are expected from occupational exposure over the next 40 years. However, workers' exposure to this substance can lead to other diseases which represent a burden for workers, employers and Member States across the EU, justifying an action at EU level.

As for the fifth substance, isoprene, the evidence gathered[53] indicates the current and future levels of workers' exposure are already lower than the health-based limit value derived by RAC in its opinion[54]. Despite the unanimous support of representatives from businesses, workers and Member States within the ACSH for setting a limit value for isoprene, an action at EU level does not seem necessary for improving workers' protection.

3.3. Subsidiarity: Added value of EU action

Improved clarity and enforcement

Establishing limit values for cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons and 1,4-dioxane will provide common reference points that are used as a practical tool by employers, workers and enforcers to assess compliance with the general requirements, in particular in those Member States with no existing limit values. Limit values can also be used by process plant and machinery designers when planning new or considering alterations to existing process plants.

The complexity and heterogeneity of the composition of welding fumes, together with the absence of harmonised classification for welding fumes in the CLP Regulation, contribute to a lack of clarity on the possible dangerousness of welding fumes for workers, and therefore a lack of appropriate RMMs. Addressing this absence of classification for welding fumes at EU level would ensure more legal clarity, which would result in better implementation of the existing rules.

Governments', employers' and workers' representatives have expressed clear support for establishing limit values for the substances subject to this initiative, and including welding fumes in Annex I to the CMRD, as it clearly results from the two-stage consultation of social partners and the opinions of the tripartite ACSH. Detailed information on the outcome of the social partners consultation and the ACSH opinions is available in annex 2.

Ensuring a similar minimum level of protection across the EU

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52 SWD(2022) 438, op. cit.
53 RPA (2024), op. cit.
54 RAC (2022), op. cit.

The CMRD aims to improve workers' health by protecting against risks arising or likely to arise from exposure to carcinogens, mutagens or reprotoxic substances at work. This objective is in line with the and Europe's Beating Cancer Plan[55].

Limit values under the CMRD are an important component of the general arrangements for the protection of workers[56] and should be established for all those carcinogens and mutagens for which the available information makes this possible.

The CMRD does not prevent Member States to adopt national limit values in the absence of EU values. However, the national limit values for the 3 substances subject to the setting of a limit value may vary considerably between Member States, where they exist. For instance, and as set out in table 3, the national limit values for cobalt range from 10 to 500 µg/m^3. Some Member States have therefore set limit values fifteen times lower than others for the same substance, while five Member States have no limit values for cobalt[57]. In the absence of any action at the EU level, very different levels of workers' protection are likely to persist.

Contribution to a more levelled playing field

Some employers' organisations stressed in their response to the social partner consultation that setting EU limit values helps to provide a level playing field for industry. The costs of complying with lower national levels are generally higher and entail, therefore, a competitive advantage for enterprises operating in markets with no or less stringent national limit values.

Setting EU limit values will not completely eliminate the differences between Member States since they can adopt more protective (lower) limits. However, it will reduce 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. It will also reduce regulatory complexity resulting from highly diverging rules between Member States, contributing to reduce the administrative burden of compliance for businesses operating across the single market.

Reducing burdens related to derivation of limit values

The process of establishing limit values is very complex and requires a high level of scientific expertise, as well as an impact assessment and discussions with the stakeholders (depending on national practices). An important advantage of setting OELs at EU level is that it eliminates the need for Member States to conduct their own analysis, including scientific assessment, with likely substantial savings on administrative costs.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

This initiative contributes to the improvement of health and safety of workers pursuant to Article 153 of the TFEU. It aims at complying with the legal obligations laid down in Article 16 of the

[55] COM/2021/44 final, op. cit.
[56] Recital 13 of Directive 2004/37/EC
[57] IT, LU, MT, PT, SI

CMRD related to the setting of limit values, and to prevent work-related deaths and diseases in line with the second key objective of the EU OSH strategic framework[58].

This report evaluates the impact of setting limit values for cobalt and inorganic cobalt compounds, PAHs and 1,4-dioxane, as well as to include welding fumes in the Annex I to the CMRD for the purpose of legal clarity. As no problem with workers' exposure to isoprene was identified, the main report does not include any assessment of options for limit values. However, as the ACSH recommended a limit value for isoprene, a thorough assessment of this option is provided in Annex 10.

4.2. Specific objectives

The specific objectives are:

- To further improve workers' protection from exposure to **cobalt and its inorganic compounds, PAHs** and **1,4-dioxane** in the EU through the adoption by employers of appropriate risk management measures;
- To increase the clarity and effectiveness of the CMRD by keeping it up to date with the latest scientific data allowing the establishment of limit values;
- To facilitate implementation, and contribute towards a better level playing field for economic operators by adopting minimum requirements at the EU level that apply to all businesses, irrespective of their location;
- To bring more clarity on the scope of the CMRD with regard to **welding fumes** so that businesses perform the mandatory risk assessment and apply, if workers are likely to be exposed to carcinogens, mutagens or reprotoxicants according to the risk assessment, all requirements when these fumes contain carcinogens, mutagens or reprotoxic substances.

The specific objectives of the initiative are relevant for the sustainable development goals[59] on good health and well-being (3rd goal) and decent work and economic growth (8th goal).

4.3. Consistency with other EU policies

4.3.1. 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[60].

4.3.2. REACH Regulation

The Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[61] ('REACH Regulation'), entered into force in 2007, establishes among others two distinct EU regulatory approaches that are restrictions and authorisations.

The applicable provisions of REACH authorisation or restriction of cobalt and its inorganic compounds, PAHs and 1,4-dioxane are summarised in the table below. As process-generated

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[58] COM/2021/323 final, op. cit.
[59] United Nations resolution entitled 'Transforming our World: the 2030 Agenda for Sustainable Development, adopted at the UN Sustainable Development Summit on 25 September 2015 in New York
[60] OJ C 202, 7.6.2016, p. 389-405
[61] OJ L 396, 30.12.2006, p. 1-849

substances, restrictions and authorisations within the meaning of REACH are not applicable to welding fumes.

Table 5: applicable provisions of REACH authorisation or restriction

Substances	Restriction	Authorisation
Cobalt and inorganic cobalt compounds	No existing restrictions	No existing authorisations
PAHs	Existing restriction concerning the use of certain products that may contain one or more PAH substances[62]. Existing restriction concerning the use of creosote and creosote containing substances in wood treatment.	No existing authorisations
1,4-dioxane	No existing restrictions	Substance included in the Substance of Very High Concern (SVHC) Candidate List for Authorisation[63] according to REACH Art. 57 (a) and 57 (f), with this triggering substitution and information requirements.

None of the existing REACH restrictions set work-related limit values for cobalt and inorganic cobalt compounds, PAHs or 1,4-dioxane. Therefore, there is no overlap between the initiative subject to this impact assessment and the existing restrictions under REACH. Furthermore, the relevant services within the Commission will ensure a successful complementarity between REACH and OSH legislations in case of future action under REACH for any of the substances subject to this impact assessment. More information related to the REACH requirements for substances subject to this impact assessment is available in annex 10.

4.3.3. Europe's Beating Cancer Plan

The aim of Europe's Beating Cancer Plan[64] is to tackle the entire disease pathway. It is structured around four key action areas where the EU can add the most value: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors.

[62] Benzo[a]pyrene, Benzo[e]pyrene, Benzo[j]fluoranthene, Benzo[a]anthracene, Chrysene, Dibenzo[a,h]anthracene, Benzo[k]fluoranthene and Benzo[b]fluoranthene
[63] Decision of ECHA dated 23.06.2021 on the inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV, available at: ECHA decision on inclusion in Candidate List (europa.eu)
[64] COM/2021/44 final, op. cit.

The occupational exposure to the five substances subject to this initiative can cause cancer, as outlined in section 2.1. Therefore, addressing them through the setting of limit values or an inclusion in the scope of the CMRD will contribute to preventing cancer.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

The policy options include a no-policy-change scenario, which serve as a baseline for assessing and comparing the policy options described under section 5.2. A timeframe of 40 years is assumed for the baseline due to the long latency periods[65] for carcinogenic substances. Cancer might indeed take a long time to develop after the exposure to a carcinogenic substance. This means that several future cancer cases would occur independently of this initiative. Therefore, the baseline does not include cancer cases resulting from past exposure[66].

5.1. What is the baseline from which options are assessed?

This section outlines the baseline scenarios for the four substances subject to the initiative. It describes how the problem is expected to evolve over 40 years in case no further action is taken at EU level. These baseline scenarios are based on the evidence gathered[67] to support this impact assessment and take account of the impact of the implementation of limit values for other substances, the effects of forthcoming changes in national legislations, the future trends (e.g. in use and recycling of the substances, in exposure concentrations due to technical improvements or in exposed workforce), and any other relevant insights for the future (e.g. impact of the green transition). More detailed information on the relevant sectors, number of enterprises with exposed workers, number of workers, exposure levels and some methodologic aspects (including trends, quantification and monetisation of costs and benefits) is provided in annexes 4 and 6.

5.1.1. Cobalt and inorganic cobalt compounds

113,000 workers in the EU are estimated to be currently exposed to cobalt and its inorganic compounds. The main sectors with exposed workers are manufacture of tools (26.5% of the total exposed workforce), machining (22.1%), ceramics (6.6%), biogas (4.8%), surface treatment of metals (4.6%), vehicles (4.6%) and medical and dental devices (4.4%).

The data and evidence gathered[68] indicates that the use of cobalt over the next 40 years will be influenced by the green transition, in particular the growing manufacturing of batteries, the transition from fossil fuels to alternatives and the growing recycling and recovery of critical raw materials. The following sectors will particularly be impacted: batteries (+5% increase in the use of cobalt every year), petrochemicals (-6%), catalysts (-6%) and metal recovery (+5%). Based on this, the exposed workforce for these sectors is assumed to follow the same trends than for the uses over 40 years, as described in table 6. For the other sectors, although the use and number of exposed workers may slightly increase, this could be counterbalanced by further automatization in some sectors. In the absence of evidence supporting another scenario, it was assumed that the number of workers would remain stable for the other sectors over 40 years.

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[65] The latency period is the time between an exposure and the occurrence of disease related to it.
[66] For this reason, the number of actual cancer cases to occur in the future as a result of exposure to the concerned substances could be considerably higher than the future disease burden provided in the following sections.
[67] RPA (2024), op. cit.
[68] RPA (2024), op. cit.

The current levels of exposure of these workers differ depending on their sectors of activity and the RMMs currently in place (see section 2 and annex 6). The sectors with the highest average levels of exposure[69] are welding (12.9 µg/m³), medical and dental devices (11.5), production of electronic components (7.6) and manufacture of other fabricated metal products (7.4). Furthermore, the evidence gathered from stakeholders[70] indicates that the ongoing implementation of the EU-wide limit values for nickel compounds, chromium VI compounds and cadmium and its inorganic compounds is expected to also decrease the exposure to cobalt and its inorganic compounds in some sectors[71], due to co-exposure. For instance, three respondents have indicated that the limit value for nickel compounds may reduce the exposure concentrations for cobalt and inorganic cobalt compounds by less than 50%. Indeed, although nickel and cobalt are typically not used together in catalysts, the same production lines are used for production. Therefore, it is important to take into account the effect of the limit value for nickel compounds on workers' exposure to cobalt when assessing costs and benefits. A table summarizing the adjusted concentration for all relevant sectors is available in Annex 6.

The levels of exposure might theoretically decrease over the next 40 years due to possible actions at company level in favour of workers' protection (e.g. further use of closed systems), an increased use of automatization in some sectors and forthcoming regulatory changes within Member States. However, in the absence of any evidence to support these assumptions and as agreed by the employers, workers and government experts steering the work of the supporting study's contractor, a trend of 0% was used for the baseline.

With these assumptions, about 19,000 workers exposed to cobalt and its inorganic compounds in the EU will become ill over the next 40 years in case of no EU action (76 lung cancer cases, 4,365 restrictive lung disease cases and 14,152 upper airway irritation cases).

Table 6: baseline scenario for cobalt and its inorganic compounds over 40 years

Number of exposed workers	113,000
Change in exposure level	0%
Change in number of exposed workers	- +5% for batteries - -6% for petrochemical, catalyst - -6% for catalysts - +5% for metal recovery - 0% for the other sectors
Future disease burden (FDB) from current and future exposure – Number of cases over 40 years	18,593 - 76 (lung cancer) - 4,365 (restrictive lung disease) - 14,152 (Upper airway irritation)
Estimated deaths due to FDB cancer over 40 years	60
Monetary value FDB cancer over 40 years	- Method 1[72]: €32 million - Method 2[73]: €61 million

[69] Inhalable fraction, with adjustment for the use of respirable protective equipment.
[70] RPA (2024), op. cit.
[71] For nickel compounds: manufacture of other inorganic basic chemicals, catalysts, steel, manufacture of cobalt and cobalt alloys, batteries / For chromium VI compounds: welding / For cadmium and its inorganic compounds: batteries
[72] Application of WTP (willingness to pay) values to each case. More information on this methodology is provided in annex 4.

Monetary value FDB other adverse health effects over 40 years	- Method 1: €98 million - Method 2: €115 million
Source: RPA (2024)	

5.1.2. Polycyclic aromatic hydrocarbons - PAHs

About 1.3 million workers in the EU are currently estimated to be exposed to PAHs across a wide range of sectors, as detailed in annex 6. More than 90% of exposed workers are active in one of the following five sectors: firefighters[74] (both professionals and volunteers – 34.2%), motor vehicle maintenance and repairs (28.9%), road paving (16.6%), steel and iron foundries, ferroalloys (7.5%), and casting of metals (5.3%).

According to the evidence gathered[75], some sectors should be impacted by a number of long-term driving forces, in particular, climate change and other environmental factors, aggravating resource scarcity and the acceleration of technical change. As a result, it is assumed that the exposed workforce will vary annually over time for the following four sectors:

- refineries (-6%/year): refinery capacity is expected to decrease by 6% per year, due to the transition to electric vehicles in the automative sector as well as alternative fuels in the maritime and aviation sectors resulting in less demand for petroleum products;
- aluminium manufacturing (+1%): demand for aluminium is expected to increase with the green transition (e.g. aluminium is used for electric vehicles for reducing weight and in batteries, electricity networks and solar panels). According to a study conducted by Eurometaux[76], the demand for aluminium will increase between 0.6-1.4% per year;
- silicon metal manufacture (+1.95%): the shift towards renewable energy is expected to result in an increase in demand for silicon metal, which is key among others for photovoltaic panels, batteries and semi-conductors. Eurometaux[77] estimates that silicon metal demand will increase by between 1.6-2.3%; and
- coal fired power plants (-2.5%): the climate-neutrality objective of the EU is the main driver behind coal power plant closures. According to the European Commission's Joint Research Center ('JRC'), up to 100% of existing coal power plants will be decommissioned by 2030. However, coal power plants have experienced a recent resurgence due to the current geopolitical climate. Based on this, an annual decrease of 2.5% in the number of workers is expected.

However, and despite the above estimated impacts on exposed workers, these sectors represent less than 4% of the total exposed workforce and it is therefore assumed that their evolution should not influence future trends in terms of the number of workers exposed.

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[73] Use of DALYs (disability adjusted life year) and their monetisation. More information on this methodology is provided in annex 4.
[74] 438,506 firefighters are assumed to be exposed to PAHs in the air. If we had the firefighters which are at risk of dermal exposure, this brings the total number of exposed firefighters to 4,385,060 (365,000 professionals and 4,020,060 volunteers).
[75] RPA (2024), op. cit.
[76] KU Leuven (2022), Metals for Clean Energy: Pathways to solving Europe's raw materials challenge. Available at: metals-for-clean-energy.pdf (eurometaux.eu)
[77] KU Leuven (2022); op. cit.

Another factor that could impact the number of exposed workers over time is the increased automatization in some sectors. Nevertheless, no robust data to support the impact of automatization was identified. It is therefore assumed that the overall number of exposed workers will keep stable.

On the other hand, the exposure levels to PAHs are expected to decrease annually by 1.2% over the next 40 years. The current average levels of exposure to PAHs differ depending on their sectors of activity and the current RMMs currently in place (see section 2 and annex 6). The sectors with the highest average levels of exposure[78] are welding of train tracks (300-400 ng/m³), coking plants (329), manufacture of refractory products (207), coal tar distillation (152) and other non-ferrous metallurgical processes (152). According to the evidence gathered[79], the implementation of other limit values, including from previous revisions of the CMRD, is not expected to lead to significant impact on PAHs exposure.

A trend of -1.2% per year for the benzo[a]pyrene[80] (BaP) exposure concentration between 1975 and 2009 was reported[81], due to several factors, including changes in the production methods or application (e.g. banning of the use of coal tar for paving, automation of oven operations in coking plants) or development in the engines releasing less PAHs. Furthermore, the evidence gathered has not identified any forthcoming changes in national limit values or protective regulation and self-regulatory initiatives. Although some possible upcoming PAHs-related REACH restrictions were identified (more details are available in annex 11), it is not possible to anticipate how they may affect the baseline. In this context, and in the absence of any evidence questioning the continuous past trend for concentration exposures, it was decided to set the same trend for the future (-1.2%).

With regard to the FDB, 3,355 workers are expected to get ill over the next 40 years due to the exposure to PAHs (184 lung cancer cases, 38 developmental toxicity case and 3,157 infertility cases). Among them, 128 workers are expected to die from cancer.

Table 7: baseline scenario for PAHs over 40 years

Number of exposed workers	1,284,052
Change in exposure level	1.2% overall
Change in number of exposed workers	0%
Future disease burden (FDB) from current and future exposure – Number of cases over 40 years	3,355 - 160 (lung cancer) - 38 (developmental toxicity) - 3,157 (infertility)
Estimated deaths due to FDB cancer over 40 years	128
Monetary value FDB cancer over 40 years	- Method 1: €130 million - Method 2: €67 million
Monetary value FDB other adverse health effects over 40 years	- Method 1: €72.7 million - Method 2: €5.3 million
Source: RPA (2024)	

[78] With adjustment for the use of respirable protective equipment.
[79] RPA (2024) op. cit., stakeholders consultation
[80] In its opinion, RAC concluded that benzo[a]pyrene is the most robust marker of overall PAHs exposure.
[81] Peters, S., Vermeulen, R., L., P., A., O., B., K., Vincent, R., et al. (2016). SYN-JEM: A Quantitative Job-Exposure Matrix for Five Lung Carcinogens. Ann. Occup. Hyg., 60(7), 795-811.

5.1.3. 1,4-dioxane

Around 30,000 workers are currently exposed to 1,4-dioxane in the EU. Almost 90% of these workers are active in three sectors: pharmaceutical production (48%), laboratories (24%) and industrial use as solvent and generation as by-product in the chemical sector (17.5%).

As a result of the recent reclassification of 1,4-dioxane as carcinogenic 1b[82] in the CLP Regulation and its inclusion in the list of SVHC[83], which are subject to potential regulatory attention under REACH, we could expect that the past trend of -2%[84] related to the number of exposed workers continues. However, the evidence gathered[85] also shows that certain sectors manufacturing or using 1,4-dioxane have seen an increase in their number of companies between 2011 and 2020 of approximatively 2% per year in total. Therefore, it is assumed that both trends will cancel each other out, resulting in no change in the number of workers exposed during the next 40 years. No forthcoming changes in national limit values or other relevant national legislation have been identified.

According to the evidence gathered, including the RMMs currently in place (see section 2 and annex 6), the highest average exposure is observed in the chemical sector (10.5 mg/m^3) where 1,4-dioxane is industrially used as a solvent and generated as by-product. Workers operating in the other sectors are exposed on average to a level lower than 3.9 mg/m^3. In the absence of data, including on technical improvements that could result in decreasing workers' exposure, no past and future trends could be identified. It is also not expected that any of the EU-wide limit values for other substances that have already been adopted but are not yet in force are likely to have a significant impact on occupational exposure to 1,4-dioxane. It was therefore assumed that the exposure concentrations would remain stable over 40 years (conservative approach).

In case of no EU action, and based on the assumptions described above, 5,512 workers would suffer from non-carcinogenic diseases over the reference period (497 with kidney effects, 633 with liver effects and 4.382 from local irritation).

Table 8: baseline scenario for 1,4-dioxane over 40 years

Number of exposed workers	31,150
Change in exposure level	0%
Change in number of exposed workers	0%
Future disease burden (FDB) from current and future exposure – Number of cases over 40 years	5,512 - 497 (kidney effects) - 633 (liver effects) - 4,382 (local irritation)
Estimated deaths due to FDB cancer over 40 years	0
Monetary value FDB cancer over 40 years	€0
Monetary value FDB other adverse health effects over 40 years	- Method 1: €4.9 million - Method 2: €6.5 million
Source: RPA (2024)	

[82] Category 1b carcinogen: presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.
[83]
[84] This past trend of -2% in the number of exposed workers was assumed based on CAREX Canada reporting an 18% decrease in workers exposed to 1,4-dioxane between 2006 and 2016, suggesting an annual decrease of 2%.
[85] RPA (2024), op. cit., sections 3.10 and 4.7 of the 1,4-dioxane report.

5.1.4. *Welding fumes*

Around 1.2 million workers are estimated to be currently exposed to welding fumes[86]. They are active in a wide range of sectors as described in annex 6. Based on Eurostat data, three quarters are operating in the following four sectors: specialised construction activities (36%), construction of buildings (19%), manufacture of fabricated metal products (12%), and wholesale and retail trade and repair of motor vehicles and motorcycles (10%).

A limit value for most of the metals and metal compounds classified as carcinogenic have been already set in the Annex III of the CMRD. Some of them (for chromium (VI) compounds and nickel compounds) have a transitional period until end of January 2025. These two groups of compounds are of particular concern as carcinogens in welding fumes from welding stainless steel (food industry, medical industry, petrochemical and power/heating plants). They can also be contained in welding fumes released when welding mild steel, although in less quantity. Theoretically, the introduction of limit values for cobalt and PAHs can also be beneficial, although to a much lesser extent. However, due to the paucity of data for welding fumes exposure in general, it was not possible to take account of the potential impact of implementation of other limit values in the calculation of the baseline.

The evidence gathered indicates[87] that the annual EU welding market growth forecast is 4.5%. This increased demand is partly attributed to the EU green transition, which requires investments in energy infrastructure (e.g. power networks, electric vehicle charging infrastructure and wind turbines). Other megatrends such as the continuing urbanisation, growing consumerism are also expected to support this growing demand. With the ongoing investment in robotics[88] and the current shortage of welders, it is expected that most of this growth is to be carried out by new and automated technologies. In the absence of robust data, it was assumed that this welding market growth forecast will lead to a growth of 0.45% in the number of welders per year (10% of the growth forecast). This assumption is supported by the current skills shortage of trained welders in Europe which encourages businesses to invest in automated technologies.

The evidence gathered[89] indicates that the past exposure levels to welding fumes declined between 2% and 4% per year. The increasing automation of welding processes will lead to further reduction in exposure to welding fumes, in particular, in the automotive sector. However, this decrease depends on the current RMMs in place. According to the evidence gathered[90], it is assumed that many businesses, in particular larger enterprises, are already applying best practices measures.

The evidence gathered suggests that EU Western Member States are more advanced in the implementation of RMMs and adoption of innovative processes than other Member States. According to some stakeholders[91], the best practice is already applied and additional RMMs will not reduce worker exposure any further. Therefore, countries (or enterprises) with lower current

[86] RPA (2024), op. cit.
[87] RPA (2024), op. cit.
[88] RPA (2024), op. cit., data provided by the European Welding Association.
[89] RPA (2024), op. cit., the paucity of exposure data does not allow for a comparison of exposure levels from a particular welding process undertaken in a particular sector.
[90] RPA (2024), op. cit.
[91] German Welding Society (DVS – Deutscher Verband für Schweißen und verwandte Verfahren) and German automative manufacturers.

workers protection from exposure to welding fumes have more to gain in RMMs. Furthermore, innovative practices to optimise welding process could also lead to reductions in exposure to welding fumes. In the absence of further data and given the above information, it was assumed that the exposure levels will continue declining but at a lower pace (1% per year) as best practices may already be implemented in some countries such as Germany and the Netherlands.

In the absence of robust data on non-cancer endpoints, the FDB is limited to lung cancer cases. Considering the future trends summarised in table 9, around 28,000 workers would get lung cancer over the next 40 years. This FDB are likely to be underestimated since the exposure of workers being in the vicinity of welding processes were not considered, due to insufficient data. As a result of their exposure to welding fumes, about 23,000 workers would lose their lives.

Table 9: baseline scenario for welding fumes over 40 years

Number of exposed workers	1,200,000
Change in exposure level	-1%
Change in number of exposed workers	+0.45%/year
Future disease burden (FDB) – Number of cases over 40 years	28,821 (lung cancer)
Estimated deaths due to FDB cancer over 40 years	23,057
Monetary value FDB cancer over 40 years	- Method 1: €11.8 billion - Method 2: €22.6 billion
Monetary value FDB other adverse health effects over 40 years	Cannot be estimated due to insufficient data
Source: RPA (2024)	

5.2. Description of the policy options

5.2.1. Structure and logic of the policy options

To meet the first three objectives outlined in the table below, limit values should be established for cobalt and inorganic cobalt compounds, PAHs and 1,4-dioxane. For each substance subject to the setting of limit values, several policy options for limit values are identified to further improve the existing regulatory framework and further levelling the playing field at EU level. These policy options always include the limit values derived by RAC (scientific experts), where any, and those recommended by the tripartite ACSH (stakeholders). These limit values are key as they represent either the limit values below which workers' exposure is not dangerous (health-based limit value derived by RAC) or the most proportionate limit values according to social partners and Member States authorities represented in the WPC/ACSH as they ensure values which are protective for workers and technically and socio-economically feasible for businesses. There are no existing health-based limit values for some substances (PAHs). In this case, RAC provides an exposure-risk relationship, which provides the correspondence between the substance concentration and the statistical probability of developing cancer (additional risk beyond the background incidence).

In addition, other relevant reference points are chosen as policy options to ensure a wide range of levels for assessment. These additional policy options were mainly based on the new methodology establishing risk-based limit values for non-threshold carcinogens[92] and the existing national limit values. According to this new methodology, limit values for non-threshold carcinogens as set out in the ACSH opinion should be set between the upper risk level of 4:1,000 (corresponding to 4 predicted cancer cases in 1,000 employees) and the lower risk level of 4:100,000. The next section provides more detailed information regarding the reasons for choosing each option. All these policy options are summarized in table 10 and further discussed in annex 9.

For each policy option, the employers would need to put in place the necessary additional RMMs to keep workers' exposure below the limit value(s). As a result, workers would be less exposed to the below hazardous substances, which should further improve OSH at EU level.

In addition to the policy options for OELs and BLVs, RAC also recommended the setting of short-term exposure limit (STEL) for 1,4-dioxane, and notations for cobalt and its inorganic compounds, PAHs and 1,4-dioxane. These accompanying measures are not expected to result in significant costs and are therefore not assessed individually. More information on these measures is provided in annex 10.

An inclusion of welding fumes in Annex I of the CMRD has been identified by relevant stakeholders represented in the ACSH as a means to meet the fourth specific objective outlined in the table below. Furthermore, the existing Senior Labour Inspectors Committee's[93] (SLIC) Guidance for National Labour Inspectors on addressing health risks from Welding Fume[94] could be updated in the coming years, which would contribute to improving awareness of the possible dangerousness of welding fumes. However, in the absence of specific information on if and how this guidance document will be updated, the effects of this option could not be assessed. More information on this possible revision is available in annex 10, under the accompanying measures.

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[92] DG EMPL (2023), Methodology establishing risk-based limit values for non-threshold carcinogens, for the purposes of Article 1 (18a) of Directive 2004/37/EC, available at: https://ec.europa.eu/social/BlobServlet?docId=27151&langId=en

[93] The SLIC has the mandate to give its opinion on all matters relating to the enforcement by the Member States of EU legislation on health and safety at work. It consists of representatives of the labour inspection services of the Member States, as mentioned in the Commission Decision of July 1995 setting up a Committee of Senior Labour Inspectors (95/319/EC). The Committee shall comprise on full member per Member State and one alternate member may be appointed for each full member.

[94] SLIC (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC

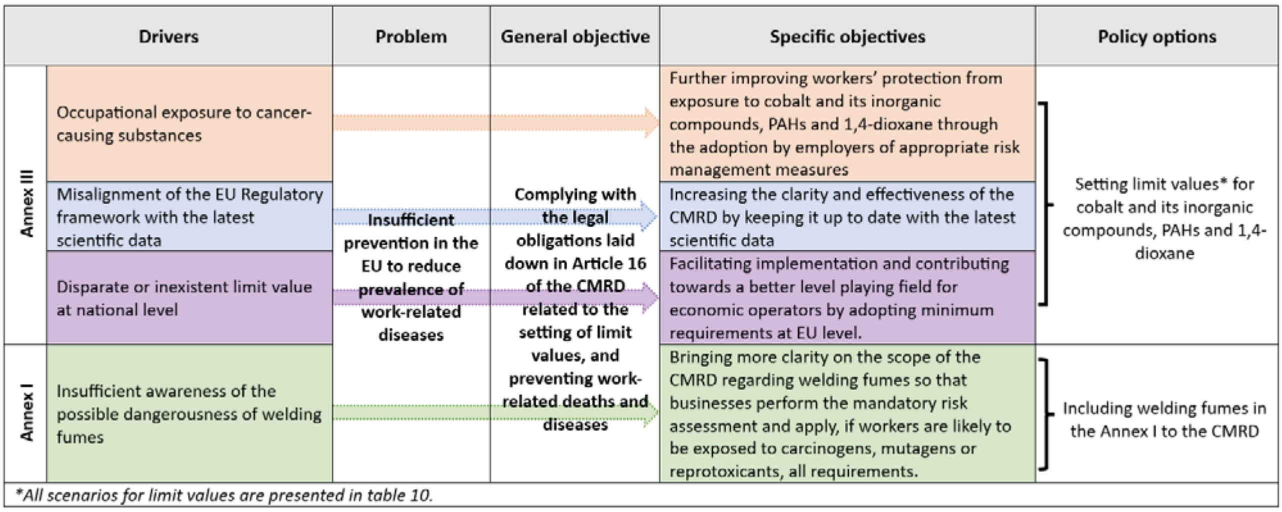

Figure 4: Intervention logic

5.2.2. Substances prioritised for the setting of limit values

This section outlines the reasons for choosing the different options for each substance, except option 1 which corresponds to the baseline scenario for all substances.

(a) Cobalt and its inorganic compounds

Option 2 are the limit values (both inhalable and respirable fraction) recommended by RAC, below which workers are assumed to be safe. **Options 4** and **5** correspond to the final limit values and the transitional limit values recommended by the ACSH, respectively. **Option 3** is an intermediate limit values between **option 2** and **option 4** to avoid a significant gap between two values. Finally, **option 6** corresponds to the combination of limit values (final and transitional), as recommended by the ACSH in its opinion[95]. This transitional limit value of 6 years at the level of option 5 would apply to all sectors, giving more time to businesses to plan their investments.

(b) PAHs

Options 2 and **4** correspond to the limit value with an associated risk of 4:100,000 and 4:1,000 according to RAC opinion[96]. **Option 3** is the final limit value recommended by the ACSH. **Option 5** corresponds to the combination of limit values (final and transitional), as recommended by the ACSH in its opinion[97]. This recommended transitional value of 140 ng/m³ (double the preferred option) would apply during 6 years and would be limited to 9 sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4) coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9)

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[95] ACSH (2023), Opinion on an EU BOEL and notations for cobalt and its inorganic compounds, Doc. 005/23, available at: ACSH Adopted opinion Cobalt and inorganic compounds 22.09.23-EN.pdf (europa.eu)

[96] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for polycyclic aromatic hydrocarbons, available at: 06454dd9-cadc-acef-a11b-439f2a0d8efa (europa.eu)

[97] ACSH (2023), Opinion on an EU BOEL for polycyclic aromatic hydrocarbons, Doc. 003/23, available at: ACSH Adopted opinion PAHs 22.09.23-EN.pdf (europa.eu) & Addendum to ACSH opinion 003/23, available at: Addendum to ACSH opinion PAHs-EN.pdf (europa.eu)

casting of metals. According to the ACSH, these 9 specific sectors are expected to face high costs and/or are at risk of discontinuation.

(c) 1,4-dioxane

Option 2 corresponds to the health-based limit value derived by RAC in its opinion[98] and is also the limit value recommended by the ACSH[99]. As both RAC and the ACSH recommended the same limit value, only one additional option (**option 3**) was considered and corresponds to the lowest existing national limit value (LV and NL).

According to RAC, occupational exposure is expected to occur via inhalation and dermal route. As an OEL only protects workers from oral exposure, it is also important in this case to set a BLV. In its opinion, RAC identified 2-hydroxyethoxyactic acid (HEAA) as the main metabolite. It also established a relationship between the mean urinary HEAA levels after the end of exposure and the air concentration of 1,4-dioxane. This function is urinary HEAA level (in mg/g creatinine) at end of exposure = 17.82 x (air concentration of 1,4-dioxane in ppm) + 9.52. This function is used in this impact assessment to calculate BLVs corresponding to each OEL option.

Table 10: policy options for each substance subject to the setting of limit values

Hazardous substance	Option 2	Option 3	Option 4	Option 5	Option 6
Cobalt and its inorganic compounds	**OEL** 1[100] / 0.5[101] µg/m³ (RAC values)	**OEL** 5 / 1.25 µg/m³ (Intermediate values[102])	**OEL** 10 / 2.5 µg/m³ (ACSH final values)	**OEL** 20 / 4.2 µg/m³ (ACSH transitional values)	**OEL** 10 / 2.5 µg/m³, with transitional limit values of 20 / 4.2 µg/m³[103] (ACSH combination of values)
PAHs[104]	**OEL** 7 ng/m³ (Excess risk of 4:100,000)	**OEL** 70 ng/m³ (ACSH final value)	**OEL** 700 ng/m³ (Excess risk of 4:1,000)	**OEL** 70 ng/m³, with transitional limit value of 140 ng/m³ for some sectors[105]	-

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[98] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for 1,4-dioxane, available at: 686365df-9485-c2ac-b342-289ec306d188 (europa.eu)
[99] ACSH (2023), Opinion on an EU BOEL, STEL, BLV and skin notation for 1,4-dioxane, Doc. 007/23, available at: ACSH Adopted opinion 1_4-dioxane 22.09.23-EN.pdf (europa.eu)
[100] Inhalable fraction, which is defined as the mass fraction of particles which can be inhaled by nose or mouth.
[101] Respirable fraction, which is defined as the mass fraction of particles that reaches the alveoli.
[102] Policy option 3 for cobalt is a pair of intermediate values between those recommended by RAC and the ACSH, given the relative gap between policy options 2 and 4.
[103] Until 6 years after entry into force of the Directive
[104] OEL options are measured as benzo[a]pyrene, which is considered as a marker substance for carcinogenic PAHs by RAC in its scientific opinion.
[105] Until 6 years after entry into force of the Directive for the following sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4) coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals.

				(ACSH combination of values)	
1,4-dioxane	**OEL** 7.3 mg/m³ (2 ppm) (RAC & ACSH value) **BLV** 45 mg HEAA in urine/g Creatinine (RAC & ACSH value / corresponding value[106] to OEL option 2)	**OEL** 20 mg/m³ (5.5 ppm) (lowest national value) **BLV** 108 mg HEAA in urine/g Creatinine (corresponding value to OEL option 3)	-	-	-

5.2.3. Welding fumes - substance subject to inclusion in the scope of the CMRD

The evidence gathered indicates that some employers are not aware that their welding processes may contain carcinogens, mutagens or reprotoxic substances. This driver was also supported by the tripartite ACSH in its opinion[107]. These employers may therefore ignore to what extent exposure to welding fumes is dangerous for their workers and include substances that are carcinogenic, mutagenic or reprotoxicant. Consequently, and despite the fact that welding can be a relatively safe activity if all the safety and exposure control measures are in place, it remains a prominent concern that welders are at high risk from various diseases, including cancers[108].

According to ECHA[109] in its scoping study on welding fumes, an entry of welding fumes in Annex I of the CMRD would bring clarity about employers' duties and which measures have to be taken. The introduction of welding fumes in Annex I to the CMRD would ensure a better implementation of the existing obligations laid down in the CMRD. This introduction aims to draw employers' attention to the possible dangerousness of the fumes generated by their welding process. As provided by the CMRD, employers have to perform a risk assessment as soon as an activity is likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances. The ECHA scoping study will support this assessment as it provides information on welding processes likely to generate carcinogens, mutagens or reprotoxic substances. If this risk assessment reveals that their welding fumes contain such hazardous substances, employers will need to take all the necessary RMMs to comply with the obligations laid down in the CMRD, including the hierarchy of controls in Articles 4 and 5. The introduction of welding fumes does not result in new rules but aims to

[106] RAC provides a relationship between the mean urinary HEAA levels after the end of exposure (extrapolated to 8 hours) and the air concentration of 1,4-dioxane. Based on this correlation, the following policy options for BLVs corresponding to the retained options for OELs were set: 45 mg, 108 mg and 188 mg.
[107] ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)
[108] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)
[109] ECHA (2022), op. cit.

ensure a correct implementation of the existing ones, which contributes to the proportionality of the proposal.

The policy option of an entry of welding fumes in Annex I was supported in its opinion[110] by the ACSH. The three interest groups consider that an inclusion into Annex I might indicate to stakeholders that more needs to be done to ensure that the RMMs are in place and will bring clarity about employer's duties on measures to be taken.

Given the broad support from the three interest groups within the ACSH, the inclusion of welding fumes in Annex I was kept as policy option.

No additional policy option other than the inclusion in Annex I and the complementary measure related the possible revision of the SLIC guidance was retained for welding fumes. Indeed, in the absence of scientific opinion from RAC on the possible setting of a limit value for welding fumes, the latter could not be considered as an option for the current initiative. Furthermore, the heterogeneous character of welding fumes makes it very difficult to establish a common OEL for all welding processes.

Furthermore, several guidance documents already exist at EU-level, including the Senior Labour Inspectorate Committee's guidance on addressing health risks from welding fumes[111] and the European Welding Association's (EWA) guidance[112]. Despite the existence of guidance at EU level, the evidence gathered shows that the welding fumes-related problem persists. Therefore, the development of new guidance was not considered relevant to address the problem. More information on both guidances is available in annex 10.

5.2.4. Isoprene-related discarded options

The evidence gathered[113] indicates that the exposure of workers to isoprene is lower than the threshold limit value derived by RAC. Therefore, no problem was identified for isoprene, as described in section 2. Consequently, no policy option was assessed in the main report of this impact assessment. However, as the ACSH recommended a limit value for isoprene, and for the sake of transparency, a fully-fledged analysis of this option was carried out and is available in annex 10.

5.2.5. Options discarded at an early stage

A number of policy options that have been considered at the early stages of this initiative have been discarded without a detailed assessment of their impacts, either because they are clearly disproportionate (banning the use of substances, directly adopting the most stringent national limit values, less stringent rules for SMEs resulting in less ability to attract workers as the latter would favour better working conditions), or unsuitable to achieve the policy objectives (providing industry-specific scientific information without amending the CMRD, guidance documents

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[110] ACSH (2023), op. cit.
[111] SLIC (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC
[112] EWA (2021), Welding Exposure Scenario – ENGL. Available at : WES-EWA-TCC-458-2021-05-English-002.pdf
[113] RPA (2024), op. cit.

(including to address the lack of awareness related to welding fumes)), or there is insufficient scientific information (setting a limit value for welding fumes). Annex 10 contains a description of those policy options and the reasons for discarding them.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Section 6 outlines for each substance the identified relevant positive and negative impacts associated with the selected policy options against the baseline. Overview tables per substance summarising all impacts are available in Annex 4. The impacts are classified in three main categories: economic, social and environmental. They mainly concern three groups of stakeholders: workers (and their families), businesses and public authorities. These impacts are mostly monetised or quantified on a 40-year reference period, to calculate the total risk over the working life. When the available data does not allow for this, impacts are discussed qualitatively. Data collection for the purpose of this impact assessment includes literature review (including scientific literature) and stakeholder consultation (targeted questionnaires, interviews, site visits and conversations). More information on stakeholder consultation is available in annex 2.

The introduction of limit values for cobalt and its inorganic compounds, PAHs and 1,4-dioxane, and inclusion of welding fumes in Annex 1 of the CMRD, is expected to reduce the occupational exposure to these hazardous substances as businesses with exposure levels higher than the options will have to invest in additional RMMs. The extent of such reduction depends on the current levels of exposure and RMMs, as well as the projected future levels of exposure in the absence of any action ('baseline scenario'). Annex 6 outlines the current RMMs in place by sector, as well as the required additional RMMs by sector for each option.

For a given reduction in exposure levels of all substances except welding fumes, the expected decrease in the incidence of ill-health over 40 years was calculated. This involved estimating the risks of adverse health effects, derived from the existing toxicological and epidemiological literature, and information about the current level of worker exposure (number of workers exposed, level, duration and frequency of exposure). The health benefits of the new limit values are calculated in terms of the costs of ill-health avoided. They are expressed in monetary terms by applying standard valuation methods[114].

The estimate of the costs for all substances except welding fumes was based on a literature research and data obtained from stakeholders and considers the following factors: the RMMs needed to comply with the proposed limit values, the costs of these RMMs for each company, the life span of the RMMs, and the number and size of companies.

While acknowledging the importance of occupational health and safety, the employers organisations' feedback during social partners consultation focused on the feasibility and economic implications of new regulations, stressing the need for transitional periods, where necessary, and careful socio-economic impact analysis to avoid harming competitiveness. Additional details on social partners consultation are available in Annex 2

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[114] Method 1 is the application of a single willingness to pay (WTP) value to each case and Method 2 is the use of disability adjusted life years (DALYs) and their monetisation. Both estimates monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect (productivity/lost earnings) impacts but use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.).

Some policy options for cobalt and its inorganic compounds and PAHs include a transitional value (combination of two different values). Transitional values are expected to reduce the adjustment costs and to make the financing of adjustment costs cheaper. Indeed, the longer time companies have to implement compliance measures, the lower are the likely costs. They can for instance better plan investments. As further described in annex 4, the total discounted value for adjustment costs would be 16% lower. Furthermore, transitional values are also expected to spread the substantial one-off investments over a number of years. Therefore, companies could already start planning their investments.

The methodology to calculate the costs and benefits of placing welding fumes in Annex 1 of the CMRD is different from the methodology applied for the substances subject to the setting of limit values. The costs and benefits presented below relate to those additional companies which would apply the already required RMMs following the increased awareness of the dangerousness of welding fumes induced by their inclusion in Annex 1. In particular, it was assumed that for 1% of welders will improve their current RMMs following the introduction of welding fumes in Annex I to the CMRD.To validate these assumptions, interviews were held with key stakeholders representing a large number of welders in the EU, who agreed that the estimates were reasonable.

Regarding benefits, in the absence of Exposure-Risk Relationship and exposure data for welding fumes, a tentative extra cancer risk of 2.7% was derived from existing toxicological and epidemiological literature. This excess risk is subject to an average trend of reducing by 1% per year[115], and this was assumed to continue for the next 40 years for the baseline. The impact of policy option 2 is assumed to reduce the excess risk by a further 1% for the first five years after the policy option takes effect[116], due to those companies which would carry out risk assessments and apply adequate RMMs following the increase of awareness of the possible presence of carcinogens, mutagens or reprotoxicants in welding fumes.

With regard to costs, two approaches[117] are applied:

- Bottom-up: this is based on the number of welders that are estimated to move from having poor or no RMMs to adequate RMMs as a result of policy option 2 and multiplying this by the estimated additional average cost of these RMMs[118]; and
- Top down: based upon the current market value of RMMs being used annually, an estimate of an assumed 1% increase in the sale of RMMs as a result of policy option 2 was applied.

More information on the overall methodology, including the key assumptions, is available in annex 4.

Due to the lack of data, the analysis of the impact on workers' health is limited to the most relevant diseases. For instance, exposure to PAHs can also result in skin cancer. However, the paucity of data does not allow for a quantification or monetisation of the impact on health. Due to this limitation, the benefits of the options are likely to be underestimated.

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[115] RPA (2024), op. cit. This trend was validated by interviews with key stakeholders where they were specifically asked their opinion on the future trend for excess risk.

[116] In other words, a 2% reduction for five years, returning to a 1% reduction from year six.

[117] RPA (2024), op. cit.

[118] In addition, only a proportion of the workers that are estimated to move to better RMMs will need to buy new RMMS; some will simply utilise the RMMs that they already have, which will not incur additional costs. This proportion is assumed to be 50% and together it enables a cost for these additional RMMs to be estimated.

Furthermore, the discontinuation costs presented below are subject to uncertainty[119]. First, the number of companies that are expected to discontinue might be lower than estimated because they could find technical solutions or alternatives to ensure compliance. Secondly, if some companies close down effectively, it is likely that a part of their activities would be absorbed by other companies in the same sector to meet the overall demand. The same uncertainty also applies to the estimated job losses. First, an overestimate of discontinuations would also mean an overestimate of job losses. Secondly, the possible transfer of activities mentioned in this paragraph would also lead to the creation of jobs that would partly offset the quantified impact below. However, in the absence of relevant data, these likely effects couldn't be quantified. Nevertheless, it is likely that the estimated discontinuations and job losses below are overestimated.

Other limitations were identified and are summarised in annex 4, in particular table 65 summarising the key limitations or uncertainties. This table indicates if these limitations might lead to under- or overestimates.

With regard to the impact on Fundamental Rights, the Article 31 of the EU Charter of Fundamental Rights states that workers have the right to fair and just working conditions that respect their health, safety and dignity. This is further developed in the EPSR which aims to build a fairer and more inclusive European Union. Each policy option ('PO') that would further improve the protection of workers from the health risks posed by exposure (resulting in avoided ill-health), would also positively impact this right. For those POs with no impact on workers' health, there would be no impact on Fundamental Rights. Given that the impact on Fundamental Rights would be equivalent for each substance, it is not further discussed below.

6.1. Cobalt and inorganic cobalt compounds

The estimates related to cobalt and inorganic cobalt compounds outlined below take account of the impact assessment commissioned by Cobalt Institute and data on exposure levels and chemical safety report also provided by Cobalt Institute. The data have been assessed along with data obtained from stakeholders' survey and other available data sources. With regard to exposure levels, exposed workforce, and number and companies with exposed workers – for those sectors covered by the Cobalt Insitute's impact assessment – the estimates used for the study[120] supporting this impact assessment are well in accordance with the data provided by Cobalt Institute.

The Cobalt Institute assessment, however, estimates the total costs of compliance significantly higher than estimated below.

The differences between the Cobalt Institute's assessment of impact and the external study primarily arise from variations in methodology, assumptions about company structures, and compliance strategies.

Detailed information on why Cobalt Institute's estimates differ from this impact assessment is provided in annex 2.

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[119] RPA (2024), op. cit.
[120] RPA (2024), op. cit.

6.1.1. Social impacts

(a) Impacts on workers' health

Setting limit values at the level of policy option 2 ('PO 2') would allow for eliminating most of the health burden over the reference period. Under these levels of exposure, no worker would suffer of restrictive lung disease and upper airway irritation (representing 4,365 restrictive lung disease cases and 14,152 upper airway irritation cases avoided) and the number of lung cancer cases would be reduced by more than 90% vis-à-vis the baseline scenario (71 out of 76 lung cancer cases).

PO 3 would allow for fully protecting workers from restrictive lung disease and for avoiding 51 lung cancer cases and 12,266 upper airway irritation cases. Overall, about 90% of all cancer and non-cancer cases would be avoided.

The limit values provided under PO 4 would reduce by 55% the total number of cancer and non-cancer cases over the reference period. As shown in table 11, 23 lung cancer cases, 2,842 restrictive lung disease and 7,363 upper airway irritation cases would be avoided.

PO 5, which provides for the less stringent combination of limit values, would have a limited impact on the total health burden. 12 (out of 76 under the baseline scenario) lung cancer cases would be avoided and 3,135 non-cancer cases would be avoided (1,000 restrictive lung disease cases and 2,135 upper airway irritation cases). The corresponding health savings are presented in the table below.

The benefits in terms of the reduced number of cases of ill-health under PO 6 would be approximatively the same as under PO 4. However, since a part of these benefits will be postponed on average by 3 years (see annex 4) due to the transitional period, the monetary value will decrease by 8%, accounting for between €68 million and €69 million.

*Table 11: number of avoided cases of ill-health and monetised health benefits over 40 years (compared to the **baseline**)*

Endpoint	**PO 2** **1 / 0.5 µg/m³**	**PO 3** **5 / 1.25 µg/m³**	**PO 4** **10 / 2.5 µg/m³**	**PO 5** **20 / 4.2 µg/m³**	**PO 6** **PO 4 with transitional value at PO 5**
Lung cancer	71 (out of **76**)	51	23	12	~PO 4
Restrictive lung disease	4,365 (out of **4,365**)	4,365	2,842	1,000	
Upper airway irritation	14,152 (out of **14,152**)	12,266	7,363	2,135	
Monetised health benefits (€ million – M1 – M2)	€ 146 – € 135	€ 126 – € 121	€ 75 – € 74	€ 29 – € 27	€ 69 – € 68[121]
Source: RPA (2024) *Note:* "~" means approximatively					

[121] The monetary value of avoided ill-health cases is estimated to decrease by 8% as the benefits will be postponed by on average three years. This decrease is mainly due to the discount factor, as further explained in annex 4.

(b) Impacts on employment

The impact on employment varies significantly depending on the PO. The more stringent the PO, the higher the need for additional risk management measures to ensure compliance and the higher the impact on employment. The evidence gathered[122] suggests that 1,086 companies will discontinue, resulting in job loss for almost 26,000 workers under PO 2, representing a social cost of about €1.95 billion. More than a half of job losses would occur in the manufacture of tools sector (17,977 job losses).

Under PO 3, the estimates indicate that more than 2,700 workers would lose their jobs. As for PO 2, the manufacture of tools would be the most impacted sector with a loss of about 1,750 jobs, representing two thirds of total job losses. POs 4 and 5 would have less impacts on employment with 1,124 and 77 job losses, respectively.

The transitional period provided under PO 6 is expected to result in less job losses as companies should use this period to avoid discontinuation (see section 6.1.2). However, the evidence gathered does not allow for any quantification.

While some of the workers made redundant might easily find another job, notably in the faster growing sectors (e.g. batteries, metal recovery), the lack of data didn’t allow to estimate the number of redundant workers. The above job losses numbers can therefore be considered as the worst-case scenario. Furthermore, as mentioned in introduction of section 6, estimates of job losses are subject to high uncertainties.

6.1.2. Economic impacts

(a) Impacts on businesses, including SMEs

Under all POs, some companies will need to invest in additional RMMs to comply with the new limit values, entailing direct **adjustment costs**. The magnitude of these costs varies significantly between the different POs.

For a limited number of companies, these additional costs or the absence of appropriate RMMs available on the market that could enable companies to ensure compliance with some POs might endanger their continuation[123]. Under PO 2, 1,086 businesses (7.1% of the total number of companies with exposed workers to cobalt) are expected to discontinue at least a part of their activities, representing a discontinuation cost of almost €6 billion. Among these businesses, 947 are small- and 109 medium-sized enterprises. The less stringent the POs, the lower the discontinuation costs as shown in table 12. Under PO 5, 10 businesses, all being small enterprises, are expected to discontinue, representing a discontinuation cost of €20 million.

With PO 6, businesses would have more time to implement major and expensive changes to RMMs; developing, finding and testing substitutes or avoiding discontinuations. The transitional value provided in PO 6 was highly recommended by both the ACSH and social partners, in

[122] RPA (2024), op. cit.
[123] For the purpose of this impact assessment, it is assumed that a company will discontinue if no existing RMMs in the cost model are sufficiently effective to achieve the reduction in exposure levels required to comply with a policy option.

particular businesses, as part of their formal consultation. It is expected therefore that the transitional period will result in less discontinuations than those estimated under PO 4. However, the evidence gathered does not allow for a quantification of such a decrease.

The manufacture of tools would be the most impacted sector in terms of discontinuation under the first three POs.

Table 12: number of discontinuations per company size and total discontinuation costs

	PO 2 1 / 0.5 µg/m³	PO 3 5 / 1.25 µg/m³	PO 4 10 / 2.5 µg/m³	PO 5 20 / 4.2 µg/m³	PO 6 PO 4 with transitional value at PO 5
Small companies	947 (out of 12,477)	128	51	10	Fewer discontinuations than under PO 4
Middle companies	109 (out of 2,065)	11	5	0	
Large companies	30 (out of 799)	3	1	0	
Total	1,086 (out of 15,341)	142	57	10	
Total discontinuation costs (in € million)	**€ 5,991**	**€ 698**	**€ 231**	**€ 20**	**Fewer discontinuation costs than under PO 4**
Source: RPA (2024)					

For the businesses remaining in the market, PO 2 would be particularly costly as it would require a total investment in additional RMMs of over €3.65 billion over 40 years, of which €1.5 billion would need to be invested during the first year.

Under POs 3 and 4, businesses would need to dedicate over the next 40 years about €1.15 billion (of which €708 million during the first year) and €350 million (€237 million), respectively. PO 5, which provides for less stringent limit values, would naturally require less investments. In total, businesses would need to spend about €110 million in additional RMMs, of which €88 million during the first year.

If we bring these figures down to the scale of a company, each of those would on average need to make investments in RMMs over the next 40 years for about €250,000 under PO 2, €75,000 under PO 3, €22,800 under PO 4 and €7,200 under PO 5.

The machining sector would bear a significant share of the investments in additional RMMs, in particular under POs 2 and 3 for which these investments would represent more than half of the total investments in RMMs for all sectors (about €1.95 out of €3.65 billion for PO 2 and €615 million out of €1.15 billion for PO 3). The medical and dental devices sector would be the second most impacted sector with investments representing 10% and 15% of the total investments to be carried out under POs 2 and 3, respectively.

With less discontinuations expected under PO 6 than under PO 4, the compliance costs for PO 6 are also expected to increase when companies are able to finance the investments in RMMs instead of closing down. On the other side, it might also be that the costs of RMMs will be reduced if companies can plan and do investments as part of investment in new production facilities and equipment. The possibility to plan and finance investments in RMMs over the transitional period will in particular be important for SMEs. The evidence gathered does not allow for a monetisation or quantification of the impact of a transitional period on the compliance costs.

The introduction of new limit values may entail **air monitoring costs** for those businesses which would need to carry out additional monitoring campaigns. The number of additional campaigns varies from 0 to 2, depending on several factors, including the existing national limit values, the size of companies[124].

According to estimates, the total air monitoring costs under PO 2 would account for €112 million, of which €23.6 million and €52.9 million would be supported by small- and medium-sized enterprises, respectively. The less stringent the limit values under the POs, the lower the air monitoring costs, as shown in table 13.

In percentage of the total compliance costs, the air monitoring costs is about 1%, 4%, 8% and 22.5% for the first four POs, respectively, with the highest percentage for PO 5.

Under PO 6, it is expected that the air monitoring costs would amount to €46.8 million. Although the final limit values under PO 6 are equivalent to PO 4, businesses will have more time to put in place the necessary RMMs and demonstrate compliance. Therefore, the total air monitoring costs should also be lower, mainly due to the discount factor[125].

Table 13: total estimated costs of up to two additional air monitoring campaigns in € million over 40 years by policy option and size of company

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (1 / 0.5 µg/m³)	23.6	52.9	35.6	**112.1**
PO 3 (5 / 1.25 µg/m³)	12.1	40.5	27.6	**80.3**
PO 4 (10 / 2.5 µg/m³)	7.2	24.7	19.0	**50.9**
PO 5 (20 / 4.2 µg/m³)	6.2	17.5	15.0	**38.8**
PO 6	6.6	22.7	17.5	**46.8**
Source: RPA (2024)				

The total costs related to the **administrative burden** of undertaking the additional air monitoring campaigns for companies are shown in table 14, broken down by PO and size of company. The lower the limit values, the higher the RMMs and the higher the number of companies that need to carry out additional monitoring campaigns to demonstrate compliance. Therefore, administrative costs are proportional to the degree of severity of the limit values considered for each PO. Overall, the administrative costs represent a negligible share of the total compliance costs under all POs, ranging from 0.1% (PO 2) to 2.5% (PO 5). Similarly to air monitoring costs, the costs related to the administrative burden are expected to amount to €6.1 million, as costs will be delayed by 3 years compared to PO 4.

[124] More information on the methodology to assess monitoring costs is available in annex 6.
[125] As costs will be delayed by 3 years (seeannex 4, section 7.4), they should decrease by 8% due to the discontinuation factor.

Table 14: total estimated costs of administrative burden of additional air monitoring by policy option and size of company over 40 years

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (1 / 0.5 µg/m³)	3.0	5.6	4.6	**13.2**
PO 3 (5 / 1.25 µg/m³)	1.4	4.1	3.3	**8.8**
PO 4 (10 / 2.5 µg/m³)	0.9	3.1	2.6	**6.6**
PO 5 (20 / 4.2 µg/m³)	0.8	2.0	1.7	**4.5**
PO 6	0.8	2.9	2.4	**6.1**
Source: RPA (2024)				

If compared with turnover, small- and medium-sized enterprises would be more impacted than larger companies under all POs. The impact would be particularly significant under POs 2 and 3 as small-sized enterprises would have to dedicate on average 1.16% and 0.32% of their turnover for compliance (including adjustment, monitoring and administrative costs) over 40 years, and medium-sized enterprises 0.65% and 0.11%, respectively. In some sectors, the share of the adjustment costs compared to the turnover under PO 2 is significantly higher than the average share for small-sized companies, in particular in the manufacture of other porcelain and ceramic products (3.08%), manufacture of tools (2.17%), manufacture of other fabricated metal products (2.10%) and manufacture of medical and dental instruments and supplies (2.04%). The impact of POs 4, 5 and 6 is more limited, with small enterprises having to invest between 0.1% and 0.02% of their turnover, and medium enterprises 0.04% and 0.009%.

All POs would also positively impact businesses as they would allow for **cost savings** from reduced ill-health. PO 2 would entail the highest benefits for employers as it would also have the highest positive health impacts. Under this PO, businesses would save €1.6 million over 40 years against 0.4 million under PO 5 over the same period. The costs savings under POs 3, 4 and 6 would be in between with €1.5, €1 million and €0.9 million, respectively. These benefits are negligible compared to the costs to businesses and are therefore not expected to mitigate the impacts described above.

(b) Impacts on competitiveness

Although of different extent, all POs are likely to have impacts on **cost and price competitiveness** as some businesses are expected to discontinue, partly or totally, due to the high compliance costs or the current absence of appropriate RMMs enabling some companies to comply with some POs. Such an impact would particularly occur under PO 2, especially for the manufacture of tools sector where more than 4% of the companies would discontinue (30% if we only consider companies with exposed workers to cobalt), which could affect product availability and prices. Under all other options, estimated discontinuations are not expected to result in significant changes in any sector.

Under all POs except PO 2, the total adjustment costs are below 1% of turnover for all sectors (including SMEs), and in most cases even below 0.1%. With regard to PO 2, adjustment costs can represent up to 3% (small-sized companies in the manufacture of other porcelain and ceramic products sector). Only SMEs in the following sectors would face adjustment costs representing more than 1%[126] of the turnover: manufacture of other porcelain and ceramic products, manufacture of tools, manufacture of other fabricated metal products, manufacture of medical and dental instruments and supplies, machining, manufacture of electronic components and boards, manufacture of motor vehicles, manufacture of air aid spacecraft and related machinery, and forging, pressing, stamping and roll-forming of metal; powder metallurgy.

Therefore, overall impacts of POs 3, 4, 5 and 6 on businesses should have no or limited impacts on consumer choices and prices as companies are expected to absorb costs which represent a small share of their turnover and no sector should be significantly impacted by discontinuations. Regarding PO 2, consumers are expected to be impacted by higher prices or lower diversity of supply in sectors where SMEs would face high adjustment costs compared to their turnover[127] or sectors would be characterised by a significant number of estimated discontinuations compared to the total number of companies with exposed workers[128].

With regard to the EU's main competitors, only Canada and Japan have binding limit values for the inhalable fraction or total dust comparable to PO 5. The other competitors have limit values higher than PO 5, or no binding limit values for cobalt. Therefore, under all POs, the **international competitiveness** of EU-based companies could be impacted when compared to their competitors who will operate without incurring the capital and operating costs of compliance with a lower limit value. Non-EU countries often have different compliance rules and methods to define exposure, which makes the comparison uncertain.

Consequently, some companies operating within the most impacted sectors might consider the possibility to relocate their activities outside the EU[129]. However, except under PO 2, the average compliance costs per company compared to the turnover are not expected to be particularly significant and should therefore not exceed the costs of relocation of activities. Therefore, the impact on international competitiveness from POs 3 to 6 should be limited and is not expected to impede the objective of increasing the overall competitiveness of the EU.

The impact on **capacity to innovate** is expected to be significant in some sectors under PO 2. According to the evidence gathered, the total compliance costs in the following 5 sectors would represent more than 20% of their expenditures in research and development (R&D) over 40 years: manufacture of tools (53%) manufacture of other fabricated metal products (36.5%), forging, pressing, stamping and roll-forming of metal; powder metallurgy (25%), manufacture of electric components and boards (23.5%) and recovery of sorted materials (20.5%). The resources used to comply with PO 2 would therefore not be available for R&D activities. Under the other four POs, the share of the total compliance costs compared to the R&D expenditures is lower than 10%, and even 1% in most sectors and POs.

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[126] Although the profitability ratio diverge from one sector to another, 1% of turnover was chosen for the purpose of this impact assessment, in line with previous impact assessments in the area of occupational safety and health.
[127] (1) Manufacture of other porcelain and ceramic products, (2) forging, pressing, stamping and roll-forming of metal; powder metallurgy; (3) machining, (4) manufacture of tools, (5) manufacture of other fabricated metal products n.e.c., (6) manufacture of electronic components and boards, (7) manufacture of motor vehicles, (8) manufacture of air and spacecraft and related machinery, (9) manufacture of medical and dental instruments and supplies.
[128] In particular (1) Manufacture of tools, and (2) Manufacture of other porcelain and ceramic products.
[129] RPA (2024, op. cit. As part of the stakeholders consultation, one large company indicated that they may relocate the most dusty processes with the highest exposure concentrations to countries outside the EU.

(c) Impacts on the single market

No Member State has an equivalent combination of limit values to those assessed in this report. For instance, despite that several Member States already have a limit value of 20 µg/m^3 (inhalable fraction), it does not apply to the same scope[130] or is not combined with a limit value for the respirable fraction. Furthermore, 5 Member States currently have no limit value for cobalt. Therefore, introducing a combination of limit value covering both the respirable and inhalable fraction, whatever their levels, would lead to a more level playing field within the single market, improving its functioning. In the absence of further information, this impact could not be quantified.

(d) Impacts on public authorities/Member States

No Member State has currently an existing combination of limit values for cobalt and its inorganic compounds in its national legislation. Therefore, they will all need to revise their legislations, which will entail **transposition costs**. Consequently, the total costs for transposition will be the same under each PO: €910,000[131].

All POs would improve the protection of workers, resulting in less ill-health cases over the next 40 years. POs 2 and 3 in particular would allow for a significant reduction of the health burden, resulting in **avoided healthcare treatment costs** for public authorities of about €8.1 and €7.2 million, respectively. Although the positive impact on health is less significant, public authorities would still benefit from a reduction of costs under POs 4, 5 and 6 (€4.4, €1.5, and €4 million, respectively).

All POs might also be beneficial for those Member States which currently have no limit value and would like to set one. Under all POs, the 5 Member States would not have to carry out an assessment in view of setting limit values for cobalt. This could represent a **benefit** of €500,000 in total for the 5 Member States, irrespective of the PO.

Under all options, the benefits to public authorities would outweigh the costs.

The Member States with the highest share of companies comprise Czechia, France, Germany, Italy and Poland. It can therefore be expected that industries in these Member States will face the largest compliance costs. These five Member States accounts for about 60% of the companies and therefore, they could also face around 60% of impacts (depending on the current RMMs in place). The mentioned Member States are also for the most the larger Member States. If compared to the total size of the industry, there is overrepresentation of companies in Czechia, Italy, Poland and Slovakia. This is a reflection of large metal industries in these Member States. Therefore, also considering that the larges costs by sector include Machining and Manufacture of metal tools, these Member States are likely to be most affected. Among these 4 Member States, Poland, which has an existing binding limit value of 20 µg/m^3 (inhalable) should be the less impacted. While Italy has no limit value for cobalt, Czechia and Slovakia have a binding limit value of 50 µg/m^3 (inhalable).

[130] Some limit values apply to less cobalt compounds or to cobalt only.

[131] In accordance with the previous impact assessments, it is assumed that the transpositions costs for Member States with currently no limit values (IT, LU, MT, PT, SI) would be of €50,000, and of €30,000 for those with an already existing limit value.

It also means that the expected reduction in discontinuation from the transitional value provided by PO 6 will also benefit all Member States identified in the previous paragraph.

(e) Impacts on digitalisation

No PO is expected to have an impact on digitalisation.

(f) Impacts on EU Open Strategic Autonomy

Cobalt is a critical raw material and is used in key technologies ensuring a successful green transition (e.g. batteries for electric vehicles and storage and magnets in wind turbines). Depending on their levels, limit values for cobalt and inorganic cobalt compounds may result in higher costs of recycling cobalt and thereby have a negative impact in this area. As a possible consequence, the EU would remain dependent on other countries for its supply of cobalt, which goes against its objective of open strategic autonomy.

Under PO 2, 10% of businesses with workers exposed to cobalt operating in metal recovery sector are estimated to discontinue their activities. The compliance costs would represent up to 0.7% of the average turnover in the sector (7.83% of the gross operating surplus). Therefore, PO 2 could negatively impact the EU objective of open strategic autonomy. PO 3 is expected to result in the discontinuation of 0.5% of businesses operating in this sector. Furthermore, the compliance costs would not exceed 0.04% of the turnover (0.49% of the gross operating surplus). Therefore, the impact under PO 3 would be negligible. Under PO 4 and PO 5, no discontinuation is estimated for the metal recovery sector and the compliance costs would represent less than 0.003% of the turnover (0.04% of the gross operating surplus). Therefore, POs 4 and 5 would have no impact on the EU objective of open strategic autonomy. Finally, the transitional period provided under PO 6 would give more time to plan investments, which would further reduce the already limited impacts arising from a limit value at the level of PO 3.

6.1.3. Environmental impacts

(a) Direct impacts on environment

To meet the new limit values, businesses might need to invest in alternative technical RMMs such as closed systems, partially closed systems, self-contained breathing apparatus, half and full facemasks and open hoods. The choice of these RMM will depend on the RMMs currently in place (see annex 6) and the PO. However, it is unlikely that the alternative RMMs contribute to higher releases of cobalt in the air. Therefore, the direct impact of all POs on the environment should be negligible or even zero.

(b) Indirect impacts on environment

The table below provides theoretical impacts on some of the objectives of the EU Green Deal.

Table 15: theoretical impacts of the introduction of limit values for cobalt and its inorganic compounds on the objectives of the EU Green Deal

Objectives of the EU Green Deal	Theoretical impacts
Mobilising industry for a clean and circular economy	See 'impacts on EU Open Strategic Autonomy' under section 6.1.2.
Accelerating the shift to	Limit values may in the short term increase the costs of

sustainable and smart mobility	batteries for vehicles and thereby have a negative impact on the shift to sustainable and smart mobility. In the longer term, the introduction of limit values may be a driver for development of alternatives and reduce the demand for critical raw materials (cobalt), and thereby have a positive impact on the shift to sustainable and smart mobility.
Supplying clean, affordable and secure energy	Limit values may increase costs of renewable energy sources (e.g. increased costs of magnets) and energy storage systems (e.g. increased costs of batteries). In the longer term, the introduction of limit values may be a driver for development of alternatives and reduce the demand for cobalt, and thereby have a positive impact on the supply of clean, affordable and secure energy.

The key sectors for the green transition are: manufacture of batteries and accumulators, manufacture of motor vehicles, manufacture of air and spacecraft and related machinery and recovery of sorted materials. PO 2 would hamper the Green Deal's objectives as some companies operating in the above-mentioned sectors would discontinue (batteries and accumulators: 1% of businesses; motor vehicles: 10%; air and spacecraft: 11%; and recovery: 10%). Furthermore, the total adjustments costs would represent a high share of the gross operating surplus, in particular for SMEs operating in the manufacture of motor vehicles (up to 33%) and in the manufacture of air and spacecraft and related machinery (15%).

Although to a lesser extent, PO 3 would also negatively impact the capacity of the Green Deal to deliver on some of its objectives. While the number of discontinuations for the sectors relevant to the Green Deal should remain limited (motor vehicles: 1%; air and spacecraft: 2.5%; and recovery: 0.5%), the adjustments costs compared to the gross operating surplus would approach the 5% for SMEs operating in the manufacture of motor vehicles and of air and spacecraft and related machinery.

POs 4 and 5 are not expected to have a negative impact on the Green Deal. There would indeed be no discontinuation except under PO 4 for businesses operating in the manufacture of air and spacecraft and related machinery (0.5% of businesses discontinuing). Furthermore, the total adjustment costs should remain very limited compared to the operating surplus, representing up to 0.5% of the gross operating surplus, except for SMEs manufacturing air and spacecraft and related machinery which would have to dedicate about 1% of their gross operating surplus under PO 4. Therefore, the impact of POs 4 and 5 on the Green Deal should be negligible or even zero.

The transitional period provided by in PO 6 should be beneficial to SMEs operating in the manufacture of air and spacecraft and related machinery, which would have more time to plan their investments. Therefore, this could result in less discontinuations, which would further reduce the already negligible impact of PO 4 on the Green Deal.

In the longer term, the introduction of limit values may be a driver for development of alternatives and reduce the demand for cobalt, and thereby have a positive impact on the supply of clean, affordable and secure energy. However, the evidence gathered did not allow for a more detailed assessment of this theoretical positive impact.

6.2. PAHs

6.2.1. Social impacts

(a) Impacts on workers' health

All POs would entail benefits for workers by reducing the number of ill-health cases compared to the baseline over 40 years. However, the magnitude of this impact varies greatly between the POs. The lowest limit value, PO 2, would have the most significant impact with 3,336 (out of 3,355 estimated under the baseline) ill-health cases avoided over 40 years, including nearly 90% of the cases of lung cancer and 100% of the cases for the other estimated endpoints.

PO 3 would also be effective in protecting workers from non-cancer ill-health since it would eliminate all cases of developmental toxicity and male infertility. However, it would only prevent less than one fourth of the lung cancer cases compared to the baseline (35 out of 160). PO 4 would not bring significant improvement for preventing work-related diseases related to exposure to PAHs. At 700 ng/m³, less than 20% of the total ill-health cases would be prevented, including 2 lung cancer cases only. Despite the transitional value, it is expected that the number of avoided ill-health cases under PO 5 should be similar to PO 3[132]. The table below summarizes the avoided cases over 40 years for each PO and also provides a monetisation of these direct positive impacts.

*Table 16: n° of avoided cases of ill-health and monetised health benefits over 40 years (against the **baseline**)*

Endpoint	**PO 2** **7 ng/m³**	**PO 3** **70 ng/m³**	**PO 4** **700 ng/m³**	**PO 5** **PO 3 with transitional value at 140 ng/m³ for 9 sectors**
Lung cancer	141 (out of **160**)	35	2	~PO 3
Developmental toxicity	38 (out of **38**)	38	7	
Male infertility	3,157 (out of **3,157**)	3,157	608	
Monetised health benefits (€ million – M1 – M2)	€ 182 – € 59	€ 97 – € 16	€ 15 – € 1	€ 13.8 - € 0.9[133]
Source: RPA (2024)				

(b) Impacts on employment

Impacts on employment are expected under POs 2 and 3, as a number of companies might be forced to discontinue (see economic impacts related sections). As a result of these discontinuations, about 47,500 (PO2) and 2,700 (PO3) workers are expected to lose their jobs out of the 1,285,000

[132] The reduction of ill-health cases should be postponed by three years as explained in the methodological note.
[133] The monetary value of avoided ill-health cases is estimated to decrease by 8% as the benefits will be postponed by on average three years. This decrease is mainly due to the discount factor, as further explained in annex 4.

workers currently exposed to PAHs in the EU. The social costs related to those job losses would be of about €4 billion and €0.25 billion for those two options, respectively.

Even if most of the sectors would be impacted under PO 2, the impact on employment would represent more than 60% of workers active in the following sectors: welding of railroad tracks (17,735 workers, representing 37% of the total number of job losses), petroleum refineries (5,739, 12%) and steel and iron foundries, ferroalloys (5,499, 11.5%).

Although its overall impact would be less significant, PO 3 would mainly impact workers operating in the following sectors: steel and iron foundries, ferroalloys (550, 20.5%), soil remediation (511, 19%), coking plants (479, 18%) and coal tar distillation (437, 16%).

Although the evidence gathered does not allow for a quantification, PO 5 is expected to result in less discontinuations than PO 3 (see section 6.2.2). Consequently, it is also expected that the number of job losses should be lower under PO 5 than under PO 3.

The evidence gathered does not allow for estimating the number of workers which would find a new job following the discontinuation of their companies. No impact on employment is expected under PO 4.

6.2.2. *Economic impacts*

(a) Impacts on businesses, including SMEs

Under POs 2 and 3, some companies are expected to discontinue because of the significant investments that they would need to make for complying with the new limit values. The impact would be particularly significant under PO 2, with 3,462 companies estimated to discontinue at least a part of their activities, all sectors combined. With a higher limit value, PO 3 is estimated to entail 146 discontinuations. In total, it would represent a discontinuation cost (considered as **adjustment costs**) of €32 billion and €2.25 billion, respectively. No discontinuation is expected under PO 4.

Under PO 2, 3 sectors would represent together more than four fifths of the total discontinuations: welding of railroad tracks (1,109 discontinuations, representing 32% of the total discontinuations), chimney sweeps (969, 28%) and soil remediation (726, 21%). The latter would continue to face difficulties under PO 3, with 68 discontinuations (representing 46.5% of the total discontinuations), followed by steel and iron foundries, ferroalloys (28, 19%) and coking plants (25, 17%).

Whether under PO 2 or 3, most of those companies which would discontinue are small-sized enterprises (93% and 88%, respectively). Although less impacted, 103 medium-sized enterprises are expected to discontinue under PO 2, against 6 under PO 3. The share of SMEs in the total discontinuation costs is lower. They would represent just under 40% for both POs. This difference is due to the lower turnover of SMEs compared to large companies[134].

With PO 5, businesses operating in the sector subject to the transitional value[135] would have more time to implement major and expensive changes to RMMs; developing, finding and testing

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[134] The discontinuation cost is taken as the loss of profit over 20 years and the average profit is assumed to be 10% of turnover of an average company in sector.

[135] Until 6 years after entry into force of the Directive for the following sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4)

substitutes or avoiding discontinuations. The transitional value provided in PO 5 was highly recommended by both the ACSH and social partners, in particular businesses, as part of their formal consultation. It is therefore expected that the transitional period will result in less discontinuations than those estimated under PO 3. However, the evidence gathered does not allow for a quantification of such a decrease. As most of the companies estimated to discontinue under PO 3 are SMEs, the introduction of the transitional period provided in PO 5 should mainly benefit them.

Table 17: number of discontinuations, including per company size and total discontinuation costs

	PO 2 **7 ng/m³**	**PO 3** **70 ng/m³**	**PO 4** **700 ng/m³**	**PO 5** **PO 3 with transitional value at 140 ng/m³ for 9 sectors**
Small companies	3,226 (out of 436,466)	129	0	Fewer discontinuations than under PO 3
Middle companies	132 (out of 3,001)	6	0	
Large companies	103 (out of 841)	11	0	
Total	**3,462 (out of 440,308)**	**146**	**0**	
Total discontinuation costs (in € million)	€ 32,392.40	€ 2,248.28	€ 0	**Fewer discontinuation costs than under PO 3**
Source: RPA (2024)				

Some of the companies that would not discontinue would need to invest in additional RMMs to comply with the new limit value, depending on their current levels of exposure and RMMs. Under PO 2, businesses would need to invest about €4.6 billion over 40 years, of which €1.7 billion during the first year. The impact of POs 3 and 4 on the need for investments in RMMs would be less significant as businesses would need to dedicate €417 million and €3.3 million over 40 years (of which €220.90 million and 4.5 million[136] during the first year).

The most impacted sectors in terms of investments in additional RMMs, irrespective of the company size, would be casting of metals (€1.2 billion over 40 years), road paving (€1.15 billion) and chimney sweeps (€765 million). While most of the investments required for the road paving sector would be recurrent (about 93%), the two other sectors would need to make about 50% of their investments during the first year.

Under POs 3, 2 sectors would concentrate almost two thirds of the required investments: road paving (€161.5 million) and welding of railroad tracks (€ 102 million). Under PO 3, investments supported by the road paving sector would be mainly recurrent (about 90%), while one third of the

coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals.

[136] It is assumed that some sectors would move from RMMs with high recurrent costs (e.g. respiratory protective equipment) to RMMs with lesser recurrent costs over the same period (e.g. closed system).

investments made by companies operating in the welding of railroad tracks sector would need to be done during the first year. Under PO 4, the total investments are less significant and would be mainly supported by the welding of railroad tracks sector (€3 million out of €3.3 million).

More than 95% of the companies operating in the two sectors mentioned in the previous paragraph are SMEs, which are usually characterised by less financial resources to make investments, in particular one-off investments (during the first year).

With less discontinuations expected under PO 5 than under PO 3, the costs of additional RMMs for PO 5 are also expected to increase when companies operating in the 9 targeted sectors are able to finance the investments in RMMs instead of closing down. On the other side, it might also be that the costs of RMMs will be reduced if companies have the opportunity to plan and do investments as part of investments in new production facilities and equipment. The possibility to plan and finance investments in RMMs over the transitional period will in particular be important for SMEs. The evidence gathered does not allow for a monetisation or quantification of the impact of a transitional period on the compliance costs.

While no Member State currently has a limit value at the level of PO 2, one (DE) and four (DE, LV, BG and NL) Member States have currently a limit value below PO 3 (+ final OEL under PO 5) and PO 4, representing 11% and 18% of businesses, respectively. Consequently, all enterprises would need to undertake additional **air monitoring** at PO 2 and over 80% at POs 3, 4 and 5.

PO 2 would represent a total monitoring cost of €550 million, against €292, €181 and €291 million under POs 3, 4 and 5, respectively. Under the three POs, most of these costs would be supported by SMEs, since they represent the largest part of the companies with exposed workers to PAHs.

Table 18: total estimated costs of up to two additional air monitoring campaigns in € million over 40 years by policy option and size of company

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (7 ng/m³)	498.25	36.28	14.93	**549.46**
PO 3 (70 ng/m³)	255.97	25.72	10.47	**292.16**
PO 4 (700 ng/m³)	157.69	16.6	7.04	**181.33**
PO 5	254.81	25.60	10.42	**290.84**
Source: RPA (2024)				

The total **administration costs** related to the running of air monitoring are shown in table 19 below. As for the monitoring costs, most of the administrative costs are attributed to SMEs, in particular small companies. The lower the limit value associated with the PO, the higher the administrative costs.

Table 19: total estimated costs of administrative burden of additional air monitoring by policy option and size of company over 40 years

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (7 ng/m³)	104.49	8.21	4.83	**117.53**
PO 3 (70 ng/m³)	55.79	6.15	3.60	**65.54**
PO 4 (700 ng/m³)	34.37	3.97	2.42	**40.76**
PO 5	55.56	6.13	3.59	**65.27**
Source: RPA (2024)				

In total, compliance costs for companies under PO 2 would be of about €37.5 billion, against €3 billion, €225 million and €2.9 billion under POs 3, 4 and 5, respectively. Under POs 2 and 3, more than three fourths of the compliance costs are due to the companies discontinuing. For PO 4, monitoring and administrative costs account for more than 95% of the total compliance costs.

All POs would positively impact businesses as they would allow for **cost savings** from reduced ill-health. The most significant benefit would be under PO 2, with cost savings estimated at €540,000, against €130,000, €10,000 and €120,000 under POs 3, 4 and 5, respectively.

(b) Impacts on competitiveness

POs 2 and 3 would have impacts on **cost and price competitiveness** with some businesses estimated to possibly discontinue, partly or totally, due to the high compliance costs. Certain sectors would be particularly affected by PO 2 which would result in the above-mentioned possible discontinuations. Among these sectors are coking plants (100% of the companies are expected to discontinue), welding of railroad tracks (44%), soil remediation (17%) and steel and iron foundries, ferroalloys (10%). Furthermore, PO 2 is expected to entail first year compliance costs (minus discontinuation costs) representing more than 10% of the gross operating surplus for 13 sectors[137]. Except for graphite and electrode manufacturers, these sectors are mainly composed of SMEs, which have less capacity to absorb additional costs. Therefore, it is likely that a share of the adjustment costs generated by PO 2 will be passed on to consumers.

Under PO 3, one sector is estimated to be particularly impacted with discontinuations, i.e. the coking plants sector with 45% of companies estimated to discontinue, which would have negative impacts on consumers both in terms of diversity of supply and prices. Furthermore, 6 sectors[138] should face first year compliance costs (minus discontinuation costs) representing more than 10% of the gross operating surplus. These sectors are mainly composed of SMEs, which are unlikely to absorb additional costs. Therefore, consumers could be impacted with a share of the costs being passed on to them. However, the shares of first year compliance costs compared to gross operating surplus are less significant than under PO 2. Therefore, the impact of PO 3 on consumers should also be less. No discontinuation is expected under option 4 and the compliance costs represent less than 10% of gross operating surplus. Therefore, the impact on consumers should be more limited, although an increase in prices cannot be excluded given the high share of SMEs.

With its transitional period, PO 5 should have less impact on cost and price competitiveness than PO 3 (which does not have transitional period). Indeed, businesses targeted by PO 5 will have the opportunity to better plan and finance the necessary investments, which might reduce the share of costs that would be passed on to consumers. Furthermore, the possible positive impact on the number of discontinuations (expected to decrease) for the coking plants sector would reduce pressure on cost and price competitiveness, and on the diversity of supply. Nevertheless, the impact on consumers cannot be excluded as compliance costs compared to gross operating surplus will remain high for some sectors, in particular graphite and carbon electrode manufacture, coking plants and other non-ferrous metallurgy. Furthermore, while the transitional measure is expected to

[137] (1) Wood preservation, (2) petroleum refineries, (3) manufacture of refractory products, (4) manufacture of bituminous products, (5) graphite and carbon electrode manufacturers, (6) steel and iron foundries, ferroalloys, (7) manufacture of aluminium, (8) other non-ferrous metallurgy, (9) casting of metals, (10) coal fired power plants, (11) soil remediation, (12) welding of train tracks, and (13) chimney sweeps.

[138] (1) coking plants, (2) manufacture of refractory products, (3) graphite and carbon electrode manufacturers, (4) steel and iron foundries, ferroalloys, (5) other non-ferrous metallurgy, and (5) coal fired power plants.

reduce discontinuations, it cannot be excluded that some companies would close down anyway, impacting negatively the diversity of supply and prices.

With regard to the impact on **international competitiveness**, certain non-EU competitors such as Canada, Japan, Norway, South Korea and Switzerland have binding limit values comparable to PO 4, or even below in some of them. Other competitors such as China, India, Australia, Turkey or Russia have no limit value for PAHs. Non-EU countries often have different compliance rules and methods to define exposure, which makes the comparison uncertain.

Since 99% of the companies with workers exposed to PAHs are small companies, they are more likely to operate at national scale and the possibility of relocation in or import from non-EU countries is limited. However, sectors such as steel and iron foundries, ferroalloys, aluminium manufacturers, other metallurgy, casting of metal and graphite and carbon electrode manufacturers already experience pressure from cheaper imports, particularly Asian countries[139]. An increase in operational costs resulting from compliance costs could lead to discussions about the possibility to relocate their activities outside the EU. It is particularly the case under PO 2, and to a lesser extent under PO 3. Under PO 5, businesses will have more time to plan their investments or find alternatives, which should reduce the impact on international competitiveness. Given the limited costs compared to gross operating surplus under PO 4, the impact on international competitiveness is considered as negligible.

Furthermore, the impact on coking plants resulting in possible discontinuations, in particular under PO 2 and to a lesser extent under PO 3, could also negatively impact downstream sectors (including coal tar distillation plants, and carbon and graphite electrode manufacturers) requiring coking plants' by-product coal tar for their production. Among the products requiring coal tar are batteries storing energy produced by wind turbines, semiconductors and electric vehicles. A more limited availability of these products would lead to greater dependence on countries outside the EU. With its 6-years transitional period applying among others to coking plants as provided by PO 5, businesses would have more time to plan their investments or find alternatives, which is likely to result in less discontinuations, and therefore lower impact on downstream users in terms of imports from outside Europe. Under PO 4, no discontinuation is expected, and there should therefore be no impact on downstream sectors.

The impact on **capacity to innovate** is closely linked to the level of compliance costs, which divert resources from other purposes, potentially including R&D. Under PO 2, compliance costs significantly outweigh the available R&D funding for most companies, with a few exceptions[140]. Although compliance costs would represent a small percentage of the R&D under PO 3, the impact on the capacity to innovate cannot be excluded, in particular for SMEs operating in the following sectors: coking plants (compliance costs represent about 160% of the R&D expenditures), soil remediation (155%), welding of railroad tracks (120-135%) and other non-ferrous metallurgy (50%). The impact of PO 4 on the capacity to innovate should be negligible given the low compliance costs. By having more time to plan and finance the necessary investments in additional RMMs, the impact on capacity to innovate under PO 5 could be lower that under PO 3. However, the compliance costs for the sectors identified above would remain high compared to turnover. Therefore, the impact on capacity to innovate for coking plants, soil remediations, welding of railroad tracks and other non-ferrous metallurgy sectors cannot be excluded.

[139] RPA (2024), op. cit., stakeholder consultation.
[140] Smokehouses, manufacture of bituminous products and waste incineration, for which costs as a percentage of R&D expenditures remain proportionally low.

(c) Impacts on the single market

11 Member States currently have no limit values for PAHs. Among those with an existing limit value, the levels vary greatly, ranging from 70 ng/m³ to 5000 ng/m³. Most of Member States with a limit value operate at levels around PO 4, except BG, DE, LV and NL. Therefore, POs 2, 3 and 5 are likely to have a positive impact on the functioning of the single market, by creating a more level playing field.

(d) Impacts on public authorities/Member States

About 438,000 firefighters are assumed to be exposed to airborne PAHs in the EU [141]. Firefighters are employed by public authorities, not private businesses. Public authorities may therefore have to bear compliance costs. The current exposure data indicates that all firefighters are exposed to levels below 70 ng/m³ . Therefore, it is assumed that no additional RMMs (**adjustment costs**) would be required under PO 4. As firefighters are not subject to the transitional period provided for by PO 5, the impact of the latter on public authorities is equivalent to PO 3 and will not be further discussed, except for the costs related to the preparatory work.

Whilst current exposure levels are expected to be lower than PO 3, 5% of the public authorities have levels close to it (69.62 ng/ m³)[142]. Therefore, it is expected that these public authorities will need to invest in alternative RMMs as a precaution, accounting for €62.5 million over 40 years, of which €16 million would be spent during the first year. Under PO 2, all public authorities are expected to invest in alternative RMMs as the exposure is higher than the limit value associate with this option. In total, these investments would represent about €5.9 billion (of which about €550 for the first year).

All POs would entail **monitoring costs**. These costs estimates vary depending on the number of Member States with existing limit values and their levels. The total monitoring costs would range from €240,000 to €870,000 over 40 years, depending on the PO, with PO 4 entailing the lowest costs. These monitoring costs are relatively low as public authorities would only undertake air monitoring on sample groups. The **administrative costs** for air monitoring would be proportionally low for the same reasons, with administrative costs ranging from € 50,000 and €180,000 over 40 years.

At all options, public authorities would save money through **reduced cases of ill-health cases**. With its low impact on workers' health, PO 4 would allow public authorities to save just €690,000 over 40 years, mainly due to the reduction of male infertility cases. POs 3 and 2 would result in higher avoided costs of approximatively €3.9 and €5.3 million, respectively. The difference between the two is explained by the higher number of lung cancer cases avoided under PO 2.

The 9 public authorities which currently have no limit value for PAHs would also benefit from all POs in terms of avoided costs linked to the process of setting a binding limit value for PAHs. Setting a limit value requires resources for carrying out the necessary analysis, including impact assessments. Under all POs, the **costs related to the preparatory work** would be borne at EU

[141] RPA (2024), op. cit., according to exposure data, team leaders, which stand at a distance from a fire, are the ones at risk of airborne exposure to PAH because they do not wear respiratory protective equipment. For this impact assessment, it was assumed that 10% of a total of 4,385,061 firefighters are team leaders. The rest of firefighters are supposed to wear self-contained breathing apparatus with an independent supply of oxygen and are therefore not considered to be exposed to airborne PAHs.
[142] RPA (2024), op. cit., section 7.4.1 of the PAHs report.

level, representing cost savings for public authorities of €900,000 in total. In addition, those public authorities with a higher existing national limit value than the values proposed in the different POs will also benefit from the analysis carried out at EU level. Those Member States will save between €0.7 (PO 4) and €0.9 million (PO 2).

Overall, the costs to public authorities are expected to significantly outweigh the benefits under PO 2. Under POs 3 and 5, the costs to public authorities would also outweigh the benefits, but to a lesser extent. Under PO 4, public authorities would save money over the reference period.

With regard to the impacts on specific Member States, based on the distribution of companies within Member States[143], at PO 2 the effects from closure of coking plants (100% discontinuation) may be most felt in Czechia (22% of plants), followed by Poland (19%), Romania (17%) and Greece and Spain (both 11%). A similar pattern should be observed at the 70 ng/m^3 with 45% closures.

A high level of discontinuations in coal tar plants (62% at PO 2 and 34% at PO 3) may be the most disruptive in Spain, followed by the remainder of Member States with plants: Belgium, Czechia, Denmark, Germany and Poland. The outputs from this sector however feed into many industries, therefore industries that are related to coal tar distillation plants will be negatively affected, regardless of the Member State in which the plants are located.

In casting of metals, up to 2% discontinuations are predicted at PO 2, which will affect Czechia and Italy the most.

The discontinuations in graphite and carbon electrode manufacturers at the PO 2 and PO 3 (44% and 16% discontinuations, respectively), may be felt mostly in France (25%), Poland and Germany (both 20%), Spain and Austria (both 10%).

Among those Member States identified above, Germany has an existing limit corresponding to PO 3. Therefore, the impact on businesses operating in Germany should be limited. All other Member States have a limit value higher even higher than PO 4 (see annex 6 for more details) or have no limit value (Italy and Belgium).

It also means that the expected reduction in discontinuation from the transitional value provided by PO 5 will also more benefit to the Member States identified above.

These impacts on specific Member States should be treated with caution as it also depends on the RMMs currently in place in each company. In the absence of such specific data, only the distribution of companies among Member States could be used.

(e) Impacts on digitalisation

By leading to discontinuations in key sectors contributing to the production of semiconductors (e.g.in particular other non-ferrous metallurgy[144] and graphite and carbon electrode manufacture[145]), PO 2 might hinder the digital transition of the EU, including the target under the

[143] The distribution of companies among Member States is based on Eurostat data or date provided by industry.
[144] Silicon metal, which is manufactured by businesses operating in other non-ferrous metallurgy sector, is used to make high purity silicon, which ultimately makes wafers.
[145] Speciality graphite and graphene are used in semiconductors.

Chips Act[146] to double the production share of semiconductors. 6.7% and 0.4% of businesses operating in other non-ferrous metallurgy and graphite and carbon electrode manufacture are estimated to be at risk of discontinuing, respectively. When only considering the share of companies using cobalt, it is about 44% of businesses that are at such a risk, for both sectors. In the absence of sufficient data, this impact could not be quantified.

PO 3 would also cause discontinuations in these two sectors, but on a lesser scale (8.8% and 16.2% of businesses using cobalt and operating in other non-ferrous metallurgy and graphite and carbon electrode manufacture, respectively). With its transitional value, PO 5 would mitigate this impact on digitalisation as businesses operating in both sectors would have more time to plan their investments and find alternative RMMs, which is expected to reduce the number of discontinuations.

PO 4 is not expected to result in impacts on digitalisation.

(f) Impacts on EU Strategic Autonomy

Among those sectors subject to international competitiveness, the structure of two sectors would be significantly impacted under PO 2: coking plants (100% of businesses expected to discontinue) and steel and iron foundries, ferroalloys (10%). This is likely to lead to greater dependence of the EU on its main foreign competitors, hampering its objective of strategic autonomy.

While the structure of the steel and iron foundries, ferroalloys market should not be significantly impacted under PO 3, 45% of coking plants are estimated to discontinue. Therefore, PO 3 would also have an impact on the EU's strategic autonomy as sectors dependent on coking plants production (e.g. coal tar) will be forced to increase their imports from outside the EU. The transitional period provided by in PO 5 is expected to result in less discontinuation, which should limit the impact of a limit value at the level of PO 3. However, the magnitude of this mitigation cannot be quantified.

As PO 4 is not expected to entail any discontinuation, the impact on the EU's strategic autonomy is likely to be zero.

6.2.3. *Environmental impacts*

(a) Direct impacts on environment

At all POs, businesses will need to invest in alternative RMMs. To limit the exposure to workers, these RMMs will need to better enclose the different processes, resulting in lower levels of PAH emissions in the air, and therefore positive impacts on the environment. This impact is all the more positive as some individual PAHs have been identified to have persistent, bio-accumulative and toxic chemicals properties, as well as very persistent and very bio-accumulative properties[147]. Although the impact could not be quantified, the number and level of enclosure of the alternative RMMs will be proportional to the strictness of the limit values.

[146] *OJ L 229, 18.9.2023, p. 1-53*
[147] RAC/SEAC (2022), Opinion on an Annex XV dossier proposing restrictions on PAHs in clay targets for shooting, available at: Revised restriction opinion template version 11/2015 v4 comments from ENV GROW RL SD SK SG (europa.eu)

(b) Indirect impacts on environment

The success of the Green Deal will depend among others on the availability of key essential products. The infrastructure needed to achieve climate neutrality by 2050 relies on metal products, such as steel, aluminium and silicon. These metals are essential for manufacturing solar panels, wind turbine blades, electric vehicles and other sustainable forms of transport, building energy efficient buildings, etc. Furthermore, some recycling of metals is dependent on carbon and graphite electrodes. A disruption in any sectors relevant for the above-mentioned products or metals in the EU would therefore compromise the success of the EU Green Deal.

PO 2 would entail an estimated high number of discontinuations in the following sectors: coking plants (100%) and steel and iron foundries, ferroalloys (10%). Furthermore, some sectors are composed of a few companies using cobalt for their production. If PO 2 would not significantly impact these sectors as a whole, it would significantly impact the share of businesses using cobalt: coal tar distillation (0.2% of the entire sector / 61.9% of businesses using cobalt for their production), other non-ferrous metallurgy (6.7% / 44%), graphite and carbon electrode manufacture (0.4% / 44%) and manufacture of aluminium (0.2% / 30%). All these discontinuations are expected to result in the disruption of essential products for the EU Green Deal.

PO 3 is also expected to result in discontinuations in the following key sectors: coking plants (45% of the entire sector / 45% of businesses using cobalt for their production), other non-ferrous metallurgy (1.3% / 8.8%), coal tar distillation (0.1% / 33.6%) and graphite and carbon electrode manufacture (0.15% / 16.2%). While the impact of PO 3 is less, the significant share of discontinuations in the coking plants sector could result in disruptions in essential supply chains, hindering the EU Green Deal's objectives.

The transitional value provided for by PO 5 would apply to all the above-mentioned sectors and is expected to reduce the number of possible discontinuations. Indeed, businesses would have more time to plan their investments or to find innovative RMMs that would allow for complying with the final limit value of PO 5 (which is equivalent to PO 3). Therefore, and although it is unquantifiable, the impact of PO 5 on the Green Deal should be limited.

As no discontinuation is expected under PO 4, the impact on the Green Deal should be zero.

6.3. 1,4-dioxane

Each BLV option was set in relation to the OELs based on a function derived in the RAC opinion[148] which establishes a correlation between both. As such, a worker exposed to levels below an OEL (e.g. 7.3 mg/m³) is assumed to be also compliant with the corresponding BLV (45 mg HEAA in urine/g Creatinine). Therefore, for each policy option, the BLV is not assumed to bring additional benefits and adjustment costs than those related to its corresponding OEL. Conversely, BLVs will result in additional monitoring costs as the procedure is different than for monitoring compliance with an OEL.

[148] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for 1,4-dioxane, available at: 686365df-9485-c2ac-b342-289ec306d188 (europa.eu)

6.3.1. Social impacts

(a) Impacts on workers' health

Only PO 2 would result in decreased health burden compared to the baseline. At this level, no worker would get ill following exposure to 1,4-dioxane. The monetised benefits resulting from the decreased health burden would account for up to €3.2 million over 40 years.

*Table 20: number of avoided cases of ill-health and monetised health benefits over 40 years (compared to the **baseline**)*

Endpoint	**PO 2** 7.3 mg/m³ & 45 mg HEAA in urine/g Creatinine	**PO3** 20 mg/m³ & 108 mg HEAA in urine/g Creatinine
Kidney effects	497 (out of **497**)	0
Liver effects	633 (out of **633**)	0
Local irritation in the nasal cavity	4,382 (out of **4,382**)	0
Monetised health benefits (€ million – M1 – M2)	€ 1.9 – € 3.2	€ 0 – € 0
Source: RPA (2024)		

(b) Impacts on employment

Under PO 2, 6 companies active in the following three sectors, with 140 workers in total, would discontinue (a) manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms, (b) manufacture of paints, varnishes, and similar coatings, printing ink and mastics, and (c) manufacture of other chemical products. The associated social costs resulting from discontinuances would account for €13 million.

No impact on employment is expected under PO 3.

6.3.2. Economic impacts

(a) Impacts on businesses, including SMEs

With regard to **adjustment costs**, PO 2 would result in the discontinuation of 5 small- and 1 medium-sized enterprises, active in the manufacturing of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms, manufacturing of paints, varnishes, and similar coatings, printing ink and mastics, and manufacturing of other chemical products. As shown in table 21, they represent a very small percentage of the enterprises with exposed workers. No discontinuation is expected under PO 3 as the evidence gathered indicates that existing RMMs are sufficiently effective to ensure compliance.

Table 21: number of discontinuations, including per company size and total discontinuation costs

	PO 2 7.3 mg/m³ & 45 mg HEAA in urine/g Creatinine	**PO3** 20 mg/m³ & 108 mg HEAA in urine/g Creatinine
Small companies	5 (out of 1,716)	0

Middle companies	1 (out of 63)	0
Large companies	0 (out of 26)	0
Total	**6 (out of 1,805)**	**0**
Total discontinuation costs (in € million)	€ 102.2	€ 0
Source: RPA (2024)		

The total costs in additional RMMs for those companies not discontinuing under PO 2 would be of €19.2 million over 40 years, mainly supported by businesses operating in the manufacturing of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms, manufacturing of paints, varnishes, and similar coatings, printing ink and mastics, and manufacturing of other chemical products[149].

According to estimates[150], companies would have to make investments of about €53 million in additional RMMs during the first year to comply with PO 2, in particular small- (€35 million) and medium-sized enterprises (€ 7.6 million). Recurrent costs for the same PO would account for -€34.2 million. This negative value is due to the lower recurrent costs linked with the new RMMs, compared to the baseline[151].

According to the evidence gathered, the current workers' exposure levels to 1,4-dioxane are already below PO 3. Therefore, no adjustment cost is expected under this option.

Some companies are expected to check that they are complying with PO 3 (e.g. by being at 10% or less of the OEL as foreseen in the UNE-EN 689 Standard on Workplace Atmospheres[152]). However, a more significant number of companies is expected to check compliance under PO 2 than PO 3.

Monitoring costs (both for OELs and BLVs[153]) for PO 2 would account for about €118.8 million over 40 years, of which 72% would be borne by larger companies. Under PO 3, businesses are expected to spend about €56.85 million to check compliance during the same period, of which about 67% would be at charge of large enterprises.

Table 22: total estimated monitoring costs in € million over 40 years by policy option and size of company

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (7.3 mg/m³ & 45 mg HEAA in urine/g Creatinine)	12.5	20	86	**118***
PO 3 (20 mg/m³ & 108 mg HEAA in urine/g Creatinine)	7.5	11	38	**56.5***
Source: RPA (2024)				

149 In particular those companies having an industrial use of 1,4-dioxane as a solvent and generation as by-product in the chemicals sector.
150 RPA (2024), op.cit., 1,4-dioxane report, section 7.2.8.
151 For instance, some sectors with existing reliance upon RMMs with high recurrent costs, such as RPE, would move to RMMs with lesser recurrent costs over the same period, such as closed systems.
152 Available at: UNE EN 689:2019+AC:2019 Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values (en-standard.eu)
153 The CMRD defines the health surveillance as the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work.

*Rounded

The **administrative costs** associated with the monitoring campaigns vary between the POs. Under PO 2, companies would need to spend over 40 years about €7,1 million for the organisation of the additional monitoring campaigns compared to the baseline, against €4 million under PO 3. Small-sized enterprises would bear about 70% of the total administrative costs related to the organisation of monitoring campaigns over 40 years.

Table 23: total estimated costs of administrative burden of additional monitoring by policy option and size of company over 40 years

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2	5	1.1	1	**7.1**
PO 3	2.95	0.6	0.45	**4**
Source: RPA (2024)				

In total, the compliance costs represent a small part of the turnover, or even negligible for PO 3. Only under PO 2 would they represent up to 0.47% for small enterprises operating in the chemical sector and which has an industrial use of 1,4-dioxane as a solvent and generate it as a by-product,.

Only PO 2 would have a positive impact on reducing the number of ill-health cases and would therefore allow businesses to achieve **cost savings** of €1.3 million over 40 years. These estimates only relate to local irritation in the nasal cavity cases, and are therefore likely to be underestimated.

(b) Impacts on competitiveness

POs 2 would have a limited impact on **cost and price competitiveness** with six businesses obliged to discontinue, partly or totally, due to the high compliance costs. However, such discontinuations would not have any impacts on the relevant sectors[154], directly impacting 0.0003% of the companies operating in these sectors (6% of the companies with exposed workers to 1,4-dioxane). No discontinuation is expected under option 3. Therefore, no impact on consumers, both in terms of price or diversity of supply, is expected, including at the most stringent PO.

With regard to the impact on **international competitiveness**, the additional costs per company as a percentage of turnover are relatively limited. Furthermore, most of the companies impacted by the different POs are SMEs, which are usually operating at national scale and are therefore not subject to relocation. Therefore, no impact on international competitiveness is expected, even under PO 2.

Even at the most stringent PO 2, the share of the compliance costs compared to average annual R&D expenditure would not exceed 0.0025%[155]. Therefore, no impact on **capacity to innovate** under all POs is expected.

[154] Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms, manufacture of paints, varnishes, and similar coatings, printing ink and mastics, and manufacture of other chemical products.
[155] RPA (2024), op. cit., 1,4-dioxane report, table 8-12 based on Eurostat data.

(c) Impacts on the single market

All Member States currently have a binding national limit value above PO 2 or no binding OEL (FI, IE and PT have an indicative OEL and the other Member States have a binding OEL). Therefore, the latter should reduce the regulatory divergences between Member States, resulting in a more level playing field in the internal market. The impact would be similar under PO 3 as 26 Member States would need to revise a more stringent or set a binding limit value for 1,4-dioxane.

Despite the establishment of a more level playing field, the impact on businesses would be limited as a significant share of them are SMEs. Therefore, it is expected that they rather operate at national scale than operating in several Member States.

(d) Impacts on public authorities/Member States

Under PO 2, all Member States would need to adapt their existing OELs, resulting in transposition costs of €810,000. The **transposition costs** related to OELs for PO 3 would be of €750,000, as a lower number of Member States would need to adapt their existing limit values (25[156]). The transposition costs are likely to be slightly underestimated as the analysis does not take into account the transposition costs for BLVs.

Avoided costs of ill health for public authorities are expected only under PO 2 as PO 3 would not result in a reduced number of ill-health cases. Public authorities are expected to save €2 million over 40 years.

Furthermore, Member States are also expected to **save money related to the process of revising a national limit value**, as the work will be done at the EU level. The costs saved related to OELs would amount up to between €1.4 (PO 2) and €1.5 million (PO 3). These costs saved are expected to be even higher if we also take into account BLVs.

The total benefits for public authorities would outweigh costs under any POs.

Under PO 2, all Member States would need to change their legislation, which would affect all companies producing 1,4-dioxane in these countries, especially businesses in Italy, Germany, Spain, France and Greece as they share more than a half of all companies in the EU with workers exposed to 1,4-dioxane. There are no companies in Cyprus with workers exposed to 1,4-dioxane.

(e) Impacts on digitalisation

No PO is expected to have an impact on digitalisation.

6.3.3. Environmental impacts

(a) Direct impacts on environment

The alternatives RMMs that businesses are expected to put in place under PO 2 are likely to have a positive impact on the environment due to the increased enclosure of processes (e.g. closed system and partially closed system). This impact could not be quantified. No direct impact under PO 3.

[156] All Member States except LV and NL.

(b) Indirect impacts on environment

No impact on the green transition is expected under PO 3. PO 2 would contribute to the zero pollution ambition for a toxic free environment by better enclosing the different processes, as described in the section related to the direct impacts on environment.

6.4. Welding fumes

6.4.1. Social impacts

(a) Impacts on workers' health

As mentioned in introduction of section 6, PO 2 (inclusion of welding fumes in Annex I) would result in an additional 1% reduction in excess risk[157] compared to the current trend[158] for five years. This additional 5-years reduction in excess risk, which is due to the additional RMMs in place, would result in more than 1,600 lung cancer cases avoided over 40 years compared to the baseline, representing between €997.5 (method 1) and €510 million (method 2) health benefits (see table 24).

*Table 24: number of avoided cases of ill-health and monetised health benefits over 40 years (compared to the **baseline**)*

Endpoint	PO 2 Inclusion of welding fumes in Annex I
Lung cancer	1,618 (out of **28,821**)
Monetised health benefits (€ million – M1 – M2)	€ 997.5 – € 510
Source: RPA (2024)	

(b) Impacts on employment

In the absence of data on current exposure levels to welding fumes, neither possible discontinuations nor impacts on employment could be quantified. However, as welding processes are often the only technically feasible option for joining metals, the impact on discontinuation, and therefore on employment, is expected to be limited or negligible.

6.4.2. Economic impacts

(a) Impacts on businesses, including SMEs

PO 2 is expected to entail **adjustment costs** for businesses between €67 (method 2[159]) and €156 million (method 1[160]) over 40 years, compared to the baseline. According to estimates[161], businesses operating in specialised construction activities would bear the highest share (36%) of

[157] RPA (2024), op. cit., this 1% reduction in excess risk was validated by feedback from key stakeholders interviewed as part of the external study supporting this impact assessment.
[158] -1%, as discussed in section 5.1.5 of this impact assessment.
[159] Based on the assumption that expenditure on fumes extraction and personal protection is 1% higher than under the baseline for each of the years to year 40.
[160] Based on the assumption that 1% of the total workers exposed to welding fumes would move from none or poor RMMs to adequate RMMs as a result of policy option 2. This 1% was validated during interviews carried out as part of the external study with six key stakeholders.
[161] RPA (2024), op. cit., section 6.2.2.7.

these adjustment costs, followed by construction in buildings (about 19%) and fabricated metal products sectors (12%). Due to insufficient data, the adjustment costs could not be distributed between one-off and recurrent costs or by company size, and possible discontinuations could not be quantified. However, as welding processes are often the only technically feasible option for joining metals, the impact on discontinuation, is expected to be limited or negligible.

However, the evidence gathered indicates that workers' protection is often weaker in SMEs than in larger companies[162] and the levels of understanding and awareness may be lower within SMEs[163]. Therefore, the costs for SMEs arising with PO 2 could be higher than for larger companies as they would need to invest in additional RMMs while having less financial resources to devote. The greatest proportion of SMEs are in the following sectors: specialised construction activities, construction of buildings, fabricated metal products, repair of motor vehicles and motorcycles, and repair and installation of machinery and equipment.

Since PO 2 is limited to improving legal clarity, no **monitoring costs** (and consequently no **administrative costs**) are expected.

With its positive impact on workers' health, PO 2 would allow businesses to achieve **cost savings** of about €4.7 million over 40 years.

(b) Impacts on competitiveness

Given the negligible compliance costs for PO2, including compared to the turnover, no impact on competitiveness is expected. Consequently, and given the expected minimal impacts on discontinuation, no impact on the open strategic autonomy is expected.

As more than 99% of businesses undertaking welding activities are SMEs, it is likely that the latter will face more difficulties to fully absorb the adjustment costs resulting from PO 2. Consequently, some of them could pass on a part of these adjustment costs to consumers directly (e.g. in the repair of motor vehicles and motorcycles sector) or indirectly (e.g. specialised construction activities and construction of buildings). However, estimates of adjustment cost remain very limited, reducing the likelihood of price increases. Therefore, the impact on **cost and price competitiveness** is considered very limited.

With regard to the impact on **international competitiveness**, some countries[164] already regulate workers' exposure to welding fumes, including by means of limit values. Therefore, PO 2 is not expected to weaken the position of EU-based companies vis-à-vis these countries, even for sectors with a high competition coming from Asia (e.g. metal product manufacturing and automotive manufacturing industry). Furthermore, since welding is often undertaken on site (e.g. welding activities for construction, civil engineering, and installation and repair of equipment across sectors), these activities are not impacted by competition coming from non-EU countries. Therefore, the impact of PO 2 on the international competitiveness should be negligible.

According to the evidence gathered[165], larger businesses make significant investment in R&D, in particular those operating in the automotive manufacturing industry and the manufacturing of

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[162] RPA (2024), op. cit., interviews with stakeholders.
[163] RPA (2024), op. cit., views from a national stakeholder.
[164] Australia, Canada (Quebec), China, India, Norway and South Korea. Japan has also set an OEL for manganese as an indicator of welding fumes.
[165] RPA (2024), op. cit. welding fumes report, table 6-33.

machinery and equipment. Conversely, SMEs active in some sectors (i.e. waste collection, treatment & disposal, materials recovery, and manufacture of furniture) have much lower R&D expenditure. In the absence of data on which sector would be more impacted by PO 2, the impact on **capacity to innovate** by sector and company size could not be quantified. However, the total adjustment costs remain limited compared to the total investments in R&D, and the impact on capacity to innovate should therefore be negligible.

(c) Impacts on public authorities/Member States

As an entry in Annex I of the CMRD is less common that the establishment or revision of a limit value, it was assumed that the **transposition costs** would be higher[166] for those with no current entry. According to the evidence gathered[167], 5 Member States have currently defined welding fumes as process-generated substances or the equivalent to Annex I process (DE, DK, FI, LT and SK). For these Member States, the transposition costs are assumed to be lower (€50,000 per Member States). In the absence of national entry in Annex I of the CMRD for welding fumes, the other Member States would bear the same transposition costs (€ 100,000 per Member State) under PO 2. In total, the transposition costs would account for €2,450,000.

The reduction of the number of lung cancer cases resulting from PO 2 would allow public authorities to avoid costs (e.g. **treatment costs**) for about €16.5 million. The data available does not allow for an analysis by Member State.

Overall, the benefits for public authorities would be six times higher than the costs.

The evidence gathered[168] did not provide an identification of the level of compliance with the CMRD in individual Member States. It however indicated that workers in Northern and Western Europe are expected to be better protected from welding fumes than in Southern and Eastern Europe[169]. Furthermore, 13 Member States have currently a limit value for welding fumes: AT, BE, CY, CZ, DK, ES, FR, DE, IE, LV, LT, NL, and SK.

The risk of worker exposure to CMRs is higher for sectors that weld high alloy steel (stainless steel) and therefore countries where those sectors are more dominant might be at higher risk. There is higher risk of worker exposure to CMRs in Germany due to there being more high alloy metal fabrication undertaken there than in other countries. However, worker protection is generally good in Germany, especially for professional welders so this risk is probably well mitigated.

No detailed analysis of direct impacts on Member States can be derived from this assessment.

(d) Impacts on digitalisation

Among the sectors with exposed workers to welding fumes is the manufacture of computer, electronic and optical products, a key sector for the digital transition. This sector is unlikely to be impacted by PO 2 as businesses are characterised by a high degree of automation. Therefore, the

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[166] For the purpose of the impact assessment, the transposition costs related to the inclusion of welding fumes would account for €100,000, which is two times more expensive than the transposition costs related to the establishment of a new OEL.
[167] RPA (2024), op. cit.
[168] RPA (2024), op. cit.
[169] RPA (2024), op. cit., stakeholders consultation

workers' exposure is expected to be very low. Consequently, PO 2 should have no impact on digitalisation.

6.4.3. Environmental impacts

(a) Direct impacts on environment

PO 2 would result in the installation of additional ventilation systems compared to the baseline. As these systems are often equipped with particle filters, the impact on the quantity of welding fumes released into the environment should be negligible, as well as the direct impact on environment.

(b) Indirect impacts on environment

Potential releases of welding fumes via additional ventilation systems may result in increased emissions of heavy metals into the environment. Theoretically, these heavy metals could build up in drinking water and bioaccumulate in food chains, negatively impacting some objectives of the EU green deal (e.g. designing a fair, healthy and environmentally-friendly food system, preserving and restoring ecosystems and biodiversity and zero pollution ambition for a tox-free environment). However, and as described above, the direct impact on the environment is deemed to be negligible thanks to the use of particle filters. Therefore, the impact on the EU Green Deal is also considered as negligible.

7. HOW DO THE OPTIONS COMPARE?

Having regard to the assessment of impacts of the POs described in section 6, the options are compared per substance, based on the criteria of effectiveness, efficiency and coherence. The main objective is to balance health considerations against economic impacts, by identifying preferred POs that are economically and technically feasible, effectively protect a maximum number of workers and are coherent with the relevant key objectives of the EU. For the purpose of comparing the POs, some indicators have been identified for each criteria.

With regard to the effectiveness, the options are compared from the perspective of the prevention of deaths and other adverse health effects, their contribution towards a better level playing field through more harmonised rules, and their consistency with the recommendations of the ACSH. Regarding the last indicator, it is assumed that the PO unanimously recommended by the ACSH will ensure effective implementation on the ground, as both employers and workers support it. In particular, POs below the limit values recommended by the ACSH might not be fully implemented by businesses as they could face economic or technical obstacles and would therefore not be considered as proportionate by governments, workers and businesses. Therefore, the closer the PO is to the ACSH opinion, the greater the positive impact on its effectiveness.

With regard to the efficiency, the options are compared on the basis of their costs/benefits ratio. However, although an option has not the best costs/benefits ratio, it does not automatically mean that the resulting costs for businesses will be disproportionate. For that reason, other indicators such as the costs compared to turnover and the number of discontinuation and job losses are taken into account. Since the evidence gathered for welding fumes does not allow for estimating the costs compared to turnover and the possible discontinuations and job losses, the following criteria were taken into consideration: costs/benefits ratio for businesses only, and costs per company.

With regard to coherence, the options are compared on the basis of their contribution to Europe's Beating Cancer Plan, whose key objective is cancer prevention. Furthermore, the different options are also compared based on their possible impact on some key objectives of the EU, such as the green transition, the digital transition and the objective of open strategic autonomy.

Co-dependencies between scores of some variables from different criteria may exist, in particular between the number of cancer and non-cancer cases and the coherence with Europe's Beating Cancer Plan. The higher the number of health-related cases is avoided, the greater the coherence with this Plan. However, this co-dependency is not expected to affect the choice of the preferred option.

Based on the above considerations, POs are scored from "0" to "+++"/"---" depending on the direction of the impact. "+"/"-" represents a small positive/negative effect and "+++"/"---" a significant positive/negative effect compared to the baseline. 0 means that the option would constitute a negligible deviation from the baseline scenario. The baseline scenario is rated 0. A "+"/"-" is in parenthesis means that it is between 0 and "+"/"-". Based on this assessment, a preferred option is identified for all policy areas and then described in Section 8.

7.1. Cobalt and its inorganic compounds

Effectiveness: PO 2 would ensure the most effective protection of workers health, by preventing about 95% (71 out of 76) of cancer cases and 100% of non-cancer cases (18,517 out of 18,517), which constitutes a significant positive impact compared to the baseline. PO 3 would ensure a positive impact on health protection by preventing about 65% of cancer cases and 90% of non-cancer cases. Although to a lesser extent, POs 4, 5 and 6 would ensure a certain level of protection of workers' health, (POs 4 and 6: prevention of 30 % of cancer cases and 55% of non-cancer cases / PO 5: prevention of 16% of cancer cases and 17% of non-cancer cases).

Harmonised limit values at EU level would contribute to a better level playing field within the single market. Currently, all Member States would be required to adapt their limit values under any POs. Therefore, all POs would have a significant positive impact on the level playing field.

In its opinion, the ACSH recommended PO 6 (corresponding to PO 4 with a transitional period of 6 years at the level of PO 5). Therefore, it is expected that PO 6 will ensure the best implementation on the ground. Although to a lesser extent, PO 4 should also be correctly implemented by a high share of businesses as they support this option, subject to a transitional period. POs 2, 3 and 5 are not supported by either employers or workers. With this strong opposition, it is expected that their implementation on the ground will not be as effective as for POs 6 and 4, which might undermine the number of expected avoided cancer cases.

Efficiency: POs 2 and 3 would result in higher (PO 3), or even significantly higher (PO 2) costs than benefits, with a C/B ratio of up to 68 and 15, respectively. Costs resulting from POs 4/6 and PO 5 would also outweigh benefits, but in less significant proportions, with C/B ratios of 8 and 6, respectively.

For all POs, most of the costs would be borne by businesses. Under PO 2, the costs in additional RMMs compared to turnover may represent a significant share for businesses operating in some sectors and result in significant negative impacts compared to the baseline. This is particularly the case for SMEs with costs representing up to 3% of their turnover, against up to 0.25% for large companies. Under PO 3, small companies would have to invest in additional RMMs representing up to 1% of their turnover (against up to 0.25% and less than 0.1% for medium and large companies, respectively), resulting in negative impacts for those small companies, in particular those operating in the manufacture of other porcelain and ceramic products. Under POs 4 and 5, the investments in additional RMMs should remain limited for all businesses in view of their turnover, even for small companies (0.4% and 0.2%, respectively). With its transitional period, PO 6 would allow more time for businesses to find and invest in RMMs that do currently not exist to comply with the final limit value. This should result in higher costs in terms of additional RMMs than under PO 4. However, these costs in additional RMMs are also expected to remain much lower than under PO 3 and should therefore be below 1%, which can be considered as limited compared to the baseline.

With 1,086 companies, (1,056 SMEs) expected to discontinue, representing about 26,000 job losses PO 2 would lead to significant negative impacts compared to the baseline. As a result of PO 3 and PO 4, 142 and 57 businesses (mainly SMEs: 139 and 56) are expected to discontinue, leading to about 2,800 and 1,124 job losses. The impact of both POs 3 and 4 compared to the baseline is considered as negative. PO 5 would result in much less discontinuations (10, all SMEs) and job losses (77) than the previous options. In view of the total number of businesses with exposed workers, the negative impact is limited. Finally, PO 6 should allow for less discontinuations than PO 4 as the transitional period recommended by the ACSH, including businesses, is considered as appropriate to allow businesses to proceed with the necessary investments. Therefore, the negative impact should also be limited.

57 businesses (of which 56 SMEs) would still discontinue under PO 4, against 10 enterprises under PO 5 (all SMEs). These discontinuations would result in 1,124 and 77 job losses, respectively. Small companies would need to dedicate on average up to 0.4% and 0.2% of their turnover to comply with PO 4 and PO 5, respectively, which is expected to be bearable. Given the higher numbers of discontinuations and job losses for PO 4, it is considered as less efficient than PO 5.

Coherence: By preventing most of the occupational cancer cases related to cobalt and its inorganic compounds, PO 2 would significantly contribute to Europe’s Beating Cancer Plan. PO 3 would also positively contribute to the objective of this plan, although to a lesser extent. Finally, PO 4/6 and PO 5 would allow to prevent about 30% and 16% of the estimated occupational cancer cases related to cobalt and its inorganic compounds, which represent a notable or limited impact compared to the baseline, respectively.

PO 2 is expected to have significant negative impacts on the EU Green Deal, in particular on the objectives to mobilise industry for a clean and circular economy, to accelerate the shift to sustainable and smart mobility and to supply clean, affordable and secure energy. Although to a lesser extent, PO 3 is also expected to negatively impact the capacity of the Green Deal to deliver on some of its objectives. None of the other three POs is expected to have a negative impact on the EU Green Deal. None of the POs should have an impact on the digital transition.

When comparing POs against their coherence with EU strategic framework, PO 2 appear to be the less consistent compared to the baseline. A significant share of businesses operating in the metal recovery sector would indeed discontinue. Furthermore, the investments in additional RMMs would also represent a high cost. These two effects combined are expected to significantly impact the strategic autonomy of the EU with regard to cobalt. Under the other POs, the impact should be very limited (PO 3) or even negligible (POs 4, 5 and 6).

There is no expected impact on digitalisation, no matter the PO.

Preferred option: Based on the above analysis, PO 6 is the most effective and coherent (together with PO 4) option. Although it is less efficient than the baseline scenario, the latter would not achieve the specific objectives described in section 4, in particular better protection of workers through the adoption by employers of appropriate RMMs and improving the level playing field. Although POs 2 and 3 would lead to a higher number of cancer and non-cancer cases avoided, they are also considered as unproportionate, in particular by businesses. Furthermore, PO 6 is more slightly efficient than PO 4 as the number of discontinautions and job losses is expected to be lower due to the transitional period giving more time to businesses to plan their investments. Therefore, PO 6 represents the best balance between all criteria, is considered proportionate despite higher costs than benefits, and is therefore the preferred option for cobalt and its inorganic compounds.

Table 25 – Comparative scoring of the policy options for cobalt and its inorganic compounds and identification of the ***preferred option***

	PO 2	PO 3	PO 4	PO 5	PO 6
Effectiveness					
Number of cancer and non-cancer cases avoided	+++	++	+(+)	+	+(+)
Contribution towards a better level playing field	+++	+++	+++	+++	+++
Consistency with the recommendation of the ACSH	---	--	++	--	+++
Total effectiveness	**+**	**+**	**++**	***(+)***	***++(+)***
Efficiency					
Costs/benefits ratio (C/B ratio)	---	--	-	-	-
Costs in RMMs compared to turnover	---	--	-	-	-(-)
Number of discontinuations and job losses	---	--	--	-	-
Total efficiency	**---**	**--**	***-(-)***	**-**	**-**
Coherence					
Coherence with Europe's Beating Cancer Plan	+++	++	+(+)	+	+(+)
Coherence with other key EU policies (EU Green Deal, EU strategic autonomy, digital transition)	---	--	0	0	0
Total coherence	***0***	***0***	**+**	***(+)***	**+**

7.2. PAHs

Effectiveness: POs 2, 3 and 5 would be equally effective in protecting workers from non-cancer diseases, preventing all cases of developmental toxicity and male infertility. However, PO 2 would ensure a higher protection of workers from lung cancer, preventing about 88% of cases (141 out of 160), against 22% of cases under POs 3 and 5. Therefore, PO 2 is expected to result in significant positive impacts compared to the baseline and POs 3 and 5 in positive impacts. PO 4 would be far less effective than the other POs, preventing 1% and 20% of cancer and non-cancer cases, respectively. Therefore, its positive impact is considered as small compared to the baseline.

POs 2, 3 and 5 would ensure the same limit value between Member States, contributing to the same extent to a more level playing field. PO 4 would also positively contribute, but to a lesser extent since some Member States already have lower national limit values in place.

With PO 2, there is a risk that some businesses will not correctly implement the limit value on the ground, as they alerted during the consultation procedure on the technical and socioeconomic difficulties they would face. This would be particularly the case in companies where workers are still exposed to high levels of PAHs. This would therefore hamper the effectiveness of the PO. PO 3 is more consistent with the ACSH recommendation than POs 2 and 4, as it was recommended by the three interest groups, including workers and businesses. However, the lack of transitional value for the 9 sectors as recommended by the ACSH could also negatively impact the effectiveness of its implementation on the ground, as for PO 4 which is not supported by workers. PO 5 is fully consistent with the recommendation of the ACSH. Therefore, it is likely that all relevant stakeholders, in particular workers and businesses, will correctly comply with its associated limit value on the ground as they fully support this option.

Efficiency: PO 2 would entail highly significant costs compared to the benefits, with a C/B ratio of between 232 and 675[170]. Compared to the baseline scenario, the negative impact of PO 2 in terms of C/B ratio would therefore be significant. The C/B ratio for POs 3/5, and PO 4 would range between 31 -154 and 14 – 115, respectively. It is therefore much less than PO 2 but still represent a high negative impact compared to the baseline.

With PO 2, 86% of the total costs (€43.5 billion) would be borne by businesses, and 13.5% by public authorities. This would represent €90,000 per company and €7.75 billion per public authority. Some SMEs would need to dedicate up to 6.3% of their turnover to comply with PO 2, which is very significant compared to the baseline. Under PO 3, businesses would bear about 98% of the total costs (€3.09 billion), and public authorities 2%. On average, a company would spend €10,000 over 40 years, against €80,000 for public authorities. Compared to PO 2, the costs per entity resulting from PO 3 are much more bearable. SMEs operating in the coking sector and coal tar distillation sector, would have to dedicate up to between 2.5% and 2.9% of their turnover for complying with PO 3. Costs compared to turnover for companies operating in other sectors are expected to be much more limited (in most cases, below 0.1%). The costs to businesses incurred by PO 5 are expected to be slightly lower (€2.89 billion) than for PO 3 due to the transitional period for businesses operating in some sectors. By extension, the costs compared to turnover are also expected to be slightly lower for those companies subject to the transitional period. Under PO 4, the costs for businesses, including SMEs, would not exceed 0.01% of their turnover, which is negligible compared to the baseline.

As a result of PO 2, 3,462 companies (of which 3,358 SMEs) are expected to discontinue, resulting in 47,758 job losses, which represent a significant negative impact in comparison to the baseline. For its part, PO 3 would result in 146 discontinuations, mainly SMEs (135), leading to 2,725 job losses. Compared to PO 2, the negative impact of PO 3 on the number of discontinuations is therefore much less significant. With its transitional option for 9 sectors, PO 5 is expected to further reduce the negative impact on discontinuations compared to PO 3. Indeed, the transitional period provided by PO 5 has been considered as appropriate by the ACSH, including employers' representatives, to mitigate the negative impacts incurred by PO 3. However, in the absence of any quantified impacts, a negative scoring was kept. No discontinuation is expected under PO 4.

Coherence: PO 2 would significantly contribute to Europe's Beating Cancer Plan when it comes to the prevention of occupational cancer occurring from exposure to PAHs as it would allow to prevent almost 90% of cancer cases. POs 3 and 5 would also positively contribute, but to a lesser extent, by preventing 20% of the total cases estimated to occur over the next 40 years. The contribution of PO 4 to Europe's Beating Cancer Plan is more anecdotal as only 1% of cancer cases would be avoided.

As described in section 6, PO 2 would result in a high number of discontinuations in key sectors for the EU Green Deal. These discontinuations are expected to result in the disruption of essential products for the EU Green Deal such as steel, aluminium and silicon and in hampering the objective of circular economy. Consequently, the impact of PO 2 on the EU Green Deal is expected

[170] Depending on the methodology used to assess benefits.

to be negative. PO 3 would also negatively impact some sectors, in particular coking plants. While the impact of PO 3 is less, the significant share of discontinuations in the coking plants sector could result in disruptions in essential supply chains, hindering the EU Green Deal's objectives. The transitional period provided by PO 5 would apply to those sectors considered as key in the EU Green Deal. Consequently, the number of expected discontinuations is likely to be lower than under PO 3 as businesses would have more time to proceed with the necessary investments and adapt. As no discontinuation is expected under PO 4, the impact on the Green Deal should be zero.

By leading to a high number of discontinuations in some key sectors for the production of semiconductors, PO 2 is expected to have a negative impact on the digital transition, potentially hindering the objective of doubling the production of semiconductors as targeted by the Chips Act. PO 3 could also negatively impact this objective as 8.8% and 16.2% of businesses using cobalt and operating respectively in other non-ferrous metallurgy and graphite and carbon electrode manufacture are expected to discontinue. With its transitional value, PO 5 would mitigate this impact on the Chips Act as businesses operating in both sectors by reducing the number of discontinuations. PO 4 is not expected to result in impacts on digitalisation.

Furthermore, PO 2 is also expected to hamper the EU's objective to progress towards its strategic autonomy. Indeed, it should significantly impact the structure of the following two sectors which are subject to international competitiveness: coking plants and steel and iron foundries. Therefore, the EU would be more dependent to its main foreign competitors, hampering its objective of strategic autonomy. To a lesser extent, PO 3 should also impact the structure of the steel and iron foundries, ferroalloys market. Consequently, sectors dependent on coking plants production will be forced to increase their imports from outside the EU. The transitional period provided by in PO 5 is expected to result in less discontinuation, which should limit the impact of a limit value at the level of PO 3. However, the magnitude of this mitigation cannot be quantified. Therefore, table 26 below include a negative scoring for the impact of PO 5 on other key EU policies, even if this impact could be lower. As PO 4 is not expected to entail any discontinuation, the impact on the EU's Open strategic autonomy is likely to be zero.

Preferred option: PO 5 is the more effective option (together with PO 3) and is also the most coherent as it contributes to Europe's Beating Cancer Plan while limiting the impacts on other EU policies. PO 5 (together with PO 4) is more efficient than the other options except the baseline scenario. Despite that costs arising from PO 5 outweigh benefits, it allows (unlike the baseline scenario) to achieve the specific objectives laid down in section 4, in particular better protection of workers through the adoption by employers of appropriate RMMs and improving the level playing field. Its consistency with the ACSH recommendation indicates that businesses are inclined to favour and implement this option, despite the costs it will generate. As a result, PO 5 constitutes the best balance between all criteria and is considered as proportionate despite that its C/B ratio is higher than 1.

Table 26 – Comparative scoring of the policy options for PAHs and identification of the ***preferred option***

	PO 2	PO 3	PO 4	PO 5
Effectiveness				
Number of cancer and non-cancer cases avoided	+++	++	+	++
Contribution towards a better level playing field	+++	+++	++	+++
Consistency with the recommendation of the ACSH	---	++	--	+++
Total effectiveness	+	++(+)	(+)	++(+)

Efficiency				
Costs/benefits ratio (C/B ratio)	---	--(-)	--	--(-)
Costs compared to turnover	---	--	-(-)	0
Number of discontinuations and job losses	---	--	0	-
Total efficiency	---	--	-	-
Coherence				
Coherence with Europe's Beating Cancer Plan	+++	+(+)	0	+(+)
Coherence with other key EU policies (EU Green Deal, EU strategic autonomy, digital transition)	---	--	0	-
Total coherence	***0***	***(-)***	***0***	***(+)***

7.3. 1,4-dioxane

Effectiveness: PO 2 would have a significant positive health impact as it would allow to prevent all ill-health cases (497 kidney effects cases, 633 liver effects cases and 4,382 cases of local irritation in the nasal cavity). Conversely, the protection of workers' health is not expected to get improved compared to the baseline under PO 3 and is therefore equivalent to the baseline.

By ensuring the same limit value within all Member States, PO 2 would ensure the highest positive impact on the level playing field. PO 3 would also result in equivalent limit values across the EU, which should theoretically contribute to a better level playing field. However, as all workers are already exposed to levels below PO 3, the latter would not result in additional investments in RMMs. Therefore, the real impact of PO 3 on the level playing field is considered as zero.

PO 2 is fully consistent with the recommendations made by the ACSH in its opinion. Therefore, it is expected that businesses and workers will ensure a full implementation of these rules through investments in relevant RMMs. PO 3 is not consistent with the ACSH opinion. This could negatively impact its implementation on the ground. However, as PO 3 is not expected to reduce the number of ill-health cases, a lack of implementation will not affect its efficiency. Therefore, it is considered that PO 3 is equivalent to the baseline when comparing against the criterion of consistency with the ACSH opinion.

Efficiency: the C/B ratio of PO 2 would be between 40 and 53, with total costs amounting to €257 million. Compared to the baseline, PO 2 is therefore expected to have a significant negative impact. The C/B ratio of POs 3 and 4 could not be calculated in the absence of quantified benefits.

On average, PO 2 would cost €137,000 by company (up to 0.47% of annual turnover). Therefore, its negative impact in comparison to the baseline is limited. PO 3 is expected to entail monitoring and administrative costs for businesses, amounting in total to €60.5 million. Consequently, PO 3 would represent an average cost per company over 40 years of €34,000. These costs are therefore very limited compared to the turnover (less than 0.1%).

As a result of PO 2, 6 out of the 1,805 businesses with exposed workers to 1,4-dioxane would discontinue, of which 5 are small- and 1 medium-sized enterprises. In total, 140 workers would lose their jobs due to these discontinuations. Although limited, the impact compared to the baseline is still negative. No discontinuation is expected under PO 3.

Coherence: Neither option will result in less cancer cases. Therefore, the coherence with Europe's Beating Cancer Plan is unchanged compared to the baseline. PO 2 is expected to be coherent with the EU Green Deal due to the increased enclosed of processes, which would contribute to the zero pollution ambition for a toxic free environment. Although unquantifiable, this impact is expected to be very limited compared to the baseline. No additional impact on the EU Green Deal, the EU Open Strategic Autonomy or the digital transitions is expected under PO 2 and PO 3.

Preferred option: PO 2 is the only option which would achieve the specific objectives described in section 4, in particular better protection of workers through the adoption by employers of appropriate RMMs and improving the level playing field. Although in a limited extent, it would also contribute to the EU Green Deal by decreasing the emissions of 1,4-dioxane in the environment. Although PO 2 is less efficient than the baseline scenario, its greater effectiveness and the support of governments, workers and employers' representatives within the ACSH justify its costs. Therefore, PO 2 is the preferred option.

Table 27 – Comparative scoring of the policy options for 1,4-dioxane and identification of the ***preferred option***

	PO 2	PO 3
Effectiveness		
Number of cancer and non-cancer cases avoided	+++	0
Contribution towards a better level playing field	+++	0
Consistency with the recommendation of the ACSH	+++	0
Total effectiveness	+++	***0***
Efficiency		
Costs/benefits ratio (C/B ratio)	---	NA
Costs compared to turnover	-	(-)
Number of discontinuations and job losses	-	0
Total efficiency	***-(-)***	***(-)***
Coherence		
Coherence with Europe's Beating Cancer Plan	0	0
Coherence with other key EU policies (EU Green Deal, EU strategic autonomy, digital transition)	(+)	0
Total coherence	***(+)***	***0***

7.4. Welding fumes

Effectiveness: PO 2, which would require additional investments in RMMs, would result in a decrease of about 5% of the total number of estimated lung cancer cases due to exposure to welding fumes. Despite it would be limited to avoid 5% of the cancer cases, it represents about 1,350 lung cancer cases, which can be considered as positive compared to the baseline.

Currently, only 5 Member States have included welding fumes in the scope of the CMRD. Consequently, PO 2 is expected to contribute towards a better level playing field for businesses by ensuring the same legal clarity about the dangerousness of welding fumes and its inclusion in the scope of the CMRD in all Member States.

In its opinion, the ACSH recommended PO 2, considering that some stakeholders, in particular small companies, might not be aware that the fumes released as a result of their welding process may contain carcinogens, mutagens or reprotoxicants. As both workers and businesses fully support PO 2, it is likely that they will also implement it on the grounds by carrying out risk assessments and, where necessary, investing in additional RMMs. This strong support would therefore increase the effectiveness of PO 2.

Efficiency: the C/B ratio for PO 2 is between 0.29 and 0.07, with benefits overweighing costs by up to 15 times. In total, PO 2 would cost between €67 and €156 million over 40 years. While almost all costs would be solely borne by businesses, in particular SMEs, PO 2 would mainly benefit to workers (more than 95% of benefits are for workers and their families). The C/B ratio for businesses only would be between 14 and 33. Although costs outweigh benefits for businesses, the costs per company are expected to be very limited considering the large number of companies with exposed workers to welding fumes (841,282).

Coherence: PO 2 would be coherent with Europe's Beating Cancer as it would contribute to prevent more than 1,600 lung cancer cases over 40 years in comparison to the baseline. PO 2 should not have any impact on digitalisation and negligible negative impact on environment and it is therefore coherent with the twin transition. Finally, no impact on the EU open strategic autonomy was identified under PO 2.

Preferred option: PO 2 is more effective, efficient and coherent than the baseline scenario. Overall, this option would generate more benefits than costs, except when limiting the analysis to businesses. The representatives of the latter within the ACSH are however in favour of this option, which should improve workers' protection, unlike the baseline scenario which would not contribute to the specific objectives laid down in section 4. Furthermore, the costs per company would be limited, which would contribute to the proportionality of the option. Consequently, and based on the above analysis, PO 2 is the preferred option.

Table 28 – Comparative scoring of the policy options for welding fumes and identification of the ***preferred option***

	PO 2
Effectiveness	
Number of cancer cases avoided	++
Contribution towards a better level playing field	+++
Consistency with the recommendation of the ACSH	+++
Total effectiveness	**+++**
Efficiency	
Costs/benefits ratio (C/B ratio)	+++
Costs/benefits ratio (C/B ratio) for businesses	--
Costs per company	(-)
Total efficiency	***(+)***
Coherence	
Coherence with Europe's Beating Cancer Plan	+++
Coherence with other key EU policies (EU Green Deal, EU strategic autonomy, digital transition)	0
Total coherence	***+(+)***

8. PREFERRED OPTION

8.1. Selection of the preferred policy options and analysis of impacts

Table 29 – preferred policy options, transitional measures and accompanying measures

Substance	Preferred policy option	Accompanying measures
Cobalt and inorganic	**PO 6**	**Notations** Dermal and

cobalt compounds	**OELs** 10 µg/m³[171] / 2.5 µg/m³[172] **Transitional OEL** 20 µg/m³[170] / 4.2 µg/m³[171] *(until 6 years after entry into force of the Directive)*	respiratory sensitisation
PAHs	**PO 5** **OEL** 70 ng/m³[173] **Transitional OEL** 140 ng/m³[172] *(until 6 years after entry into force of the Directive and limited to 9 sectors[174])*	**Notations** Skin notation
1,4-dioxane	**PO 2** **OEL** 7.3 mg/m³ (2 ppm[175]) **BLV** 45 mg HEAA in urine/g creatinine	**STEL** 73 mg/m³ (20 ppm) **Notations** Skin notation
Isoprene	**Baseline scenario**	NA
Welding fumes	**PO 2** Inclusion of welding fumes in Annex I of the CMRD	NA

According to the evidence gathered[176], all policy options for one substance will have no or negligible effects on the occupational exposure to the other substances. Therefore, the overall impacts on workers, businesses, environment and digitalisation are expected to be the sum of the impacts for each substance, as well as for benefits for public authorities. Conversely, the overall costs on public authorities is expected to be lower than the sum of the impacts as explained below.

Finally and as explained in section 6, the estimated discontinuations and job losses are subject to uncertainty and are likely to be overestimated.

The selection of the preferred policy option also reflects stakeholders' preferences, as documented in more details in Annex 2

[171] Inhalable fraction
[172] Respirable fraction
[173] Measured as benzo[a]pyrene
[174] (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4) coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals.
[175] The limit values for 1,4-dioxane expressed in parts per million (ppm) are based on the conversion factor of 1 mg/m³ = 0.273 ppm as provided by ECHA in its Annex 1 in support of RAC for evaluation of limit values for 1,4-dioxane at the workplace, available at: 073d44ca-5ad2-8128-fd15-8c74a4bdb126 (europa.eu).
[176] RPA (2024), op. cit., section 4.1 of each substance-specific reports

8.1.1. Overall impacts on workers

Overall, the preferred options are expected to prevent 1,676 lung cancer cases and 18,912 non-cancer cases[177] over the reference period. These avoided ill-health cases represent savings amounting to up to €1.16 billion[178]. Along with these benefits, the preferred options are also expected to result in discontinuations. Without any transitional periods for cobalt and its inorganic compounds and PAHs, it was estimated that about 4,000 workers[179] would have lost their jobs. However, both policy options for those two groups of chemicals have a transitional value which were strongly recommended by the ACSH, including businesses. There transitional values are provided for reducing the number of discontinuations by giving more time to businesses to plan their investments or find RMMs which would technically allow for complying with the preferred options. In the absence of data, the impacts of the transitional measures for cobalt and inorganic cobalt compounds and PAHs could not be reflected in the overall impacts on workers. However, it is expected that much less than 4,000 workers would lose their jobs due to discontinuations resulting from the preferred options for PAHs and cobalt and its inogarnic compounds.

Furthermore, although this could not be quantified, and as explained in section 6, it is likely that a share of these job losses would be offset by the creation of new jobs linked to the growth of some companies absorbing the activity of those discontinuing. Furthermore, given the current low level of unemployment in the EU[180], it is also likely that workers losing their job due to discontinuation would find another job in the short term. This non-quantified effect could be amplified by some EU instruments and national labour market policies.

8.1.2. Overall impacts on businesses, including SMEs

The total adjustment costs incurred by the preferred options over 40 years would amount up to €3.3 billion. In the absence of evidence, it is not possible to break adjustment costs into investments in additional RMMs (1st year and recurrent) and discontinuations costs. However, it is expected that the transitional period provided by the package of preferred options for cobalt and its inorganic compounds and PAHs will result in less discontinuations compared to a scenario with the same limit values without any transitional periods, for which 209 discontinuations were estimated. Therefore, the discontinuation costs should be much less than the €2.6 billion expected without transitional period. As 95% of businesses expected to discontinue in the absence of transitional periods were SMEs, the inclusion of transitional measures in the package of preferred options would mainly benefit to them. As discontinuations are estimated to decrease with this package of preferred options, it is also assumed that the investments in additional RMMs should also increase. Indeed, businesses escaping discontinuations would invest in RMMs allow them to comply with the package of preferred options. The evidence gathered does not allow for a precise quantification of the total investments in additional RMMs. However, it should be higher than €0.8 billion, which represents the total investments of businesses in additional RMMs to comply with the limit values without transitional measures.

[177] 2,842 restrictive lung disease, 7,363 upper airway irritation, 38 developmental toxicity, 3,157 male infertility, 497 kidney effects, 633 liver effects and 4,382 local irritation in the nasal cavity.
[178] Application of WTP (willingness to pay) values to each case (= method 1).
[179] In the absence of data for welding fumes, the impact on employment could not be quantified.
[180] 6% in the EU in February 2024 according to Eurostat.

In addition, businesses will also need to support monitoring and administrative costs amounting for about €535 million over 40 years. Overall, the total costs for businesses arising from the preferred options amount to approximatively €3.8 billion during the same period.

Although the total costs for businesses are significant compared to the baseline, they would be spread over a high number of businesses. Consequently, most of businesses would face costs representing less (and often far less) than 1% of their turnover. Nevertheless, SMEs operating in the coking and coal tar distillation sectorswould face higher costs compared to the turnover.

The impact of these high costs is however expected to be mitigated thanks to the transitional values provided by in the package of preferred options, and supported by both the ACSH and employers' organisation as part of the social partners consultation. Such transitional periods would enable employers to make the necessary investments in additional RMMs and to explore technical possibilities to ensure compliance. To this regard, existing EU programmes (e.g. Horizon Europe) might help to develop innovative solutions to protect workers' health. This will be further specified in a recital accompanying the legislative proposal.

In addition to the costs, businesses will also benefit from the package of preferred options. The package of preferred policy options will indeed result in workers being less at risk of occupational illness, which would allow businesses to save costs (e.g. reduced productivity, costs of replacement, rehabilitation costs and medical costs[181]). In total, businesses are expected to avoid costs for a total of about €7 million.

With regard to SME, the share of compliance costs compared to turnover or gross operating product is higher for SMEs than large companies operating in the same sector. Therefore, they are likely to be more impacted by the package of preferred options compared to larger enterprises. Furthermore, as described in section 6, SMEs are more likely to experience discontinuations than larger companies. Therefore, the transitional measures provided by in the package of preferred options will benefit more to SMEs than large companies. SMEs will have more time to plan their investments, which should also reduce the number of discontinuations compared to the same package of options without transitional periods. The impact on SMEs, although higher than on larger companies, should therefore remain limited. These transitional measures contribute to avoid imposing financial constraints in a way which would hold back the creation and development of SMEs.

SMEs tests for all substances, in which the effects of the preferred POs on SMEs are analysed, are available in Annex 12.

8.1.3. Overall impacts on competitiveness

Coking plants, manufacturers of refractory products, manufacturers of graphite and carbon electrode, steel and iron foundries and ferroalloy companies, businesses operating in other non-ferrous metallurgy sector and coal fired power plants would need to make investments in additional RMMs from the very beginning which would represent more than 10% of their gross operating surplus. As most of these companies (except for graphite and electrode manufacturers) are mainly SMEs, they have less capacity to absorb these compliance costs. Furthermore, it cannot be excluded that some businesses would discontinue, which would negatively impact the availability of products, the diversity of supply, and would push prices up for consumers. As explained in section

[181] More information on cost savings for employers is provided in annex 4.

6, the transitional periods for cobalt and its inorganic compounds and PAHs provided in the package of preferred options are expected to limit the number of discontinuations and give more time to businesses, in particular SMEs, to plan and make the necessary investments in additional RMMs. This would improve businesses' ability to absorb costs and limit the number of discontinuations. As a result, the impact on consumers dependent on these sectors should also be more limited, while remaining negative. For the other sectors, which represent a majority of companies directly concerned by this initiative, the costs compared to turnover or gross operating surplus are very limited and these sectors are not expected to face discontinuations. Therefore, the impact on these consumers, both in terms of prices or diversity of supply/availability of products, is expected to be negligible.

The package of preferred option might also negatively impact the capacity of some businesses to innovate. Although for most businesses, compliance costs represent less than 10% or even less than 1% of their R&D expenditures, the share is higher for SMEs operating in the following sectors: coking plants (costs to businesses represent up to 160% of R&D expenditures), soil remediation (up to 155%), welding of railroad track (up to 120-135%) and other non-ferrous metallurgy (up to 53%). Again, the transitional measures provided by in the package of preferred options is expected to mitigate this negative impact as businesses will have more time to plan their investments. Therefore, the impact on R&D expenditures should be overall negligible, excepted for the sectors mentioned above which might face more difficulties to maintain their investments and for which the transitional measures might play an important role.

With regard to the impact on international competitiveness, sectors such as steel and iron foundries, ferroalloys, aluminium manufacturers, other metallurgy, casting of metal and graphite and carbon electrode manufacturers already experience pressure from cheaper imports, particularly from Asian countries. Therefore, additional operational costs arising from compliance costs could negatively impact their competitiveness against cheaper imports from outside the EU. Furthermore and as mentioned above, it cannot be ruled out that some businesses will discontinue as a result of the package of preferred options, in particular coking plants. Depending on the number of discontinuations, downstream users dependent on the production of coking plants could become more dependent on imports from outside of the EU. This is particularly the case for companies producing batteries storing energy produced by wind turbines, semiconductors and electric vehicles. All these negative impacts are expected to be mitigated by the introduction of transitional measures in the package of preferred options, which should reduce the number of discontinuations and give more time to businesses for proceeding with the necessary investments. Overall, the impact on international competitiveness should be negligible, except for those sectors mentioned above, in particular coking plants. Transitional measures are therefore important to mitigate these negative impacts, although the evidence gathered does not allow for a precise quantification of these effects.

More details on the impact on competitiveness are available in Annex 5.

8.1.4. Overall impacts on public authorities

Overall, the package of preferred options would cost to public authorities about €66 million over 40 years, of which more than 95% are related to the adjustment, monitoring and administrative costs related to PO 5 for PAHs. These costs aim to ensure that firefighters' exposure does not exceed the level provided by PO 5. On average, it would cost about €80,000 per public authority over 40 years.

The remaining 5% relates to transposition costs. Public authorities will need to transpose in their national legislations the package of preferred options as soon as the latter are stricter than existing national rules. Since Member States are expected to carry out the transposition in one go, the transposition costs described in section 6 for each substance will not be cumulative. Since no Member State currently has a national legislation which is in full compliance with the package of preferred options, it is reasonable to assume that Member State will need to dedicate up to €100,000 (corresponding to the highest transposition costs for welding fumes) for the transposition of the new rules.

The package of preferred options would also bring benefits for public authorities, amounting in total to about €30.4 million, in particular in the form of cost savings (e.g. healthcare cost savings due to fewer cancer and non-cancer cases) amounting to €26.65 million. The remaining benefits relates to avoided costs of setting limit values following national processes, which would represent up to €3.75 million.

The net costs over 40 years for public authorities would therefore amount to about €35.5 million, of which about €15 million would be one-off costs and correspond to investments in RMMs to protect firefighters against exposure to PAHs.

8.1.5. Overall impacts on green and digital transitions

The package of preferred options would result in an increasing enclosure of some processes, leading to less release of some hazardous substances in the environment. However, this direct impact on environment is expected to be negligible.

The package of preferred options might have some negative indirect impacts on the green transition ot the digital transition due to discontinuations in key sectors. The assessment performed in section 6 indicates that the sectors subject to discontinuations and which are key for the green or the digital transition are: coking plants, other non-ferrous metallurgy, coal tar distillation and graphite and carbon electrode manufacture. These sectors play a key role for the development of the circular economy, the manufacture of green infrastructures and the manufacture of semiconductors. Therefore, a disruptions in the supply chains might hamper the EU objective to progress toward a green and digital transition. However, the risk of discontinuing is expected to be mitigated by the transitional measures provided in the package of preferred options, in particular the transitional period for PAHs. Consequently, the number of discontinuations in these sectors is expected to be limited and should not disrupt the supply chains which are essential for the green and digital transition. Therefore, the overall indirect impact on the green and the digital transition should be limited.

8.1.6. Overall impacts on EU Open Strategic Autonomy

The package of preferred options is not expected to hinder the recycling of cobalt as critical raw material to ensure an EU Open strategic autonomy. Indeed, the number of discontinuations in metal recovery sector is expected to be negligible or even zero and the compliance costs would represent a negligible share of the turnover. Nevertheless, this package could result in some coking plants discontinuing. As a result, those sectors dependent to the production of coking plants (e.g. coal tar) might need to import their products from outside the EU. which would hinder the EU's open strategic autonomy in its objective of green and digital transition as coal tar is essential in the production of batteries storing energy produced by wind turbines, semiconductors and electric vehicles. However, this negative impact should be mitigated by the transitional measures for PAHs in the package of preferred options, which is expected to reduce the number of possible discontinuations in the coking sector. No further impact on EU Open Strategic Autonomy is expected.

8.2. Subsidiarity and proportionality

In view of the available evidence, establishing binding limit values for cobalt and inorganic cobalt compounds, PAHs, 1,4-dioxane, and including welding fumes in Annex I of the CMRD would result in higher protection of workers' health. The need for a binding limit value for isoprene is not expected to bring benefits as no problem was identified. The baseline is thereforethe most appropriate policy option. The protection of workers' health against risks arising from exposure to these substances is already covered by EU legislation, in particular by the CMRD, which can be amended only at EU level. Thepreferred options for cobalt and inorganic cobalt compounds, PAHs, 1,4-dioxane and welding fumes build on long and intensive discussions with all stakeholders (representatives from workers' associations, employers' associations and governments) that helps to ensure that the principles of subsidiarity and proportionality are well respected.

Updating the CMRD is an effective way to ensure that preventive measures would be updated accordingly in all Member States, providing a uniform level of minimum requirements designed to guarantee a better standard of health and safety and thus minimising the disparities in health and safety protection levels of workers between Member States. The harmonisation of minimum requirements would also contribute to a level playing field for operators in the internal market. Updating the CMRD therefore complies with the principle of **subsidiarity**.

The **proportionality** principle is respected as the package of preferred options is limited to revising the annexes to the existing CMRD, where necessary, on the basis of the scientific and technical data available, as legally requested by Article 16 of the CMRD providing that limit values must be set out for all carcinogens, mutagens or reprotoxic substances for which this is possible. Setting limit values for cobalt and its inorganic compounds, PAHs and 1,4-dioxane would contribute to the effective implementation of the existing employer's obligations related to the hierarchy of controls as laid down in Articles 4 and 5 of the CMRD, namely substitution, use of closed systems and minimisation of workers' exposure. The introduction of welding fumes in Annex I to the CMRD would also ensure a better implementation of the existing obligations laid down in the CMRD. This introduction aims to draw employers' attention to the possible dangerousness of the fumes generated by their welding process. As provided by the CMRD, employers have to perform a risk assessment as soon as an activity is likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances. Therefore, if this risk assessment reveals that their welding fumes contain such hazardous substances, employers will need to take all the necessary RMMs to comply with the obligations laid down in the CMRD, including the hierarchy of controls in Articles 4 and 5. The introduction of welding fumes does not result in new rules but aims to ensure a correct implementation of the existing ones, which contributes to the proportionality of the proposal.

Furthermore, the package of preferred options also offers a certain margin of flexibility to Member States for those substances subject to the setting of limit values through the initiative supported by the present impact assessment. In accordance with Article 153(4) of the TFEU, setting OELs at the EU level does not prevent Member States from maintaining or introducing more stringent protective measures (i.e. lower limit values).

With regard to the **proportionality of the package of preferred options**, the estimated costs outweigh the monetised benefits for all preferred options, except for welding fumes. However, the proportionality of this package does not only depend on the costs/benefits ratio comparison. Other factors are taken into consideration to assess the proportionality of the preferred options, such as the EU strong commitment to fight against cancer, the stakeholders' views, the impact on businesses, the existence of mitigating measures and the coherence with other key EU policies. Overall, preferred options are considered as proportionate as soon as they contribute to achieve as much as possible the general objective of this initiative, while maintaining the costs at a level which is acceptable for businesses and preserving key priorities of the EU.

The general objective of this initiative is to ensure to workers the right to a high level of protection of their health and safety at work. This objective is in line with the European Pillar of Social Rights, which enshrines workers' rights to healthy, safe and well-adapted work environment, and with Europe's Beating Cancer Plan. Overall, the package of preferred options is expected to prevent 1,676 lung cancer cases and 18,912 non-cancer disease cases over the next 40 years.

Some POs would have allowed to make even greater progress in the fight against occupational cancer. However, these POs would have had significant consequences on businesses, leading to a high number of discontinuations and job losses and a substantial loss of competitiveness for European companies operating in certain sectors. They would have negatively impacted the Open Strategic Autonomy of the EU, as well as its transition towards a greener and more digital European Union. This is in line with what employers' organisations raised as part of the 2nd phase of the social partners consultation, namely that this initiative could have more far-reaching consequences for the European industry, including in terms of strategic autonomy, relocation of production sites outside of the EU, etc. To this regard, SMEunited called the Commission not to go beyond what was agreed by the ACSH, and by extension beyond the package of preferred options (except for isoprene). For its part, Business Europe supported the ACSH opinions.

On the other side, some POs (including the baseline scenario) would be less costly for businesses than the package of preferred options. However, the positive effect of these options on workers' health would be more limited and would not consequently contribute to the general objective in a satisfactory manner.

The package of preferred options, which is the result of the impact analysis and comparison carried out in the previous sections, aims to ensure a balanced approach, i.e. to prevent as much as possible industries from closures or severe economic disadvantages while providing an adequate protection of the workers at the EU level and being coherent the key objectives of the EU, including Europe's Beating Cancer Plan, the twin transition and the EU strategic autonomy.

Socio-economic and feasibility factors have been taken into account after intensive discussions with all stakeholders within the ACSH (representatives of workers' organisations, representatives of employers' organisations, and representatives of governments). These discussions were supported by evidence gathered through an external study which fully involved Member States, workers and businesses, both through data collection and validation. This thorough consultation of the ACSH contributed to identify a package of preferred options which is considered as proportionate by those that will be impacted (from an economic, social and health point of view) on the ground and coherent with the strategic vision of the EU.

In particular, the thorough consultation of those stakeholders which will be directly impacted by the initiative subject to this impact assessment enabled to identify transitional measures for mitigating the negative impacts resulting from the package of preferred options, in particular the possible discontinuations and their consequences on the EU economy, the twin transition and the EU strategic framework. With regard to businesses, the transitional periods were considered as necessary and appropriate by the social partners and Member States authorities represented in the WPC/ACSH to give enough time to businesses to adapt. The main objective of these measures recommended by stakeholders and retained in the package of preferred options is to significantly limit the number of discontinuations. As the number of discontinuations resulting from the package of preferred options should be limited thanks to the transitional measures, the coherence with the key objectives of the EU, including the twin transition and the EU open strategic autonomy, will also be improved. Therefore, these transitional measures largely contributes to have a package of preferred options which is proportionate, namely that it improves as much as possible workers' protection, while preserving businesses and supporting the EU's strategic vision. These transitional measures contribute therefore to the proportionality of the package of preferred options by ensuring a more appropriate temporal margin for businesses to adapt, where necessary.

It is worth noting that Cobalt Institute considers PO 5 for cobalt as the optimal option to protect workers and let the cobalt industry grow in Europe. These views, which are based on their own impact assessment, are however not consistent with the results of this impact assessment, including in terms of workers' protection. Annex 2 describes the main methodological differences between both impact assessments.

Finally, the introduction of transitional measures for cobalt and its inorganic compounds and for PAHs is expected to significantly mitigate the possible negative impacts on businesses and on the key objectives of the EU. Therefore, the package of preferred options aims to ensure a balanced approach, i.e. to prevent as much as possible industries from closures or severe economic disadvantages (avoiding also that consequences are passed on to consumers) while providing an adequate protection of the workers at the EU level and being coherent with the key objectives of the EU, including Europe's Beating Cancer Plan, the twin transition and the EU strategic autonomy.

8.3. REFIT (simplification and improved efficiency)

With regard to the simplification and the efficiency improvement of the existing legislation, the package of preferred option eliminates the need for Member States to conduct their own scientific analysis to address the different substances. Employers also benefit from the simplification in ensuring legal compliance, particularly those operating in different Member States.

8.4. Application of the 'one in, one out' approach

All the administrative costs identified in section 6 relate to monitoring and therefore are exempted from the offsetting obligation under the 'one in, one out' approach[182].

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

9.1. Monitoring arrangements

Progress towards achieving the objectives of the initiative will be monitored by a series of core indicators. These and the related data sources are summarised below.

Table 30 - indicators and monitoring arrangements/data sources

Specific objective	Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators
Further improving workers' protection from exposure to the substances subject to this impact assessment	Reductions in exposure to the identified CMR substances in the workplace to	Rates of adoption of improved RMM. by businesses and increased	Data notified by employers to the competent national authorities as regards record keeping in accordance with CMRD Art. 15; Data submitted by Member States in the national implementation reports on CMRD on the

[182] According to Better Regulation tool #58 EU Standard Cost Model, inspection on behalf of public authorities (e.g. businesses having to monitor working and other conditions, such as those related to occupational safety and health) is not subject to offsetting in the context of the 'one in, one out' approach.

through the adoption by employers of ap-propriate risk management measures	levels which are deemed safe.	coverage of workers Numbers of cases breaching limit values and actions taken.	implementation of the directives, submitted in accordance with Art. 17a of Directive 89/391/EEC. Surveys/commissioned by EC and Member State Authorities.
		The reduction of work-related ill-health associated with these CMR substances in the EU, timing in accordance with latency period	Member State data on ill-health associated with these CMR substances
Increasing the clarity and effectiveness of the CMRD by keeping it updated with the latest scientific data	To ensure that relevant in-formation on CMR substances and safe exposure levels are generated and utilised to in-form revisions to the CMRD	Bodies, processes and timelines established, operational and effective for reviewing information and making timely decisions on revisions. Revisions to CMRD incorporating up-dated scientific data, time to re-vise/adopt	Reports on operations and functioning of scientific bodies. Commission reports on adoption of revisions. Revisions to CMRD.
Facilitating implementation and contribute towards a better level playing field for economic operators by adopting minimum require-ments at EU level.	The reduction of costs related to occupational ill-health for economic operators and for social security systems in the EU.	Differences in costs related to occupational ill-health for economic operators (e.g., loss of productivity) and social security systems in the EU.	The monitoring of this indicator would require the comparison of the expected figures on the burden of occupational ill-health 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 based on the data on the number of cases of occupational ill-health. The cases of occupational ill-health accounted for should be those related to exposure to cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons (PAHs), 1,4-dioxane and welding fumes
	Consistent limits faced by businesses across the EU	Number of MS adopting minimum re-quirements within time set by revised Directive. Number of MS adopting standards in excess of minimum requirements. Comparisons of	Member State legislation Research studies commissioned by EC and Member State Authorities.

		EU minimum require-ments with those of competing coun-tries. Member State transposition of revised CMRD Costs for companies operating across Member States (including familiarisa-tion and standardisation.)	
Increasing the effectiveness of the CMRD by bringing more clarity on its scope with regard to welding fumes.	Improved awareness of the potential dangers from welding fumes.	Guidelines developed by the Member States, awareness-raising campaigns, trainings and other related-activities.	Questionnaire sent to the Member States on the practical implementation of the OSH Directives under the 5-yearly review in accordance with Article 17a of Directive 89/391/EEC. Information from the ACSH and the Senior Labour Inspectors Committee (SLIC).
		Number or proportion of companies encouraging good practices that prevent cases of ill-health associated with the use of CMR substances	EU-OSHA's European Survey of Enterprises on New and Emerging Risks (ESENER). Eurofound's European Working Conditions Survey (EWCS). Information from the SLIC.

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 level, employers must ensure that the exposure does not go above the limit values set out in the annexes to the CMRD. The monitoring of application and enforcement will be undertaken by national authorities, particularly by the national labour inspectorates. At EU level, the Committee of Senior Labour Inspectors (SLIC) informs the Commission regarding problems relating to the enforcement of the Directive.

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.

Legislative action needs to be followed up through effective implementation at the workplace. Companies have a broad range of tools, information and good practices provided by EU-OSHA in the context of a Healthy Workplaces Campaign on dangerous substances[183].

9.2. 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 98/24/EC and Directive 2004/37/EC. Using these reports as a basis, the Commission is required to evaluate the implementation of the directives and, to inform the European Parliament, the Council, the European Economic and Social Committee and the ACSH of the results of this exercise and, if necessary, of any initiatives to improve the operation of the regulatory framework. The implementation review for the period 2018-2022 is currently ongoing and is expected to be finalised by end 2025. The next implementation review will be for the periods, 2023-2027 and 2028-2032.

A key indicator to implementation review of the EU OSH Directives, and therefore the CMRD, is the full and correct transposition by the Member States. On the one hand, Member States should notify the Commission of their transposition of EU Directives into national legislation before the deadline mentioned in the EU Directive. Afterwards, the Commission will perform a conformity check of the transposition and, in case of inaccuracies in transposition, will request clarifications or corrective actions from Member States.

Until recently the number of binding limit values under CMRD was limited, and the above implementation review tended not to address specific chemicals and instead had a focus on the general requirements of the directives. Following successive legislative updates, there is now a significant number of limit values. Therefore, for future implementation review under Article 17a of Directive 89/391/EEC, it will be appropriate to consider developing a range of indicators to enable an assessment of the practical implementation of the substance-specific limit values to be carried out in the future, together with a continuation of the current practice described above.

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[183] The campaign pursued several objectives, including raising awareness on the importance of preventing risks from dangerous substances, promoting risk assessment, heightening awareness of risks to exposure to carcinogens at work or increasing knowledge of the legislative framework. It was carried out in 2018-2019

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: Directorate-General Employment, Social Affairs and Inclusion [Unit C2 - Health and Safety at Work, EU-OSHA].

Agenda planning: PLAN/2022/1707

2. ORGANISATION AND TIMING

An Interservice Steering Group (ISG) was set up to accompany the work on the initiative. The following DGs participated in this ISG: SG, SJ, BUDG, GROW, EMPL, ENER, ENV, RTD, CNECT, EAC, SANTE, JUST, ESTAT and EU-OSHA.

The Impact Assessment was discussed in the ISG on 28 February (present DGs: SG, EMPL, GROW, CNECT, RTD, EU-OSHA) and 12 April 2024 (present DGs: SG, EMPL, GROW, ENV, CNECT and EU-OSHA).

3. CONSULTATION OF THE RSB

The draft IAR for the initiative was submitted to the Regulatory Scrutiny Board (RSB) on 24 April 2024 and the meeting with the RSB took place on 29 May 2024. Following this meeting, the RSB gave a negative opinion on 31 May 2024.

The table below summarises the RSB comments as well as the revisions introduced in response to them:

Table 31 – Summary of RSB comments and explanations on how they were addressed

What to improve	How comments were addressed
(1) The policy context should better explain the choice, (including the criteria applied and the main arguments used for each substance by the different actors involved) of the five substances out of the list of 28 substances to be scientifically assessed. Those explanations should enable to better understand the choices in particular for substances with limited health impact.	A new section 1.3 was added, outlining the procedure supporting the revision of the CMRD, in particular the important role played by our key stakeholders, namely Member States and Social Partners. One step of this procedure relates to the selection of chemicals for scientific evaluation. Furthermore, section 1.3 also provide information on the composition of the ACSH and how it allows for covering a large number of sectors and activities. This large covering allows for opinions that reflect the situation on the ground, including in terms of technical and socioeconomic feasibility. Furthermore, we further explained in section 2.1 how these 5 substances were selected, namely based on a consultative approach with the members of the WPC, as well as on specific considerations for each substance. These specific considerations are also presented in section 2.1.

The problem analysis should better justify the grounds for EU action, taking into account the scale of the problem related to each substance. It should better assess the magnitude of the problem by presenting the available evidence, especially in relation to health dangers coming from isoprene and welding fumes.	A table presenting estimates on the number of workers exposed to each substance in the EU, as well as the estimates of current (in 2023) and future (over 40 years) burden disease per substance (including for isoprene and welding fumes) were included in section 2.1. This table also present the most critical adverse health effects resulting from exposure to each chemical. In addition, data related to the costs of ill-health for businesses and public administration was also included in section 2.1, so it is better aligned with figure 2 outlining the problem tree. As showed in the new table 2, most of the costs of ill-health for businesses and public authorities are due to workers' exposure to welding fumes. Furthermore, the absence of problem for isoprene was stressed in section 2.1. The evidence gathered as part of this impact assessment indeed showed that workers are currently exposed to levels already below the health-based occupational limit value derived by RAC. Finally, the sub-section 3.2 now discusses the magnitude of the problem for all substances, dividing them in three categories: 1. Substances (cobalt, PAHs and welding fumes) which are expected to cause occupational cancer over the next 40 years and for which an action is necessary in view of Europe's Beating Cancer Plan; 2. Substances (1,4-dioxane) which are not expected to cause cancer but well other diseases across the EU over the next 40 years, demonstrating the importance to act at EU level; and 3. Substances (isoprene) which are not expected to cause cancer or non-cancer cases over the next 40 years, and for which an action at EU level does not appear necessary.
Based on robust evidence, the problem drivers should cover, in more detail, issues related to existing employers' practices, such as limited or uneven take up of risk management measures, or most modern technology.	Under section 2.2.1 related to 'driver 1: high-exposure levels to cancer-causing substances', it is now explained that the current high workers exposure levels in some sectors are the result of insufficient risk management measures in place. Some examples have been included to illustrate this link. Furthermore, some data related to the current exposure concentrations by sectors was included in Annex 6, in addition to the existing data on the number of exposed workers by sectors. Finally, a refence to this Annex 6 was included under

	section 2.2.1 to draw the attention of the reader on this existing data.
The conclusion on the lack of awareness of workers and employers regarding the dangerousness of welding fumes should be also based on robust evidence.	A new paragraph was included under section 2.2.4 related to 'driver 4: insufficient awareness of the possible dangerousness of welding fumes' to differentiate the dangerousness of welding fumes based on the different processes, based on the European Chemicals Agency's (ECHA) scoping study on welding fumes. Furthermore, a table summarising the welding processes, their generated substances, an indication of the presence of carcinogens, mutagens or reprotoxic substances, and workers exposure was included in Annex 6, based on the ECHA scoping study. Section 2.2.4 refers to this annex 6 when differentiating the difference welding processes. Section 2.2.4 demonstrates the insufficient awareness of the possible dangerousness of welding fumes on the basis of the ECHA scoping study and the evidence gathered through the consultation of relevant stakeholders. As mentioned by ECHA in its scoping study, despite the fact that welding can be a relatively safe activity if all the safety and exposure control measures are in place, it remains a prominent concern that welders are at high risk from various diseases, including cancers. The evidence gathered through the consultation of six key stakeholders representing a large number of welders in the EU indicates that some employers are not aware that welding fumes may contain carcinogens, mutagens or reprotoxic substances (such as chromium(VI) compounds, nickel compounds, cadmium and its inorganic compounds, and beryllium and its inorganic compounds) and lead to health risks. These employers may therefore ignore to what extent exposure to their welding processes and materials used can be dangerous for their workers and do not apply the measures prescribed by the CMRD to minimise workers' exposure.
(2) The problem analysis should better investigate how the problems would evolve under the dynamic baseline, considering other related initiatives at EU and national level as well as existing obligations and exposure limits. The baseline scenario should	In introduction of section 5.1 related to the baseline, it was specified that this section describes how the problem is expected to evolve over 40 years in case of no further action is taken at EU level. It also specifies that the baseline takes account of the impact of the implementation of limit values for other substances, the effects of forthcoming changes in national legislations, the future trends (e.g. in use and recycling of the substances, in exposure concentrations due to technical

reflect whether there is expected technology progress which could reduce the health dangers and the current and future worker safety and automation trends in production in the industries affected, making good use of foresight insights as well as information and awareness measures taken by the competent authorities.	improvements or in exposed workforce), and any other relevant insights for the future (e.g. impact of the green transition. Still in section 5.1, the description and analysis of the baseline scenario was strengthened. The description of the baseline scenarios now refers to the current RMMs in place in the different sectors when discussing the current levels of exposure. A reference to section 2 and annex 6 for more detailed information on the current RMMs was also added. In addition, the baseline scenarios now include a description of how the ongoing implementation of the EU-wide limit values for some chemicals (e.g. nickel compounds, chromium VI compounds and cadmium and its inorganic compounds) are expected to influence the future levels of exposure from the substances subject to this impact assessment. Tables summarizing the adjusted concentrations for all relevant sectors were also added in annex 6. The description of the baseline also better embed strategic foresight to support the different trends, including with regard to the change in the number of workers exposed. Finally, the baseline scenario better reflects whether there is expected technology progress or information and awareness measures taken by the competent authorities which could reduce the health dangers.
(3) The objectives section should better present what the initiative aims to achieve to have a clearer and more measurable view of what success would look like. It therefore should better structure the specific objectives, present them in more SMART terms and link them clearly to the problem drivers to be tackled. The report should present a more complete illustration of the intervention logic, linking the problems, their drivers, the policy objectives, and the policy options.	Under section 4.2, the description of the specific objectives was further improved to have a clearer and more measurable view of what success would look like. Furthermore, an intervention logic was developed and included in section 5.2.1 (figure 4). This intervention logic links the drivers, the specific objectives and the policy options. This section also includes a description of the structure and the logic of the policy options. This intervention logic also contributes to better present the specific objectives of this initiative, as they are now directly linked with their relevant drivers.
(4) The report should clearly present upfront and subsequently fully analyse and compare all the relevant options, including the	A description of each policy option by substances was added under section 5.2.2. This description provides a justification of the choice of these specific options, including when they were recommended by the relevant stakeholders, in particular the ECHA's Risk

transitional options.	Assessment Committee (scientific body) and the ACSH. Furthermore, two new options were added for cobalt and its inorganic compounds and PAHs. These new options are clearly presented upfront and are now fully assessed in section 6 and compared with the other options in section 7. They reflect a combination of an existing option and a transitional option. Both options were recommended by the ACSH and social partners.
It should better link the individual options and the corresponding risk management measures	Section 6 now refers to what extent businesses will need to invest in additional RMMs for each policy option. It says that the introduction of limit values for cobalt and its inorganic compounds, PAHs and 1,4-dioxane, and inclusion of welding fumes in Annex 1 of the CMRD, is expected to reduce the occupational exposure to these hazardous substances as businesses with exposure levels higher than the options will have to invest in additional RMMs. The extent of such reduction depends on the current levels of exposure and RMMs, as well as the projected future levels of exposure in the absence of any action ('baseline scenario'). Furthermore, annex 6 now includes data on the required additional RMMs by sector for each option. A reference to this information was added in section 6 to inform the reader about this available data.
It should explain how adding welding fumes to Annex I of the Directive is an effective way to tackle the corresponding health issues arising from certain types of welding fumes, better ensure effective implementation of preventive measures and thus deliver the expected health benefits.	The introduction of welding fumes in Annex I to the CMRD would ensure a better implementation of the existing obligations laid down in the CMRD. This introduction aims to draw employers' attention to the possible dangerousness of the fumes generated by their welding process. As provided by the CMRD, employers have to perform a risk assessment as soon as an activity is likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances. The ECHA scoping study will support this assessment as it provides information on welding processes likely to generate carcinogens, mutagens or reprotoxic substances. If this risk assessment reveals that their welding fumes contain such hazardous substances, employers will need to take all the necessary RMMs to comply with the obligations laid down in the CMRD, including the hierarchy of controls in Articles 4 and 5. The introduction of welding fumes does not result in new rules but aims to ensure a correct implementation of the existing ones, which contributes to the proportionality of the proposal. This is now explained in section 5 when presenting the policy option for welding fumes.

The rationale behind proposing at this point only a single option for welding fumes and not presenting options setting differentiated limit values should be better explained.	A new sub-section 5.2.5 was added to introduce the discarded options, including for welding fumes. For welding fumes, there is currently insufficient scientific information to set a limit value. Under this section, a reference to annex 10 was also added, where more detailed information on this lack of scientific information is provided. Furthermore, a reference to the possible revision of the existing Senior Labour Inspectors Committee's (SLIC) Guidance for National Labour Inspectors on addressing health risks from Welding Fumes was included in introduction of section 5.2.1. As mentioned, this update would contribute to improving awareness of the possible dangerousness of welding fumes. However, in the absence of specific information on if and how this guidance document will be updated, the effects of this option could not be assessed. It is also specified that more information on this possible revision is available in annex 10, under the accompanying measures.
The report should better elaborate on the discarded options (including in the main report), in particular why non-regulatory options were discarded, such as guidance and awareness rising activities.	A new sub-section 5.2.5 was added to introduce the discarded options. This new section explains that some policy options, which had been considered at the early stages of this initiative, have been discarded either because they are clearly disproportionate (banning the use of substances, directly adopting the most stringent national limit values, less stringent rules for SMEs), or unsuitable to achieve the policy objectives (providing industry-specific scientific information without amending the CMRD, guidance documents), or there is insufficient scientific information (setting a limit value for welding fumes). A reference to annex was also included in this new sub-section. Annex 10 includes a description of those discarded policy options, including guidance documents, and the reasons for discarding them.
It should also clarify why it presents options for isoprene in the absence of any clear evidence on the existence of a problem.	A new section 5.2.4 was added to explain that in the absence of problem for isoprene, no policy option was assessed in the main report of this impact assessment. This new section also mentions that as the ACSH recommended a limit value for isoprene, and for the sake of transparency, a fully-fledged analysis of this option was carried out and is available in annex 10.
(5) The report should present a clearer and more developed analysis of impacts on competitiveness and SMEs. It should better assess the impacts on competitiveness, for example	The impacts on competitiveness ware further discussed for both cobalt and its inorganic compounds and PAHs, in particular to identify those sectors which may need to pass on costs to consumers of be impacted by non-EU competitors. The analysis was reinforced in section 6 when assessing the impacts, and annex 5 related to the

by being more nuanced on how the estimated level of compliance costs affects cost competitiveness and by avoiding relativising negative impacts against external circumstances and thus ignoring potential cumulative cost effects. Costs should be assessed not only in relation to turnover, but also to rates of profitability if available.	competitiveness check. Furthermore, section 8 now includes a new sub-section related to the overall impact of the package of preferred options on competitiveness. The paragraph related to external circumstances was also removed from the analysis. A SME test for each substance was developed and included in a new annex 12, following Better Regulations guidelines. Furthermore, SMEs were further taken into consideration when assessing the different impacts in section 6 and comparing the options in section 7. The costs/gross operating surplus was used in section to assess and discuss the impacts on EU Strategic Autonomy and on environment for cobalt and its inorganic compounds, and the impact competitiveness for PAHs. Furthermore, it was also used to discuss the overall impacts on competitiveness of the package of preferred options under section 8.
The report should present in a more balanced manner the expected impacts on SMEs (including on competitiveness) by providing a comprehensive four-step of SME test.	A SME test for each substance was developed and included in a new annex 12, following Better Regulations guidelines.
The competitiveness check in Annex 5 should fully reflect the competitiveness analysis developed in the main report.	In section 8, a new sub-section related to overall impact on competitiveness was included. This new sub-section is fully in line with the reinforced analysis on competitiveness provided in section 6 and the reinforced analysis on competitiveness in annex 5. Overall, the impact on competitiveness, which is described in several sections and annex of the impact assessment is better aligned and coherent.
(6) The report should clearly assess the impact of the proposed measures on the EU's strategic autonomy in critical raw materials (e.g., cobalt), steel and substances vital to the digital and green transitions (graphite, graphene etc). It should assess the risk that the proposed measures will either lead to discontinuation of EU production thereby creating a strategic dependence or to offshoring of production leading to de-skilling of the EU workforce.	An analysis of the impacts of the different policy options on the EU strategic autonomy was added in section 6, both for cobalt and its inorganic compounds and PAHs. Impact on EU strategic autonomy was also taken into account in section 7 when comparing the options. The coherence of the policy options was added as criteria for comparing the options. Finally, a new sub-section was also included in section 8 to present the overall impact of the package of preferred options on the EU strategic autonomy.

(7) The report should further develop the analysis of distributional effects. It should provide a more developed analysis of the impacts on consumers to justify the conclusion that the impact on consumers should be limited or even negligible for all substances. In this respect, it should provide evidence on the capacity of companies to absorb significant compliance costs and on the likelihood that the costs may be passed on to consumers. It should include the analysis on the likely impact on consumer prices and a range of goods offered on the market.	Under section 6, the assessment of the impact on consumers has been significantly improved, in particular for cobalt and its inorganic compounds and PAHs. The analysis of these impacts takes better into consideration the particularities of SMEs, which usually face higher costs than larger companies and have less opportunities to absorb incremental costs. It also better take into account the structure of the markets. Other ratio and data, such as the costs compared to the gross operating surplus and the 1st year costs, were also used to improvement the assessment of the impact on consumers, in particular for PAHs. In annex 5 and section 8, the analysis of the overall impact on consumers was also significantly improved, by using the improved analysis in section 6. It also better take into account the impacts of the transitional measures.
The report should also further develop the analysis of the impacts, in particular of business discontinuation, on Member States.	For each substance, we have added information in section 6, sub-section renamed 'impact on public authorities/Member States' on those Member States that could be more impacted due to their high share of companies in the relevant sectors. The analysis specifically mentions those Member States which are likely to be more impacted. This analysis is also nuanced, where relevant, with the existing national limit values in those Member States.
(8) More generally, the impact analysis should bring out clearer the evidence underpinning the cost and benefit estimates. It should better present the costs and benefits for each option, including transitional options, and should include a summary of this analysis in an overview table. The report should be clearer on how robust the estimates are, what the related uncertainties are, and how they are perceived by affected stakeholders. It should more explicitly explain how industry evidence has been taken into account in the analysis and why there are significant differences in the estimates of costs by the industry and in the report.	In introduction of section 6, a summary of the methodology used to calculate costs and benefits was added. This introduction also refers to the limitations related to discontinuations and also refer to annex 4 for information on other limitations. To this regard, a new table 65 was added in annex 4 to outline the main limitations or uncertainties, together with an explanation and its likeliness. Section 6 also includes an analysis of the impacts of the two new policy options providing for transitional values. Where the evidence gathered allows it, the impacts are quantified or monetised. When the evidence gathered is insufficient, the impacts are assessed qualitatively. In addition, a new section 7.4 was added in annex 4 to present the methodology developed and used to monetise the impacts of the transitional values. In Annex 2, a new section 3.6 was included to provide information on the existence of an impact assessment carried out at the request of cobalt institute, a global trade association representing cobalt industry. This section also describes in detail why the impacts

	assessed by cobalt institute differ from the impact presented in this impact assessment. In introduction of section 6.1 related to the assessment of the impacts for cobalt and its inorganic compounds, a paragraph was added to explain to what extent the data of Cobalt Institute's impact assessment were used in the present impact assessment. It also clearly mentions that the impacts assessed for the purpose of this impact assessment differ from the impacts of Cobalt Institute's impact assessment. It also refers to the new sub-section 3.6 in annex 2 for more details about the differences in terms of methodology between the two impact assessment.
(9) The comparison of options by substance should be presented immediately after their assessment.	Section 7 was fully re-organised to ensure that the comparison of options is presented immediately after their assessment.
When subsequently identifying the preferred package of options, the report should provide clear comparison criteria and explain their interaction, relative weighting and co-dependency. It should also explain how the scoring of options (numbers of pluses and minuses) was carried out and reflects the collected evidence on impacts. The coherence of the options with underlying legal frameworks, including provisions on SMEs should be assessed.	Additional information was added as introductory part of section 6 to present the three criteria (effectiveness, efficiency and coherence) and their respective indicators for the purpose of the comparison. For instance, with regard to the effectiveness, the options are compared from the perspective of the prevention of deaths and other adverse health effects, their contribution towards a better level playing field through more harmonised rules, and their consistency with the recommendations of the ACSH. Regarding the last indicator, it is assumed that the policy options unanimously recommended by the ACSH will ensure effective implementation on the ground, as both employers and workers support it. Compared to the previous version of the impact assessment, the list of indicators was reworked to avoid overlapping and better take into account additional analysis performed in section 6, such as impact on EU strategic autonomy. With regard to the reworked list of indicators, the criterion related to coherence with EU OSH strategic framework was removed as it overlaps with the number of ill health cases avoided. With regard to their relative weighting, section 6 now clearly refers to the objective of balancing health considerations against economic impacts, by identifying preferred POs that are economically and technically feasible, effectively protect a maximum number of workers and are coherent with the relevant key objectives of the EU. In addition, section 6 describes how the POs are ranked and when comparing the options, it is specified if the

	impact is positive or negative and its order of magnitude, so it is aligned with the tables providing the score. With regard to the latter, the tables were improved so the score for each indicator is also provided. Finally, the comparison clearly differentiates, where relevant, SMEs from larges companies.
On this basis, the report should better demonstrate the proportionality of the preferred policy package, in particular regarding cobalt and polycyclic aromatic hydrocarbons (PAHs).	Section 8.2 related to subsidiarity and proportionality was further improved to better justify why the preferred options for cobalt and its inorganic compounds and PAHs are proportionate. First, we now refer to policy options that were fully assessed in section 6 and subject to the comparison exercise in section 7. Secondly, this section better refers to the views of the stakeholders, in particular employers, workers and Member States, which fully support the policy options for cobalt and its inorganic compounds, PAHs, 1,4-dioxane and welding fumes. Thirdly, the section refers to the thorough consultation of the social partners and Member States, which allow to identify the need for some transitional measures. These transitional measures ensure the proportionality of the options, as mentioned at the end of this section. Fourthly, the section clearly explains that the proportionality of the package of preferred options should be seen as the package of options which ensure the best balanced approach, i.e. to prevent as much as possible industries from closures or severe economic disadvantages while providing an adequate protection of the workers at the EU level and being coherent the key objectives of the EU, including Europe's Beating Cancer Plan, the twin transition and the EU strategic autonomy.
The coherence with other initiatives aimed to build EU strategic autonomy, such as Critical Raw Materials and Chips should be better reflected.	Under section 7, the list of indicators was reworked, including to include new indicators such as coherence with EU strategic autonomy. In addition, the comparison as such was also further developed to better compare the options, including with regard to the coherence with other initiatives such as EU strategic autonomy, EU Green Deal and digital transition.
(10) The report should better analyse and present various stakeholder views, with clear differentiation between different affected groups. This should	This was addressed in section 3, with the addition of the numbers and distribution of stakeholders.

apply to stakeholder views on the magnitude of the problem, feasibility and usefulness of the options, and significance of the impacts. The report should clearly present the numbers and distribution of stakeholders who provided their views and analyse the representativeness of stakeholder feedback.	
The analysis should make more evident what various stakeholders think about the preferred policy package.	Section 8.2 provides the views of BusinessEurope, SMEunited and ETUC with regard to the package of preferred options.
(11) The evaluation arrangements in the report need clarification, in particular regarding the timing of the evaluation.	This was addressed by introducing clarification as regards evaluation of transposition of the legislative proposal.
Monitoring and evaluation section should present what the success will look like and propose a set of SMART indicators capturing the whole intervention logic (e.g. take up of risk management measures by businesses).	This was addressed by updating table 30 related to indicators and monitoring arrangements/data sources, in line with RSB requirements

A revised version of the draft IAR for the initiative was re-submitted to the Regulatory Scrutiny Board (RSB) on 2 December 2024 through written consultation. The RSB issued a positive opinion with reservations on 19 December 2024.

The table below summarises the RSB comments as well as the revisions introduced in response to them:

Table 32 – Summary of RSB comments (2nd opinion) and explanations on how they were addressed

What to improve	How comments were addressed
The rationale for intervention regarding welding fumes is not demonstrated.	According to estimates, the scale of the problem would be significant as this would result in 28,821 lung cancer cases over the next 40 years in case of no EU action. Given the high significance of the problem compared to the other substances, this will be further stressed in the impact assessment (IA), section 2.1. A key specific driver identified for welding fumes-related problem is the insufficient awareness of the possible dangerousness of welding fumes. This lack of awareness leads

	to insufficient protective measures, including risk assessment, implementation of appropriate risk management measures (RMMs) and the information and training of workers. According to the evidence gathered, the improvement of risk management measures following the introduction of welding fumes in Annex I to the CMRD will concern about 1% of workers involved in welding activities. This was added under section 2.2.4. Other drivers might be considered (see answer "c."). No publication that could provide an indication of the level of compliance with the CMRD in individual Member States was identified. This will be clearly mentioned in the IA, section 2.2.1. According to the evidence gathered, the lack of awareness is considered as an important driver by key stakeholders. Another survey carried out with twelve national stakeholders (comprising one company, two trade unions, three OSH experts and six training/trade associations) revealed that the perceived level of awareness of the presence of CMRs in welding fumes in their members, employees, or students ranged widely from 20%-100%. As a consequence, employers do not perform the mandatory risk assessment and do not implement all necessary measures. Therefore, some workers might not be adequately protected from welding fumes exposure, leading to possible hazardous health effects. The IA will include in its section 2.2.4 the above evidence to support the driver and its causal link with the excessive exposure to welding fumes. The lack of inspection for non-compliance with CMRD was identified as a driver and was discussed under a new section 2.2.5 The specific objective regarding welding fumes was reformulated to better link with the cause of the problem, namely the lack of awareness and its possible consequence on the non-performance of risk assessment. According to Article 3 (2) of the CMRD, in the case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. Guidance at EU level already exists: • A European Guidance on welding activities, developed by the SLIC in 2018, already exists at EU level. Although this guidance was developed for inspectors, companies can also follow it to ensure they are meeting their requirements. This guidance includes background information such as health risks, types of welding, the legal framework for regulation, typical control measures, health surveillance and key information. It also includes a

	welding fumes task sheets with specialised guidance on each welding activity including approaches to control welding fumes exposure, illustrative photographs, etc. • The European Welding Association (EWA) has developed guidance for different exposure scenarios and operational conditions, with recommended Risk Management Measures (RMMs), with the aim of outlining how metals, alloys and metallic articles and mixtures can be safely welded with respect to exposure to welding fumes and gases. Despite the existence of guidance at EU level, the evidence gathered shows that the problem persists. Therefore, the development of a new guidance was not considered as relevant to address the problem. This was added in section 5.2 and Annex 10. Due to the complexity and heterogeneity of the composition of welding fumes, as well as the absence of harmonised classification in the CLP Regulation, employers might ignore that the fumes generated by their welding activities might include carcinogens, mutagens or reprotoxic substances. Consequently, those employers might not carry out the risk assessment provided in the CMRD when workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work. In the absence of such a risk assessment, employers are likely not to implement all necessary RMMs to comply with the CMRD and adequately protect their workers. The evidence gathered confirms that some employers are not aware that welding fumes may contain carcinogens, mutagens or reprotoxic substances (such as chromium (VI) compounds, nickel compounds, cadmium and its inorganic compounds, and beryllium and its inorganic compounds) and lead to health risks. This is further developed in section 2.2.4 According to the evidence gathered, it is assumed that many businesses, in particular larger enterprises, are already applying best practices measures and will not need change their practices. Following interviews with key stakeholders, it was assumed that 1% of welders will improve their current RMMs following the introduction of welding fumes in Annex I to the CMRD. This will be further reflected under sections 2 and 5. Furthermore, data related to the current RMMs in different sectors as collected through the external study will be added in Annex 6. The heterogeneous character of welding fumes makes it very difficult to establish a common OEL for all welding processes. This was added in section 5 and annex 10 when discussing the discarded option for welding fumes.

	The revised impact assessment better presents the methodology and the evidence for welding fumes in introduction of section 6, in particular the methodology to calculate costs and benefits. It also further discusses in a qualitative way the impacts on employment and on discontinuations. Given the absence of impacts on discontinuation, employment and competitiveness, no impact on the open strategic autonomy of the EU is expected. It is mentioned in section 6.4.2 (b).
The report does not sufficiently analyse the impacts of the transitional options. The comparison of options and the identification of the preferred options for each substance as well as the evidence base to justify the preferred option combination is not robust.	The expected effects of transitional options have been further described in introduction of section 6, to show how they would allow businesses to reduce costs and to better plan their investments. This addition allow to better understand the impacts discussed under section 6.4. Some benefits from section 1 of Annex 3 were updated in line with the rest of the Annex 3 and the main report. An explanation on how the preferred options were chosen, based on the analysis provided in the comparison-related section was added for each substance in section 7. The scores related to (i) the number of cancer and non-cancer cases and (ii) the coherence with Europe's Beating Cancer Plan are co-dependent. The higher the number of cases avoided, the greater the coherence with Europe's Beating Cancer Plan. However, this co-dependency is not expected to affect the choice of the preferred option. The number of cancer and non-cancer cases constitute one single indicator. This was clarified in introduction of section 7. The closer the policy option is to the ACSH opinion, the greater the positive impact on its effectiveness. This was made clearer in the methodology for the comparison, in introduction of section 7. The section related to the proportionality of the package of preferred options was further improved to stress all factors taken into account when carrying out the proportionality analysis. In addition to the costs/benefits analysis, these factors are the EU strong commitment to fight against cancer, the stakeholders' views, the impact on businesses, the existence of mitigating measures and the coherence with other key EU policies.
The impacts on competitiveness and on consumers are not adequately analysed. The recording of stakeholder views in the report is partial.	The analysis was further nuanced so not to give the impression that no sector is expected to be impacted in terms of competitiveness. As part of changes brought in the main report, the claim that for most businesses, including SMEs, the package of preferred options will not have any impact on their competitiveness was removed. Transitional measures are expected to mitigate the negative impacts on businesses, and consequently competitiveness, entailed by policy options without transitional options. The text now better explains that transitional measures do not mean that

	there will be no impact. In sections 6 and 8, as well as in Annex 5, the capacity to absorb costs, in particular for SMEs, and the cascading consequences are further discussed. SMEs are in particular unlikely to absorb additional costs, which would result in consumers being impacted by raising prices. In sections 6 and 8, as well as in Annex 5, the impacts on consumers prices and diversity of supply are further discussed. In particular, the text as revised clearly links those impacts with their causes, namely the incapacity for businesses to absorb additional costs, and the changes in some sectors' structure due to discontinuations (in particular coking plants). In section 2 of annex 2 direct links to the individual ACSH opinions were added. We have introduced, where needed, reference to *Table related to stakeholders targeted and interests represented* which is also part of annex 2. Generic formulations as regards stakeholders were analysed throughout the document and, where necessary, clarifications were added. New paragraphs with summary of stakeholders consultation and references to Annex 2 were added in subsection 1.3, section 6, subsection 6.1, subsection 8.1, Three paragraphs were added under new sub-section "3.6. Key findings" and, as studies will be made publicly available with the legislative proposal, we introduced footnote "RPA (2024), op. cit." which was already used for same purpose in the IAR.

4. Evidence, sources and quality

The following Commission reports have fed into the Impact Assessment:

- Commission SWD Ex-post evaluation of the European Union occupational safety and health Directives (REFIT evaluation), SWD/2017/010 final
- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions – EU strategic framework on health and safety at work 2021-2027 Occupational safety and health in a changing world of work, COM/2021/323 final
- Commission SWD List of substances to be scientifically assessed for the purposes of Article 18a, third paragraph, of Directive (EU) 2004/37/EC on presenting an action plan to achieve new or revised occupational exposure limit values for at least 25 substances, groups of substances or process-generated substances, SWD (2022) 438 final

The following expert advice have fed into the Impact Assessment:

1. Risk Assessment Committee's opinions

The scientific expertise provided by ECHA's Risk Assessment Committee allowed for an assessment of health effects of the carcinogens, mutagens or reprotoxic substances subject to this initiative.

RAC prepares the opinions of ECHA related to the risks of substances to human health and the environment. RAC delivers among other scientific opinions on occupational exposure limits supporting Union regulatory activity in the field of occupational safety and health. More information on about what this committee does can be found on the website of ECHA[184].

RAC develops high quality comparative analytical knowledge and ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence. Based on a Service Level Agreement (SLA) signed by DG EMPL and ECHA, this Committee assists the Commission delivering scientific evaluations, upon request, on the toxicological profiles of each of the selected priority chemical substances in relation to their adverse health effects on workers. These scientific evaluations shall, where appropriate, include proposals for OELs, biological limit values/biological guidance values and/or notations.

Members of RAC are highly qualified, specialized, independent experts selected on the basis of objective criteria.

For the purpose of this initiative, the Commission services have used the relevant chemical agent-related RAC opinions which are summarised as follows:

RAC opinion on cobalt and inorganic cobalt compounds

In its opinion on cobalt and inorganic cobalt compounds, RAC recommended:

- OELs (as 8-hour TWA) of 0.5 µg Co/m^3 (respirable fraction) and 1 µg Co/m^3 (inhalable fraction); and
- "skin sensitisation" and "respiratory sensitisation" notations.

This opinion, which was adopted by consensus on 1 December 2022, was prepared by the following RAC members: Tiina Santonen and Ruth Moeller.

RAC opinion on polycyclic aromatic hydrocarbons

In its opinion on polycyclic aromatic hydrocarbons, RAC recommended:

- skin notation.

RAC considered that benzo-a-pyrene (BaP) is a marker substance for carcinogenic PAHs. However, RAC did not recommend limit values for BaP because BaP and PAHs containing BaP are non-threshold carcinogens. Therefore, no health-based OEL can be identified. Instead, RAC the following cancer exposure-risk relationship (ERR).

[184] Committee for Risk Assessment - ECHA (europa.eu)

Cancer exposure-risk relationship (ERR)*

Concentration of BaP (ng/m^3)	Excess (life-time) lung cancer risk (cases per 100 000 exposed)
1	0.56
2	1.1
5	2.8
10	5.6
20	11
50	28
100	56
200	110
500	280
1000	560

* Assuming an 8-hour exposure per day and 5 days per week, over a 40-year working life; the air concentration values for BaP refer to the inhalable fraction.

This opinion, which was adopted by consensus on 1 December 2022, was prepared by the following RAC members: Thomas Gebel (with support from Kevin Kohns) and Andrea Hartwig.

RAC opinion on 1,4-dioxane

In its opinion on 1,4-dioxane, RAC recommended:

- OEL (as 8-hour TWA) of 7.3 mg/m^3 (2 ppm);
- STEL of 73 mg/m^3 (20 ppm);
- BLV of 45 mg 2-hydroxyethoxyacetic acid/g creatinine; and
- Skin notation.

This opinion, which was adopted by consensus on 18 March 2022, was prepared by the following RAC members: Gerlienke Schuur and Andrea Hartwig.

RAC opinion on isoprene

In its opinion on isoprene, RAC recommended:

- OEL (as 8-hour TWA) of 8.5 mg/m^3 (3 ppm).

This opinion, which was adopted by consensus on 18 March 2022, was prepared by the following RAC members: Andrea Hartwig and Gerlienke Schuur.

2. ECHA's scoping study

On 17 November, ECHA delivered at the request of the Commission a scoping study of welding fumes and fumes generated from other processes. This scoping study identifies the extent, range and nature of the key processes, and the substances involved, that lead to the exposure of workers from welding fumes+.

3. Study performed by external consultants

The Commission launched a call for tender on 14 July 2022 to carry out a study providing data on the social, economic and environmental impacts of a number of POs with regard to the protection of workers from the risks arising from the occupational exposure to the five substances subject to the initiative.

The contract started on 4 November 2022 and lasted 21 months. The outcome of this study provides the main basis for this impact assessment report and is summarised in the relevant sections of this document.

Annex 2: Stakeholder consultation (Synopsis report)

The following consultation activities have been performed:

1. ***Social Partners Consultation:*** as required by the TFEU Article 154, a formal two-stage consultation of the social partners at EU level is required prior to submitting proposals in the social policy field. The legislative initiative subject to this consultation on the sixth revision of the CMRD tested a new procedure of the two-stage social partners simplified consultation carried out through two ad-hoc meetings with the participation of all concerned recognised social partners and the possibility to send written contributions as agreed with cross-sectoral social partners. Such a two-stage consultation has been performed in 2023. The first phase consultation was launched on 16 February and ended on 31 March 2023. The first ad-hoc meeting, corresponding to the first phase of the social partners consultation to gather the views of European social partners on the proposal, was organised online on 16 March 2023. The second phase consultation closed on 21 November 2023 and confirmed these 5 substances as to be addressed in this initiative. More information about these two-stage consultation is provided below in this annex 2.

2. ***Tripartite consultation (ACSH):*** the tripartite Advisory Committee on Safety and Health (ACSH), composed of three full members per Member State, representing national governments, workers', and employers' organisations, is consulted on regular basis. It gives, considering the input of the RAC as well as socio-economic and feasibility factors, opinions which are used to prepare the Commission's proposal. More information about this tripartite consultation is provided below in this Annex 2.

3. ***Consultation of other stakeholders*** (e.g., industry of employees' associations specifically concerned): These consultations have been carried out in the context of the RPA study to collect detailed information on the potential impacts of establishing or revising OELs under the CMRD that is not available in published literature and internet searches. The results of the impact assessment by eftec (2023) for the Cobalt Institute / REACH Cobalt Consortium have been taken into account and used as an input for the market analysis.

Based on the broad consultation of various stakeholders, social partners and Member States' competent authorities, no public consultation on this very technical topic was foreseen, in line with the previous amendments of the CMRD.

1. Social partners consultation

1.1. Results of the 1st phase of the social partners consultation

During the first stage of social partners consultation, social partners were consulted on the need for, and possible direction of, EU action. In addition to the interventions made during the 16 March 2023 meeting, three recognised social partners sent written replies during the first-phase consultation, including one workers' organisation (European Trade Union Confederation – ETUC) and two employers' organisations (SGI Europe, SMEunited). The first phase of Social Partners consultation closed on 31 March 2023.

The Commission consulted the Social Partners among others on the establishment and/or revision of further binding OELs in Annex III to the CMRD.

Commission identified a first proposed list of priority substances for a subsequent amendment revision of the CMRD in the first phase consultation document, as follows:

a) welding fumes;
b) polycyclic aromatic hydrocarbons;
c) cobalt and its inorganic compounds;
d) 1,4-dioxane (CAS no. 123-91-1); and
e) isoprene (CAS no. 78-79-5).

1.1.1. Workers' organisations

During the meeting of 1st stage social partners simplified consultation, workers' organisations:

- expressed support to the simplified consultation procedure of the social partners and to the five substances prioritised for the planned initiative;
- stressed the need for taking into consideration the most stringent existing national limit values when establishing EU-wide OELs;
- encouraged the Commission to endorse the ACSH opinion on a risk-based approach to set OELs.

Workers' organisations written response was specific per (group of) substance(s) and complements the issues identified by the Commission with the following observations and demands:

a) Welding fumes

Workers' organisations are of the opinion that welding fumes must be included in Annex I of CMRD because the International Agency for Research on Cancer (IARC) classified welding fumes (and UV radiation) from welding as "carcinogenic to humans" (Group 1). Moreover, exposure to welding fumes can cause lung damage and various types of cancer, including of the lung, larynx and urinary tract. It is estimated that 2 million workers are potentially exposed to welding fumes in the EU (mainly welders).

As the CMRD covers substances meeting the criteria for classification as carcinogenic, mutagenic or reprotoxic substances category 1A/1B according to the CLP regulation, workers' organisations demand that it is clarified in the 6th revision of the CMRD that the scope of annex I not only covers carcinogens but also includes mutagens and reprotoxic substances.

Workers' organisations are also of the opinion that an entry in annex I is obvious and it would be just a legal clarification that welding fumes containing CMR substances are automatically in the scope of the Directive. Therefore, the entry into annex I is not enough and other measures are necessary to adequately improve the protection of the health and safety of workers exposed to welding fumes.

The scoping study on welding fumes prepared by ECHA has identified several additional measures that could complement an entry of welding fumes in annex I. The following measures should therefore be assessed:

- set a generic OEL for inhalable and respirable dust. This means setting a generic OEL for inhalable and respirable dust in addition to the OEL requirements of the CMRD and Chemical Agents Directive 98/24/EC (CAD), specific to welding fumes.

- set mandatory protective/control measures for welding techniques that lead to greater emissions of welding fumes or promoting of low emission techniques.
- introduce health surveillance programmes for welders under certain conditions.

Workers’ organisations are of the opinion that these measures should be included in the legal text as soon as possible.

b) Polycyclic aromatic hydrocarbons (PAHs)

After the inclusion of PAHs in CMRD annex I in Directive 2019/130 (second revision of CMRD), workers’ organisations find it coherent and necessary to complement the entry into annex I with a binding OEL for PAHs in CMRD Annex III (using benzo-a-pyrene (BaP) as a marker for exposure to PAHs). Workers’ organisations also highlighted that this complex mixture of carcinogens is produced during the combustion and pyrolysis of organic material and is therefore “process-generated”. Exposure to PAHs can cause lung, skin, bladder cancers as well as leukaemia. It is estimated that 7 million workers are potentially exposed to PAHs in the EU.

c) Cobalt and inorganic cobalt compounds

Workers’ organisations support the adoption of binding OELs for cobalt and inorganic cobalt compounds in CMRD annex III. According to them these compounds are used in the metal industry to produce alloys, in the chemical industries as catalysts and for the production of batteries for electric vehicles, tablets and smartphones. Exposure to cobalt and cobalt compounds causes lung cancers, reproductive disorders and respiratory effects. It is estimated that more than 80,000 workers are potentially exposed to these compounds. Particular attention should be paid to workers in the waste and recycling sectors as these workers might be increasingly exposed in the future due to the energy transition and all measures to counter climate change and environmental degradation in the European Green Deal.

Workers' organisations stress that several Member States already have a national OEL for cobalt and cobalt compounds. However, these OELs vary a lot from one country to another and there is a need to adopt an ambitious OEL in annex III CMRD which will help improve the protection of all exposed workers across the EU. The adoption of an ambitious EU OEL for cobalt and cobalt compounds should be facilitated by the fact that these compounds are generally used in the industry with other heavy metals like nickel and cadmium compounds for which EU OELs have already been adopted under the CMRD. Since the risk management measures are common to many heavy metal compounds and they are already in place to comply with the existing OELs, no additional protection measures will be needed in many cases.

d) 1,4-dioxane

Workers’ organisations are of the opinion that a binding OEL needs to be included in annex III CMRD for 1,4-dioxane. According to them, this solvent is used in industrial settings and causes in exposed workers nasal and liver cancers on top of respiratory tract irritation, nephrotoxicity and hepatotoxicity. It is estimated that more than 35,000 workers are potentially exposed to 1,4-dioxane in the EU.

According to workers’ organisations, most Member States already have a national OEL for 1,4-dioxane since an indicative OEL was adopted for this solvent in the CAD. However, the national OELs vary a lot from one country to another with some Member States having a national OEL much more protective compared to the current EU indicative OEL.

Workers' organisations would like to point out that for OEL setting what is feasible in one Member State is also feasible in the other Member States and therefore expects the future EU binding OEL on 1,4-dioxane to be at least as protective as the lowest national OEL already in place in the EU.

e) Isoprene

Workers' organisations support the adoption of a binding OEL for isoprene in the annex III of CMRD. According to them, isoprene is an intermediate in the chemical and rubber producing industry. The carcinogenicity of isoprene in animal studies has been clearly demonstrated and it is therefore important to set an EU limit value for the protection of workers potentially exposed to isoprene.

Moreover, only a few Member States have a national OEL for isoprene and it is therefore an additional argument to adopt an OEL for that carcinogen at EU level.

As a general remark, workers' organisations would like to draw the attention of the Commission on the recent adoption of an opinion of the ACSH on a risk-based methodology to set limit values for non-threshold carcinogens. Workers' organisations believe that this methodology should be applied for the first time to relevant substances subject to the 6th amendment of CMRD and therefore considers that the residual risk of cancer must remain in the agreed risk boundaries. Moreover, workers' organisations demands that this residual risk of cancer is clearly mentioned in the legal text (new column in annex III). Information related to residual risk, made publicly available at EU level, would be valuable for future work to limit risks from occupational exposure to carcinogens, including by revising the limit values set out in this Directive. Transparency of such information should be further encouraged.

1.1.2. Employers' organisations

During the meeting of 1st stage of social partners simplified consultation, employers' organisations:

- expressed support to the new simplified format of the social partners consultation;
- highlighted the key role of the ACSH and its WPC in the process of developing Commission's legislative proposals;
- identified welding fumes and cobalt and its inorganic compounds (and to a lesser extent PAHs) as the key substances for this planned initiative;
- stressed the need for better protecting workers while preserving the competitiveness of EU-based companies;
- asked for having the second meeting of the social partners consultation after the adoption of the ACSH opinions on the 5 substances.

In their written response, employers' organisations underlined that establishing limit values or reviewing the existing ones has always a strong impact on SMEs. An approach solely based on setting limit values is not sufficient for effective protection. These limits must also be implementable by crafts and SMEs. Therefore, employers' organisations insist that the socio-economic impact of new OELs is well-taken into account and that small enterprises receive enough well adapted guidance, guidelines and monitoring tools on how to tackle the issue of carcinogens and other substances. Furthermore, on the issue of protective equipment, SMEs also require targeted advice as well as financial support.

Employers' organisations welcomed the decision of the European Commission to place new substances under the scope of the CMRD and agreed with its consultation document concerning the necessity to heed the new scientific evidence which allows to better understand occupational hazards or exposure and allow for better prevention and protection at the workplace.

Employers' organisations expressed that the impacts on individual health, family life and on national health and social systems cannot be continually ignored and thus, in parallel of the Europe's Beating Cancer Plan of the Commission, actions to fight cancer at the workplace through continuous revision of the CMRD are considered as key to tackle the issue.

Further, employers' organisations stressed the need to carefully evaluate each substance and to consider their specific characteristics and impacts. Nevertheless, some substances have a greater level of complexity and could indirectly impact the European competitiveness (welding fumes) or switch to renewable energies (cobalt). In this regard, employers' organisations are still enquiring how their members will be indirectly impacted by the revision of the OEL, in particular members in energy and waste management sectors.

Hence, employers' organisations think that it is necessary to consider each substance separately and to carry out a socio-economic impact analysis on the outcomes and the challenges that could result from changing the exposure limit value of these substances. Therefore, the opinion of the ACSH's WPC, which considers the technical and socio-economic feasibility of changing OEL, is crucial. However, the socio-economic feasibility should not play a disproportionate role in establishing limit values.

Employers' organisations also believe that the limit values should be implemented in a transitional period. The revision would be done by progressively lowering the exposure level, which would give companies the technical and financial capacity to change their way of producing.

In addition to the above more general remarks, there were more detailed comments concerning specific substances.

a) Welding fumes

As regards welding fumes, employers' organisations consider that the impact of stricter rules goes far beyond the metal sector and can affect almost all industry and handicraft sectors. It depends on the process of welding and the type of metal used. In their opinion, the background document could contain more data on the impact that the new OELs could have on reducing work-related diseases and cancer. It would be necessary to have a more thorough analysis of the impact and presumed benefits of setting new OELs. In addition, the socio-economic impact of introducing new OELs needs to be duly taken into consideration when assessing cross-legislative impacts, in particular on achieving the goals of the European Green Deal.

Employers' organisations also drew attention to the additional possible impacts of introducing new OELs for welding fumes. These possible impacts include:

- apprenticeship training: Stricter regulations for welding fumes can become an unsolvable problem for apprenticeship training. There is a great danger that the related tightening (e.g. welding ban in rooms where apprentices are also employed) will result in apprenticeship training in metalworking professions being called into question or no longer feasible. By jeopardizing apprenticeship training, the new rules would have negative consequences far beyond the area of workers protection. In times of a shortage of skilled workers, this might lead to unwanted consequences.
- costs burdens due to necessary retrofitting/conversions: A production hall or workshop in which welding is carried out would have to be converted or retrofitted with top exhaust air

systems and extraction systems, welding cabins, etc., if this at all were technically possible and financially viable for the company.

- far-reaching concern: As already noted before, the concern goes far beyond the classic metal sector. The main areas affected are mechanical engineering, vehicle construction, plant construction, rail vehicles, agricultural machinery, construction (reinforcing steel, steel construction), vehicle repair shops, metalworking shops, maintenance and repairs in production companies. Welding equipment is used throughout the maintenance and production process.
- bureaucratic burdens: It should also be considered that new rules within the EU will make the product more expensive and the added value could migrate out of the EU.
- relocation of production: If all welding fumes are classified as carcinogenic and a limit value is set, this would pose a massive existential threat to the metalworking sector. Substituting alternative processes on such a large scale would not be possible and would also not be economically viable. The relocation of production outside the EU would probably be the result.

b) Cobalt and its inorganic compounds

As regards cobalt and its inorganic compounds, employers' organisations invited the Commission to assess thoroughly the impact of introducing an OEL, knowing that cobalt cannot be replaced by other materials in some sectors (for example, dentistry). As for the other substances, the socio-economic impact of introducing a new OEL for cobalt and its inorganic products needs to be duly taken into consideration when assessing cross-legislative impacts, namely the European Green Deal.

1.2. Results of the 2nd phase of the social partners consultation

The Commission launched a second phase consultation of the Social Partners which closed on 21 November 2023.

During the second stage of social partners consultation, social partners were consulted on objectives and avenues of EU action, possible legal instruments and willingness to enter negotiations with a view to concluding an agreement under Article 155 TFEU. In addition to the contributions made during the 7 November 2023 meeting, three recognised social partners sent written replies during the first-phase consultation, including one workers' organisation (European Trade Union Confederation – ETUC) and two employers' organisations (BusinessEurope, SMEunited).

In the second ad-hoc meeting which took place on 7th of November 2023, the Commission asked the Social Partners the following questions:

- **What are your views on the objectives of possible EU action?**

Workers' organisations concur with the analysis put forth in the background document with analytical elements, especially in alignment with the primary overarching policy objective of this initiative, which is to uphold a strong standard of health and safety for workers throughout the EU. This legislation will additionally aid in establishing a consistent standard for occupational safety and health (OSH) protection within the EU, thereby diminishing disparities in the levels of protection currently offered at the national level.

Employers' Organisations considers it necessary to take all the necessary legislative and non-legislative measures for ensuring a good health and safety environment at work and to prevent diseases such as cancer. Crafts and SMEs employers recognise that adequate Occupational Health and Safety (OSH) measures help to prevent risks of diseases and accidents and increase productivity. A good health and safety environment depends amongst others on the right legislative framework that is fit for purpose and support for compliance. Therefore, they (SME United) firmly support social partners' involvement and engagement, and takes note of the opinions adopted by the Advisory Committee on Safety and Health and would like to point out that limit values must be technically and economically feasible for companies and be proportionate. Moreover, compliance with the new limit values must be monitored in each Member State to ensure a level-paying field.

- **What are your views on the possible avenues for EU action?**

Workers' organisations representatives endorse the first option: Enacting binding legislation to address the protection of workers from exposure to the identified substances. Conversely, they are against the third option - guidance - as a considerable number of employers may not be motivated to invest in and adhere to OSH protection measures unless they are legally mandatory.

Thus, they expressed support to the reviewing the directive and continue process to achieve the best possible protection of workers. They welcomed the tripartite opinion and considered that it is not necessary to reopen the debate between employers and trade unions because the dialogue has already been carried out in the ACSH and it was a very fruitful dialogue. They would also like to see in the legal text considerations to the possibility of further reviewing the occupational exposure limits and other measures enacting the legislation in the light of potential future scientific and technological development, especially as regards cobalt.

Workers' organisations representatives stressed the need for harmonisation of national limit values to ensure the same level of protection for all EU workers and this can be realised by establishing EU-wide occupational exposure limits (OELs). This can only be done by a legislative instrument and reviewing the directive is the right way forward. They also acknowledged that there will be costs for companies and they agree that, at the same time, there is a need to ensure protection of the economical and industrial sustainability of the EU companies from dumping and ensure protection of the safety and health of all workers without harming the competition. The need to improve the gender-based approach was also highlighted, because impacts of health on workers differ according to gender and their age, take into consideration the exposure to combinations of substances and consequences of these combinations of substances, promote the substitution of toxic substances with new generation of substances have less impact and a recital about the need to respect the hierarchy of the protective measures to be provided by the employer reminding that technical and organizational protective measures should go before personal protective equipment and underlined the importance of educating workers and keep them healthy and safe to enable them to work by improving working conditions

Employers' organisations support guidance documents as the most welcome approach or alternatively moderate step-by-step amendments of the current directives aiming to revise or establish new binding limit values at the EU level. They (BusinessEurope) confirm what has been put forward by the Advisory Committee, recognises the outcome of these opinions as the balanced compromise between all three interest groups and called (SMEunited) the Commision not to go beyond what was agreed by the ACSH and ensure sufficient transition periods for SMEs and the affected sectors. Considering additional expenses for SMEs resulting from such amendments is highly recommend as lowering exposure levels for these specific substances will have a considerable impact on companies' activities, already overwhelmed by a whole set of standards.

Accompanying measures such as financial support and guidance should be foreseen to ensure that SMEs are able to adequately implement the new exposure levels.

- **What are your views on the possible legal instruments presented?**

According to the Workers' organisations (ETUC), the most advisable course of action is to revise the Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work and calls on the European Commission to respect the consensus reached by the Advisory Committee on Safety and Health at Work (ACSH) when presenting its legislative proposal to the European Council and the Parliament. Furthermore, they ask for the inclusion of the additional elements highlighted in its initial response to the first consultation such as defining hazardous medicinal products (HMPs), addressing combined exposure, and adopting a gender-specific approach as guiding principles for the legislation.

They reiterate their request for the recognition of firefighters as a carcinogenic profession. Their proposal advocates for acknowledging the systematic exposure of firefighters to carcinogens without specifically delineating a comprehensive list of "carcinogenic professions".

Workers' organisations underscore that women workers are vastly underrepresented in research into the health risks that are associated with workplace exposures to chemicals. Likewise, wrong assumptions about the jobs that many women workers undertake can mean that their health and safety is overlooked. It is essential that the Commission includes a specific focus on the gender differences in this and its future initiatives to improve workers' protection from chemical risks.

Additionally, it's crucial to address all factors influencing greater exposure to risks from carcinogens, mutagens, and reprotoxic substances. Special attention must be given to workers with various characteristics: advanced age, psycho-physical impairments, precarious working conditions, extensive overtime or shift work, and exposure to high temperatures. Not undertaking specific action to encompass these workers can lead to overlooking their health and safety risks. Therefore, they consider that the Commission should prioritize a comprehensive approach considering these factors in future initiatives to enhance workers' protection from chemical risks.

It is also crucial to establish precise implementation timelines at the outset of the revision process. This proactive approach aims to prevent unforeseen delays in the ordinary legislative procedure, as previously experienced with other occupational safety and health-related legislations".

Employers' organisations stress the importance of ensuring the technical adaptation of SMEs both in terms of production and protective measures. A harmonised approach by national authorities exhausting all options, including personal protective equipment, should be a key element of the future revision (e.g.: use of protective masks and time allowed for using the same mask). Employers' organisations ask the European Commission to consider several elements in the impact assessment accompanying any future initiative in this field. Firstly, a thorough analysis of all impacted sectors. For example, sectors which are key for the green transition are not the only ones using cobalt. Dentistry and other niche sectors are also using this substance and cannot substitute it. Secondly, Employers' organisations recommend to well analyse the impact of the lower values on the competitiveness of companies. In many industries, the intended limit values cannot be achieved only through technical adjustments to the workplace, or with the substitution of the material. There is a need to use personal protective equipment such as respirators to ensure that workers are adequately protected, and companies can comply with their legal obligations. Therefore, an impact assessment regarding the impact of the limit values on the goals of the Green Deal as well as maintaining and strengthening competitiveness of European companies is essential.

Employers' organisations put forward, in their written reply, some further comments on the following substances:

a) Welding fumes

Due to the frequent use of welding processes in industry and crafts in the EU, numerous economic sectors will be impacted by a potential future revision of the limit value. If in the future, the substitution of welding is necessary, it would force companies to completely change their product design. The economic impact of such changes should duly be considered. When setting limit values, specific attention should be taken to ensure that the impact on apprenticeships is well analysed. Classifying welding fumes as carcinogenic might damage the attractiveness of the whole sector and sharpen the labour and skills shortages. In addition, the impact assessment should also consider how the implementation can be realistically carried out in companies such as repair shops (motor vehicles, agricultural machinery, etc.) that only weld sporadically and how this affects the exposure of apprentices. A lack of career opportunities in the above-mentioned and related sectors further increases the shortage of skilled workers and may contribute to a further loss of competitiveness.

While supporting the new proposed entry into Annex I: "Work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP regulation" they consider that a footnote should be added to the new entry to Annex I in line with the ACSH opinion to clarify that currently Annex I contains only a list of carcinogenic substances, mixtures and processes and that reprotoxic substances, mixtures and processes need to be included in order to be consistent with the proposed welding fumes entry. Furthermore, there is a need to distinguish between the requirements applying to carcinogens versus those for reprotoxic substances, clarifying that:

- for the new entry, reprotoxic effects have to be included, but not for the previous entries;
- provisions for reprotoxic substances are not the same that for carcinogens or mutagens.

Finally, the footnote should clarify that the entry in Annex I can only be applied to welding fumes under the following two conditions:

- they contain substances that are classified as carcinogens, mutagens or reprotoxic according to CLP;
- they exceed the relevant generic or specific concentration limit.

The lack of this clarifying footnote could have potential adverse effects on the search for existing, but especially future skilled workers in an already tight labour market. As the welding profession deals with an increasing attractiveness problem, with huge shortages of qualified welders in amongst others the metal sector, labelling an entire profession as "carcinogenic" would not only be blatantly dishonest but could also have disastrous effects on the profession.

The ACSH opinion clarifies that over a period of at least two years, guidelines will be created by the ACSH to clarify the introduction of this new entry into Annex I. They firstly underline that it is paramount to retain this timeline as the absolute minimum to avoid overburdening the ACSH in their workload. The guidelines should furthermore highlight that this new entry can only be intended to raise awareness and attention to the fact that certain welding fumes could produce cancer in exposed workers and preventive measures will therefore need to be adopted as well as health surveillance to prevent it.

The guidance should furthermore refer to the following elements:

- ensuring that occupational exposures to the individual airborne compounds of hygienic significance in welding fume can be maintained below established exposure limits (already fully considering the CMR status of the applicable fume components).
- providing adequate ventilation is ultimately key to preventing workplace overexposures, and in turn, their potential health effects.
- continuing to evaluate and refine welding operations for the reduction of airborne contaminants in accordance with established occupational exposure standards and industry guidelines.

Finally, they note that a more detailed socio-economic impact assessment will be necessary for the entry of welding fumes into Annex I of the CMRD and should take into consideration the financial burdens, especially for small and medium sized enterprises in the EU, due to necessary new investments in plant technology for air pollution control.

b) Cobalt and its inorganic compounds

Cobalt, among other most classical applications, is used in more niche sectors, such as in dentistry or for example, as a filler material in welding technology for wear-resistant cored wires. The range of uses for cobalt in this specific field is all types of wear protection layers (e.g. for drill heads in tunnel construction, excavator shovels, crushers). The area of use is hardly known to the public except among experts but is of great importance in its niche. To be able to apply such wear protection layers, high proportions of cobalt are necessary in the filler material. Tight limit values are therefore very difficult to achieve. For example, it would be difficult to reapply worn excavator blades or similar, if the wear protection layer has been removed. In addition, the achievement of a limit value for cobalt also depends on the areas of production. There is a difference in the measured values and such a distinction should also apply in the future. Finally, Employers' organisations would like to point out that cobalt cannot be substituted in many cases, therefore it is important to guarantee that sectors using this substance can continue to operate.

Employers' organisations support the proposed limit value of 20 µg Co/m3 for the inhalable fraction and 4.2 µg Co/m3 for the respirable fraction as a reasonable outcome. Whilst it is the lowest value in the world, many industries already meet these levels and achieving them has been shown to be feasible. They furthermore recognise the OEL of 10 µg Co/m3 2 for the inhalable fraction and 2.5 µg Co/m3 for the respirable fraction as the outcome of technical as well as political negotiations. However, it should be noted that an OEL value of 20 µg Co/m3 is already very strict. Any tightened level will require long transition periods due to the high level of investment and potentially innovation needed, for companies in a start-up phase with production in constant development. In some cases, innovation is required for redesigning process equipment and potentially the entire process. Furthermore, all the studies indicate that there is no increased cancer risk linked to cobalt exposure at the levels that have been relevant in these studies. They include measurement data and health data from people who have worked since the 50s and 60s when exposure levels were higher than today or are entirely based on animal studies.

Employers' organisations stressed on the need for a more detailed and evidence-based socio-economic impact assessment of the impact of the proposed OEL of 10 µg Co/m3 after the transition period of six years. They noted in this regard that the Cobalt Institute is currently in the process of conducting such a study to estimate the real cost of the ACSH opinion as the basis for the Commission's upcoming proposal. This will be crucial information as cobalt and inorganic cobalt compounds is considered one of the key strategic and critical raw materials at the basis of the European Commission's green transition and strategic autonomy ambitions.

Employers' organisations underlined that in the Critical Raw Materials Act cobalt has been labelled a Strategic Raw Material, with benchmarks set to ensure 40% of Europe's cobalt needs come from domestic processing and refining, and 15% of needs come from domestic recycling. Applied specifically to cobalt, these targets imply that Europe's cobalt refining and processing industry needs to grow by 122% (2.2 times) and recycling by 150% (2.5 times) by 2050. It will furthermore need to increase cobalt use by 350% by 2050 to meet the needs of the green transition, driven using cobalt in battery cathodes, with a 135% increase in cobalt jobs by 2030 alone.

Employers' organisations estimate that 65,000 new cobalt jobs will be created in the EU by 2030 to meet the demands of the green transition. This industry will require huge investments to grow to the size needed to sustain the European green goals. Nevertheless, preliminary figures by the Cobalt Institute show that the implementation of the proposed OEL of 10 µg Co/m3 could:

- cost the industry 19.3 billion euros over 40 years;
- result in 110,000 job losses out of a total of 641,000 jobs;
- lead to the closure of 1,550 sites out of 9,000 sites in total.

Ensuring the access to financial support as well as guidance to implement the OEL will therefore be necessary, for small and medium enterprises.

Employers' organisations expect that internal and foreign investment into this sector will decrease significantly due to overly stringent rules in the EU as compared to the rest of the world. This could result in the likely relocation of production sites to countries and regions outside the European Union and, associated with this, distortion of competition in international comparison, irrespective of the serious effects in training and qualification. This initiative could therefore have more far-reaching consequences for the European industry than only the increased protection of workers. This is of particular importance in a time where Europe is trying to refocus on increasing their overall competitiveness as well as to position themselves as a more credible actor in line with 3 the principle of strategic autonomy. To address these issues, it is important that DG EMPL liaises closely with their colleagues from DG GROW to correctly assess the socio-economic impact of the proposed OELs on the European industry.

Lastly, Employers' organisations noted that cobalt and inorganic cobalt compounds are used in a wide range of sectors e.g. batteries, sharpeners, dentistry, etc. Whilst many sectors want to make the necessary investments needed to achieve a new OEL, it should be noted that for some this will only be possible through the accompanied use of personal protective equipment (PPE). Ensuring that all Member States support the adequate access to PPE will therefore need to be an important element of the upcoming proposal by the Commission.

c) PAHs

Employers' organisations support the proposed limit value of 70 ng/m3as well as the proposed two-step transition period for specific sectors or processes:

- 2 years after entry into force of the directive, a BOEL of 140 ng/m^3;
- 6 years after entry into force of the directive, a BOEL of 70 ng/m^3

Nevertheless, Employers' organisations underline that for many Member States the proposed reduction of the OEL for PAH is significant and will require substantial investments, especially for indoor workplaces. For example, the OEL for benzo(a)pyrene in Sweden is 2,000 ng/m^3, as compared to the newly proposed BOEL of 70 ng/m^3. For many Swedish companies, the first step towards a lower BOEL of 140 ng/m³ is therefore already too large compared to the OEL of today. Against this background, Employers' organisations call upon the Commission to consider the different starting points of the various Member States in implementing a new BOEL in the Impact Assessment. This will allow for a more robust cost-benefit analysis that better reflects the required investments from different sectors and different-sized companies in the various Member States, with the aim of developing a better-designed implementation period for this substance to achieve the OEL of 70 ng/m³.

Are the European social partners willing to enter negotiations with a view to concluding an agreement under Article 155 TFEU with regard to any of the elements set out in Section 6?

As regards willingness to enter negotiations with a view to concluding a Social Partners agreement, the social partners reaffirmed support the current process to amend the CMRD, including the key role of the ACSH/WPC, and do not want to initiate a dialogue under Article 155 TFEU

2. CONSULTATION OF THE ACSH/WPC

The Advisory Committee on Safety and Health at Work (ACSH) has adopted opinions for welding fumes, polycyclic aromatic hydrocarbons, cobalt and its inorganic compounds, 1,4-dioxane and isoprene in the context of the sixth amendment of the CMRD.

The ACSH is proposing as possible approaches for these chemicals one or several binding OELs with additional notations for all of them.

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

Table 33 - ACSH recommendations for Annex III and Annex IIIa

Name of agent	EC No	CAS No	Limit values						Notation	Transitional measures
			8 hours			Short-term				
			mg/m³	ppm	f/ml	mg/m³	ppm	f/ml		
Cobalt and its inorganic compounds	-	-	10 µg/m3 (inhalable fraction) 2.5µg/m3 (respirable fraction)	0.45	-	-	-	-	Dermal and respiratory sensitisation	Limit Values of 20 µg/m³ (inhalable fraction) and 4.2 µg/m³ (respirable fraction) until 6 years after entry into force of the Directive
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are which are carcinogens, mutagens or reprotoxic within the meaning of this Directive	-	-	70 (*) ng/m3	-	-	-	-	-	skin	Limit value of 140 ng/m³ for the following sectors: •steel and iron foundries, which includes ferroalloy manufacturers; • aluminum manufacturers; • carbon and graphite electrode manufacturers; • coking plants; • coal tar distillation; • manufacture of refractory products; • welding of train tracks. • other non-ferrous metallurgical processes • casting of metals. until 6 years after entry into force of the directive

1,4-dioxane	204-661-8	123-91-1	7.3	2.0	-	73	20	-	Skin	-
Isoprene	201-143-3	78-79-5	8.5	3	-	-	-	-	-	-

(*) measured as benzo[a]pyrene

The ACSH recommended for 1,4 dioxane the setting of a binding biological limit value of 45mg HEAA in urine/g Creatinine, at the end of exposure or shift.

ACSH recommendations for Annex I

The ACSH strongly recommends the Commission to adopt as soon as possible the below new entry into Annex I under Directive 2004/37/EC:

- Work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP regulation[1].

[1] The limit values listed in annex III of this directive must be respected if a given welding process is related to an exposure to CMR substances. Most of the relevant hazardous substances for welding processes are already listed there (or are on the way to be listed).

3. Consultation of other stakeholders

In the context of the external study, consultation activities have been carried out to collect detailed information on the potential impacts of modifications to the CMRD that is not available in published literature and internet searches via desk-based research. Although some information on current OELs, STELs, BLVs and notations is available, limited information is available on the specific concrete risk management measures already in place, as well as those that would need to be implemented, should the proposed measures be introduced into the CMRD.

The primary aim of the consultation activities was to identify information not available via desk-based research. Consultation carried out for the purposes of the study consisted of the following main activities:

- targeted questionnaires, these included: substance specific questionnaires, Member State Authorities, OSH Experts, Trade Unions and a further short questionnaire for welding;
- interviews;
- site visits; and
- conversations (these consisted of email exchanges and online calls).

The study team have consulted a range of organisations whose activities are relevant to the five substances. Information collected via consultation included the sectors and processes in which the relevant substances are used, the size of companies that would be impacted, estimates of numbers of workers exposed currently, current air concentrations of substances concerned (both 8-hour time weighted averages (8-h TWA) and 15-minute reference periods), current biological limit values, as well as risk management measures currently in place, and risk management measures that would need to be implemented should the limits be introduced and the associated costs.

Consultation activities have been conducted by those with expertise; substance experts (those writing the substance-specific reports) and national experts (with knowledge of the situation in their Member State and native language competence) conducted the interviews with stakeholders.

A large amount of information has been collected via consultation, particularly through means of the targeted online questionnaires, telephone interviews and email correspondence. Efforts have been made to contact a variety of relevant stakeholders (see Table 34) in all the Member States, for each of the relevant substances, from companies of varying sizes. Through the combination of desk-based research, questionnaire responses, interviews, and site visits, it has been possible to compile a significant amount of detailed information in relation to the potential impacts of introducing the proposed measures.

3.1. Targeted online questionnaires

Around 691[185] stakeholders were invited to take part in the questionnaire. However, the true number of stakeholders that were contacted is likely to be higher as many industry and EU associations were contacted and asked to distribute the survey to their members. The online

[185] Companies 15.63% , Education and Training 0.14% , Industry associations 59.62% , Laboratories 0.14%, Public authority 20.69% , NGO 1.45% , OSH Professional 2.32%

targeted survey opened on 23 January 2023 and ran until 27 March 2023. The deadline was extended twice to allow for a broader range of stakeholders to respond and address low response rates for certain substances.

Stakeholders were initially contacted via email. A link rather than an attachment was used to decrease the size of the email and reduce the number of emails automatically directed to junk folders. Five separate questionnaires were created for each of the substances for companies, three for the different stakeholder groups (Member State Authorities, Occupational Safety and Health Experts, Trade Unions) and an additional welding questionnaire:

The questionnaires for companies, from which approximately 50% represents SME's, were available as a link to EU Survey. The questionnaire for Member State authorities and occupational safety and health experts was available as a Word document which could be downloaded and sent using the designated email address. Trade Unions and specific welding stakeholders were also contacted by national experts and invited to interview for the questionnaire.

The questionnaires aimed to collect information on processes during which worker exposure to the substances in question is likely to occur, risk management measures that are already in place, current exposure concentrations, risk management measures that would need to be implemented should the limit be lowered, and any other impacts that could result from the introduction of EU-level limits. As mentioned above, the questionnaires were targeted, focusing on the evidence needed for the analyses. In that regard, particular focus was placed on risk management measures, as only limited information on these is available in the literature.

Translations of each of the substance questionnaires were available in German, French, Italian, Polish and Spanish and respondents also had the option to ask for the questionnaire in a language of their choice. Translations were initially requested through EU Survey and were then checked and edited by the National Experts.

At the end of the questionnaire, respondents were given the opportunity to add any further comments and were asked if they were willing for a substance expert to ask potential follow-up questions and whether they would be willing to host a site visit. Follow-up interviews were very useful when there were gaps in a stakeholder's response and questions could be asked further to fill in missing information. Other consultation methods were used to probe further into respondents' answers and gain a more in-depth understanding of the topic and potential impacts.

3.2. Online interviews

National experts and substance specific experts conducted interviews with relevant stakeholders (see Table 34) . Some of the interviews were based on the responses to the questionnaire. The meeting notes were shared with the company after the interview, and that occasion was also used to ensure mutual agreement on the level of confidentiality required.

Online interviews were conducted with stakeholders whose activities are relevant to the five substances. The aim of these interviews was to build upon the information provided in response to the questionnaires, to fill any information gaps. and to obtain detailed information on processes, to pinpoint exactly where exposure is likely to occur, to investigate what types of risk management measures are already in place and how effective they are, as well as what risk management measures would be required if limits were lowered and other potential ramifications for the company, etc.

3.3. Conversations

Email requests have also been used to collect information for the study. The purpose of email requests is similar to the interviews, with stakeholders being asked for further detail on their answers to the questionnaire, as well as making requests for additional information such as industry statistics.

3.4. Site visits

Companies whose activities are likely to be affected by the potential modifications to the CMRD were also asked whether they would be willing to welcome for a site visit. Companies to be visited were identified via the questionnaire or via contact established via industry associations.

The purpose of the site visits was to gain a more operational understanding of the risk management measures currently in place to protect against exposure to the substances concerned, as well as of the risk management measures that would be needed should the CMRD be modified.

Detailed notes from each site visit were drafted and sent back to the company to ensure that the information recorded is accurate. This process enabled the company to add more detail and information to the study, where possible, and to confirm the level of confidentiality accorded to the information.

Site visits were undertaken during Spring and Summer 2023, once significant progress had been made with data collection. This ensured that site visits added more nuance to the data already collected and helped to fill remaining information gaps.

3.5. Stakeholders targeted

The following table summarises information on stakeholder groups targeted and the interests represented. The table demonstrates that all relevant stakeholder groups have been reached out to.

Table 34 - stakeholders targeted and interests represented

Stakeholder type	Interests represented
EU Associations and REACH Consortia	Industry
Member State Authorities	Member State authorities
Manufacturers/users	Industry
National industry associations	Industry
Trade Unions	Workers
Occupational Health & Safety Professionals	Contacted to obtain scientific information
Working Party on Chemicals (WPC)	Industry Workers Member State Authorities
Laboratories	Contacted to obtain information on sampling and analysis
Source: RPA (2024)	

3.6. Key findings

The feedback received from consultation of stakeholders suggested that the lowest of the OEL options would pose substantial challenges to certain SMEs, potentially affecting their competitiveness and financial stability. Small and medium-sized enterprises (SMEs) expressed particular concern about the potential impacts of implementing lower occupational exposure limits

(OELs). The potential costs and competitiveness challenges associated with these limits were a significant worry for smaller companies.

There was an acknowledgment of the need for effective risk management measures to protect workers from exposure, with discussions on existing measures and those needed if limits were adjusted. The financial burden of complying with stricter OELs was a significant concern, especially for small companies in specific sectors. These companies faced a higher cost as a proportion of annual turnover if strict limits were implemented.

Specific information obtained from the stakeholder consultation on exposure levels, exposed workforce, applied RMMs, costs of compliance with reference OELs, etc. is included in the substance-specific reports[186].

3.7. Cobalt Institute's impact assessment

During the stakeholder consultation, the Cobalt Institute submitted three reports prepared specifically for the purpose of providing information for the study. The studies have been presented by the Cobalt Institute for the Working Party on Chemicals (WPC) at a videoconference August 2023. According to the presentation for the WPC, the Institute supports establishing an OEL at EU level for the inhalable fraction at 20 µg/m^3.

No similar reports were submitted for the other four substances.

The impact assessment commissioned by the Cobalt Institute and prepared by the consultancy company eftec as well as data on exposure levels and CSRs (Chemical Safety Reports) provided by the Cobalt Institute have been used as key stakeholder inputs for the external study. The data have been assessed along with data obtained from stakeholder surveys and other available data sources. With regard to exposure levels, exposed workforce, and number and companies with exposed workers - for those sectors covered by the Cobalt Institute impact assessment - the estimates used for the external study are well in accordance with the data provided by the Cobalt Institute.

The Cobalt Institute impact assessment, however, estimates the total costs of compliance significantly higher than estimated for the external study. The background for the differences in estimated compliance costs between the two impacts assessments can be summarised as follows:

1. **The overall methodology applied is different between the two impact assessments:** The Cobalt Institute impact assessment extrapolates the costs and compliance level from survey responses from 59 companies to a total of 4,962-9,821 companies. The costs of compliance with each policy option are extrapolated from the costs estimated by those companies, which consider they would not be in compliance with the policy option. At an OEL of 20 µg/m^3, as an example, 22% of the respondents consider they would not be in compliance, i.e. the total costs for all sectors are extrapolated from responses from about 10 companies representing only some sectors. The external study applies a costs model which use actual exposure levels across sectors and the modelled costs of reducing the exposure levels in order to be in compliance with the different policy options. The cost model has been used for impact assessments of more than 10 substances/substance groups under this and previous OELs assessments. The average costs provided by the companies for the Cobalt Institute impact assessment are for large

[186] RPA (2024), op. cit.

companies and SMEs well in accordance with the estimates provided by companies for the external study and likely many of the respondents for the two impact assessments are the same. For the external study the costs provided by the companies have been used for informing the study and model estimates but are not considered representative and has not been used for extrapolation.

2. **The two studies assume different shares of large companies.** The Cobalt Institute impact assessment assumes for the extrapolation of costs that 19% of the companies with exposed workers are large companies (the percentage reflects the percentage of responding companies). The external study estimates the share of large companies at 5% based on an assessment of the sector structures. For comparison, the overall share of large companies within the covered sectors in the Eurostat SBS (Structural Business Statistics) is 0.7%. The extrapolation of unit costs of large companies to a high share of all companies results in significant higher costs in the Cobalt Institute impact assessment than estimated in the external study.

3. **The Cobalt Institute impact assessment is based on the assumption that companies for all processes have to achieve compliance with the OELs without taking RPEs (Respiratory Protection Equipment) into account. The external study provides data on exposure levels by sector both with and without RPE**. These data demonstrates that for some processes, the exposure levels without taking the used RPE into account (i.e. the exposure concentration in the workplace) are typically above the highest of the policy option of 20 µg/m³ but is below 20 µg/m³ when the applied RPE is taken into account. For the costs estimates for the external study, in accordance with the methodology used in previous impact assessments, it is assumed that RPE may be used to bring the exposure below the OEL for some exposure situations where the use of RPE is in general accepted today and where the scope for further technical preventive measures for limiting workers' exposure has already been exhausted (e.g. some cleaning and maintenance operations). This result in major differences in costs estimates in particular at the higher OEL levels. It should be noted that the use of RPE is last resort and the CMRD in any case, irrespective of an OEL, stipulates that other RMMs should be applied where possible.

4. **The Cobalt Institute impact assessment assumes that all companies would need biomonitoring and this account for a significant part of total costs.** The costs of biomonitoring are estimated in the Cobalt Institute impact assessment at 33% for an OEL of 10 µg/m³ and around 38% for an OEL of 20 µg/m³. As RAC has not proposed a BLV and the CMRD does not require that compliance with an OEL is demonstrated by use of biomonitoring, it is in the external study considered that companies' possible costs of biomonitoring cannot be allocated to the introduction of an OEL.

5. **The Cobalt Institute impact assessment assumes that companies need annual air monitoring in order to demonstrate compliance and this account for a significant part of the total costs.** The costs of air monitoring are estimated in the Cobal Institute impact assessment at 12% for an OEL of 10 µg/m³ and around 14% for an OEL of 20 µg/m³. The external study applies a model for calculating monitoring costs based on an assessment of actual practice of monitoring and the requirements of the CMRD and the European standard for demonstrating compliance with an OEL (EN 689:2018+AC:2019). The estimated incremental costs are significantly lower than estimated by the Cobalt Institute impact assessment as the compliance costs model takes into account that many companies already undertake monitoring today and that the frequency of compliance monitoring will be lower when companies have implemented the necessary RMMs and demonstrated compliance.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

1.1. Consumers/workers

- Some of the quantified costs to business may be passed on to the citizens/consumers as increased prices. However, the impact on consumers should be limited or even negligible for all substances.
- Workers must 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 new binding limit values).
- Some workers exposed to cobalt and its inorganic compounds, PAHs or 1,4-dioxane might lose their jobs because of the new limit values set at EU level.
- Workers would be better protected from the exposure to the substances subject to this initiative, leading to the prevention of 1,676 lung cancer cases and 18,912 non-cancer cases, resulting in cost savings of up to €1.16 billion.
- In addition to the direct benefits, it will result in decreased loss of present and future earnings (both for the person affected and for their carers.

1.2. Businesses

- Some businesses have to adjust the working practices to comply with the new limit values or following the improved legal clarity related to welding fumes, in particular making investments to reinforce existing risk managements measures, such as additional ventilation systems or closed systems (e.g. adjustment costs will be more predominant for PAHs, followed by cobalt and inorganic cobalt compounds and welding fumes).
- Improved health and safety at work results in direct cost savings for businesses, such as higher labour productivity or reduced administrative or legal costs relating to workers' illnesses, accounting for €7 million (without counting indirect benefits).
- Improved health and safety at work as a result of adjusted working practices and reduced reputational risks can result in improved staff recruitment and retainment rates for some businesses, with the potential to reduce recruitment costs and increase workers' productivity as a result of reduction in absenteeism.

1.3. Public authorities

- Public authorities must transpose the amendment to the CMRD into national legislation.
- Public authorities have to make investments in additional RMMs to ensure compliance with the new limit value for PAHs, accounting for about 62.5 million.
- Public authorities benefit from reduced healthcare treatment costs and higher productivity due to avoided illnesses.

2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	Direct benefits	
Cost savings for workers and their families	Method 1: €1.16 billion Method 2: €600 million	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding ill-health.
Cost savings for businesses	€7 million	Cost savings made by businesses due to workers being less at risk of work-related illness, i.e.: higher labour productivity resulting from reductions in absenteeism and associated production losses, reduced administrative or legal costs relating to workers who are ill, reduced insurance premiums, reduced reputational risks and reduced sick leave 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.
Cost savings for public authorities	€26.65 million	Cost savings made by public authorities, i.e.: healthcare treatment costs, productivity loss due to mortality and lost earnings due to morbidity.
	Indirect benefits	
Cost savings for public authorities	(up to) €3.75 million	Cost savings made by public authorities from not having to define their own national limit values, as a result of the introduction of an EU limit value. Defining a national limit value has associated costs for public authorities to carry out impact assessments and define a suitable level of avoided risk.

Note: estimates are rounded and relative to the baseline.

II. Overview of costs – Preferred option				
	Businesses		**Administrations**	
	One-off	**Recurrent**	**One-off**	**Recurrent**

Direct adjustment costs[187]	(At least) €511 million	(Less than) Method 1: €2.9 billion Method 2: €3 billion	€16 million	€46.5 million
Direct monitoring costs	€0	€456 million	€0	€390,000
Direct administrative costs	€0	€78.5 million	€0	€90,000
Transposition costs			(up to) €2.7 million	€0

Note: estimates are rounded and relative to the baseline.

III. Application of the 'one in, one out' approach – Preferred option(s)			
[million€]	**One-off** (annualised total net present value over the relevant period)	**Recurrent** (nominal values per year)	**Total**
Businesses			
New administrative burdens (INs)	€0	€78.5 million	€78.5 million
Removed administrative burdens (OUTs)	€0	€0	€0
Net administrative burdens*	€0	€78.5 million	€78.5 million
Adjustment costs**	(At least) €511 million	(Less than) Method 1: €2.9 billion Method 2: €3 billion	
Citizens			
New administrative burdens (INs)	€0	€0	€0
Removed administrative burdens (OUTs)	€0	€0	€0
Net administrative burdens*	€0	€0	€0
Adjustment costs**	€0	€0	
Total administrative burdens***	**€0**	**€78.5 million**	**€78.5 million**

(*) Net administrative burdens = INs – OUTs;
(**) Adjustment costs falling under the scope of the OIOO approach are the same as reported in Table 2 above. Non-annualised values;
(***) Total administrative burdens = Net administrative burdens for businesses + net administrative burdens for citizens.

[187] In the absence of sufficient data to split the adjustment costs for welding fumes between one-off and recurrent, they are all considered recurrent costs.

3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

IV. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 3 – Good health and well-being	Expected prevention of 1,410 lung cancer cases and about 19,000 non-cancer cases over the next 40 years.	The expected progress might be slightly mitigated by the introduction of transitional measures for cobalt and its inorganic compounds, and PAHs.
SDG no. 8 – Decent work and economic growth	Expected higher economic productivity and promotion of safe and secure working environments due to the better health protection of about 2.65 million workers.	The expected progress might be slightly mitigated by the introduction of transitional measures for cobalt and its inorganic compounds, and PAHs. Furthermore, it is expected that 4,000 workers would lose their job following the introduction of protective limit values for cobalt and inorganic cobalt compounds, PAHs and 1,4-dioxane.

Annex 4: Analytical methods and multi-criteria analysis

This annex provides a summary of the key data and assumptions used for the purpose of this impact assessment to monetise and quantify the different key impacts identified, where possible. More information is available in the relevant report of the external study[188] supporting this impact assessment.

1. Identification of the key impacts

The table below summarises the key impacts, which are screened to identify all potentially important impacts – considering both positive/negative, direct/indirect, intended/unintended as well as short/long-term effects. The impacts considered to be the most significant are indicated with a "Yes".

Table 35 - relevant key impacts for the purpose of this impact assessment

Impact category	Yes/No
Climate	N
Quality of natural resources (water, soil, air etc.)	Y
Biodiversity, including flora, fauna, ecosystems, and landscapes	N
Animal welfare	N
Working conditions, job standards and quality	Y
Public health & safety and health systems	Y
Culture	N
Governance, participation, and good administration	N
Education and training, education, and training systems	N
Conduct of business	Y
Position of SMEs	Y
Administrative burdens on business	Y
Sectoral competitiveness, trade, and investment flows	Y
Functioning of the internal market and competition	Y
Public authorities (and budgets)	Y
Sustainable consumption and production	N
Efficient use of resources renewable & non-renewable	N
Land use	N
The likelihood or scale of environmental risks	Y
Employment	Y
Income distribution, social protection, and social inclusion of particular groups)	N
Technological development / digital economy	Y
Consumers and households	Y
Capital movements; financial markets; stability of the euro	N
Territorial impacts (specific (types of) regions and sectors)	Y

[188] RPA (2024), op. cit., Methodological note and consultation synopsis

Innovation (productivity and resource efficiency); research (academic and industrial)	Y
Fraud, crime, terrorism, and security, including hybrid threats	N
Resilience, technological sovereignty, open strategic autonomy, security of supply	N
Transport and the use of energy	N
Food safety, food security and nutrition	N
Waste production, generation, and recycling	N
Third countries, developing countries, and international relations	N
Sustainable development	Y
Fundamental rights	Y
Subsidiarity and proportionality principles	Y
Source: RPA (2024)	

2. Derivation of the ERRs and DRRs

The exposure-risk relationship (ERR) of a carcinogenic substance refers to the relationship between the substance concentration and the statistical probability of developing cancer (additional risk beyond the background incidence). The dose-response relationship (DRR) is the relationship between the amount of exposure (dose) to a substance and the resulting changes in body function or health (response).

The starting point for a health risk impact assessment is the OEL (and/or an ERR) proposed by RAC and the respective RAC opinion, together with the annexed background report.

For PAH and cobalt and inorganic cobalt compounds RAC provided ERRs for the assessment of cancer risks. In case of PAH a linear ERR based on Benzo[a]pyrene (BaP) as an indicator substance was derived to estimate the risk of lung cancer after exposure to PAH mixtures. For cobalt and inorganic cobalt compounds RAC also derived an ERR for the risk of lung cancer with a break point to reflect the amplifying effect of the inflammation in the lung on cancer development above the break point.

Despite the fact that 1,4-dioxane is classified as a 1B carcinogen, no ERR was derived by RAC This is due to the fact that 1,4-dioxane-mediated carcinogenicity is only relevant above the saturation level of the metabolism which is in humans above 180 mg/m³. Since this value is above the highest policy option considered in the current project, carcinogenicity of 1,4-dioxane is not considered, no ERR is derived, and non-cancer endpoints are in the focus for the current project.

For isoprene RAC did not derive an ERR either. RAC followed the approach by other institutions and proposed an OEL which considers the internal isoprene formation in humans. However, carcinogenicity of isoprene is also relevant at low concentration. Therefore, an ERR based on animal data, considering the differences between animals and humans regarding the metabolism was derived for the current assessment.

The assessment of welding fumes was limited to the policy option of including this process-generated mixture into Annex I of the CMRD. An ECHA scoping report on welding fumes analysed the scope of welding fumes and similar fumes in the context of their potential inclusion in Annex I. In the absence of reliable dose-response data for cancer and non-cancer health effects neither ERRs nor DRRs could be derived. The results from a recent meta-analysis on the epidemiological evidence for lung cancer caused by welding fumes were used to describe approximate risk levels under the conditions of the workplaces.

For non-cancer endpoints, the RAC opinions as well as other recent evaluations and literature reports, have been reviewed to identify the most relevant endpoints for humans. The RAC opinions were always used as the key source of information. In those cases where it was necessary to fill information gaps, the sources used did not contradict or challenge the conclusions of RAC.

3. Estimation and monetisation of health impacts

3.1. Introduction

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

- ERRs and DRRs for the relevant health effects;
- Numbers of workers exposed;
- Exposure concentrations; and
- Past and future trends in the exposed workforce and exposure concentrations.

3.1.1. Cost categories considered for the estimation of cost savings from avoided ill-health (benefits)

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

- Direct costs: these are the costs of healthcare, namely the medical costs associated with the treatment of cancer and other costs, including non-medical costs. Other direct costs may be incurred by the patients (say the cost of transport to attend appointments) but also by their family/friends, for example, through providing unpaid care.
- 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. 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.

3.1.2. The model

The following table provides a summary of the key endpoints per substance for which quantitative estimations are provided in this impact assessment.

Table 36 - carcinogenic and non-carcinogenic endpoints

Substance	Carcinogenic endpoints	Non-carcinogenic endpoints
Cobalt and inorganic cobalt compounds	Lung cancer	Restricted lung disease Upper airway irritation

Isoprene	Liver cancer	Degeneration of olfactory epithelium Degeneration of spinal cord white matter
Polycyclic aromatic hydrocarbons (PAHs)	Lung cancer	Developmental toxicity Male reproductive toxicity (infertility)
Welding fume	Lung cancer	
1,4-dioxane		Kidney effects Liver effects Local irritation: effects in nasal cavity

The key model inputs are summarised below. These are used to estimate the number cases of ill health over the relevant period. The exposed workforce is divided into several bands which are characterised by variations in some of these inputs and for which the incidence of ill health is estimated separately and subsequently aggregated into totals for each substance.

Table 37 - key model inputs

Parameter	Explanation
Exposure-risk/dose-response relationship	Exposure-Risk Relationship (ERR) for cancer effects or Dose-Response Relationship (DRR) for non-cancer effects
Exposed workforce	Number of workers exposed
Exposure concentration	For OELs: 8-hr TWA (time-weighted average) that the workers are exposed to (real concentration, i.e. if personal protective equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible) For STELs: 15-min peak exposure (real concentration after taking into account PPE) For BLVs: the concentration of the relevant substance or metabolite in the relevant biological media such as blood or urine
Trends	Past and future trends in numbers of workers exposed and/or exposure concentrations
Source: RPA (2024)	

In addition to the key inputs set out above, the model relies on a range of assumptions that determine when the relevant effect occurs or is diagnosed, the nature and severity of its effects, and how long these effects (or their consequences) last. These assumptions differ by substance and health outcome. Some of these assumptions are a simplification of complex real-life scenarios or best estimates (where authoritative evidence could not be identified from available literature).

The key areas in which assumptions had to be made to enable the model to estimate and monetise the incidence of ill-health over the relevant assessment period are set out in the table below.

Table 38 - further assumptions for the estimation of the year of occurrence of the relevant effects and their monetisation

Parameter	Explanation
Onset of the disease	
MinEx	The minimum exposure duration required to develop the endpoint
MaxEx	The time needed to reach the maximum risk (i.e. after the MaxEx has been

	reached, the risk does not increase further)
Lat	The latency with which the effect is demonstrated
Dist	The distribution of cases over the period between MinEx and the MaxEx: the default assumption is a linear accumulation of risk over the relevant period
The effects of the disease	
Mortality	Mortality rate as a result of the relevant condition
Severity	The typical severity (mild to severe) of the relevant outcome – where a range of severities is expected, a weighted average has been estimated
Value of a case	Monetary value of a case taking into account the direct, indirect, and intangible costs estimated relying either on a) Willingness to Pay (WTP) for a case of mortality or morbidity or b) monetised Disability Adjusted Life Years (DALYs)
Source: RPA (2024)	

The model provides an approximation of the order of magnitude of the expected impacts. The outputs of the model include:

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

3.2. Inputs

3.2.1. ERRs and DRRs

The risk of developing the relevant effects is estimated by combining exposure concentrations with the ERRs (for cancer) and DRRs (for non-cancer endpoints).

3.2.2. ExW: exposed workforce

As a default value, in the previous impact assessment it was assumed that there is a staff turnover of 5% per year corresponding to an average employment in a sector of 20 years. The 5% per year is lower than the turnover ratios in most of the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors. However, it is common that workers would continue to work within similar type of jobs for a major part of their work life, but it is uncertain to what extent they would continue with a job function with a specific exposure situation.

A meta study[189] of exposure in the hard-metal industry covering 32,354 workers reported that 30.4 % were employed for less than 1 year, 24.4% had an employment duration of 1-4 years, 26.7% had 5-19 years and 18.4% at least 20 years. If it is assumed that the fourth group covers the 20-40 years

[189] Marsh et al. (2017), Mortality Among Hardmetal Production Workers: Pooled Analysis of Cohort Data From an International Investigation.. Journal of Occupational and Environmental Medicine, December, 59(12), pp. e342-e364.

period, the average exposure time would be about 12.5 years. According to a study[190] on a cohort of workers in the French stainless steel industry, comprising 4,897 subjects, the mean duration of employment was of 17 years.

It is common that in some industries such as construction, workers continue to work within in the same industry for a major part of their work life, but it is uncertain to what extent they would continue with a job function with a specific exposure situation. It was assumed for this impact assessment that this applies to welders, particularly because the demand for welders across the EU is high and appears likely to remain so for many years. It also seems likely to be correct for several of the other heavy industries, vehicle repair, and firefighting that apply to cobalt, PAHs and isoprene. Although this assumption may not be as appropriate for the sectors relevant to 1,4-dioxane as for the sectors relevant to the other substances assessed within this impact assessment, the default staff turnover of 5% per years used in the previous impact assessment is retained for purposes of consistency.

3.2.3. Exposure concentrations

For each substance, one or more exposure scenarios have been modelled based on data sourced from literature and consultation – these scenarios are used for the estimation of the costs and benefits (cost savings from reduced ill-health) of the policy options.

The number of workers exposed at levels of relevance for the assessment of establishing an OEL is derived from consultation with relevant companies and industry associations, databases, literature, workers' associations and other sources. For each of the relevant sectors, distributions of workers over exposure levels were established. In general, it is assumed that the exposure concentrations are lognormal distributed EN689 European Standards (2019), and exposure data collected for this study are fitted to a lognormal distribution for which the key parameters such as the 50th, 75th, 90th and 95th percentiles are estimated (please note that these parameters may differ between substances).

When the main parameters (different percentiles) of a lognormal distribution have been estimated, the exposed workforce is divided into several (typically five) exposure bands and each of these exposure bands is assigned a representative exposure or biomonitoring concentration. For the band with the lowest exposure, the highest exposure concentration in that band is typically taken as representative. For the highest exposure band, the geometric mean (GM) of the concentrations in that band is taken as representative. For the intervening bands, the arithmetic mean (AM) of each band is taken as representative.

Exposure concentrations estimated based on data from literature or consultation have been sense-checked against existing OEL and BLVs in EU Member States to ensure that they are representative of present-day exposure which is expected to be defined by national legal requirements. Consequently, it has not been necessary to take the existing OELs into account when estimating the effects of introduction of a new OEL/BLV.

[190] Moulin, J. et al., (2000). Risk of lung cancer in workers producing stainless steel and metallic alloys. International Archives of Occupational and Environmental Health, Volume 73, pp. 171-180.

3.2.4. Values used in the benefits and costs models

In both the benefits and costs models, the exposed workers or enterprises with exposed workers are split into five percentile groups. The exposure level assumed to be experienced by this group is calculated as shown in the table below.

Table 39 - calculation of exposure levels used in benefits and costs models

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for modelling
0 - 50	50%	Median or 50th percentile
51 - 75	25%	Arithmetic mean of 50th and 75th percentiles
76 - 90	15%	Arithmetic mean of 75th and 90th percentiles
91 - 95	5%	Arithmetic mean of 90th and 95th percentiles
96 - 100	5%	Geometric mean of 95th and 100th percentiles
Source: RPA (2024)		

3.2.5. The effect of introducing an OEL/BLV

The background for the models used is the approach set out in EN 689:2018: "Workplace exposure. Measurement of exposure by inhalation to substances. Strategy for testing compliance with occupational exposure limit values". This standard is widely relied on when determining compliance with an OEL. A summary of the approach in this standard is provided in the box below.

Box 1 - summary of the approach in EN689

In the standard, compliance with an OEL is determined by either a screening test or a test of compliance. **Screening test** The **screening test** requires three to five exposure measurements on workers belonging to a SEG. a) If all results are below: 1) 0.1 * OEL for a set of three exposure measurements or, 2) 0.15 * OEL for a set of four exposure measurements or, 3) 0.2 * OEL for a set of five exposure measurements then it is considered that the OEL is respected: **Compliance**. b) If one of the results is greater than the OEL, it is considered that the OEL is not respected: **Non-compliance.** In case that the first measurement result is above the OEL, it is not necessary to perform any additional measurements. c) If all the results are below the OEL and a result above 0.1 * OEL (set of three results) or 0.15 * OEL (set of four results) or 0.2 * OEL (set of five results) it is not possible to conclude on compliance with the OEL. **No-decision.** In this situation additional exposure measurements shall be carried out in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OELV, as specified below. **Test of compliance with the OEL** According to the standard, the appraiser shall select a statistical test of whether the exposures in a similar exposure group (SEG) comply with the OEL. The test shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OEL.
Source: RPA (2024), based on EN689 European Standards (2019)

EN689:2019 requires that "less than 5% of exposures exceed the OEL" - this can be interpreted as meaning that 5% of the measurements may be above the OEL. As a result, compliance in the model developed for this study is taken to mean that the 95th percentile (P95) of the exposure distribution is at or below the OEL or BLV.

Consequently, the effects of lowering an OEL or BLV are modelled as follows:

- The 95th percentile of the current exposure distribution (air or biomonitoring concentrations) is compared with the target OEL/BLV and a reduction factor is estimated to show by how much the 95th percentile of the distribution needs to reduce.
- It is expected that the whole exposure distribution is reduced by this factor and the reduction factor is thus applied to all exposure bands. This reflects the expectation that there is variability even between measurements carried out for workers in similar exposure situations.
- No health effects are expected to occur when exposure has been reduced below a threshold.

This means that, even when the OEL/BLV has been lowered to a value that is the threshold for the relevant health effects, some ill health can still be expected to occur because some exposure will still exceed the P95(=OEL/BLV) value.

3.3. Assumptions

3.3.1. Onset of the disease

(a) MinEx & MaxEx – The minimum and maximum exposure duration required do develop the endpoint

No cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has been reached (see table below). No further increase in risk is assumed to arise with increasing exposure time after the expiration of the MaxEx.

Table 40 - minimum and maximum exposure duration to develop a condition (MinEx and MaxEx)

Substance	Endpoint (ERR or DRR)	MinEx (years)	MaxEx (years)
Cobalt and inorganic cobalt compounds	Lung cancer	0	40
	Restricted lung disease	0	1
	Upper airway irritation	0	0
Isoprene	Liver cancer	0	40
	Degeneration of olfactory epithelium	0	1
	Degeneration of spinal cord white matter	0	1
Polycyclic aromatic hydrocarbons (PAHs)	Lung cancer	0	40
	Developmental toxicity (miscarriage)	0	0
	Male reproductive toxicity (infertility)	0	0
Welding fume	Lung cancer	0	40
1,4-dioxane	Kidney effects	0	1
	Liver effects	0	1
	Local irritation: effects in nasal cavity	0	0
Source: RPA (2024)			

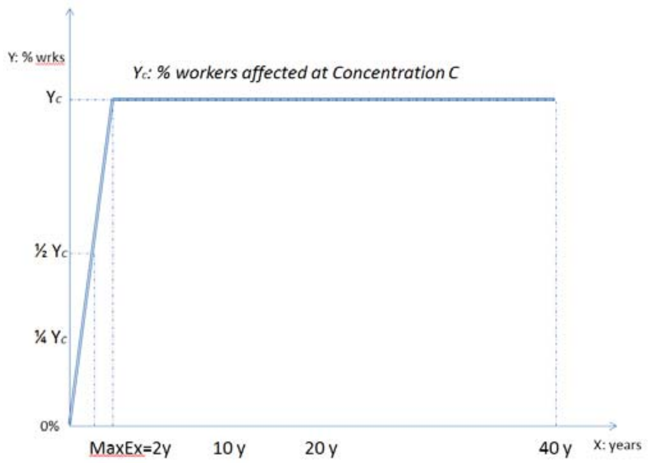
(b) Dist – The distribution of cases over time

Valuing the cost of work-related illness involves applying discounted costs to future cases which requires that the estimated cases over the period between MinEx and MaxEx are assigned to specific years.

The distribution of cases between start of exposure and the MaxEx is modelled based on the assumption of a linear accumulation of risk over time with the maximum risk being achieved at MaxEx. The risk in a given year thus equals Risk=Risk at MaxEx/(MaxEx-MinEx). It is assumed that the distribution is linear, i.e. 1/40 of the excess risk arises in Year 1 and 100% of the excess risk predicted for a specific exposure concentration arises by Year 40.

For cancer endpoints, the MaxEx is typically the full working life, i.e. 40 years. For non-cancer endpoints, the MaxEx can be shorter, and the full risk estimated by the DRR can arise sooner than at the end of a person's working life. This is illustrated in the figure below.

Figure 5 - Non-cancer endpoints – fraction affected over time - example with a MaxEx of 2 years



Source: RPA (2024)

(c) Lat – Latency

The estimated risk is combined with latency to estimate the specific year of diagnosis of a case. The below tables provide the latency periods assumed for cancer and non-cancer endpoints for the purpose of this impact assessment.

Table 41 - latency periods of cancer endpoints

Substance	Endpoint	Latency (years)
Cobalt and inorganic cobalt compounds	Lung cancer	30
PAHs		
Welding fume		
Isoprene	Liver cancer	18

Source: RPA (2024)

Table 42 - latency periods of non-cancer endpoints

Substance	Endpoint	Latency (years)
Cobalt and inorganic cobalt compounds	Restricted lung disease	0
	Upper airway irritation	0
Isoprene	Degeneration of olfactory epithelium	0
	Degeneration of spinal cord white matter	0
PAHs	Developmental toxicity (miscarriage)	0
	Male reproductive toxicity (infertility)	0
1,4-dioxane	Kidney effects	0

	Liver effects	0
	Local irritation: effects in nasal cavity	0
Source: RPA (2024)		

3.3.2. The effects of the disease

(a) MoR – mortality rate

Mortality rate 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 43 - mortality rate over 5 years

Substance	Endpoint	Mortality rate
Cobalt and inorganic cobalt compounds	Lung cancer	80%
	Restricted lung disease	0
	Upper airway irritation	0
Isoprene	Liver cancer	90%
	Degeneration of olfactory epithelium	0
	Degeneration of spinal cord white matter	0
Polycyclic aromatic hydrocarbons (PAHs)	Lung cancer	80%
	Developmental toxicity (miscarriage)	0
	Male reproductive toxicity (infertility)	0
	Bladder cancer*	50%
Welding fume	Lung cancer	80%
1,4-dioxane	Kidney effects	0
	Liver effects	0
	Local irritation: effects in nasal cavity	0
Source: RPA (2024)		

(b) 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.

Table 44 - treatment period

Substance	Endpoint	Treatment period (years)
Cobalt and inorganic cobalt compounds	Lung cancer	5
	Restricted lung disease	1
	Upper airway irritation	1
Isoprene	Liver cancer	5
	Degeneration of olfactory epithelium	1
	Degeneration of spinal cord white matter	1
Polycyclic aromatic	Lung cancer	5

hydrocarbons (PAHs)	Bladder cancer	3
	Developmental toxicity (miscarriage)	20
	Male reproductive toxicity (infertility)	1
Welding fume	Lung cancer	5
1,4-dioxane	Kidney effects	1
	Liver effects	1
	Local irritation: effects in nasal cavity	1
Source: RPA (2024)		

(c) Monetary value of the relevant endpoint

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

Table 45 - cost saving framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[191]	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	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 (2024)		

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

- Method 1: Application of WTP values to each case (differentiating between mortality and morbidity); and

[191] 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 cost savings (benefits) as generated by this study.

- Method 2: Use of DALYs (Disability adjusted life year) and their monetisation.

The only difference between Method 1 and Method 2 is the way in which avoided cases of ill health are monetised. Both methods monetise the same number of avoided cases of ill health.

Cost savings for workers and 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 of 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 in non-cancer cases). 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. None of the non-cancer endpoints have a mortality rate and therefore no VSLs are given for non-cancer endpoints.

Values for value of statistical life and value of cancer morbidity required for cancer endpoints by Method 1 are summarised in the box below. Value of morbidity required for non-cancer endpoints by Method 1 are summarised in table 46.

Box 2: Method 1 and cancer – Value of statistical life and value of cancer morbidity

Willingness to Pay (WTP) for avoided mortality and morbidity

Value of Statistical Life – VSL: With regard to the value of a statistical life, the figure adopted is **€4,710,000**. This is based on Better Regulation Tool #32. Here, a range from €3.5 to 5 million is suggested. We use the mid-point (€4,250,000), updated from 2012 to 2021 prices used in Better Regulation Tool #32 using Eurostat's GDP deflator.

Value of Cancer Morbidity -VCM: Not all cancers will lead to death and it will therefore be important to also include the willingness of individuals to pay to avoid a case of non-fatal cancer. The available literature offers a broad range of estimates for the willingness to pay to avoid a non-fatal cancer. A value of €410,000 (2012 prices) has been adopted as the willingness to pay to avoid a non-fatal case of cancer[192]. This figure has been updated to 2021 prices: **€455,000.**

Source: RPA (2024), based on ECHA's WTP reference mentioned in BR tool #32

[192] ECHA 2016 Valuing selected health impacts of chemicals, 2016, https://echa.europa.eu/documents/10162/17228/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc

Table 46 - method 1 and non-cancer – Value of morbidity - VM

Endpoint	Comment	Value of morbidity - VM
Restricted lung disease	Calculated based upon the disability weight of 0.033 and a DALY of one year valued at €100,000	€3,300
Upper airway irritation	Based on upper values for WTP for skin irritation[193]	€700
Degeneration of olfactory epithelium	This value is based on the fact that a person irreversibly loses, partially or completely, one of the senses, which can result in adverse psychological and social impacts.	€32,000
Degeneration of spinal cord white matter	This value is based upon the adjusted values for Parkinson's disease Five WTP thresholds for a QALY gained were used: 0, 20,000, 40,000, 60,000, and 80,000 euro[194]. In The Netherlands, the disability weight of Parkinson's disease is 0.497 (scale, 0-1),21 and this corresponds to a WTP per QALY of nearly 40,000 euros. The disability weight for degeneration of spinal cord white matter is 0.01, which is proportional to a WTP per QALY of nearly 805 euros. As these are figures for 2015, the value has been adjusted for inflation to €1,000.	€1,000
Developmental toxicity (miscarriage)	Based on WTP of couples with infertility problems to conceive of €22,000 at 2012[195]. This value covered early and later miscarriages and stillborns, and was therefore reduced by two thirds, and adjusted for inflation.	€9,600

[193] ECHA (2016), op. cit.

[194] Sturkenboom, Ingrid & Hendriks, Jan & Graff, Maud & Adang, Eddy & Munneke, Marten & Nijhuis-van der Sanden, Maria & Bloem, Bas. (2015). Economic evaluation of occupational therapy in Parkinson's disease: A randomized controlled trial: Economic Evaluation OTIP Study. Movement Disorders. 30. 10.1002/mds.26217. https://www.researchgate.net/publication/275057433_Economic_evaluation_of_occupational_therapy_in_Parkinson's_disease_A_randomized_controlled_trial_Economic_Evaluation_OTIP_Study/citation/download

[195] ECHA (2017): 32nd Meeting of the Committee for Socio-Economic Analysis, 6-15 September 2016, Helsinki, Finland. SEAC/32/2016/05.2 Rev1+ https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

Male reproductive toxicity (infertility)	Based on WTP of couples with infertility problems to conceive of €22,000 at 2012[196], adjusted for inflation.	€30,000
Kidney effects	Based on WTP for temporary kidney effects €532 in 2012, taken as €1,000 for 2021, as unclear just how temporary these effects are[197].	€1,000
Liver effects	Liver effects (temporary) taken as being the same as kidney effects[198].	€1,000
Local irritation: effects in nasal cavity	Based upon WTP for skin irritation, twice a year for 10 years, €447[199].	€500
Source: RPA (2024)		

Method 2 is summarised below.

Box 3 - Method 2 - DALYs

One DALY can be thought of as one lost year of 'healthy life', and the burden of disease can be thought of as a measurement of the gap between current health status and an ideal situation where everyone lives into old age, free of disease and disability.

DALYs were developed to reflect the sum of years of life lost (YLL) due to premature mortality and years lived in disability/disease (YLD). YLLs are calculated as the number of deaths at each age multiplied by the standard life expectancy for each age. YLDs represent the number of disease/disability cases in a period multiplied by the average duration of disease/disability and weighted by a disease/disability factor.

DALYs take into account the number of years of life lost due to either premature mortality or to living in a less than perfect health state, and are calculated as follows:

$$DALY = YLD + YLL$$

YLD, which stands for Years Lived with Disability, is calculated as follows:

$$YLD = Number\ of\ cases * Average\ disease\ duration * Disability\ weight$$

YLL, which stand for Years of Life Lost due to premature death, is calculated as:

$$YLL = Number\ of\ deaths * Life\ expectancy\ at\ age\ of\ death\ in\ years$$

Source: RPA (2024)

Years of life lost dur to premature mortality

[196] ECHA (2017), op. cit.
[197] ECHA (2016), op. cit.
[198] ECHA (2016), op. cit.
[199] ECHA (2016), op. cit.

The average life expectancy used for the calculations in the model is 82 years. In the absence of other information and taking into account the age distribution of cancer deaths, it is assumed that a typical cancer death occurs at the age of 60 and the number of years lost is thus 22.

Average disease duration after treatment

The average disease duration after treatment is given below.

Table 47 – average disease duration after treatment

Substance	Endpoint	Disease duration after treatment (years)
Cobalt and inorganic cobalt compounds	Lung cancer	5
	Restricted lung disease	30
	Upper airway irritation	1
Isoprene	Liver cancer	5
	Degeneration of olfactory epithelium	30
	Degeneration of spinal cord white matter	30
Polycyclic aromatic hydrocarbons (PAHs)	Lung cancer	5
	Bladder cancer	10
	Developmental toxicity (miscarriage)	1
	Male reproductive toxicity (infertility)	1
Welding fume	Lung cancer	5
1,4-dioxane	Kidney effects	1
	Liver effects	1
	Local irritation: effects in nasal cavity	1
Source: RPA (2024)		

Disability weight

The disability weights derived in the European Disability Weights project are used for cancer as these are most relevant to the European population. For the other effects, disability weights have been estimated in the substance specific reports[200].

Table 48 – disability weights used in this impact assessment

Endpoint	During treatment	After treatment
Degeneration of olfactory epithelium	0.005	0.005
Degeneration of spinal cord white matter	0.01	0.01
Developmental toxicity (miscarriage)	0.114	0
Kidney effects	0.004	0
Liver cancer	0.45	0.049
Liver effects	0.016	0
Local irritation: effects in nasal cavity	0.006	0
Lung cancer	0.265	0.515

[200] RPA (2024), op. cit., substance-specific reports

Male reproductive toxicity (infertility)	0.008	0
Restricted lung disease	0.033	0.019
Upper airway irritation	0.007	0.007
Bladder cancer*	0.426	0.123
Source: RPA (2024)		

Cost savings for employers

Introducing limit values has obvious cost savings for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also accrue cost savings from their employees being less at risk of work-related illness. Such cost savings include:

- Higher labour productivity resulting from reductions in absenteeism and associated production losses;
- Reduced administrative or legal costs relating to employees who are ill;
- Reduced insurance premiums;
- Reduced reputational risks; and
- Reduced sick leave payments.

A study commissioned by DG Employment (2011) considers the socio-economic costs of accidents and ill-health relating to work and the cost savings to employers of implementing effective health and safety management policies. The report estimates that the cost to employers for a single case of a high-severity accident or disease is €11,760. This figure is based on data pertaining to cost categories such as:

Based on a study considering the socio-economic costs of accidents and ill-health relating to work and the cost savings to employers of implementing effective health and safety management policies[201], the cost to employers for a single case of a high-severity accident or disease was updated to 2021[202] resulting in **€13,200**.

No values of cost savings for employers are available for non-cancer endpoints, but there should be savings for employers with workers suffering from degeneration of spinal cord white matter (which is similar to mild Parkinson's disease) and local irritation caused by effects in nasal cavity (which is similar to a bad cold). Based upon the value of €13,200 taken for cancer, €5,000 and €500 are taken for these endpoints respectively, because the impacts are constant but minor for degeneration of spinal cord white matter (or mild Parkinson's disease), and occasional and minor for local irritation caused by effects in nasal cavity.

It is recognised that companies may also incur court/PR costs and these may not be fully reflected in the estimate above. However, there are insufficient data to estimate the avoided court costs for compensation due to ill health and/or and cost of bad publicity.

[201] DG EMPL, 2011. Socio-economic costs of accidents at work and work-related ill health. Available at: http://ec.europa.eu/social/BlobServlet?docId=7416&langId=en

[202] Eurostat's GDP deflator (Dataset: GDP and main components (output, expenditure and income) [namq_10_gdp]) was used to adjust the estimate from 2011 to 2021 prices. The adjustment factor used is 1.122.

Cost savings for workers

Individuals will incur costs associated with their inability to work in terms of a loss of earnings, including losses linked to days of treatment as well as days off due to illness. Luengo-Fernandez et al.[203] 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 €5,047 (rounded to €5,000) is given for productivity losses and €1,118 (rounded to €1,000) for the costs associated with lost working days due to morbidity effects (with these based on lost wages as the measure of lost output).

Workers will also incur costs of unpaid care (the monetary value of the working and/or leisure time) provided by relatives or friends to those with cancer. This care costs an average of approximately €3,000 annually.

Cost savings for the public sector – cost of healthcare

Cancer

Each lung cancer patient costs the UK healthcare system £9,071 annually[204]. Hence, inflated to 2020 (from 2012) and converted to euros, the cost would be €11,500.

The median cost per liver cancer patient over 2 years was $9,065[205]. Hence, one year costs inflated to 2020 (from 2016) and converted to euros would be €5,500.

In the UK, the 3-year average cost per for non-muscle invasive bladder cancer, recurrence and progression to muscle invasive bladder cancer is approximately £5000 per year[206], which converted to euros the cost would be roughly €5,600.

Table 49 – estimates of the annual healthcare costs per cancer patient

Cancer	Healthcare costs (€)
Lung cancer	€11,500
Liver cancer	€5,500
Bladder cancer*	€5,600
Source: RPA (2024)	

[203] Luengo-Fernandez et al. (2013) Economic burden of cancer across the European Union: a population-based cost analysis. The Lancet. Oncology, 14(12), pp. 1165-1174. Available at: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70442-X/fulltext
[204] (Cancer UK, 2012)' Lung cancer UK price tag eclipses the cost of any other cancer https://news.cancerresearchuk.org/2012/11/07/lung-cancer-uk-price-tag-eclipses-the-cost-of-any-other-cancer
[205] Cullen K, Jones M, Pockett RD, Burton A, Cross TJS, Rowe IA, Paley L, Tataru D, Alexander G, Marshall A, Fitzsimmons D. Cost of hepatocellular carcinoma to the national health service in England: a registry-based analysis. BMJ Open Gastroenterol. 2023 Feb;10(1):e000998. doi: 10.1136/bmjgast-2022-000998. PMID: 36810207; PMCID: PMC9945044.
[206] Cox E, Saramango P, Kelly J, Porta N, Hall E, Tan WS, Sculpher M, Soares M (2020) Effects of Bladder Cancer on UK Healthcare Costs and Patient Health-Related Quality of Life: Evidence From the BOXIT Trial. Clin Genitourin Cancer. 2020 Aug;18(4):e418-e442. doi: 10.1016/j.clgc.2019.12.004. Epub 2019 Dec 14. PMID: 32144049; PMCID: PMC7427321.

Non cancer

A mild Parkinson's disease is used as a proxy for degeneration of spinal cord white matter. According to Weir et al.[207], mean costs attributable to Parkinson's disease rose steadily from £2,471 per patient in the first year following diagnosis up to £4,004 per patient in year ten. As the first year of Parkinson's disease is considered mild, the healthcare costs attributable to this period are used for costs associated with degeneration of spinal cord white matter, which, inflated to 2020 (from 2013) and converted to Euros, would be approximately €3,100.

The cost of treating developmental toxicity has been derived from UK 2021 NHS data on miscarriage[208] and an academic paper modelling the economic costs of stillbirth (NIHR, 2017). The study team have calculated the average cost of miscarriage as £1,884 (approximately €2,220 in 2023), and the average cost of stillbirth as £4,200 (approximately €4,850 in 2023). As developmental toxicity refers to both health effects, and both stillbirth and miscarriage have varying degrees of severity and by extent, varying costs, the study team have taken an approximate median value of €3,500.

The cost of treating male infertility varies depending on the severity of illness, the types of treatment available, and personal preferences to repeat treatment campaigns. Cost of treatment of €1,400 is taken from values used in previous studies.

As no treatment is available for degeneration of olfactory epithelium, upper airway irritation, local irritation: effects in nasal cavity, and liver effects, the cost of treatment has been set to €500 to only reflect visits to doctors for diagnosis.

Restricted lung disease and kidney effects also require little or no treatment, and the cost of treatment has been set to €1,000 to only reflect visits to doctors for diagnosis, and possibly a small amount of treatment.

Table 50 – estimates of the annual healthcare costs per non cancer patient

Non cancer	Healthcare costs (€)
Kidney effects	€1,000
Liver effects	€500
Restricted lung disease	€1,000
Upper airway irritation	€500
Local irritation: effects in nasal cavity	€500
Degeneration of olfactory epithelium	€500
Degeneration of spinal cord white matter	€3,100
Repro – women – miscarriage	€3,500
Repro – men - fertility	€1,400
Source: RPA (2024)	

[207] Weir S, Samnaliev M, Kuo TC, Tierney TS, Walleser Autiero S, Taylor RS, Schrag A. Short- and long-term cost and utilization of health care resources in Parkinson's disease in the UK. Mov Disord. 2018 Jul;33(6):974-981. doi: 10.1002/mds.27302. Epub 2018 Mar 30. PMID: 29603405 https://pubmed.ncbi.nlm.nih.gov/29603405/

[208] Tommys, (2021) Key statistics about pregnancy and loss in the UK, https://www.tommys.org/baby-loss-support/pregnancy-loss-statistics

3.4. Bringing it all together

The cost savings (benefits) that have been estimated for each substance are summarised below.

Table 51 - costs considered

Category	Cost	Notes
Direct	Ch	Healthcare
	Ci	Informal care
	Ce	Total cost to an employer
Indirect	Cp	Productivity loss due to mortality
	Cl	Lost earnings due to morbidity
Intangible	Cvsl	Value of statistical life
	Cvsm	Value of cancer morbidity/value of statistical morbidity
	Cdaly	Value of DALYs
	Ch	Healthcare
Source: RPA (2024)		

The total avoided cost of ill health is calculated using the following two methods:

Method 1: *Ctotal= Ch+Ci+Ce+Cp+Cvsl+Cvsm*

Method 2: *Ctotal= Ch+Ci+Ce+Cp+Cl+Cdaly*

Cl is not considered under Method 1 since *Cvsm* may already include these costs.

In terms of assigning the cost savings (benefits) to the different stakeholder groups, the table below provides an overview of who bears the costs quantified in this study.

Table 52 - quantified costs and stakeholder groups

Stakeholder group	Costs	Method of summation
Workers/family	Ci, Cl, Cvsl, Cvcm, Cdaly	Method 1: CtotalWorker&Family=Ci+Cvsl+Cvcm Method 2: CtotalWorker&Family=Ci+(0.8*Cl)+Cdaly
Governments	Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue)	CtotalGov=Ch+0.2(Cp+Cl)[209]
Employers	Ce, Cp	CtotalEmployer=Ce+0.8*Cp
Source: RPA (2024)		

209 Assumes 20% tax.

3.5. Estimating the current burden of disease

The current burden of disease (i.e. the number of cases diagnosed in 2023) is estimated on the basis of historical exposure.

The estimates relate to the sectors where exposure to the substances currently occurs and do not represent the total burden of past occupational exposure to substances. The total burden from all past occupational exposure to the substances would require consideration of sectors where occupational exposure no longer takes place and which may not be relevant to the problem definition for this impact assessment.

The following parameters are estimated from the data collected through literature review and consultation:

- Past rate of change in the exposed workforce; and
- Past rate of change in exposure concentrations.

If an endpoint has a latency of 30 years, the model assumes that the cases diagnosed in 2023 reflect the risk that occurred 30 years ago in 1993, due to latency, and thus reflects the number of workers exposed in 1993 and the exposure concentrations in 1993.

In addition, for endpoints with latency greater than zero, there will continue to be cases due to exposure in the last 40 years which occur in the next 40 years. These are provided as the legacy burden of disease, together with the current burden of disease.

3.6. Estimating the future burden of disease

The future burden of disease also takes into account the following parameters:

Future rate of change in the exposed workforce; and

Future rate of change in exposure concentrations.

The FBD is always given as the cases over the next 40 years and is the number of cases generated by exposure in over the next 40 years (and not the number of cases actually happening in the next 40 years). Latency may cause many of the cases caused by exposure in the next 40 years, particularly of cancer, to occur beyond the 40 year period. For this reason, the number of cases is not divided by 40 to indicate a number of cases per year as this would be misleading.

3.7. Indirect benefits

Member States may gain an indirect benefits from not having to define their own national OEL or BLV, as a result of the introduction of an EU limit value. Defining a national OEL and/or BLV has associated costs for Member States public administrations to carry out impact assessments and define a suitable level of avoided risk.

The data used are based on the assumption that all Member States without a national OEL and/or BLV would want to implement one and that all Member States with an existing OEL and/or BLV would want to revise them to ensure higher degrees of worker protection.

The assumption if that the avoided cost of both OEL and BLV is the sum of both costs: there is no economy of scale for introducing both together.

Table 53 – avoided costs related to the setting of national limit values

Member State situation	Avoided cost per Member State
Member States without an existing OEL and/or STEL	€100,000
Member States requiring alteration of an existing OEL and/or STEL	€50,000
Member States without an existing BLV	€100,000
Member States requiring alteration of an existing BLV	€50,000
Source: RPA (2024)	

4. Estimation and monetisation of health impacts

4.1. Introduction

4.1.1. Key features of the compliance cost model

The key impact are the compliance costs for industry. It represents the costs for a group of similar companies incurred in reducing exposure to a target limit value based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost.

4.2. Key model inputs and assumptions

4.2.1. Overview of key inputs

The key model inputs include:

- Current exposure concentrations;
- OEL/BLV policy options;
- Assumptions about how compliance with the OEL/BLV is determined;
- Number of small, medium and large enterprises at each of the current exposure concentrations;
- Estimated average number of exposed workers and workstations using the substance in a company;
- Discount rates;
- Current RMMs;
- RMM effectiveness;
- Cost of RMMs (one-off and recurrent) as well as their average lifespan; and
- Suitability of specific RMM types for each of the sector.

4.2.2. Current exposure concentrations

The key input is the distribution of exposure concentrations in each relevant industry sector. This involves dividing exposures into several (typically 5) exposure bands and assigning a representative concentration to each exposure band. For the band with the lowest exposure, the highest exposure concentration in that band is typically taken as representative. For the highest exposure band, the geometric mean (GM) of the concentrations in that band is taken as representative. For the intervening bands, the arithmetic mean (AM) of each band is taken as representative.

4.2.3. OEL/BLV policy options

The different policy options are described in section 5.2 of this impact assessment.

4.2.4. Compliance with an OEL

The procedures for determining compliance with an OEL differs among Member States and may even be different within a Member State.

The methodology for defining compliance with an OEL is described in section 3.2.5 of this annex.

4.2.5. Number of enterprises in each exposure band

One of the key inputs is the number of enterprises in each exposure band, split by sector and enterprise size (small, medium, large).

The model assumes that companies are distributed over the different exposure bands in the same manner as workers, i.e. for example where 10% of exposure measurements are over a certain level, 10% companies have exposure over that level.

4.2.6. Estimated average number of exposed workers and workstations using the substance per company

The average number of exposed workers and workstations was estimated for small, medium and large companies in each sector.

4.2.7. Discount rates

Based upon the discount rates used in other Member States, equal discounting of costs and benefits and a static discount rate was assumed as the most appropriate approach, and a static discount rate of 3% over the 40-year period was retained.

4.2.8. Current RMMs

The following types of RMM are considered:

- 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).

Companies are expected to continue using RPE to keep exposure levels below the OEL. The assumption is that companies initially continue to use the existing and gradually (where possible) replace the RPE with other measures in accordance with the general requirements of the CMRD and to bring the concentration in the workplace in compliance with the OEL. As the replacement is done gradually (e.g. when new equipment is introduced) the costs of implementing other RMMs is assumed to balance the saved costs of using the RPE. Over a 40-year period, the use of RPE is not necessarily cheaper than implementing other RMMs so this assumption is not unjustified.

For each type of RMM, several levels that companies can achieve have been defined. These levels are summarised below.

4.2.9. RMM effectiveness

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

Table 54 - percentage reduction in exposure achieved with RMMs and used in the cost model

Type of RMM	% reduction
Substitution possible	100%
Substitution not possible	0%
RWK Rework	50%
LEV3 Full enclosure	100%
LEV2 Partial enclosure	90%
LEV1 Open hood	80%
LEV0 No LEV	0%
WE2 Pressurised or sealed	100%
WE1 Simple enclosed cab	80%
WE0 No enclosure	0%
RPE3 Breathing apparatus	100%
RPE2 Half or full-face negative pressure respirator or similar	95%
RPE1 FFP mask/ simple mask or similar	60%
RPE0 No mask	0%
OH1 Organisational measures	30%
OH0 No organisational measures	0%
GDV1 General dilution ventilation	30%
GDV0 No general ventilation	0%
Source: RPA (2024)	

In cases where the required reduction in exposure cannot be achieved using a single RMM, the model allows for the possibility that organisational and hygiene measures (OH1) or rework (RWK) are combined with any other RMM to increase their effectiveness.

Where the required reduction in exposure cannot be achieved using the RMMs in the table above or combining them with OH1 or RWK, it is expected that the company in question would have to substitute the substance, or where this is not possible, the company would have to discontinue the operations that involve exposure to the relevant substance.

4.2.10. RMM costs and lifespan

Costs of RMMs depend on the size of the operations of the relevant company. RMM costs have thus been estimated by company size band.

Table 55 - RMM unit costs

RMM	One-off costs	Recurrent costs	Lifespan

LEV 3: Full enclosure	Based on IOM[210] – high end of costs	10% based on one-off costs as recommended by US-OSHA (most likely electricity, maintenance & repairs) US-OSHA is no longer available, and no further studies giving an indication of the cost of recurrent costs have been found. It is considered that the value of 10% is a reasonable assumption.	
LEV 2: Partial enclosure	Estimated reported in literature which range from €60,000 to €120,000 per company	10% based on US-OSHA (most likely electricity, maintenance & repairs, compensation air, heating)	
LEV 1: Open hood or add-on	Estimates reported in published literature which range from €1,700 to €15,500	10% based on US-OSHA (most likely electricity, maintenance & repairs, compensation air, heating)	
WE 2: Pressurised or sealed cabin	Assumed the same as LEV 2	Assumed the same as LEV2	Assumed the same as LEV2
WE 1 : Simple enclosure	Assumed the same as LEV1	Significantly lower than LEV 1, assumed 3%	Assumed the same as LEV1
RPE 3: Breathing apparatus	Frontline Safety (undated) cost of a belt and a mask: €1,300 Assume cylinder is then rented	Boconline (undated): €50 for one hour of work (cylinder rental & refill) If used every working day for 1 hour, 1,000% of one-off costs	Assumed 2 years
RPE 2: Half or full face negative pressure respirator/ Mask with HEPA filters or similar	Hakimian et al.[211]: €25 Assumed a new mask has to be purchased every two months due to wear and tear/accidental damage, etc. Cost per worker €150	Hakimian et al.: €9 for a pair of HEPA filters Usage time 30 hours (Ok, et al. 2008) Annual cost per worker €75, i.e. 50% of one-off costs	Mask: 1 month, Filter: 30 hours
RPE 1: FFP mask/	Hakimian et al.: €1	Not relevant but one-off costs incurred	

[210] IOM (2011): SHEcan Report P937/4, Health socio-economic and environmental aspects of the possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

[211] Hakimian, A. et al., 2015. Economic analysis of CNT lithium-ion battery manufacturing. Environmental Science: Nano, Issue 5, pp. 463-476.

simple mask or similar	per disposable mask Assumed a new mask is required every workday, resulting in an annual cost of €260/worker	every year	
OH1: Organisational & hygienic measures	Some data provided through consultation for Cd (International Cadmium Association, ICdA) as part of CMRD 3, also consistent with IOM A large range of measures with different costs Assumed €1,000 per worker	Some data provided through consultation for Cd (ICdA) for CMRD 3 Ok, et al[212].: Training annual instructor cost €540 A large range of measures with different costs Assumed 50%	Only incurred once
GDV1: General dilution ventilation	Hakimian et al.: €22 per cfm (cubic feet per minute) required (Ok, et al. 2008): €10 per cfm Figure used: €20 per cfm Assumed 10 Air Changes Per Hour Assumed cfm required: Small: 300 cfm, Medium: 2,000 cfm, Large: 5,000 cfm	Hakimian (2015): Approx. 30% of one-off costs (Ok, et al. 2008): 30% but this is for 24hr operation Figure used: 30%	20 years
Source: RPA (2024)			

Where unit costs were only available for one or two company size bands, these were extrapolated to other size bands based on the numbers of exposed workers and work stations in the different size bands.

[212] Ok et al (2008). Risk Analysis Modeling of Production Costs and Occupational Health Exposure of Single-Wall Carbon Nanotube Manufacturing. Journal of Industrial Ecology, 12(3), pp. 411-434.

The costs of implementing each of the RMMs in a specific company depend on the number of exposed workers or workstations using the relevant substance.

Table 56 – costs of various RMMs in €

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	**One-off 2021**	**Lifespan years**	**Recurrent (% of one-off)**	**One-off 2021**	**Lifespan years**	**Recurrent (% of one-off)**	**One-off 2021**	**Lifespan years**	**Recurrent (% of one-off))**
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	3%	90,000	20	3%	260,000	20	3%
RPE 3: Breathing apparatus	2,000	2	500%	27,000	2	500%	75,000	2	500%
RPE2: Half or full face negative pressure respirator	400	Mask: 2 months	17%	5,400	Mask: 2 months	17%	15,000	Mask: 2 months	17%
RPE 1: FFP mask/ simple mask	2 per day	Not relevant, 1 per day	Not relevant	27 per day	Not relevant, 1 per day	Not relevant	75 per day	Not relevant, 1 per day	Not relevant
OH 1: Organisational measures	4,000		50%	54,000		50%	150,000		50%
GDV 1: General dilution ventilation	6,000	20	30%	40,000	20	30%	100,000	20	30%
Source: RPA (2024)									

4.2.11. Suitability of RMMs for each sector

Operational characteristics of the activities in each sector mean that not every RMM is suitable to control exposure in each sector. The model thus considers the suitability of each RMM in each of the relevant industry sectors.

The amount of exposure is split into work where the worker is exposed to the substance for less than an hour a day and for more than an hour a day. This also equates to exposure for more or less than 2.5 days/month. Many production activities only occasionally use the relevant substances. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use personal protective equipment (PPE) such as masks with filters or breathing apparatus.

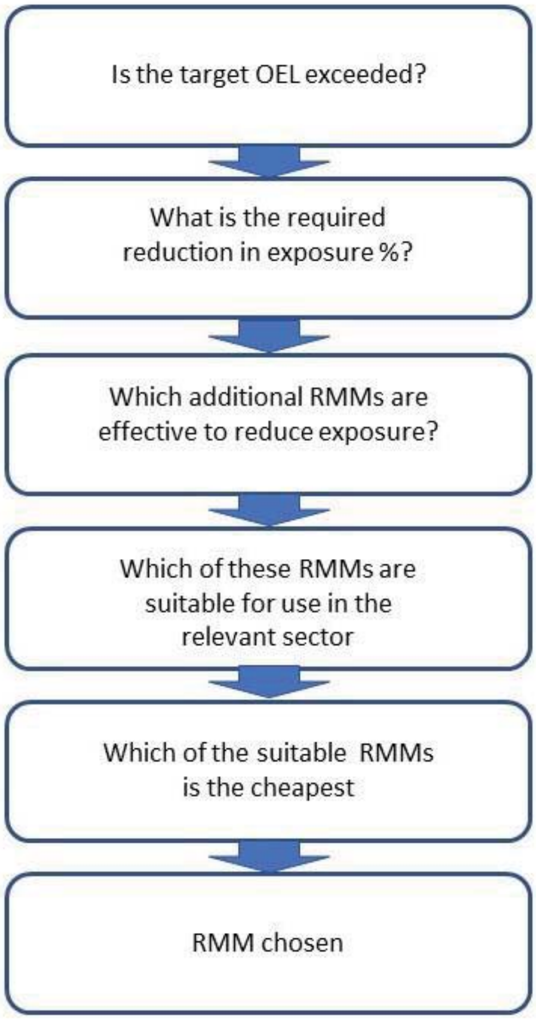
The form of substance to which workers are exposed varies considerably from dust and fibres to vapour, fumes, gas, mist and aerosol. Again, the form of substance has a direct bearing on the types of RMM that are suitable. For example, general dilution ventilation is not advised for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: dust, which also includes fibres; and gas, which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and causes exposure to workers beyond the area where the substance is being worked. This means that administrators, managers and sales staff may be exposed.

Table 57 - Suitability of various RMMs to duration of exposure, form of the substance and extent of spread

Type of RMM	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
Substitution	Y	Y	Y	Y	Y	Y	Y
Rework	Y	Y	Y	Y	Y	Y	Y
Full enclosure	Y	Y	Y	Y	Y	Y	Y
Partial enclosure	Y	Y	Y	Y	Y	Y	Y
Open hood	Y	Y	Y	Y	Y	Y	Y
No LEV	Y	Y	Y	Y	Y	Y	Y
Pressurised or sealed	N	Y	Y	Y	N	Y	Y
Simple enclosed cab	N	Y	Y	Y	N	Y	Y
No enclosure	Y	Y	Y	Y	Y	Y	Y
Breathing apparatus	Y	N	Y	Y	Y	Y	Y
Neg. pressure respirator	Y	N	Y	Y	Y	Y	Y
FFP mask	Y	N	Y	Y	Y	Y	Y
No mask	Y	Y	Y	Y	Y	Y	Y
Organisational measures	Y	Y	Y	N	Y	Y	Y
No organisational measures	Y	Y	Y	Y	Y	Y	Y
General dilution ventilation	N	Y	N	Y	N	Y	Y
No general ventilation	Y	Y	Y	Y	Y	Y	Y
Source: RPA (2024)							

4.3. Calculation of the RMMs required for each policy option



Source: RPA (2024)

4.4. Other key issues

4.4.1. Discontinuations in the cost model

The cost model considers every scenario of sector, current exposure concentration, target exposure concentration and evaluates for the current RMMs, which available RMMs can achieve the target exposure concentration. Only these RMMs can be selected for the scenario. The potential RMMs include the option of substitution and also the worst-case option of discontinuation. The model selects the RMMs with the lowest cost and calculates the cost of this scenario by multiplying it by the number of companies (the cost differs for each size of company, enabling the cost for each size of company to be found). This means that the model knows how many companies, by size, are allocated the RMMs for each scenario.

The cost of discontinuation is invariably the RMM with the highest cost, therefore if this is selected, it means that no other RMMs in the cost model are sufficiently effective to achieve the reduction in exposure levels required to comply with an OEL/BLV policy option.

The model assumes that small and medium enterprises discontinuing the operations that involve exposure to the relevant substance would result in the entire company going out of business. The logic behind this is that small and medium sized organisations are more likely to experience closure if their sole or main operation becomes unfeasible. In contrast, large companies are more likely to discontinue divisions, lines or specific operations which would not result in the full closure of the business but the discontinuation of the line/process using the relevant substance. The assumption is that 10% of a large company would close.

The discontinuation cost is taken as the loss of profit[213] taken over 20 years and the average profit is assumed to be 10% of turnover. Historically, the two sectors that are most strongly represented in the substance specific reports are Manufacturing (operating profit margin 10%) and Construction (operating profit margin 11%). A value of 10% is therefore taken as a typical profit margin in the modelling carried out for this study.

The average turnover of small, medium and large companies is estimated taking the Eurostat activity categories (which, however, sometimes only partly correspond to the relevant sectors where exposure occurs), stakeholder consultation and internet searches into account.

5. THE COST MODEL FOR ESTIMATING BENEFITS AND COSTS FOR INTRODUCING WELDING FUMES IN ANNEX I OF THE CMRD

The methodology for calculating the benefits and costs of policy option 2 (Annex I) for welding fume are different to those used for limit values, because there are no data available about welding fume exposure levels.

Since policy option 2 is about legal clarity (and therefore increased awareness of the risks and better supply and use of RMMs), estimates relate to the costs and benefits of additional companies applying already required RMMs

5.1. Benefits

The benefits model used for calculating the value of benefits due to reductions in ill-health due to lower limit values was adapted for use with welding fume. The key differences are:

- Use of a single excess risk for all welders, taking into consideration all exposure levels, and all levels of exposure. This was done because there is no exposure data available for welding fume and no Exposure Risk Relationship (ERR) can be derived;
- This excess risk is subject to an average trend of reducing by 1% per year, and this was assumed to continue for the next 40 years for the baseline. This trend was based upon various studies in the past and the view of the study team: it was validated by interviews and conversations with key stakeholders where they were specifically asking their opinion of the future trend for excess risk; and
- The impact of the policy option 2 (Annex I) is assumed to be a further 1% reduction for the first five years after the policy option takes effect, in other words, a 2% reduction for five years, returning to a 1% reduction from year six.

[213] In RAC/SEAC 2017, on page 30, SEAC states that the "welfare impacts should be measured in terms of the expected profit losses as those correspond to the loss in producer surplus."

5.2. Costs

The costs model used to calculate the cost of risk management measures for companies due to changes in limit values could not be used as it relies on detailed information about exposure levels which are not available.

Two completely different approaches were devised; The approaches are:

- Bottom up – this is based upon the number of welders that are estimated to move from having poor or no risk management measures (RMMs) to adequate RMMs as a result of policy option 2 (Annex I) and multiplying this by the estimated additional average cost of these RMMs. In addition, only a proportion of the workers that are estimated to move to better RMMs will need to buy new RMMS; some will simply turn on, or wear, the RMMs that they already have, which will not incur additional costs. This proportion is assumed to be 50% and together it enables a cost for these additional RMMs to be estimated.
- Top down - based upon the current market value of RMMs being used annually, an estimate of an assumed 1% increase in the sale of RMMs as a result of policy option two (Annex I) can be calculated.

5.3. Assumptions

There is little data available to build estimates of costs and benefits. Several assumptions had to be made for the purpose of calculating costs and benefits, often with little basis. To attempt to validate these estimates, six interviews with key stakeholders were held to present the assumptions, calculations and estimates and asking their opinions about them (three EU level and three Member State level stakeholders on condition of anonymity). Generally, the consensus was that the estimates were a reasonable guess. In a few cases, one or more stakeholders felt that an assumption was too high or too low.

6. ESTIMATION OF THE COSTS OF MONITORING, BIOMONITORING, HEALTH SURVEILLANCE AND ADMINISTRATIVE BURDEN

The costs of monitoring air concentrations (sampling and analysis) and the costs of biomonitoring and associated health surveillance are estimated separately to the core cost model. The cost of monitoring does not include the administrative burden or internal cost to the company of managing the monitoring or biomonitoring and health surveillance campaigns, which is often performed by an external contractor.

6.1. Air monitoring costs

To what extent demonstration of compliance with an OEL involves actual measurements in the workplaces differs by Member States and sizes of the enterprises and consequently the estimate of total monitoring costs for air concentrations is subject to high uncertainty.

6.1.1. Number of samples per monitoring campaign

It is assumed that the strategy for sampling is in accordance with the European Standards EN689. According to the experts consulted, it is common for medium and large sized companies to follow EN 689 whereas for small companies less demanding strategies are often applied, for example, taking only one or a few indicative measurements.

The strategy described in the European Standards EN689 gives a procedure for the employer to overcome the problem of variability and to use a relatively small number of measurements to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations exceeding the OELs.

The European Standards EN689 comprises three main steps concerning groups of workers in a similar exposure group (SEG): these are groups of workers undertaking the same tasks. The compliance with an OEL is determined by either a screening or a test of compliance.

The screening test requires three to five exposure measurements on workers belonging to a SEG.

- If all results are below:
    1. OEL for a set of three exposure measurements or,
    2. 0.15 * OEL for a set of four exposure measurements or,
    3. 0.2 * OEL for a set of five exposure measurements
- then it is considered that the OEL is respected: Compliance.
- If one of the results is greater than the OEL, it is considered that the OEL is not respected: Non-compliance. If the first measurement result is above the OEL, it is not necessary to perform any additional measurements.
- If all the results are below the OEL and a result above 0.1 * OEL (set of three results) or 0.15 * OEL (set of four results) or 0.2 * OEL (set of five results) it is not possible to conclude on compliance with the OEL. No-decision. In this situation additional exposure measurements shall be carried out to apply the test based on the calculation of the confidence interval of the probability of exceeding the OEL, as specified below.

By the Test of compliance with the OEL, the appraiser shall select a statistical test of whether the exposures of the similar exposure group (SEG) comply with the OEL. The test shall measure, with at least 70% confidence, whether less than 5% of exposures in the SEG exceed the OEL.

6.1.2. Assumed number of measurements

The number of measurements is not dependent on the number of potentially exposed workers, but the number of similar exposure groups (SEGs). A SEG may undertake more than one of the tasks defined by the Worker Contributing Scenarios (WCSs) in the Chemical Safety Reports (CSRs), and in general, it is assumed that the number of SEGs is smaller than the number of WCSs. It is furthermore assumed that the number of SEGs is higher in larger companies than in medium and small companies even within the same sector, as the WCS may be divided on more SEGs in the larger companies.

The assumed number of SEGs and number of exposure measurements for compliance testing is shown in the table below.

*Table 58 - assumed number of SEGs and number of exposure measurements per campaign for compliance testing**

	Small	Medium	Large
Average number of SEGs per company	1	4	6
OEL / median ≥ 2 ** Number of measurements per SEG,	3	3	3
Total number of measurements	**3**	**12**	**18**

OEL / median < 2 ** Number of measurements per SEG,	5	5	5
Total number of measurements	**5**	**20**	**30**

Source: RPA (2024)

** Each "exposure measurement" may consists of more samples if more than one parameter is measured.*

*** Median of sector's exposure concentrations*

6.1.3. Frequency and percentage of companies undertaking monitoring

A significant number of the companies are expected to measure exposure concentration to refine their risk assessment and possibly to demonstrate compliance with the new OEL. The costs are based on the following overall considerations:

- Additional monitoring would not be needed in Member States where the OEL is already at the level of the policy option or lower.
- Larger companies in general undertake more often monitoring than smaller companies.
- The percentage of companies which would need to monitor increases as the OEL decreases (the larger the difference between the new OEL and current exposure concentrations).
- Not all companies would need additional monitoring - some companies already undertake monitoring and some companies, in particular smaller companies, would install additional RMMs without monitoring.

It is assumed that those companies that monitor would need either one or two monitoring campaigns:

- For all companies that monitor at all, one monitoring campaign before the new RMMs are introduced to establish which RMMs are required; and
- For some of the companies, one further monitoring campaign after the introduction of the RMMs to demonstrate compliance if there is uncertainty as to whether the new RMMs will achieve compliance.

It is assumed that the first campaign takes place at the introduction of the OEL (first year of the assessment period) and the second campaign takes place three years later and the costs are discounted by the general rate used for the assessment.

It is, furthermore, assumed that companies in Member States with an OEL at or below the level of a policy option would not need any additional monitoring to demonstrate compliance with the OEL of the policy option.

For the companies in Member States with no OEL (for all relevant parameters) or an OEL above a policy option, the following monitoring is assumed in companies:

- At the lowest OEL level, all large and medium-sized companies will undertake a monitoring campaign to determine which RMMs would be needed to comply with the new OEL. In some companies with recent monitoring data and a good overview of the current exposure levels, at the higher OEL levels, existing data may be used for determining the need for further RMMs. These companies would only need a campaign after installing additional RMMs.

- For small companies, it is assumed that an increasing percentage would undertake a campaign at lower OELs and at the highest OEL level only 20% would actually measure the concentration. The remainder would implement further RMMs without measuring concentrations but based on results of the existing risk assessments and general guidelines. It is assumed that even a smaller percentage would undertake more than one campaign because the costs of monitoring would be significant in comparison with the costs of just implementing further RMMs.

The percentage of companies assumed to require additional monitoring in those Member States with no OEL or an OEL above the policy option in shown in the table below.

Table 59 - percentage of companies undertaking additional monitoring in those MS with no OEL or an OEL above the policy option

Policy option	Percentage of companies undertaking additional monitoring					
	Before installing additional RMM, % of all companies			After installing additional RMMs, % of companies installing RMMs		
	Small	Medium	Large	Small	Medium	Large
Lowest OEL level	25%	100%	100%	25%	90%	100%
Intermediate level 2	15%	90%	90%	15%	70%	80%
Intermediate level 1	10%	70%	70%	10%	50%	60%
Highest OEL level	10%	60%	60%	10%	30%	40%
Source: RPA (2024)						

6.1.4. Assumed costs of planning, sampling, reporting

The number of samples, man-hours and costs of planning, execution and reporting for a campaign where an 8-h TWA for either the inhalable or respirable fraction is measured is shown in the table below. For campaigns where both respirable and inhalable fraction for the 8-h TWA is measured it is assumed that the number of samples is twice the number indicated here. However, this may vary with substance. In addition, the cost of an inhalable and respirable sample may not be the same. The cost per sample is higher for measurements below a certain LOQ, so the monitoring cost is higher for the lowest policy options.

Table 60 - assumptions for time and costs for planning, sampling and reporting

	Number	Unit
Planning (independent of number of workplaces)	6	man-hours/company
Sampling basic costs per day incl. first workplace	9	man-hours/company
Time per workplaces in addition to first workplace the same day	1	man-hours/workplace
Number of workplaces one person can sample a day	5	workplaces/day
Reporting independent of number of workplaces	5	man-hours/company
Additional reporting per workplace	0.25	man-hours/workplace

Rent of pump first day	80	EUR/workplace
Rent of pump subsequent days	40	EUR/workplace
Average daily rate of worker at all levels	500	EUR/day
Average hourly rate of worker at all levels	67	EUR/hour
8-h TWA, respirable or inhalable, LOQ1 (higher)	230	EUR/sample
8-h TWA, respirable or inhalable, LOQ2 (lower)	260	EUR/sample
Source: RPA (2024)		

The average rate for this kind of service for the EU as a whole is set at €67/hour. The starting point has been typical Danish rates for this kind of OHS services of €120/h and data on wages and salaries for professionals in the EU Member States showing that the EU27 average was at 69% of the Danish salary rates. For the OELs4 study, the estimated rates used in the UK using this approach was quite similar to the actual rates used.

The actual wages would vary by Member State but for simplicity, in accordance with the methodology used for previous OEL studies, EU averages has been applied. The total costs at EU level will not be influenced by this, but it results in some uncertainly as to the distribution by Member State and sectors.

6.1.5. Assumed costs of planning, sampling, reporting

Below are the estimated costs per company of both monitoring campaigns. Each substance report uses these values to calculate the cost of monitoring based on all the companies that need to do monitoring, given the existing OELs in their Member State, size, and sector (higher or lower level of monitoring).

Table 61 - costs of planning, execution, reporting and analysis of monitoring exclusive per company by size of company

Activity Unit cost	Unit cost	OEL / median > 2			OEL / median < 2		
		S	M	L	S	M	L
Campaign 1 (Year 1)							
Workstations (number of samples)		3	12	18	5	20	30
Total manhours		23	50	66	25	68	97
Sampling days		1.0	3.0	4.0	1.0	4.0	6.0
Planning, man-hours	€67	€402	€402	€402	€402	€402	€402
Execution, man-hours	€67	€737	€2,412	€3,350	€871	€3,484	€5,226
Reporting, man-hours	€67	€385	€536	€637	€419	€670	€838
Rent of equipment, first day	€80	€80	€80	€80	€80	€80	€80
Rent of equipment, subsequent days	€40	€0	€80	€120	€0	€120	€200
Costs excl. analysis		€1,604	€3,510	€4,589	€1,772	€4,756	€6,746
Analysis, LOQ 1	€230	€690	€2,760	€4,140	€1,150	€4,600	€6,900
Analysis, LOQ 2	€260	€780	€3,120	€4,680	€1,300	€5,200	€7,800
Total costs, LOQ 1		€2,294	€6,270	€8,729	€2,922	€9,356	€13,646

Total costs, LOQ 2		€2,384	€6,630	€9,269	€3,072	€9,956	€14,546
Campaign 2 (Year 3) discounted costs							
Total costs, LOQ 1		€2,100	€5,738	€7,988	€2,674	€8,562	€12,488
Total costs, LOQ 2		€2,182	€6,067	€8,482	€2,811	€9,111	€13,311
Source: RPA (2024)							

6.2. Biomonitoring and health surveillance costs

6.2.1. Assumed number of measurements

Unlike air monitoring, where a sample of measurements is taken, all exposed workers within a facility that requires health surveillance have to be monitored. Therefore, the number of biomonitoring and health surveillance tests carried out equals the number of exposed workers in situations where health surveillance is required. If a biomonitoring test is required, the study team assumes that effectively full health surveillance also has to take place, as the worker will need to provide the sample and will require a follow up meeting with a medical doctor to receive the results.

6.2.2. Frequency of biomonitoring and health surveillance campaigns

Some companies are expected to conduct health surveillance already to refine their risk assessment or to comply with national BLVs. The model is developed under the following overall considerations:

- Additional monitoring would not be needed in Member States where the BLV is already at the level of the policy option or lower, provided that the company's BLVs and OELs are less than a given percentage of the BLV and OEL set down in Annexes IIIa and III of the CMRD. This percentage is set at 50%.
- The percentage of exposed workers which would need biomonitoring and health surveillance increases as the BLV decreases (the larger the difference between the new BLV and current BLVs in the Member State).

It is assumed that those companies that monitor would need either one, two or three biomonitoring and health surveillance campaigns:

- For all companies that monitor at all, one monitoring campaign before the new RMMs are introduced to establish which RMMs are required.
- For some of the companies, one further monitoring campaign after the introduction of the RMMs to demonstrate compliance if there is uncertainty as to whether the new RMMs will achieve compliance.
- Campaign 1: Year 1, biomonitoring only of all exposed workers except those in Member States with a BLV below the target BLV.
- Campaign 2: Years 2 to 6, annual biomonitoring and health surveillance by the proportion of exposed workers in each sector whose exposure will take them above a given percentage of the new BLV, which is set for each substance.
- Campaign 3: Years 7 to 40, annual biomonitoring and health surveillance for a proportion of companies multiplied by the number of exposed workers in campaign 2, which is set for each sector by the study team. The default value for this factor for most sectors is set at 10%. However, the study team believes that some sectors will never be able to achieve the

lowest policy options for BLVs and will always have to do health surveillance, whereupon this factor is set to 100%.

6.2.3. *Assumed costs of planning, sampling and reporting*

The number of samples, man-hours and costs of planning, execution and reporting for a biomonitoring and health surveillance campaign is shown in the table below. The cost per sample went up for measurements below a certain LOQ, so the monitoring cost can be higher for the lowest policy options.

Two estimates or costs for the analysis of a 3-hydroxybenzo-a-pyrene sample, not including transport costs were obtained. One from a laboratory not yet analysing 3-hydroxybenzo-a-pyrene, which estimated €125/sample. One from a laboratory that does analyse 3-hydroxybenzo-a-pyrene, which said €150-170/sample, depending on circumstances. These were from German laboratories, which are probably more expensive than in some Member States. The average cost of analysing a sample from two French laboratories was €60-65 per sample. Prices for analysis usually fall if they become more popular, so there is reason to think that these might also fall as measuring 3-hydroxybenzo-a-pyrene is not common at present. Based on this information, the cost of a standard analysis is taken as €100/sample, and a sample requiring a lower LOQ is taken as €200/sample.

Analysing samples of 1,4-dioxane is likely to be similar in cost to as analysing samples of 3-hydroxybenzo-a-pyrene, therefore the costs for standard and lower LOQs are also taken as €100/sample and €200/sample respectively.

Table 62 - assumptions for time and costs for planning, sampling and reporting a biomonitoring and health surveillance campaign

	Number	Unit
Biomonitoring manpower (Campaign 1)		
Medical doctor's time to see worker	0.25	man-hours
Biomonitoring and health surveillance manpower (Campaigns 2 and 3)		
Worker's time, before, test and after	1	man-hours
Manager's admin time	0.25	man-hours
Medical doctor's time to see worker	0.5	man-hours
Biomonitoring analysis		
Biomonitoring, LOQ1 (higher)	100	EUR/sample
Biomonitoring, LOQ2 (lower)	200	EUR/sample
Source: RPA (2024)		

The average rate for this kind of service for EU as a whole is set at €67/hour equating to €500/day. The actual wages would vary by Member State but for simplicity, in accordance with the methodology used for previous OEL studies, EU averages has been applied. The total costs at EU level will not be influenced by this, but it results in some uncertainly as to the distribution by Member State and sectors.

6.2.4. *Estimated costs per exposed worker of three biomonitoring and health surveillance campaigns*

Below are the estimated costs per exposed worker of both monitoring campaigns. Each substance report uses these values to calculate the cost of monitoring based on all the companies that need to do monitoring, given the existing OELs in their Member State, size, and sector (higher or lower level of monitoring).

Table 63 - costs of planning, execution, reporting and analysis of monitoring exclusive per exposed worker (Euro PV discounted over relevant number of years)

	LOQ1	LOQ2
Campaign 1	184	284
Campaign 2	995	1,537
Campaign 3	3,778	5,517
Source: RPA (2024)		

6.3. Administrative burden for companies

For enterprises, the cost of planning, executing, and reporting the sampling and analysis of monitoring is part of adjustment costs and is most often done by a specialist company. However, someone in the enterprise has to work out what is required and the management of monitoring by the third party and this administrative task is included in the company administrative burden. The number of days required to manage a campaign discounted over 40 years is shown below.

6.3.1. Air monitoring administration burden

The administrative burden costs for air monitoring per company by size are shown below, together with the days assumed to be required by companies by size to set up the monitoring each year. As in the previous calculations of cost of the monitoring, the cost of a worker or manager is assumed to be €500/day.

Table 64 - costs of companies' administrative burden to manage first and second air monitoring campaigns, by size of enterprise

	Small	Medium	Large
Days to administrate monitoring one campaign	1	3	6
Campaign 1 costs	€500	€1,500	€3,000
Campaign 2 costs (discounted)	€458	€1,373	€2,745
Source: RPA (2024)			

6.3.2. Biomonitoring and health surveillance administration burden

The administrative burden costs for biomonitoring and health surveillance per company by size are shown below, together with the days assumed to be required by companies by size to set up the biomonitoring and health surveillance each year. As in the previous calculations of cost of the biomonitoring and health surveillance, the cost of a worker or manager is assumed to be €500/day.

Table 65 - costs of companies' administrative burden to manage three campaigns for biomonitoring and health surveillance, by size of enterprise

	Small	Medium	Large

Days to administrate monitoring one campaign	1	3	6
Campaign 1 (year 1)	€500	€1,500	€3,000
Campaign 2, (year 2-6 discounted)	€2,290	€6,870	€13,739
Campaign 3, (year 7-40 discounted)	€9,114	€27,343	€54,686
Source: RPA (2024)			

6.4. Transposition costs for Member State Authorities

Member States incur costs for the transposition of relevant changes into national legislation. The exact costs depend on the specific changes agreed in EU legislation, and the level of national autonomy in the transposition (which influences e.g. the number of departments involved in transposition or implementing the Directive). Some Member State may further require regulatory impact assessments. Sweden is for example obliged to carry out an impact assessment on new EU legislation. The transposition costs are therefore likely to vary significantly between Member States.

Specific data on the costs of transposition of EU legislation by specific Member States are not readily available. For one UK impact assessment for example, "the costs of amending current regulations to implement a Directive are thought to be around £700,000" (around €950,000 in 2021[214]). Whereas no details are provided for that calculation, it is expected that these costs correspond to a substantial legislative change, which would include the costs of making (e.g. preparing an impact assessment, drafting and discussing a legislative proposal), printing and publishing the legislation. A second estimate by the UK Department for Transport[215] provides a substantially lower value, stating that "a combination of legal and technical resources as well as policy advisors are usually required to implement such a change, costing approximately £15,687 per amendment" (approximately €20,000 in 2021).

This impact assessment thus assumes €50,000 per Member State as an approximation of the general order of magnitude of the transposition costs in Member States that do not currently have an OEL, STEL or BLV. For those Member States that have an OEL, STEL or BLV, and need to change to a lower value is assumed to entail a lower cost of €30,000. Member States that already have an OEL, STEL or BLV at or below each policy option do not incur a cost.

This impact assessment thus assumes €100,000 per Member State as an approximation of the general order of magnitude of the transposition costs for putting welding fume into Annex I because this is likely to be accompanied by other changes to the CMRD to fix some contradictions caused by putting welding fume into Annex I, see section 5 of the welding fume substance report.

[214] RPA (2012) Ex-Post Evaluation and Impact Assessment Study on Enhancing the Implementation of the Internal Market Legislation Relating to Motor Vehicles.
[215] UK Department for Transport (2011), The potential cost and benefits to the United Kingdom of the measures outlined in the proposal for a Regulation of the European Parliament and of the Council on the approval and market surveillance of two or three wheel vehicles and quadricycles. Available at : https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/2585/dft-2011-26-ia.pdf

7. Approach to other issues

7.1. Assumptions and robustness of the estimates

The overall methodology behind the impact assessment involves estimating the costs and benefits as accurately as possible. The key data required for each element are:

- Benefits:
  - Number of exposed workers by sector and size of company;
  - Exposure distributions by sector;
  - Exposure risk relationships (ERRs) and dose response relationships (DRRs) for each ill-health endpoints; and
  - Discount rates.

- Costs:
  - Number of companies with exposed workers by sector and size of company;
  - Exposure distributions by sector; and
  - Discount rates and many economic indicators.

Occasionally, when the number of companies is low, all companies with exposed workers could be identified accurately. Nevertheless, the numbers of workers and companies by sector and size are usually taken from Eurostat. However, the companies and workers actually using the specific substance generally does not include every company in that sector, in which case the appropriate proportion has to be estimated. Furthermore, only a proportion of workers in a company are exposed to the specific substance. Generally, the consultation survey enables an estimate of the proportion of exposed workers to all workers on a site to be calculated and used for a sector, but usually there are some sectors that are not represented in the survey. An estimate was then made, based on the substance, risk management measures expected to be in place, and the proportions in similar industries.

The ERRs and DRR are based on complex toxicological assessments and calculations, which in turn may be based on imperfect data such as animal and/or old data. Wherever possible, an ERR and DRR is derived for all cancer and non-cancer endpoints that have an effect within the exposure concentrations likely to be found. However, sometimes there are known endpoints, both cancer and non-cancer, where there is insufficient or no evidence with which to derive an ERR or DRR and these endpoints have to be excluded from the analysis.

Arguably the most difficult data of all to gather and analyse are the exposure data. There are three main sources of this data:

- Consultation survey;
- Academic papers; and
- Confidential REACH chemical safety reports.

There are often many issues with this data including:

- No indication as to whether personal protective equipment (PPE) or respiratory protective equipment (RPE) is used, and thus whether the measurement provided is what the worker was exposed to, or what they would have been exposed if they had not been using PPE or RPE;

- There is no indication of the RMMs in place;
- The format of the data varies and could include any or all of statistics such as the arithmetic mean, median, various percentiles (25^{th}, 75^{th}, 90^{th}, 95^{th}), highest and lowest;
- Many records might indicate that they are below the limit of quantification (LoQ), but there is no indication of the value of the LoQ for this measurement;
- Often the data has to be converted, for example between inhalable and respirable fraction, and sometimes the conversion factors are contentious; and
- The data are old and the technology has substantially changed since it was gathered.

All the available information was gathered, manually evaluated, interpreted and the exposure distribution for each sector was assembled, and then the models was run. Both the exposure distributions and the costs and benefits were checked, adjusting the exposure distribution and other inputs, if necessary, until it is feels that both inputs and outputs are sensible.

The discount rate has a huge effect on the estimates of costs and benefits. Finally, a wide range of other economic indicators are used in the cost model, but these are not discussed any further here.

All of the assumptions are explained in detail in the specific substance reports[216].

In each of the substance reports, there is a table listing the limitations and uncertainties for the substance and indicating their potential impact on the conclusions. Where there is an * this refers to significant over/underestimations. The absence of an asterisk indicates lesser impacts of the over/underestimations. The table below brings together all of the limitations that are considered to be significant. There are no significant impacts for isoprene.

Table 66 – Overview of the key limitations/uncertainties for the substances

Limitation or uncertainty	Substance	Explanation	Likely U (underestimates) or O (overestimates)	
			Costs	Benefits
Exposed workers	All	See text	U or O	U or O
Companies with exposed workers	All	See text	U or O	U or O
ERRs and DRRs	All	See text	U or O	U or O
Exposure distributions	All	See text	U or O	U or O
Discount rates	All	See section 4.2.7	U or O	U or O

[216] RPA (2024), op. cit.

Limitation or uncertainty	Substance	Explanation	Likely U (underestimates) or O (overestimates)	
			Costs	Benefits
Cost assessment – biomonitoring firefighters	PAH	Public authorities may not undertake biomonitoring and health surveillance for volunteer firefighters due to irregular (<1% of time) and low exposure. The cost is modelled based on professional and volunteer firefighters being subject to biomonitoring.	O	
Additional health endpoints – skin cancer	PAH	Skin cancer has also been definitively linked to PAH exposure but there are no quantifiable data on which to develop an impact assessment.		U
Additional health benefits from the introduction of a BLV	PAH	The main routes for occupational exposure to PAH are inhalation and skin contact and both routes result in increased metabolite concentrations that can be monitored by the introduction of a BLV. However, it is not possible to quantify benefits because the presence of a substance in a biological matrix does not necessarily mean that it will result in adverse effects, while the absence does not necessarily indicate that an individual was not exposed. There is no ERR to link metabolite concentration to effects and the health benefits of introducing a BLV cannot be quantified.		U
Contribution of dermal exposure to total uptake	1,4-dioxane	There is limited evidence base to assess the contribution of dermal exposure to the total uptake. A significant dermal uptake would mean that both the costs and the benefits could be underestimated.	U	U
Cost assessment assumptions	Welding	Some key stakeholders thought that policy option two could result in a bigger investment in RMMs and reduction in worker exposure, but other key stakeholders thought that the policy would have no or negligible impact on worker protection.	U or O	U or O
Exposed workforce	Welding	Only full-time welders have been taken into account, not part-time or occasional welders, or bystanders (non-welders)	U	U
Additional health endpoints	Welding	Additional health endpoints were not included and cannot be included in the calculations as there are no data available.	-	U
Response to policy option assumption	Welding	Some key stakeholders said that they thought there would be little further improvement in RMMs, whilst others felt the baseline was still low.		U or O
Future trends	Welding	Increasing demand for welding due to Green Transition compounded by Russian invasion of Ukraine, requiring faster transition to renewables with associated investment in infrastructure requiring welding.	U	U
RMMs in place	Welding	Baseline little understood.	U or O	

Some of the exposure data used derives from outside the EU. This is usually included when there is either no or poor data available, or when detailed and/or recent academic research contains data from outside the EU. The countries providing nearly all of the non-EU data are USA, UK, Japan and Australia. It is expected that the use of non-EU data increases the robustness of the estimates.

7.2. One-off costs and these costs versus annual turnover

The first year costs include only the following costs:

- Initial costs in first year, (one-off and recurrent); and
- Monitoring and associated administrative burden costs for campaign 1 in the first year.

These first year costs are used in calculations where first year costs are calculated as a percentage of annual turnover and annual operating surplus. The discontinuation costs are not included in the first year costs. This is an issue because these costs are not only the costs of closing a facility, but also a proxy for costs incurred when a company can find RMMs that will enable it to company, but this cannot be modelled, and it is likely to be high in cost. However, these figures indicate the financial impact upon companies that are not expected to discontinue or experience severe difficulty complying.

Separate calculations are made to evaluate the financial burden upon the whole sector over time, and these costs do include discontinuation costs. The total present value cost of compliance (risk management measures, monitoring and administrative burden, discounted over 40 years) is calculated as a percentage of both turnover and operating surplus discounted over 40 years.

7.3. Unemployment

Under the proposed OEL options, employment conditions and workers health are expected to improve. However, employment impacts will result from companies forced to cease operations involving the substance if they cannot comply with the limit values.

There are many potential scenarios, some positive and some negative. Some of the positive effects will still have a cost, such as retraining. If a site closes, staff at all levels lose their jobs. The scenarios include:

- In areas of low unemployment, some people will be re-employed quickly;
- Some people find jobs relatively quickly, say within six months, but may need benefits or use insurance to cover their interim costs;
- Some people need retraining, with the cost of the training and their time whilst training to consider;
- Some people need to relocate, with associated relocation costs;
- Some people retire early incurring social benefits or the loss of tax income;
- Some people may be unemployed for a long time;
- Some sites may have a much bigger impact on a town, particularly if it is the major employer;
- Some regions have a concentration of certain sectors, and several closures in one region could have a disproportionate impact; and
- The closing facility might be taken over by a competitor that can manage or afford the compliance, although there will often be efficiency savings, which can often take the form of fewer middle managers. This is likely to be restricted to specific sectors and/or regions.

If a sector and/or region is likely to have an overall impact that is much more positive or negative than average, this is indicated, and the calculations adjusted for the social cost of unemployment.

The impacts associated with the potentially temporary loss of employment can be monetised based on the approach set out in ECHA[217] and adapted from Haveman R, H. and Weimer, D.[218], and Duborg[219]. The impacts include the following components:

- The value of output/wages lost during the period of unemployment;
- The costs of job search, hiring and firing employees;
- The "scarring effect", i.e. the impact of being made unemployed on future employment and earnings; and
- The value of leisure time during the period of unemployment.

The study team has calculated the number of job losses based on the following:

- Number of companies discontinuing (by size of company (modelled)) x average number of employees per company (by size of company (Eurostat)).
- Modelling is based on discontinuations in small and medium sized companies resulting in full company closure. Discontinuations in large companies would result in partial closure or termination of the production line where exposures occur; this is taken as 10% of large companies discontinuing.

Social cost calculated[220] as follows:

- Average salary (based on Eurostat figures per sector) x job losses (per sector, by size) x ratio of social cost per job loss over annual pre-displacement wage.
- Ratio = 2.57 (EU27) - This ratio is calculated on the population in EU Member States and subsequently has been amended since previous OELs in which the ratio included the United Kingdom (a previous ratio of 2.72 for EU28).

7.4. Transitional periods

Throughout this section, the final OEL is called the "FOEL" and the transitional OEL is the "TOEL". In addition, the OEL under normal conditions without a transition is called the "OEL".

Normally Member States have two years to amend their legislation after the change to the CMRD, therefore, although the cost and benefits models work out costs and benefits from today, in reality, they will usually start from two years after the legislation is passed. However, as long as the costs and benefits are calculated using the same time periods, the cost benefit ratio will be unchanged even if the actual costs and benefits would be reduced by the discount rates slightly.

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[217] ECHA (2016) *The social cost of unemployment*. Available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25.

[218] Haveman R, H. and Weimer, D., L. (2015) 'Public Policy Induced Changes in Employment', *Journal of Benefit-Cost Analysis*, 6, pp. 112–153. Available at: https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/public-policy-induced-changes-in-employment-valuation-issues-for-benefitcost-analysis/98CA383367695FE9C92928D87DFE08D3#.

[219] Duborg, R. (2016) 'Valuing the social costs of job losses in applications for authorisation', *The Economics Interface Limited*. Available at: https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554.

[220] Duborg, R. (2016), op. cit., table A7

The purpose of the transition period is to enable companies to comply in a controlled manner:

- Enabling them to implement major and expensive changes to RMMs;
- If possible, developing, finding and testing substitutes; and
- If possible, avoiding discontinuations and avoiding the associated disruption of supply chains.

The purpose of the transition period is not to reduce costs: these companies will still have high costs. There may be fewer discontinuations as a result of the transitional period – this means that the transitional period has the potential to reduce the overall costs. However, even if the actual costs were reduced and/or there are fewer discontinuations and therefore less unemployment, the change in these costs and/or unemployment is impossible to calculate.

Therefore, the impact on the costs and benefits is only due to the discount factor.

The same methodology is used for transitional costs and benefits as for calculations of costs and benefits of OELs without transition, in particular:

- For the start of enforcement and the point when the one-off costs fall, this would mean:
- For the OEL and the TOEL, the enforcement date is at the end of year 2 and the costs and benefits start at the beginning of year 1.
- For the FOEL, the enforcement date is at the end of year 6 and the costs and benefits start at some point between years 1 and 5.
- Costs and benefits are calculated over a 40 year period.

There are three categories of company regarding the TOEL and FOEL:

- Currently operating below the FOEL – these companies have no costs and no benefits associated with them and are not considered further;
- Currently operating between the FOEL and the TOEL – these companies should find it relatively easy to comply. Some will go ahead immediately and make the changes; others will wait until the latest reasonable point (year 5), to implement the RMMs. Taking all these companies together, the costs and benefits are assumed to start at the midway point in the transitional period, which is at the end of year 3.
- Currently operating above the TOEL – these companies may find it harder to comply.

For some companies, complying with the TOEL will be nearly as difficult as complying with the FOEL, therefore, where possible, they will comply with the FOEL after two years: few companies want to make two sets of major changes only four years apart unless absolutely necessary.

Some companies that have real difficulty complying with the FOEL may well not comply with the TOEL after two years. This may lead to greater use of RPE to comply with the TOEL than normal.

Taking all of these companies together, the costs and benefits are assumed to start at the midway point in the transitional period, which is at the end of year 3.

If we assume a 40 year period for everything, the only difference in the transitional costs and benefits compared with the costs and benefits for OELs without a transitional period is a delay of three years, which equates to a reduction due to discount factors of 8.48%. This is rounded to 8% to avoid spurious accuracy.

It does not matter how the one off costs or operating costs fall, such as every year, every other year, or year 1 and 20 only, the factor is always 8%. The change in the benefits due to a delay of three years is exactly the same, 8%.

All costs and benefits due to monitoring, administration and health surveillance would reduce by 8% too. The only cost that would not alter is Member State transposition costs and these are insignificant in comparison. As both the costs and benefits reduce by 8%, the cost benefit ratios are unchanged.

The costs and benefits under the transitional period scenario are not calculated in detail for the following reasons:

- The factor of 8% is broad, enveloping many assumptions: calculating every number minus 8% is confusing, unnecessary, and indicates a level of accuracy that cannot be justified;
- All of the costs and benefits are based on many, sometimes considerable assumptions. They are best viewed as an order of magnitude estimate. A movement of 8% is relatively insignificant within the bigger picture.

Therefore, overall, the transitional period will delay impacts by an average of three years and reduce the value of costs and benefits by approximately 8% for all stakeholders, employers, workers and public administrations. The transitional periods for cobalt and its inorganic compounds and for PAH are thus expected to have an impacts on the following categories:

- EU competitiveness, research and development and SMEs;
- EU single market, the environment, and fundamental rights;
- Green Deal and the EU Strategic goals;
- Digitalisation; and
- EU strategic autonomy.

8. Mutli-criteria analysis

8.1. Cobalt and inorganic cobalt compounds

Table 67 – Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy options for cobalt and its inorganic compounds, € million

Impact	Stakeholders affected	PO 2	PO 3	PO 4	PO 6	PO 5
Direct costs – adjustment and monitoring						
Risk management measures - first year	Companies	€ 1,481	€ 708	€ 237	Cannot be monetised	€ 88
Risk management measures - recurrent	Companies	€ 2,171	€ 427	€ 111	Cannot be monetised	€ 21
Risk management measures - discontinuations	Companies	€ 5,991	€ 698	€ 231	Cannot be monetised	€ 20
Risk management measures - total	Companies	€ 9,643	€ 1,833	€ 579	€ 530	€ 129
Risk management measures - total per company (in '000 €)	Companies	€ 629	€ 119	€ 38	€ 35	€ 8
Risk management measures excluding discontinuation costs -total per continuing company (in '000 €)	Companies	€ 256	€ 80	€ 24	Cannot be monetised	€ 8
Monitoring (sampling and analysis)	Companies	€ 112	€ 80	€ 51	€ 47	€ 39
Direct costs - administrative						
Company cost of administration burden	Companies	€ 13	€ 9	€ 7	€ 6	€ 4
Direct compliance costs – total						
Adjustment, monitoring and administration burden costs	Companies	€ 9,768	€ 1,922	€ 636	€ 582	€ 172
Adjustment, monitoring and administration burden costs per company (in '000 €)	Companies	€ 637	€ 125	€ 41	€ 38	€ 12
Direct costs - enforcement costs						
Transposition costs	Public sector	€ 0.91	€ 0.91	€ 0.91	€ 0.91	€ 0.91
Indirect costs - other						

Firms exiting the market - No. of company closures	Companies	1,086	142	57	Cannot be quantified	10
Firms discontinuing at least a part of their business - %	Companies	7.1%	0.9%	0.4%	Cannot be quantified	0.1%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	Up to 3% (small companies)	Up to 1% (small companies)	Up to 0.4% (small companies)	Cannot be quantified	Up to 0.2% (small companies)
First year compliance costs as % of turnover over 40 years (excluding discontinuations)	Companies	Up to 29% (small companies), but up to 4% (medium companies)	Up to 10% (small companies), but up to 1.5% (medium companies)	Up to 5.8% (small companies), but up to 0.75% (medium companies)	Cannot be quantified	Up to 2.3% (small companies), but up to 0.3% (medium companies)
Employment – Jobs lost	Workers & families	25,849	2,761	1,124	Cannot be quantified	77
Employment – Social cost	Workers & families	€ 1,970	€ 217	€ 83	Cannot be monetised	€ 7
International competitiveness	Companies	Negative impacts	No significant impacts	No significant impacts	No significant impacts	No significant impacts
Consumers	Consumers	Negative impacts in some sectors	No impact	No impact	No impact	No impact
Internal market	Companies	Positive effects though not of significant importance.				
Innovation	Companies	Negative impact	Limited negative impact	No or limited negative impact	No or limited negative impact	No or very limited impact
Specific MSs/regions - MSs that would have to change OELs	Public sector	All	All	All	All	All
Direct benefits – improved well-being - health						
Reduced cases of ill health – lung cancer	Workers & families	71	51	23	23	12
Reduced cases of ill health – restrictive lung disease	Workers & families	4,365	4,365	2,842	2,842	1,000
Reduced cases of ill health – upper airway irritation	Workers & families	14,152	12,266	7,363	7,363	2,135
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 146 - 135 million	€ 126 - 121 million	€ 75 - 74 million	€ 69 - 68 million	€ 29 - 27 million
Direct benefits – improved well-being – safety						
Avoided costs	Companies	€ 2	€ 2	€ 1	€ 1	€ 0
Avoided costs	Public sector	€ 8	€ 7	€ 4	€ 4	€ 1

Direct benefits – improved well-being - environmental						
Environmental releases	All	Limited reduction of environmental release of cobalt. Changes to cobalt free alternatives will have positive impact whereas increased costs of some articles may have a negative. Increased costs of recycling may have a negative impact.				
Direct benefits – market efficiency						
Level playing field	Companies	A harmonised OEL at EU level would help to ensure a level playing field between companies operating in different EU Member States.				
Indirect benefits						
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for companies with operations across multiple Member States.				
Avoided cost of setting OEL[221]	Public sector	€ 0.5	€ 0.5	€ 0.5	€ 0.5	€ 0.5
Other impacts						
Recycling – loss of business	Recycling companies	Negative impacts due to compliance costs.	Negative impacts due to compliance costs.	Minor negative impacts.	Minor negative impacts.	Minor negative impacts.
Impacts on fundamental rights	All	Compulsory monitoring of cobalt levels will help to ensure that the fundamental right of workers to workplace environments which respect human health is reliably enforced.				
Impacts on EU Green Deal	All	PO 2 is expected to result in negative impacts on the EU Green Deal (including EU Strategic Autonomy), PO 3 would lead to limited negative impacts while POs 4, 5 and 6 should not entail negative impacts.				
Impacts on digitalisation	Companies	No impacts on digitalisation are expected.				
Contributions to the UN sustainable development goals	All	In relation to the third sustainable development goal – "*good health and wellbeing - improved worker and family health*" – the above comment for impacts on fundamental rights also applies.				

Source: Study team.

** For large companies it is only 10% of the company activities that are assumed to close down. The share of large companies in the number of discontinuations is less than 3%.*

[221] This element of avoided cost might be an under estimation of the total avoided costs. It could be that some Member States with an existing OEL would want to revise it during the assessment period to increase worker protection. It is however not certain how many Member States would do that. This possible underestimation would be insignificant compared with the other benefits.

8.2. PAHs

Table 68 – Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy options for PAHs, € million

Impact	Stakeholders affected	PO 2	PO 3	PO5 *	PO 4
Direct costs – adjustment					
Risk management measures - first year	Companies	€ 1,727	€ 220	Cannot be monetised	€ 5
Risk management measures – recurrent	Companies	€ 2,872	€ 196	Cannot be monetised	-€ 1
Risk management measures - discontinuation	Companies	€ 32,392	€ 2,248	Cannot be monetised	€ 0
Risk management measures total	Companies	€ 36,993	€ 2,666	€ 2,529	€ 3
Risk management measures total per company	Companies	€ 0.08	€ 0.01	€ 0.01	€ 0
Monitoring (sampling and analysis)	Companies	€ 549	€ 292	€ 290	€ 181
Risk management measures - first year	Public sector	€ 544	€ 16	€ 16	€ 0
Risk management measures – recurrent	Public sector	€ 5,328	€ 47	€ 47	€ 0
Risk management measures - discontinuation	Public sector	€ 0	€ 0	€ 0	€ 0
Risk management measures total	Public sector	€ 5,872	€ 63	€ 63	€ 0
Risk management measures total per public authority	Public sector	€ 7.75	€ 0.08	€ 0.08	€ 0
Monitoring (sampling and analysis)	Public sector	€ 0.87	€ 0.39	€ 0.39	€ 0.24
Transposition costs	Public sector	€ 1.27	€ 1.24	€ 1.24	€ 1.24
Direct costs - administrative					
Monitoring administrative burden	Companies	€ 118	€ 66	€ 65	€ 41
Monitoring administrative burden	Public sector	€ 0.18	€ 0.09	€ 0.09	€ 0.05
Direct costs – total compliance					
Adjustment, monitoring and	Companies	€ 37,660	€ 3,024	€ 2,885	€ 226

administration burden costs (OEL only)					
Adjustment, monitoring and administration burden costs per company (OEL only)	Companies	€ 0.09	€ 0.01	€ 0.01	€ 0.001
Adjustment, monitoring and administration burden costs (OEL only)	Public sector	€ 5,873	€ 63	€ 63	€ 0.29
Adjustment, monitoring and administration burden costs per public authority (OEL only)	Public sector	€ 7.75	€ 0.08	€ 0.08	€ 0
Total compliance costs (OEL only)	**Companies Public authorities**	**€ 43,533**	**€ 3,087**	**€ 2,949**	**€ 226**
Direct costs - enforcement costs					
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.			
Indirect costs - other					
Firms discontinuing at least a part of their business - No. of company closures	Companies	3,462	146	The number is likely to be lower than 146	-
Firms discontinuing at least a part of their business - %	Companies	0.79%	0.03%	The number is likely to be lower than 0.03%	-
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	Up to 6.3% (C19.1 Coking plants – small & medium enterprises)	Up to 2.9% (C19.1 Coking plants – small & medium enterprises)	Cannot be estimated Up to 2.9% (C19.1 Coking plants – small & medium enterprises)	Up to 0.01% (several sectors and company sizes)
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Up to 19% (C16.1 wood preservation – small enterprises)	Up to 3% (C24.45 other non-ferrous metallurgy – small enterprises)	Cannot be estimated	0.7% (several sectors – small enterprises)
Employment – Jobs lost	Workers & families	47,758	2,725	Cannot be estimated – may be a reduction jobs lost due to fewer discontinuations	-
Employment – Social cost	Workers & families	€ 4,028	€ 226	Cannot be estimated – may be a reduction jobs	€ 0

				lost due to fewer discontinuations	
International competitiveness	Companies	Significantly negative impacts	Negative impacts	Limited negative impacts	No significant impacts
Consumers	Consumers	Costs for enterprises at 7 ng/m^3 and 70 ng/m^3 make up a significant proportion of turnover/GOS and costs are expected to be passed onto consumers through increased prices; including C20.13 carbon black manufacturers, C19.1 coking, C24.45 other metallurgy, C10.13 and C10.2 smokehouses, G45.2 automotive repair, N81.22 chimney sweeps, C16.1 wood preservation, E38.2 soil remediation, F42.11 road paving, and F42.12 welding of railroad tracks. The impact of PO3 would be more limited than under PO 2.		The transitional period provided for by PO 5 will delay the increase in consumer prices, or allow for a gradual increase over 6 years. Costs at 700 ng/m^3 are less substantial and may not result in as significant price increases for consumers.	
Internal market Lowest to highest OEL	Companies	1 : 1	1 : 1	1 : 1	1 : 10
Specific MSs/regions - MSs that would have to change OELs	Public sector	27 Member States: AU, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK	26 Member States: AU, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK	26 Member States: AU, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK	23 Member States: AU, BE, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, PL, PT, RO, SE, SI, SK
Direct benefits – improved well-being - health					
Reduced cases of ill health (lung cancer)	Workers & families	141	35	35	2
Reduced cases of ill health (developmental toxicity)	Workers & families	38	38	38	7
Reduced cases of ill health (male infertility)	Workers & families	3,157	3,157	3,157	608
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 182 - 59	€ 97 - 16	€ 89 - 15	€ 15 - 1
Direct benefits – improved well-being - safety					
Avoided costs	Companies	€ 0.54	€ 0.13	€ 0.12	€ 0.01
Avoided costs	Public sector	€ 5.26	€ 3.87	€ 3.87	€ 0.69
Direct benefits – improved well-being - environmental					

Environmental releases	All	Increased reduction in PAH emissions at all levels. In some sectors environmental emissions are expected to reduce as OELs become more stringent. This is due to RMMs resulting in greater containment/abatement of emissions (e.g. through increased use of closed systems or novel cleaner processes as they become available). It is unclear whether the use of alternatives would produce different levels of emissions and the extent to which this may occur, although as outlined in this report alternatives are not viable for most sectors. In the example of road paving where alternatives may be available, it is unknown whether emissions would be affected.			
Direct benefits – market efficiency					
Level playing field	Companies	A harmonised OEL at EU level would help to ensure a level playing field between companies operating in different EU Member States. As shown above ('Specific MSs/regions - MS that would have to change OELS'), at all policy option levels the introduction of an EU wide OEL would result in greater alignment of Member States.			
Indirect benefits					
Administrative simplification	Companies	Should all Member States have a harmonised OEL/BLV this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification. Sectors with the highest costs are typically medium and large enterprises which may benefit from such an administrative simplification.			
Avoided cost of setting an OEL	Public sector	€ 1.80	€ 1.75	€ 1.75	€ 1.60
Other impacts					
Recycling – loss of business	Recycling companies	Metallurgical sectors may result in discontinuations at the lowest policy option levels, which in turn would result in less production of materials within the EU. However, it is anticipated that companies would continue to source materials from outside the EU to meet demand and subsequently materials available for recycling would be unaffected. However, metallurgical sectors also undertake secondary production (recycling) of metals which would also be subject to costs related to OELs. At 7ng/m^3 metallurgical sectors are expected to have significant discontinuations resulting in loss of EU capacity to recycle metals. At 70 ng/m^3 the impacts to metallurgical sectors are less significant in terms of discontinuations, thereby assuming capacity to recycle metals is maintained. Recycling is not considered to be impacted in other areas.			
Impacts on fundamental rights	All	Positive impact on health and safety. Increased monitoring will help to ensure that future exposures remain controlled and worker risk remains low.			
Impact on EU Green Deal	All	PO 2 is expected to result in negative impacts on the EU Green Deal (including EU Strategic Autonomy), PO would also lead negative impacts, although more limited thant under PO 2. PO 5, with its transitional period, is expected to have limited impacts on EU Green Deal. PO 4 is expected not to have any impacts.			
Impacts on digitalisation	Companies	Digitalisation may be impacted by high costs to silicon metal and graphite manufacturers (used in semiconductor manufacturing, fuel cells, PV solar panels and EV batteries). Costs and discontinuations related to silicon (C24.45) are estimated to be significantly negative at 7 ng/m^3, negative at 70ng/m^3, and negligible at 700 ng/m^3 suggesting			

		impacts on digitalisation would mainly be experienced at the most stringent policy option level. Regarding graphite production (C23.99b) modelling estimates significantly negative costs at 7 ng/m^3 and negative costs at 70 ng/m^3 indicating cost impacts on digitalisation at these levels (no impacts at 700 ng/m^3). Synthetic graphite production is reliant upon C19.1 coking which also experiences significant costs at the lowest two policy options. Collectively the difficulties of silicon and graphite production sector to meet costs at the two lowest policy options may result in negative impacts on digitalisation through increased material costs or greater reliance upon imports from third countries (primarily China). With its transitional value, PO 5 is expected to have more limited impacts on digitalisation than PO 3.
Contributions to the UN sustainable development goals	All	Goal 3 – positive Goal 7 – positive Goal 8 – positive Goal 14 and 15 – positive

Source: Study team.

* Transitional period: 140 ng/m^3 & 0.3 nmol/mol creatinine for six years and then 70 ng/m^3 & 0.3 nmol/mol creatinine

8.3. 1,4-dioxane

Table 69 – Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy options for 1,4-dioxane, € million

Impact	Stakeholders affected	PO 2	PO 3
Direct costs - adjustment			
Risk management measures - first year	Companies	€ 53	€ 0
Risk management measures – recurrent	Companies	-€ 34	€ 0
Risk management measures - discontinuation	Companies	€ 102	€ 0
Risk management measures total	Companies	€ 121	€ 0
Risk management measures total per company	Companies	€ 0.067	€ 0
Monitoring (sampling and analysis)	Companies	€ 2.35	€ 0.55
Direct costs - administrative			
Administration burden	Companies	€ 0.74	€ 0.21
Direct costs – total compliance			
Adjustment, monitoring and administration burden costs	Companies	€ 125	€0.76
Adjustment, monitoring and administration burden costs per company	Companies	€ 0.07	€ 0.0004
Direct costs - enforcement costs			
Transposition costs	Public sector	€ 0.81	€ 0.78
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.	
Indirect costs - other			
Firms discontinuing at least a part of their business - No. of company closures	Companies	6.3	0
Firms discontinuing at least a part of their business - %	Companies	0.4%	0%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	0.8%	0.01%
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Up to 14.3% (C20.1, C20.3 and C20.5 chemicals - small enterprises)	Up to 0.06% (M72.1 laboratories - small enterprises)
Employment – Jobs lost	Workers & families	140	0
Employment – Social cost	Workers & families	€ 13	€ 0
International competitiveness	Companies	Some non-EU countries would have less stringent OELs	
Consumers	Consumers	No significant impact	No significant impact
Internal market Lowest to highest OEL	Companies	7.3 mg/m^3-7.3 mg/m^3	20 mg/m^3-20 mg/m^3
Specific MSs/regions - MSs that would have to change	Public sector	27	25

OELs			
Direct benefits – improved well-being - health			
Reduced cases of ill health (kidney effects)	Workers & families	497	0
Reduced cases of ill health (liver effects)	Workers & families	633	0
Reduced cases of ill health (local irritation in the nasal cavity)	Workers & families	4,382	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 2 - 3 million	€ 0 - 0 million
Avoided costs	Companies	€ 1.6	€ 0
Avoided costs	Public sector	€ 2	€ 0
Direct benefits – improved well-being - environmental			
Environmental releases	All	Potentially, a reduction in emissions into the air but unclear impact on emissions to water	
Direct benefits – market efficiency			
Level playing field	Companies	The ratio between the maximum and minimum national OEL is currently 3.65. The ratio between the maximum/minimum STEL is 2.08. A reduction in the OEL and STEL is likely to improve the level playing field in the internal market.	
Indirect benefits			
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for enterprises with operations across multiple Member States. However, the majority of enterprises under review are small and are unlikely to have multinational operations and be unaffected by this simplification.	
Synergy	Companies	Synergies in terms of exposure reduction for other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.	
Avoided cost of setting OEL	Public sector	€ 2.7	€ 1.8
Other impacts			
Recycling – loss of business	Recycling companies	No impacts expected	
Impacts on fundamental rights	All	Improved occupational health	
Impacts on EU Green Deal	All	No impact expected.	
Impacts on digitalisation	Companies	No impact expected.	
Contributions to the UN sustainable development goals	All	Potential for reduced emissions into the air but it is unclear whether this would not increase emissions into wastewater.	

Source: RPA (2024)

8.4. Isoprene

Table 70 – Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy options for isoprene, € million

Impact	Stakeholders affected	8.5 mg/m^3
Direct costs – adjustment		
Risk management measures – first year	Companies	€ 0
Risk management measures – recurrent	Companies	€ 0
Risk management measures - discontinuation	Companies	€ 0
Risk management measures – total	Companies	€ 0
Risk management measures – total per company	Companies	€ 0
Monitoring (sampling and analysis)	Companies	€ 0.19
Transposition costs	Public sector	€ 1.22
Direct costs – administrative		
Company cost of administration burden	Companies	€ 0.11
Direct costs – total compliance		
Adjustment, monitoring and administration burden costs	Companies	€ 0.30
Adjustment, monitoring and administration burden costs per company	Companies	€ 0.004
Direct costs - enforcement costs		
Enforcement costs except transposition	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.
Indirect costs – other		
Firms discontinuing at least a part of their business - No. of company closures	Companies	0
Firms discontinuing at least a part of their business - %	Companies	0
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	Up to 0.002% (Synthetic rubber manufacture – small companies)
First year compliance costs as % of turnover over 40 years (excluding discontinuations)	Companies	Same as above
Employment – Jobs lost	Workers & families	0
Employment – Social cost	Workers & families	€ 0
International competitiveness	Companies	No impact
Consumers	Consumers	No impact
Internal market Lowest to highest OEL*	Companies	1 : 1
Specific MSs/regions - MSs that would have to change OELs	Public sector	AU, BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LU, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK
Regulation	Companies	€ 0
Direct benefits – improved well-being - health		
Reduced cases of ill health – liver cancer	Workers & families	0
Reduced cases of ill health – degeneration of olfactory epithelium	Workers & families	0

Reduced cases of ill health – degeneration of spinal cord white matter	Workers & families	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 0
Direct benefits – improved well-being - safety		
Avoided costs	Companies	€ 0
Avoided costs	Public sector	€ 0
Direct benefits – improved well-being - environmental		
Environmental releases	All	No direct or indirect impacts on the environment and environmental legislation will occur under any of the policy options.
Direct benefits – market efficiency		
Level playing field	Companies	A harmonised OEL at EU level would help to ensure a level playing field between companies operating in different EU Member States. See row on 'internal market' for how harmonisation would occur at each policy option.
Indirect benefits		
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for companies with operations across multiple Member States. This reduction in administrative burden however would be less likely to have significant impacts in the case of isoprene due to the estimation that all companies already have relatively consistent operating processes which would not be influenced by the implementation of any of the policy options.
Avoided cost of setting OEL	Public sector	€ 2.40 million
Other impacts		
Recycling – loss of business	Recycling companies	No impacts are expected to be felt by recycling companies as a result of any of the policy options.
Impacts on fundamental rights	All	Compulsory monitoring of isoprene levels will help to ensure that the fundamental right of workers to workplace environments which respect human health is reliably enforced.
Impacts on EU Green Deal	All	No impacts on EU Green Deal
Impacts on digitalisation	Companies	No impacts on digitalisation are expected.
Contributions to the UN sustainable development goals	All	In relation to the third sustainable development goal – "*good health and wellbeing - improved worker and family health*" – the above comment for impacts on fundamental rights also applies.

Source: RPA (2024)

8.5. Welding fumes

Table 71 – Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy options for welding fumes, € million

Impact	Stakeholders affected	PO 1
Direct costs – compliance		
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€ 67 - 156
Monitoring (sampling and analysis)	Companies	None expected
Direct costs - administrative burdens		
Company cost of administration burden	Companies	N/A
Direct costs – total		
Compliance, monitoring and administration burden costs per company	Companies	€ 67 – 156
Direct costs - enforcement costs		
Transposition costs	Public sector	€ 2.7
Enforcement costs	Public sector	None
Monitoring costs	Public sector	None
Adjudication costs	Public sector	None
Indirect costs – other		
Firms exiting the market - No. of company closures	Companies	None predicted
Employment – Jobs lost	Workers & families	Not quantified. No legal change, awareness raising.
Employment – Social cost	Workers & families	Not estimated
International competitiveness	Companies	International competition is low for welding as welding often needs to be done *in situ* on site and cannot be exported.
Consumers	Consumers	None predicted.
Internal market Lowest to highest OEL	Companies	Not quantified.
Specific MSs/regions - MSs that would have to change their policy or OELs	Public sector	Less compliance in Eastern and Southern EU Member States according to anecdotal evidence heard by the study team.
Direct benefits – improved well-being – health		
Reduced cases of cancer	Workers & families	1,618
Reduced fatalities	Workers & families	1,079
Reduced non-fatalities	Workers & families	270
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	M1: €997.5 M2: €510
Direct benefits – improved well-being – safety		
Avoided costs	Companies	€4.7
Avoided costs	Public sector	€16.4
Direct benefits – improved well-being – environmental		
Environmental releases	All	Not quantified
Direct benefits – market efficiency		
Level playing field	Companies	Awareness raising may lead to an improved

		level playing field between and within Member States.
Indirect benefits		
Administrative simplification	Companies	Not applicable
Avoided cost of setting OEL (EU27)	Public sector	Not applicable
Other impacts		
Recycling – loss of business	Recycling companies	Not applicable. Circular economy principles in EU27 encourage recycling including recycling of metal products which will sometimes involve welding. This is not predicted to be exported, due to the subsidiarity principle - waste management including recycling should be undertaken by local and regional authorities.
Impacts on fundamental rights	All	Not applicable
Impacts on EU Green Deal	All	No impact
Impacts on digitalisation	Companies	Not applicable
Contributions to the UN sustainable development goals	All	Positive minor impact towards UN SDG 3: good health and wellbeing and UN SDG 8: Decent work & economic growth

Source: RPA (2024)

ANNEX 5: COMPETITIVENESS CHECK

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness	**“0”** to **“-”**	Sections 6.1.2 (b), 6.2.2 (b), 6.3.2 (b), 6.4.2 (b) and 6.5.2 (b)
International competitiveness	**“0”** to **“-”**	Sections 6.1.2 (b), 6.2.2 (b), 6.3.2 (b), 6.4.2 (b) and 6.5.2 (b)
Capacity to innovate	**“0”** to **“-”**	Sections 6.1.2 (b), 6.2.2 (b), 6.3.2 (b), 6.4.2 (b) and 6.5.2 (b)
SME competitiveness	**“0”** to **“-”**	Sections 6.1.2 (a), 6.2.2 (a), 6.3.2 (a), 6.4.2 (a) and 6.5.2 (a)

2. SYNTHETIC ASSESSMENT

In total, the costs to businesses (including SMEs) resulting from the package of preferred options represent a small share of turnover for all sectors (below 0,6%), with the exception of small and medium-sized enterprises operating in coking plants and coal tar distillation sectors where they might represent between 2% and 3% of turnover over 40 years. If we take the situation in the short term, businesses operating in coking plants, manufacturers of refractory products, graphite and carbon electrode manufacturers, steel and iron foundries, ferroalloys, other non-ferrous metallurgy companies, and coal fired power plants. would need to make investiments in additional RMMs from the very beginning which would represent more than 10% of their gross operating surplus. Except for graphite and electrode manufacturers, these sector are mainly composed of SMEs, which have less capacity to absorb additional costs. Therefore, consumers dependent on the above sectors are likely to be impacted with a share of adjustment costs being passed on to them. As all these sectors, except coal fired power plants, are subject to the transitional period, these companies would have more time to plan their investments. Therefore, the impact on consumers is expected to be mitigated but not totally excluded.

Furthermore, the structure of most of the sectors concerned by the package of preferred option should remain unchanged, in particular with the introduction of some transitional measures for PAHs and cobalt and its inorganic compouds. Despite the introduction of these measures, it cannot however be excluded that some businesses would still discontinue in some sectors, in particular coking industry. However, this impact is expected to be much lower than the same limit values without any transitional periods as the latter corresponds to what employers within the ACSH judged as necessary. Therefore, the presence of transitional values in the package of preferred option should limit the negative impact on **consumers,** without guarantee of completely excluding it in certain sectors. For that reason, the impact on consumers, both in terms of prices and diversity of supply, dependent on the above sectors is expected to be negative. For all other sectors, which represent a majority of those sectors impacted by this initiative, the impact is likely to be negligigble or even null.

The impact of the package of preferred options on the **capacity to innovate** should be negligible for most sectors as the total costs to companies represent a very small share of their R&D expenditures. However, some impacts on innovation cannot be excluded for SMEs operating in the following sectors: coking plants (costs to businesses represent up to 160% of R&D expenditures), soil remediation (up to 155%), welding of railroad track (up to 120-135%) and other non-ferrous metallurgy.

With regard to the impact of the package of preferred options on **international competitiveness**, although the package of preferred options would lead to more stringent provisions to comply with for companies operating in the EU compared to those active in non-EU countries, the costs compared to turnover are overall very limited in most sectors. Therefore, the compliance costs are expected to not exceed the costs of relocation of activities, so that businesses would not be encouraged to relocate their activities outside of the EU. Furthermore, most of businesses potentially impacted by the package of preferred options are SMEs. They usually operate at national scale, or even on-site, which limits either the possibility to relocate or the competition from outside of the EU.

Despite this, sectors such as steel and iron foundries, ferroalloys, aluminium manufacturers, other metallurgy, casting of metal and graphite and carbon electrode manufacturers already experience pressure from cheaper imports, particularly from Asian countries. Additional operational costs arising from compliance costs could negatively impact their competitiveness against cheaper imports. Nevertheless, this negative impact will be mitigated by the transitional period for PAHs (and to a lesser extend for cobalt and its inorganic compounds) as businesses will have more time to plan their investments. Nevertheless, it cannot be ruled out that the package of preferred options will have an impact on the competitiveness of these sectors. Furthermore, a significant share of coking plants were expected to discontinue with the introduction of the final limit value for PAHs without transitional period. With the transitional measures provided by in the package of preferred option, the number of discontinuations is expected to be lower. However, it cannot be excluded that some coking plants would still discontinue, which would result in a greater dependence on imports from non-EU countries for those companies using products from coking plants, such as in the production of batteries for the storage of energy produced by wind turbines, semiconductors and electric vehicles.

Overall, the impact on international competitiveness should be negligible for most sectors. However, some businesses operating in the sectors mentioned above might be negatively impacted by the package of preferred option, while the transitional measures provided by in this package should limit this negative impact. Therefore these transitional options contribute to avoid imposing financial constraints in a way which would hold back the creation and development of SMEs[222]

More than 99% of businesses with exposed workers to the substances subject to this impact assessment are **SMEs**. Overall, the share of compliance costs compared to turnover or gross operating product is higher for SMEs than large companies operating in the same sector. Therefore, they are likely to be more impacted by the package of preferred options compared to larger enterprises. Furthermore, as described in section 6, SMEs are more likely to experience more discontinuations than larger companies (although the number of SMEs possibly impacted remains very limited compared to its total number. As an example, the number of SMEs for all substances expecting to discontinue represent – up to 0.04% of the total number of SMEs with exposed workers). The transitional measures provided by in the package of preferred options will benefit more to SMEs than large companies as SMEs will have more time to plan their investments, which should also reduce the number of discontinuations compared to the same package of options without transitional periods. Therefore, the impact on the competitiveness of SMEs should be limited.

[222] As requested by TFUE in its Article 153 (2) (b)

ANNEX 6: RELEVANT SECTORS, USES, EXPOSURE CONCENTRATIONS AND NATIONAL REGULATORY FRAMEWORKS

1. COBALT AND INORGANIC COBALT COMPOUNDS

1.1. Relevant sectors with exposed workers

Table 72 - relevant sectors with risk of exposure to cobalt and inorganic cobalt compounds

NACE code	Short name for sector	NACE description	Uses / processes
C10.91	Manufacture, feeds	Manufacture of prepared feeds for farm animals	Manufacture of prepared feeds for farm animals
C19.20	Petrochemical, catalyst	Manufacture of refined petroleum products	Service life of catalysts in oil refining
C20.12	Manufacture of dyes and pigments	Manufacture of dyes and pigments	Manufacture of dyes and pigments
C20.13-20.14	Manufacture of basic chemicals	Manufacture of other inorganic basic chemicals; Manufacture of other organic basic chemicals	Manufacture of other inorganic cobalt compounds Production of polyamide powder for cosmetics Manufacture of driers/paints Manufacture of formulations for surface treatment Manufacture of cobalt carboxylates and resinates (intermediate use)
C20.30	Manufacture of paints and inks	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	In-house manufacture of organic cobalt driers
C20.59	Catalysts	Manufacture of other chemical products n.e.c.	Production of catalysts; use of cobalt as an intermediate in the manufacture of catalysts
C20.59	Formulation	Manufacture of other chemical products n.e.c.	Manufacture and use of aqueous mixtures for local metallization of cobalt and cobalt alloys Formulation of water treatment chemicals Formulation of products for biogas production Formulation of products for biotechnology
C21.20	Pharmaceuticals	Manufacture of pharmaceutical preparations	Manufacture of veterinary preparations with cobalt
C22.11	Production of tyres	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	In-house manufacture of organic cobalt adhesion agents

C23.1	Glass	Manufacture of glass and glass products	Use of pigments and decolouriser in glass
C23.4	Ceramics	Manufacture of other porcelain and ceramic products	Use of pigments in ceramics industry
C23.7	Cutting stone	Cutting, shaping and finishing of stone	Service life of diamond tools
C24.10	Steel	Manufacture of basic iron and steel and of ferro-alloys	Production of cobalt alloyed steels
C24.45	Manufacture of cobalt and cobalt alloys	Other non-ferrous metal production	Production of primary cobalt metal Recovery of slags, matte, slimes and sludges from non-ferrous metal production Production of cobalt alloys powder
C25.5	Powder metallurgy	Forging, pressing, stamping and roll-forming of metal; powder metallurgy	Production of sintered articles not covered elsewhere
C25.61	Surface treatment of metals	Treatment and coating of metals	Plating and passivation (surface treatment) Thermal spraying Painting metal (non-metallic surface treatment)
C25.62	Machining	Machining	Service life of hardmetal tools and diamond tools
C25.73	Manufacture of tools	Manufacture of tools	Production of hardmetal tools and diamond tools
C25.99	Manufacture of other fabricated metal products n.e.c.	Manufacture of other fabricated metal products n.e.c.	Use of cobalt metal in additive manufacturing (3D-printing) Production of magnets Use of cobalt-containing alloys for sandblasting in industrial setting Industrial use of cobalt-containing mixtures in brazing technique
C26.1	Production of electronic components and boards	Manufacture of electronic components and boards	Production of varistors and other electronic components Production of printed circuit boards
C26.51	Humidity indicator cards	Manufacture of instruments and appliances for measuring, testing and navigation	Production of humidity indicators
C27.2	Batteries	Manufacture of batteries and accumulators	Production of batteries
C28.11	Engines and turbines	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	Use of cobalt alloys (thermal spraying, welding, machining, etc.)
C29.10-30	Automotive	Manufacture of motor vehicles, trailers and semi-trailers; Manufacture of	Plating and passivation (surface treatment) Service life of hardmetal tools

		other transport equipment	
C30.30	Air and spacecraft	Manufacture of air and spacecraft and related machinery	Use of cobalt alloys (thermal spraying, welding, machining, etc.)
C32.50	Medical and dental devices	Manufacture of medical and dental instruments and supplies	Production of medical and dental implants and restorations
E38.32	Metal recovery	Recovery of sorted materials	Manufacture of secondary cobalt metal Recycling of hardmetal scrap Recycling of batteries Recycling of catalysts Recycling of electrical and electronic waste (WEEE)
	Cross-sectoral activities	Biogas	Nutrient in biogas production
	Cross-sectoral activities	Welding	Welding of cobalt alloys (various sectors)
Source: RPA (2024)			

1.2. Estimated number of enterprises with exposed workers in the EU

Table 73 – estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Number of enterprises			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
C10.91	Manufacture, feeds	264	30	6	300
C19.20	Petrochemical, catalyst	0	41	41	82
C20.12	Manufacture of dyes and pigments	0	4	11	15
C20.13-20.14	Manufacture of basic chemicals	12	11	7	30
C20.30	Manufacture of paints and inks	6	3	1	10
C20.59	Catalysts	0	7	6	13
C20.59	Formulation of other chemical products	14	11	11	35
C21.20	Pharmaceuticals	0	0	8.0	8
C22.11	Production of tyres	0	0	3	3
C23.1	Glass	28	15	7.5	50
C23.4	Ceramics	350	105	45	500
C23.7	Cutting stone	970	20	10	1,000
C24.10	Steel	2	4	1	7
C24.45	Manufacture of cobalt and cobalt alloys	0	0	6	6
C25.5	Powder metallurgy	11	17	3	30

C25.61	Surface treatment of metals	329	94	47	470
C25.62	Machining	4,800	900	300	6,000
C25.73	Manufacture of tools	2,024	230	46	2,300
C25.99	Manufacture of other fabricated metal products n.e.c.	113	30	8	150
C26.1	Production of electronic components and boards	188	50	13	250
C26.51	Humidity indicator cards	3	1	1	5
C27.2	Batteries	-	8	8	15
C28.11	Engines and turbines	105	17	8	130
C29.30	Automotive, parts	108	13	9	130
C30.30	Air and spacecraft	113	10	7	130
C32.50	Medical and dental devices	300	150	50	500
E38.32	Metal recovery	-	7	8	15
	Biogas	2,697	279	124	3,100
	Welding	40	8	3	50
	Total	**12,476**	**2,063**	**795**	**15,334**

Source: RPA (2024)

1.3. Estimated number of exposed workers in the EU

Table 74 – estimated number of workers in the EU exposed to cobalt and inorganic cobalt compounds

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers in companies *	Number exposed per company	Percentage exposed in companies
C10.91	Manufacture, feeds	1,800	300	9,000	6	20%
C19.20	Petrochemical, catalyst	600	82	88,200	7	1%
C20.12	Manufacture of dyes and pigments	2,300	15	10,500	153	22%
C20.13-20.14	Manufacture of basic chemicals	2,900	30	10,100	97	29%
C20.30	Manufacture of paints and inks	200	10	1,100	20	18%
C20.59	Catalysts	910	13	4,600	70	20%
C20.59	Formulation	1,700	35	8,100	49	21%
C21.20	Pharmaceuticals	950	8	5,100	119	19%
C22.11	Production of tyres	300	3	5,900	100	5%
C23.1	Glass	900	50	8,600	18	10%
C23.4	Ceramics	7,500	500	55,300	15	14%
C23.7	Cutting stone	3,000	1,000	20,900	3	14%
C24.10	Steel	100	7	700	14	14%

C24.45	Manufacture of cobalt and cobalt alloys	660	6	2,200	110	30%
C25.5	Powder metallurgy	900	30	3,800	30	24%
C25.61	Surface treatment of metals	5,200	470	44,000	11	12%
C25.62	Machining	25,000	6,000	83,300	4	30%
C25.73	Manufacture of tools	30,000	2,300	114,400	13	26%
C25.99	Manufacture of other fabricated metal products n.e.c.	1,120	150	6,400	7	17%
C26.1	Production of electronic components	3,000	250	20,700	12	15%
C26.51	Humidity indicator cards	100	5	1,200	20	8%
C27.2	Batteries	1,950	15	6,900	130	28%
C28.11	Engines and turbines	2,200	130	7,300	17	30%
C29.10-30	Vehicles	5,200	130	17,300	40	30%
C30.30	Air and spacecraft	2,200	130	6,300	17	35%
C32.50	Medical and dental devices	5,000	500	16,700	10	30%
E38.32	Metal recovery	1,100	15	3,300	73	33%
	Biogas	5,400	3,100	36,900	2	15%
	Welding	550	50	4,700	11	12%
Total		**113,000**	**15,334**	**872,300**	**7**	**13%**
Source: RPA (2024) **Rounded figures*						

1.4. Exposure concentrations by sectors

Table 75 - summary of exposure concentrations (in µg Co/m3, inhalable fraction) by sectors, with adjustment for the use of RPE.

Sector		AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	0.3	0.2	0.4	0.8	1.2	2.7
C19.20	Petrochemical, catalyst	3.4	2.2	4.1	7.3	10.3	19.4
C20.12	Manufacture of dyes and pigments	6.5	3.2	7.3	15.6	24.5	57.0
C20.13-20.14	Manufacture of basic chemicals	2.4	1.1	2.5	5.6	9.0	22.0
C20.30	Manufacture of paints and inks	4.0	1.25	3.7	9.8	17.6	52.8

C20.59	Catalysts and other chemicals	0.3	0.1	0.2	0.6	1.0	2.8
C20.59	Formulation other chemicals	2.6	0.8	2.3	6.1	11.0	33.0
C21.20	Pharmaceuticals	0.3	0.0	0.1	0.5	1.0	3.7
C22.11	Production of tyres	1.2	0.2	0.8	2.5	4.8	16.7
C23.1	Glass	3.0	1.5	3.3	6.8	10.5	23.4
C23.4	Ceramics	6.7	3.5	7.7	16.0	24.6	55.0
C23.7	Cutting stone	2.5	0.9	2.5	5.9	10.0	26.6
C24.10	Steel	5.4	2.7	6.0	12.6	19.4	43.7
C24.45	Manufacture of cobalt and cobalt alloys	5.3	2.6	5.9	12.5	19.4	44.5
C25.5	Powder metallurgy	4.8	3.0	5.7	10.3	14.5	27.9
C25.61	Surface treatment of metals	3.2	1.7	3.7	7.3	11.1	23.9
C25.62	Machining	6.3	4.8	7.8	12.2	15.8	25.8
C25.73	Manufacture of tools	4.8	3.0	5.7	10.3	14.5	27.9
C25.99	Manufacture of other fabricated metal products n.e.c.	7.4	4.0	8.7	17.8	27.1	59.8
C26.1	Production of electronic components	7.6	4.2	9.0	17.9	27.0	58.3
C26.51	Humidity indicator cards	0.2	0.1	0.2	0.5	0.7	1.8
C27.2	Batteries	1.3	0.4	1.2	3.0	5.1	14.2
C28.11	Engines and turbines	6.2	4.7	7.7	12.2	15.9	26.4
C29.10-30	Automotive	3.2	1.7	3.6	7.2	10.9	23.6
C30.30	Air and spacecraft	6.2	4.7	7.7	12.2	15.9	26.4
C32.50	Medical and dental devices	11.5	7.8	14.5	25.2	35.2	65.7
E38.32	Metal recovery	3.8	2.6	4.6	7.9	11.0	19.9
	Biogas	0.0	0.0	0.0	0.0	0.06	0.13
	Welding, etc.	12.9	8.0	16.8	32.7	48.7	100.2
Source: RPA (2024)							

Table 76 - summary of exposure concentrations (in µg Co/m3, inhalable fraction) by sectors, without adjustment for the use of RPE.

Sector		AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	4.0	1.8	4.2	9.0	13.8	31.8
C19.20	Petrochemical, catalyst	27.3	17.6	32.8	58.4	82.0	155.2
C20.12	Manufacture of dyes and pigments	6.5	3.2	7.3	15.6	24.5	57.0
C20.13-20.14	Manufacture of basic chemicals	19.5	8.4	20.0	44.8	72.0	176.0
C20.30	Manufacture of paints and inks	31.7	10.0	29.6	78.4	140.8	422.4
C20.59	Catalysts and other chemicals	2.1	0.4	1.6	4.8	8.0	22.4
C20.59	Formulation other chemicals	21.0	6.0	18.4	48.8	88.0	263.6

C21.20	Pharmaceuticals	1.0	0.2	0.6	1.9	3.9	14.7
C22.11	Production of tyres	9.4	1.6	6.4	19.6	38.4	133.6
C23.1	Glass	23.9	11.6	26.4	54.4	83.6	187.2
C23.4	Ceramics	53.7	28.0	62.0	127.6	196.4	440.4
C23.7	Cutting stone	10.1	3.6	9.8	23.6	39.8	106.4
C24.10	Steel	42.9	21.6	48.4	100.4	154.8	349.6
C24.45	Manufacture of cobalt and cobalt alloys	42.3	20.8	47.6	99.6	155.2	356.0
C25.5	Powder metallurgy	38.0	24.0	46.0	82.0	116.0	222.8
C25.61	Surface treatment of metals	25.9	13.6	29.2	58.4	88.4	191.2
C25.62	Machining	50.2	38.8	62.8	97.2	126.0	206.0
C25.73	Manufacture of tools	38.0	24.0	46.0	82.0	116.0	222.8
C25.99	Manufacture of other fabricated metal products n.e.c.	59.5	32.0	70.0	142.0	216.4	478.8
C26.1	Production of electronic components	60.7	33.6	72.0	143.2	216.0	466.8
C26.51	Humidity indicator cards	0.8	0.2	0.8	1.8	2.8	7.0
C27.2	Batteries	10.6	3.2	9.6	23.6	40.8	113.2
C28.11	Engines and turbines	24.7	18.8	31.0	48.6	63.6	105.6
C29.10-30	Automotive	12.8	6.6	14.4	28.8	43.6	94.4
C30.30	Air and spacecraft	24.7	18.8	31.0	48.6	63.6	105.6
C32.50	Medical and dental devices	46.0	31.2	57.8	100.8	140.8	262.8
E38.32	Metal recovery	15.2	10.4	18.6	31.8	43.8	79.6
	Biogas	0.0	0.0	0.0	0.0	0.1	0.1
	Welding, etc.	103.6	64.0	134.0	261.2	389.6	801.6
Source: RPA (2024)							

Table 77 - summary of exposure concentrations (in µg Co/m3, respirable fraction) by sectors, with adjustment for the use of RPE.

Sector		R:I *	AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	1:4	0.1	0.0	0.1	0.2	0.3	0.7
C19.20	Petrochemical, catalyst	1:4	0.9	0.6	1.0	1.8	2.6	4.9
C20.12	Manufacture of dyes and pigments	1:4	1.6	0.8	1.8	3.9	6.1	14.3
C20.13-20.14	Manufacture of basic chemicals	1:4	0.6	0.3	0.6	1.4	2.3	5.5
C20.30	Manufacture of paints and inks	1:4	1.0	0.3	0.9	2.5	4.4	13.2
C20.59	Catalysts and other chemicals	1:4	0.1	0.0	0.1	0.2	0.3	0.7
C20.59	Formulation other chemicals	1:4	0.7	0.2	0.6	1.5	2.8	8.2
C21.20	Pharmaceuticals	1:4	0.1	0.0	0.0	0.1	0.2	0.9

C22.11	Production of tyres	1:4	0.3	0.1	0.2	0.6	1.2	4.2
C23.1	Glass	1:4	0.7	0.4	0.8	1.7	2.6	5.9
C23.4	Ceramics	1:4	1.7	0.9	1.9	4.0	6.1	13.8
C23.7	Cutting stone	1:4	0.6	0.2	0.6	1.5	2.5	6.7
C24.10	Steel	1:8	0.7	0.3	0.8	1.6	2.4	5.5
C24.45	Manufacture of cobalt and cobalt alloys	1:8	0.7	0.3	0.7	1.6	2.4	5.6
C25.5	Powder metallurgy	1:8	0.6	0.4	0.7	1.3	1.8	3.5
C25.61	Surface treatment of metals	1:4	0.8	0.4	0.9	1.8	2.8	6.0
C25.62	Machining	1:8	0.8	0.6	1.0	1.5	2.0	3.2
C25.73	Manufacture of tools	1:8	0.6	0.4	0.7	1.3	1.8	3.5
C25.99	Manufacture of other fabricated metal products n.e.c.	1:8	0.9	0.5	1.1	2.2	3.4	7.5
C26.1	Production of electronic components	1:4	1.9	1.1	2.3	4.5	6.8	14.6
C26.51	Humidity indicator cards	1:4	0.1	0.0	0.1	0.1	0.2	0.4
C27.2	Batteries	1:4	0.3	0.1	0.3	0.7	1.3	3.5
C28.11	Engines and turbines	1:8	0.8	0.6	1.0	1.5	2.0	3.3
C29.10-30	Automotive	1:4	0.8	0.4	0.9	1.8	2.7	5.9
C30.30	Air and spacecraft	1:8	0.8	0.6	1.0	1.5	2.0	3.3
C32.50	Medical and dental devices	1:8	1.4	1.0	1.8	3.2	4.4	8.2
E38.32	Metal recovery	1:8	0.5	0.3	0.6	1.0	1.4	2.5
	Biogas	1:4	0.00	0.00	0.01	0.01	0.02	0.03
	Welding, etc.	1:2	6.5	4.0	8.4	16.3	24.3	50.1

Source: RPA (2024)
** R:I =respirable to inhalable ratio used for calculating respirable concentrations from inhalable.*

Table 78 - summary of exposure concentrations (in µg Co/m³, respirable fraction) by sectors, without adjustment for the use of RPE.

Sector		R:I *	AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	1:4	1.0	0.5	1.1	2.3	3.5	8.0
C19.20	Petrochemical, catalyst	1:4	6.8	4.4	8.2	14.6	20.5	38.8
C20.12	Manufacture of dyes and pigments	1:4	1.6	0.8	1.8	3.9	6.1	14.3
C20.13-20.14	Manufacture of basic chemicals	1:4	4.9	2.1	5.0	11.2	18.0	44.0
C20.30	Manufacture of paints and inks	1:4	7.9	2.5	7.4	19.6	35.2	105.6
C20.59	Catalysts and other	1:4	0.5	0.1	0.4	1.2	2.0	5.6

	chemicals							
C20.59	Formulation other chemicals	1:4	5.2	1.5	4.6	12.2	22.0	65.9
C21.20	Pharmaceuticals	1:4	0.3	0.0	0.1	0.5	1.0	3.7
C22.11	Production of tyres	1:4	2.4	0.4	1.6	4.9	9.6	33.4
C23.1	Glass	1:4	6.0	2.9	6.6	13.6	20.9	46.8
C23.4	Ceramics	1:4	13.4	7.0	15.5	31.9	49.1	110.1
C23.7	Cutting stone	1:4	2.5	0.9	2.5	5.9	10.0	26.6
C24.10	Steel	1:8	5.4	2.7	6.0	12.6	19.4	43.7
C24.45	Manufacture of cobalt and cobalt alloys	1:8	5.3	2.6	5.9	12.5	19.4	44.5
C25.5	Powder metallurgy	1:8	4.8	3.0	5.7	10.3	14.5	27.9
C25.61	Surface treatment of metals	1:4	6.5	3.4	7.3	14.6	22.1	47.8
C25.62	Machining	1:8	6.3	4.8	7.8	12.2	15.8	25.8
C25.73	Manufacture of tools	1:8	4.8	3.0	5.7	10.3	14.5	27.9
C25.99	Manufacture of other fabricated metal products n.e.c.	1:8	7.4	4.0	8.7	17.8	27.1	59.8
C26.1	Production of electronic components	1:4	15.2	8.4	18.0	35.8	54.0	116.7
C26.51	Humidity indicator cards	1:4	0.2	0.1	0.2	0.5	0.7	1.8
C27.2	Batteries	1:4	2.6	0.8	2.4	5.9	10.2	28.3
C28.11	Engines and turbines	1:8	3.1	2.4	3.9	6.1	8.0	13.2
C29.10-30	Automotive	1:4	3.2	1.7	3.6	7.2	10.9	23.6
C30.30	Air and spacecraft	1:8	3.1	2.4	3.9	6.1	8.0	13.2
C32.50	Medical and dental devices	1:8	5.8	3.9	7.2	12.6	17.6	32.8
E38.32	Metal recovery	1:8	1.9	1.3	2.3	4.0	5.5	10.0
	Biogas	1:4	0.00	0.00	0.01	0.01	0.02	0.03
	Welding, etc.	1:2	51.8	32.0	67.0	130.6	194.8	400.8

Source: RPA (2024)
** R:I =respirable to inhalable ratio used for calculating respirable concentrations from inhalable.*

1.5. Current risk management measures

Table 79 – Percentage breakdown of primary RMMs currently used by sector (row total = 100%)

Sector		Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
C10.91	Manufacture, feeds	10%	30%	30%	0%	0%	0%	10%	10%	0%	10%	0%
C19.20	Petrochemical, catalyst	0%	0%	30%	0%	0%	0%	20%	40%	0%	10%	0%
C20.12	Manufacture of dyes and pigments	10%	30%	40%	0%	0%	0%	0%	10%	0%	10%	0%
C20.13-20.14	Manufacture of basic chemicals	10%	30%	30%	0%	0%	0%	20%	0%	0%	10%	0%
C20.30	Manufacture of paints and inks	10%	20%	30%	0%	0%	0%	30%	0%	0%	10%	0%
C20.59, 1	Catalysts	10%	40%	35%	0%	0%	0%	5%	0%	0%	10%	0%
C20.59, 2	Formulation	10%	40%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C21.20	Pharmaceuticals	40%	20%	20%	0%	0%	0%	10%	0%	0%	10%	0%
C22.11	Production of tyres	10%	30%	30%	0%	0%	0%	30%	0%	0%	0%	0%
C23.1	Glass	10%	40%	20%	0%	0%	0%	20%	0%	0%	10%	0%
C23.4	Ceramics	0%	40%	35%	0%	0%	0%	15%	0%	0%	10%	0%
C23.7	Cutting stone	0%	20%	20%	0%	0%	0%	20%	10%	0%	10%	20%
C24.10	Steel	10%	20%	20%	0%	0%	0%	20%	20%	0%	10%	0%
C24.45	Manufacture of cobalt and cobalt alloys	10%	30%	25%	0%	0%	0%	15%	0%	0%	20%	0%
C25.5	Powder metallurgy	10%	25%	25%	0%	0%	0%	20%	10%	0%	10%	0%
C25.61	Surface treatment of metals	10%	30%	20%	0%	0%	0%	10%	30%	0%	0%	0%
C25.62	Machining	0%	0%	70%	0%	0%	0%	10%	0%	0%	0%	20%
C25.73	Manufacture of tools	30%	20%	20%	0%	0%	0%	10%	20%	0%	0%	0%
C25.99	Manufacture of other	10%	30%	20%	0%	0%	0%	10%	30%	0%	0%	0%

	fabricated metal products n.e.c.											
C26.1	Production of electronic components ad boards	10%	30%	10%	0%	0%	0%	30%	10%	0%	10%	0%
C26.51	Humidity indicator cards	10%	30%	20%	0%	0%	0%	0%	20%	0%	20%	0%
C27.2	Batteries	10%	45%	20%	0%	0%	0%	15%	0%	0%	10%	0%
C28.11	Engines and turbines	20%	30%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C29.10-30	Automotive	20%	30%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C30.30	Air and spacecraft	10%	30%	25%	0%	0%	0%	15%	20%	0%	0%	0%
C32.50	Medical and dental devices	0%	20%	25%	0%	0%	0%	15%	20%	0%	20%	0%
E38.21	Biogas											
E38.32	Metal recovery	10%	20%	25%	0%	0%	0%	15%	20%	0%	10%	0%
	Welding	0%	20%	25%	0%	0%	0%	45%	0%	0%	10%	0%
Source: RPA (2024), stakeholder survey												

1.6. Risk management measures required to achieve compliance

Table 80: RMMs required to meet policy options (values = number of processes requiring RMM)

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
Policy option 20 / 4.2 µg/m³												
C19.20 Manufacture of refined petroleum products (1)	100% (1)											
C20.12 Manufacture of dyes and pigments (6)	83% (5)											
C20.13 Manufacture of other inorganic basic chemicals (20)	5% (1)	30% (6)	25% (5)	25% (5)	10% (2)	15% (3)		60% (12)	20% (4)	25% (5)		20% (4)
C20.14 Manufacture of other organic basic chemicals (4)	25% (1)	25% (1)	75% (3)	75% (3)				50% (2)				
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	100% (7)		14% (1)	14% (1)		14% (1)		14% (1)		43% (3)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	50% (12)	13% (3)	8% (2)	4% (1)								4% (1)
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)	100% (1)				100% (1)							
C23.4 Manufacture of other porcelain and ceramic products (15)	100% (15)											
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)	75% (3)											25% (1)
C24.45 Other non-ferrous metal production (16)	50% (8)	44% (7)	13% (2)		6% (1)			25% (4)	13% (2)	13% (2)		
C25.61 Treatment and coating of	25% (1)								25% (1)			

metals (4)												
C25.73 Manufacture of tools (40)	15% (6)	60% (24)	28% (11)	18% (7)	8% (3)		5% (2)	25% (10)	3% (1)	23% (9)		15% (6)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	90% (9)							20% (2)	20% (2)			
C32.50 Manufacture of medical and dental instruments and supplies (4)		25% (1)					25% (1)	50% (2)	25% (1)			
F42 Civil engineering (4)		25% (1)										
Grand Total (163)	**43% (70)**	**26% (43)**	**15% (24)**	**10% (17)**	**4% (7)**	**2% (4)**	**2% (3)**	**20% (33)**	**7% (11)**	**12% (19)**	**1% (2)**	**8% (13)**
Policy option 10 / 2.5 µg/m^3												
C19.20 Manufacture of refined petroleum products (1)			100% (1)	100% (1)								
C20.12 Manufacture of dyes and pigments (6)		50% (3)		83% (5)								
C20.13 Manufacture of other inorganic basic chemicals (20)	20% (4)	30% (6)	15% (3)	15% (3)	20% (4)	25% (5)		40% (8)		20% (4)		20% (4)
C20.14 Manufacture of other organic basic chemicals (4)												
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	71% (5)		14% (1)	14% (1)		14% (1)		14% (1)		43% (3)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	38% (9)	17% (4)	4% (1)	4% (1)				8% (2)			13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including					100% (1)							

technical glassware (1)												
C23.4 Manufacture of other porcelain and ceramic products (15)	100% (15)											
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	25% (4)	44% (7)	31% (5)	19% (3)	13% (2)	13% (2)		25% (4)	13% (2)	13% (2)		13% (2)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)	13% (5)	33% (13)	13% (5)	13% (5)	5% (2)		5% (2)	15% (6)	5% (2)	20% (8)	3% (1)	15% (6)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	80% (8)	10% (1)	10% (1)				10% (1)	30% (3)	10% (1)			
C32.50 Manufacture of medical and dental instruments and supplies (4)												
F42 Civil engineering (4)												
Grand Total (163)	**31% (51)**	**21% (34)**	**10% (17)**	**12% (19)**	**6% (9)**	**5% (8)**	**2% (3)**	**15% (24)**	**4% (6)**	**10% (17)**	**4% (6)**	**8% (13)**
Policy option 5 / 1.5 µg/m³												
C19.20 Manufacture of refined petroleum products (1)			100% (1)	100% (1)				100% (1)				
C20.12 Manufacture of dyes and pigments (6)			33% (2)									
C20.13 Manufacture of other inorganic basic chemicals (20)	5% (1)	35% (7)	10% (2)	20% (4)	10% (2)			20% (4)			15% (3)	
C20.14 Manufacture of other organic basic chemicals (4)												

C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	14% (1)		14% (1)			14% (1)				29% (2)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	21% (5)	8% (2)	4% (1)	8% (2)				13% (3)			13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)					100% (1)							
C23.4 Manufacture of other porcelain and ceramic products (15)			53% (8)	40% (6)						87% (13)		
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	19% (3)	50% (8)	38% (6)	19% (3)	25% (4)	6% (1)	25% (4)	13% (2)	6% (1)	13% (2)		6% (1)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)	10% (4)	33% (13)	5% (2)	3% (1)			13% (5)	3% (1)	3% (1)	3% (1)	3% (1)	3% (1)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	60% (6)	20% (2)	20% (2)	10% (1)			10% (1)	10% (1)	10% (1)			
C32.50 Manufacture of medical and dental instruments and supplies (4)												
F42 Civil engineering (4)												
Grand Total (163)	**13% (21)**	**20% (32)**	**15% (25)**	**11% (18)**	**4% (7)**	**1% (2)**	**6% (10)**	**7% (12)**	**2% (4)**	**11% (18)**	**6% (9)**	**2% (3)**

Policy option 1 / 0.5 µg/m³												
C19.20 Manufacture of refined petroleum products (1)		100% (1)	100% (1)	100% (1)			100% (1)	100% (1)				
C20.12 Manufacture of dyes and pigments (6)		50% (3)		50% (3)					50% (3)			
C20.13 Manufacture of other inorganic basic chemicals (20)		35% (7)		20% (4)	20% (4)			20% (4)			15% (3)	
C20.14 Manufacture of other organic basic chemicals (4)												
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)		29% (2)								29% (2)		
C20.59 Manufacture of other chemical products n.e.c. (24)		21% (5)		8% (2)		8% (2)		17% (4)	17% (4)		13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)												
C23.4 Manufacture of other porcelain and ceramic products (15)		93% (14)							100% (15)			
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	25% (4)	75% (12)	38% (6)	44% (7)	38% (6)	13% (2)	38% (6)	25% (4)	13% (2)	25% (4)	38% (6)	13% (2)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)		40% (16)	3% (1)	3% (1)			18% (7)		3% (1)	3% (1)	5% (2)	
C26.1 Manufacture of electronic												

components (2)													
C27.2 Manufacture of batteries and accumulators (10)	50% (5)	40% (4)	60% (6)	10% (1)			30% (3)	50% (5)	40% (4)				
C32.50 Manufacture of medical and dental instruments and supplies (4)													
F42 Civil engineering (4)													
Grand Total (163)	**6% (10)**	**39% (64)**	**9% (14)**	**12% (19)**	**6% (10)**	**2% (4)**	**10% (17)**	**11% (18)**	**18% (30)**	**4% (7)**	**9% (14)**	**1% (2)**	
Source: RPA (2024), stakeholder survey													

1.7. National limit value(s)

Table 81 - current OELs and STELs in EU Member States and selected non-EU countries

Country	OEL (µg/m^3)	Specification of OEL	STEL (µg/m^3)	Specification of STEL
EU Member States				
Austria [1,2,3]	100 (I) *	Cobalt and cobalt alloys, cobalt oxide, cobalt sulphate and cobalt sulphide - TRK value[#], Carc, Srd, Sk A value of 0.5 for certain processes	400 (I) *	- TRK value[#], Carc, Srd, Sk
Belgium [1,2,4]	20 (I, V) **	Cobalt metal (dust and fume) - Carc	-	
Belgium [4]	5 (R) **	Hardmetal of cobalt and tungsten carbide, as Co	-	
Bulgaria [5]	100 **	Cobalt and inorganic compounds	-	
Croatia [6]	100 **	Cobalt and its compounds - Srd	-	
Cyprus [7]	100 **	Metal dust and fumes, total dust	-	
Czechia [8]	50 (R) *	Cobalt and its compounds - Carc, Repro, S	0.1 (R) *	- Carc, Repro, S
Denmark [1,2,9]	10 **	Cobalt, powder, dust, smoke, and inorganic compounds Carc	20 **	- powder, dust, and smoke, Carc
Estonia [10]	50 *	Cobalt and its inorganics compounds - S	-	
Finland [1,2,11]	20 (I) ^^	Cobalt and its inorganics compounds	-	
France [2,12]	2.5 ^	Cobalt compounds, excluding hardmetals Recommendation derived by ANSES	12.5 ^	- recommendation derived by ANSES
Germany [1,2,13]	4 (R) § * 0.2 (R) $ 20 (I) !	Cobalt and cobalt compounds classified as Carc 1A and 1B	40 (R) § *	- Cobalt compounds classified as Carc 1A and 1B, 15 min average value
Greece [14]	100 *	Cobalt and its compounds	-	
Hungary [1,2,15]	20 15 *	Cobalt and its inorganic compounds, S [15] A value of 0.1 mg/m^3 applies for cobalt and its compounds [1,2]	400 *	- Cobalt and its compounds [1,2]
Ireland [1,2,16]	20 ^	Cobalt and its compounds, S	-	
Italy [17]	-		-	

Latvia [1,2,18]	500 **	- Cobalt, cobalt (II) and (III) oxide	-	
Lithuania [19]	50 **	Cobalt and its inorganic compounds - Carc, S	-	
Luxembourg [20]	-		-	
Malta [21]	-		-	
Netherlands [1,2,22]	20 (D, F) **	Cobalt (dust and smoke)	-	
Poland [1,2,23]	20 **	Cobalt and its inorganic compounds	-	
Portugal [24]	-		-	
Romania [1,2,25]	50 *	Cobalt, cobalt oxide,	100 *	- Cobalt, 15 min average value
Slovakia [26]	50 **	Cobalt and its compounds, total dust - S	-	
Slovenia [27]	-		-	
Spain [1,2,28]	20 (I) ^^	Cobalt and inorganic cobalt compounds - S, Carc (cobalt and specific compounds)	-	
Sweden [1,2,29]	20 (I) **	Cobalt and its inorganic compounds - Carc, S, Sk	-	
European Union	-		-	
RAC [2]	1 (I) 0.5 (R)	Cobalt and its inorganic compounds - Srd	-	
Candidate countries				
Albania [45]	-		-	
Bosnia and Herzegovina [46]	-		-	
Georgia [47]	-	- S	-	
Moldova [48 49]	50 *	Cobalt (oxide of cobalt) - Carc, S (Cobalt in urine 15 µg/l Sampling time: at the end of the work shift or work week)	100*	- S
Montenegro [50]	-		-	
North Macedonia [51]	500 (I)	Cobalt (metal, cobalt oxide and cobalt sulfide) - obtaining powder from coal catalysts, carbide substrates and and powder, compaction and mechanical treatment of magnets (prep	-	

	100 (I)	unsintered pieces) - Others		
Serbia [52]	-		-	
Turkey [40]	-		-	
Ukraine [53]	-		-	
EU candidate countries				
Albania				
Bosnia and Herzegovina				
Georgia				
Moldova,				
Montenegro				
North Macedonia,				
Serbia,				
Turkey [40]	-		-	
Ukraine				
Non-EU countries				
Australia [1,30]	50 (D, F) ***	- S	-	
Brazil [31]	-		-	
Canada, Ontario [32]	-		-	
Canada, Québec[1,33]	20 ***	- Carc, S	-	
China [1]	50%		100%	- 15 min average value
India [34]	-		-	
Japan, MHLW [1,35]	20 ***		-	
Japan, JOSH [1,36]	50 ^^^	- Carc, Srd	-	
Norway [1,2, 37]	20 (T)& ^^	- Cobalt and its inorganic compounds, except Co(II)	-	
Russia [38]	4% 1%	- Cobalt, acceptable risk under daily exposure (at least 24), Sk - Cobalt, acceptable risk under chronic exposure (at least 1 year), Sk	-	
South Korea [1]	20%		-	
Switzerland [1,2, 39]	50 (I) *	- Cobalt and its compounds, Carc, Repro, S, Sk	-	
United Kingdom [1,2,41]	100 *	- Cobalt and its compounds, Carc (only for cobalt dichloride and sulphate), S	-	
USA, ACGIH [42]	20 (I) ^	- Carc, Srd	-	
USA, NIOSH [1,43,$$]	50 (D, F) ^	- Cobalt	-	
USA, OSHA [1,2,44]	100 (D, F) *	- Cobalt	-	
Source: RPA (2024)				

Notes:

** Binding value according to country-specific source*

*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018
(Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific) source unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire
! The adoption of this value is currently being discussed.

(T) Total dust
ANSES = French Agency for Food, Environmental and Occupational Health & Safety
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
TRK value= Technical Guidance Concentrations ('Technische Richtkonzentrationen') in Austria
(I) = inhalable fraction/aerosol
(R) = respirable fraction/aerosol
(V) = vapour
(D) = dust
(F) = fume
Carc = notation for carcinogenicity. Where a more detailed notation for carcinogenicity was given, the following notations were reported:
Repro = notation for reproductive toxicity assigned
S = notation for sensitisation assigned. Where a more detailed notation for sensitisation was given, the following notation was reported:
Srd = respiratory and skin/dermal sensitisation
Sk = skin notation assigned or danger of skin absorption
- no value available
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk
$$ For NIOSH recommended exposure limits (RELs), 'TWA' indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.'; Online: https://www.cdc.gov/niosh/npg/pgintrod.html, assessed December 2022
 # TRK value ('Technische Richtkonzentration', Technical Guidance Concentration), based on technical feasibility

Sources:
1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/, accessed on 02.12.2022
2: RAC, Committee for Risk Assessment (RAC, 2022).
3: Austria (2021) Grenzwerteverordnung 2021 – GKV. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418, accessed on 02.12.2022
4: Belgium (2021) List of limit values (Titel 1. – Chemische agentia. and Titel 2. – Kankerverwekkende, mutagene en reprotoxische agentia). Available at: https://werk.belgie.be/nl/themas/welzijn-op-het-werk/algemene-beginselen/codex-over-het-welzijn-op-het-werk, accessed on 02.12.2022
5: Bulgaria (2021) List of limit values. Available at: https://www.lex.bg/laws/ldoc/2135477597, accessed on 05.12.2022
6: Croatia (2021) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2021_01_1_10.html, accessed on 05.12.2022
7: Cyprus (2021) Legislation on chemical agents and legislation on carcinogenic-mutagenic agents. Available at: https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/E3237CC15BD91575C2257E030029E9FF?OpenDocument and https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/D74ACEE6A814B7EAC2257E03002A76C9?OpenDocument, accessed on 05.12.2022
Limit value indicated in Member State survey
8: Czechia (2022) List of limit values. Available at: https://www.tzb-info.cz/pravni-predpisy/narizeni-vlady-c-361-2007-sb-kterym-se-stanovi-podminky-ochrany-zdravi-pri-praci, accessed on 05.12.2022
9: Denmark (2022) List of limit values. Available at: https://www.retsinformation.dk/eli/lta/2022/1054, accessed on 05.12.2022
10: Estonia (2022) List of limit values. Available at: https://www.riigiteataja.ee/aktilisa/1120/3202/2025/VV_30m_lisa.pdf#, accessed on 05.12.2022
11: Finland (2020) List of limit values. Available at: https://julkaisut.valtioneuvosto.fi/handle/10024/162457, accessed on 05.12.2022

12: France (2022) List of limit values. Available at: https://www.inrs.fr/media.html?refINRS=outil65 and recommendation by ANSES (2018). Available at: https://www.anses.fr/en/system/files/VLEP2007SA0431RaEN.pdf, accessed on 05.12.2022

13: Germany (2022) List of limit values for carcinogenic hazardous substances (TRGS 910). Available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/910/910-cobalt.pdf?__blob=publicationFile&v=3 / accessed 5 April 2023.

14: Greece (2019) List of limit values. Available at: https://www.elinyae.gr/sites/default/files/2019-10/oriakes%20times%202019_L_0.pdf, accessed on 05.12.2022

15: Hungary (2022) List of limit values. Available at: https://net.jogtar.hu/jogszabaly?docid=a2000005.itm, accessed on 05.12.2022

16: Ireland (2021) List of limit values. Available at: https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf, accessed on 05.12.2022

17: Italy (2022) List of limit values and amendments. Available at: https://www.ispettorato.gov.it/it-it/strumenti-e-servizi/Documents/TU-81-08-Ed.-Agosto-2022.pdf, accessed on 06.12.2022

18: Latvia (2022) List of limit values. Available at: https://likumi.lv/doc.php?id=157382&from=off, accessed on 06.12.2022

19: Lithuania (2022) List of limit values. Available at: https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr, accessed on 06.12.2022

20: Luxembourg (2020) List of limit values (2018) and list of carcinogens and mutagens (2020). Available at: http://legilux.public.lu/eli/etat/leg/rgd/2018/07/20/a684/jo and http://legilux.public.lu/eli/etat/leg/rgd/2020/01/24/a37/jo, accessed on 06.12.2022

21: Malta (2021) List of limit values. Available at: https://legislation.mt/eli/sl/424.24/eng/pdf, accessed on 06.12.2022

22: Netherlands (2022) List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII, accessed on 06.12.2022

23: Poland (2021) List of limit values from 2018 and amendments in 2020 and 2021. Available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001286/O/D20181286.pdf, http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200000061, and https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210000325/O/D20210325.pdf, accessed on 06.12.2022

24: Portugal (2022) List of limit values. Available at: https://dre.pt/dre/legislacao-consolidada/decreto-lei/2012-115495237, accessed on 07.12.2022

25: Romania (2021) List of limit values. Available at: https://legislatie.just.ro/Public/DetaliiDocument/75978, accessed on 07.12.2022

26: Slovakia (2020) List of limit values. Available at: https://www.epi.sk/zz/2006-355, accessed on 07.12.2022

27: Slovenia (2021) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252, accessed on 07.12.2022

28: Spain (2022) List of limit values. Available at: https://www.insst.es/el-instituto-al-dia/limites-de-exposicion-profesional-para-agentes-quimicos-2022, accessed on 07.12.2022

29: Sweden (2022) List of limit values and amendments. Available at: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/, accessed on 07.12.2022

30: Australia (2022) List of limit values. Available at: https://www.safeworkaustralia.gov.au/doc/workplace-exposure-standards-airborne-contaminants-2022, accessed on 07.12.2022

31: Brazil (2021) List of limit values. Available at: https://www.guiatrabalhista.com.br/legislacao/nr/nr-15-anexo-11.pdf, accessed on 07.12.2022

32: Canada, Ontario (2020) List of limit values. Available at: https://www.ontario.ca/laws/regulation/900833, accessed on 07.12.2022

33: Canada, Québec (2022) List of limit values. Available at: https://www.legisquebec.gouv.qc.ca/en/document/cr/S-2.1,%20r.%2013, accessed on 07.12.2022

34: India (2007) List of limit values. Available at: https://dgfasli.gov.in/en/book-page/permissible-levels-certain-chemical-substancesin-work-environment, accessed on 08.12.2022

35: Japan (2022) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 12.12.2022

36: Japan - JOSH (2022) List of limit values. Available at: https://www.sanei.or.jp/english/files/topics/oels/oel_en.pdf, accessed on 08.12.2022

37: Norway (2022) List of limit values. Available at: https://lovdata.no/dokument/SF/forskrift/2011-12-06-1358#KAPITTEL_8, accessed on 10.12.2022

38: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022?index=21&rangeSize=1, accessed on 10.12.2022

39: Switzerland (2022) List of limit values. Available at: https://www.suva.ch/de-ch/services/grenzwerte#gnw-location=%2F, accessed on 10.12.2022

40: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 10.12.2022

41: United Kingdom (2020) List of limit values. Available at: https://www.hse.gov.uk/pubns/priced/eh40.pdf and https://www.hse.gov.uk/pubns/priced/l132.pdf, accessed on 10.12.2022

42: ACGIH, American Conference of Governmental Industrial Hygienists (2022), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.

43: USA, NIOSH (2022) List of limit values. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 10.12.2022

44: USA, OSHA (2022) List of limit values. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 10.12.2022

45: Albania (2014) Albania (2014) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/115604/ALB-115604.pdf; accessed on 26.03.2024
46: Bosnia and Herzegovina (2020) Law on protection at work - part one. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/112339/BIH-112339.pdf; accessed on 26.03.2024
47: Georgia (2014) List of permissible concentrations of metals in the air of the working area. Available at: https://matsne.gov.ge/ka/document/view/2198163?publication=0, accessed on 28.03.2024
48: Moldova (2013) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/97247/PDF.pdf, accessed on 26.03.2024
49: Moldova (2013) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/97247/PDF.pdf, accessed on 26.03.2024
50: Montenegro (2023) List of carcinogens and mutagens. Available at: and https://www.gov.me/dokumenta/d41be940-6c22-499d-8c32-3619e0a6d332, accessed on 27.03.2024
51: North Macedonia (2010) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/94988/MKD-94988.pdf, accessed on 27.03.2024
52: Serbia (2018) List of limit values. Available at: http://www.socijalnoekonomskisavet.rs/cir/publikacije/propisi%20bzr.pdf, accessed on 28.03.2024
53: Ukraine (2020) List of limit values and amendments (2023). Available at: https://zakon.rada.gov.ua/laws/show/z0741-20#Text, accessed on 28.03.2024

2. PAHs

2.1. Relevant sectors with exposed workers

Table 82 - relevant sectors with risk of exposure to PAHs

NACE code	NACE definition	Refined short name for relevant sub-sector	Description of activity
C10.13, C10.20	Production of meat and poultry meat products; Processing and preserving of fish, crustaceans and molluscs	Fish and meat smoke houses	Smoking of fish and meat for preservation purposes
C16.1	Sawmilling and planing of wood	Wood preservation (creosote)	Impregnation of wood with creosote
C19.10	Manufacture of coke oven products	Coking plants	Carbonation of coal
C19.2	Manufacture of refined petroleum products	Petroleum refineries	Refining of crude oil
C20.13	Manufacture of other inorganic basic chemicals	Manufacture of carbon black	Reaction of aromatic compounds to manufacture carbon black
C20.14	Manufacture of other organic basic chemicals	Coal tar distillation	Refining of coal tar
C23.2	Manufacture of refractory products	Manufacture of refractory products	Manufacture of refractory products with coal tar pitch high-temperature (CTPht)

C23.99a	Manufacture of other non-metallic mineral products n.e.c	Manufacture of bituminous products	Use of bitumen to manufacture road paving and roofing products
C23.99b		Graphite and carbon electrodes manufacture	Use of carbon solids and binding agents such as CTPht to manufacture graphite and carbon electrodes, via baking, impregnation, shaping and graphitisation at high temperatures
C24.1	Manufacture of basic iron and steel and of ferro-alloys	Steel and iron foundries, ferroalloys	Use of coal, coal powders and graphite electrodes to manufacture iron and steel
C24.45	Other non-ferrous metal production	Other non-ferrous metallurgical processes	Use of Söderberg electrodes, briquettes or paste at high temperature to manufacture non-ferrous metals and products
C24.42	Aluminium production	Manufacture of aluminium	Use of carbon and graphite electrodes to manufacture aluminium
C24.5	Casting of metals	Casting of metals	Casting of metals in sand moulds
D35.11	Production of electricity	Coal fired power plants	Use of coal to generate electricity
E38.2	Waste treatment and disposal	Waste incineration	Incineration of municipal or hazardous waste
E39	Remediation activities and other waste management services	Soil remediation	Thermal soil remediation of soil contaminated with PAH, may include excavation
F42.11	Construction of roads and motorways	Road paving	Paving or roads with bitumen
F42.12	Construction of railways and underground railways	Welding of train tracks	Welding of train tracks impregnated with creosote oil
G45.2	Maintenance and repair of motor vehicles	Motor vehicle maintenance and repairs	Maintenance and repair of motorised vehicles
N81.22	Other building and industrial cleaning activities	Chimney sweeps	Cleaning of chimneys
O84.25	Fire service activities	Firefighters	Extinguishing and monitoring fires

Source: RPA (2024)

2.2. Estimated number of enterprises with exposed workers in the EU

Table 83 – estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Total number of enterprises	Number of enterprises with exposed workers		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
C10.13	Meat and poultry smokehouses	210	194	13	3
C10.2	Seafood smokehouses	330	287	36	7
C16.1	Wood preservation (creosote)	40	39	1	-
C19.1	Coking plants	55	48	2	5
C19.2	Petroleum refineries	81	30	12	39
C20.13	Manufacture of carbon black	25	-	20	5
C20.14	Coal tar distillation	7	-	3	4
C23.2	Manufacture of refractory products	5	4	1	-
C23.99a	Manufacture of bituminous products	1,180	1,057	99	24
C23.99b	Graphite and carbon electrode manufacture	22	-	-	22
C24.1	Steel and iron foundries, ferroalloys	2,769	2,523	112	134
C24.42	Manufacture of aluminium	9	-	3	6
C24.45	Other non-ferrous metallurgy	80	67	8	5
C24.5	Casting of metals	4,742	4,017	541	184
D35.11	Coal fired power plants	196	126	45	25
E38.2	Waste incineration	650	597	43	10
E39	Soil remediation	3,378	3,280	88	10
F42.11	Road paving	30,949	29,375	1,285	289
F42.12	Welding of railway sleepers	2,016	1,914	83	19
G45.2	Motor vehicles maintenance and repairs	374,183	373,527	606	50
N81.22	Chimney sweeps	19,381	19,381	-	-
O84.25	Firefighters	758	N/A	N/A	N/A
Total		**441,066**	**436,466**	**3,001**	**841**
Source: RPA (2024)					

2.3. Estimated number of exposed workers in the EU

Table 84 – estimated number of workers in the EU exposed to PAHs

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers in companies	Number exposed per company	Percentage exposed in companies
C10.13	Meat and	713	210	4,753	3	15%

	poultry smokehouses					
C10.2	Seafood smokehouses	1,626	330	10,841	5	15%
C16.1	Wood preservation (creosote)	1,000	40	1,200	25	83%
C19.1	Coking plants	2,516	55	2,795	46	90%
C19.2	Petroleum refineries	20,266	81	57,941	179	25%
C20.13	Manufacture of carbon black	1,020	25	3,400	41	30%
C20.14	Coal tar distillation	750	7	2,500	107	30%
C23.2	Manufacture of refractory products	86	5	171	17	50%
C23.99a	Manufacture of bituminous products	5,800	1,180	31,994	5	18%
C23.99b	Graphite and carbon electrode manufacture	1,001	22	12,500	46	8%
C24.1	Steel and iron foundries, ferroalloys	95,752	2,769	319,174	35	30%
C24.42	Manufacture of aluminium	626	9	2,985	70	21%
C24.45	Other non-ferrous metallurgy	616	80	2,465	8	25%
C24.5	Casting of metals	68,109	4,742	204,348	14	33%
D35.11	Coal fired power plants	18,001	196	36,000	92	50%
E38.2	Waste incineration	1,888	650	18,882	3	10%
E39	Soil remediation	10,550	3,378	30,144	3	35%
F42.11	Road paving	212,757	30,949	607,877	7	35%
F42.12	Welding of railway sleepers	6,437	2,016	64,376	3	10%
G45.2	Motor vehicles maintenance and repairs	371,532	374,183	1,092,742	1	34%
N81.22	Chimney sweeps	24,500	19,381	32,667	1	75%
O84.25	Firefighters	438,506/ 4,385,060	758	4,385,060	579/5785	10/100%

Total	1,284,052/5,230,606	441,066	6,947,938	2.9	21%/88%
Source: RPA (2024)					

2.4. Exposure concentrations by sectors

Table 85 - summary of exposure concentrations (in ng/m3) by sectors, with adjustment for the use of RPE.

Sector		AM	Median	P75	P90	P95	P100
C10.13, C10.20	Fish and meat smokehouses	10	0.50	2.8	13	32	220
C16.1	Wood preservation (creosote)	8.1	8	8.8	9.5	10	11
C19.10	Coking plants	329	216	405	700	942	1645
C19.2	Petroleum refineries	23	15	36	81	130	320
C20.13	Manufacture of carbon black	20.4	14.25	25.3	42.3	57.5	102.5
C20.14	Coal tar distillation	152	57.5	169	346	558	397.5
C23.2	Manufacture of refractory products	207	25	100	350	735	2982
C23.99a	Manufacture of bituminous products	38	20	43	86	130	280
C23.99b	Graphite and carbon electrode production	--	24.5	270	270	270	825
C24.1	Steel and iron foundries, ferroalloys	28	12	30	63	100	219
C24.42	Manufacture of aluminium	--	13.2	99	99	99	500
C24.45	Other non-ferrous metallurgical processes	152	71.4	164	345	540	1250
C24.5	Casting of metals	63	50	79	120	150	240
D35.11	Coal fired power plants	20	14	25	41	56	100
E38.2	Waste incineration	0.6	0.4	1.4	4.6	9.2	33.8
E39.0	Soil remediation	76	42.5	88	169	251	523
F42.11	Road paving	34	0.74	4.8	26	70	460
F42.12	Welding of train tracks	300-400	270	440	690	900	1500
G45.20	Motor vehicle maintenance and repairs	4.23	2.16	4.72	9.54	14.5	31
N81.22	Chimney sweeps	18	13	22	35	51	69
O84.25	Firefighters	29	25	35	48	58	83
Source: RPA (2024)							

2.5. Current risk management measures

The following table presents the percentage breakdown of the primary RMMs used by enterprises in each sector. This is based upon information obtained through stakeholder consultation and literature review[223].

[223] RPA (2024), op. cit.

Table 86 – Percentage breakdown of primary RMMs currently used by sector (row total = 100%)

Sector	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Org. measures	General dilution ventilation	No ventilation
C10.13 & C10.2	5%	80%	-	-	-	-	-	5%	-	10%	-
C16.1	40%	-	-	-	-	-	40%	-	-	10%	10%
C19.1	-	40%	20%	-	-	-	20%	-	20%	-	-
C19.2	60%	-	10%	-	-	-	-	10%	-	-	20%
C20.13	50%	10%	20%	-	-	-	10%	-	-	10%	-
C20.14	50%	10%	20%	-	-	-	10%	-	-	10%	-
C23.2	-	25%	50%	-	-	-	25%	-	-	-	-
C23.99a	-	-	-	-	-	-	-	-	-	-	100%
C23.99b	15%	15%	15%	-	15%	2%	18%	10%	-	10%	-
C24.1	20%	10%	-	-	20%	-	-	-	-	50%	-
C24.42	10%	15%	25%	25%	-	-	25%	-	-	-	-
C24.45	10%	15%	25%	25%	-	-	25%	-	-	-	-
C24.5	-	-	40%	-	-	-	20%	-	-	40%	-
D35.11	40%	-	-	-	-	-	-	-	-	20%	40%
E38.2	50%	-	-	-	-	10%	10%	10%	-	20%	-
E39	-	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
F42.11	-	-	20%	-	20%	-	-	-	10%	-	50%
F42.12	-	-	-	-	-	-	-	10%	-	-	90%
G45.2	-	-	-	-	-	-	-	-	-	-	100%
N81.22	5%	10%	35%	-	10%	-	10%	10%	-	-	20%
O84.25	-	-	-	-	-	-	30%	-	20%	-	50%

Source: RPA(2024), stakeholder survey

2.6. Risk management measures required to achieve compliance

The table below outlines the number of processes (by sector) that are currently using RMMs and which RMM they would likely change to meet the require reduction of exposure for each policy option.

Table 87: RMMs required to meet policy options (values = number of processes requiring RMM)

RMMs required / **Sector (n)** **OEL: ng/m³ & BLV: nmol/mol creatinine**	**No action required as OEL already achieved**	**Continuous measurement to detect unusual exposures**	**Formal RPE cleaning & filter changing regime**	**Further cleaning**	**Further training and education**	**Separate storage facilities for work clothes**	**REACH restriction training (future)**	**Conventional or disposable overalls, boiler suits, aprons**	**Coveralls/hazardous materials suits**	**Disposable respirators (FFP masks)**	**Face screens, face shields, visors**	**Gloves**	**Gloves with a cuff, gauntlets and sleeving**	**Half and full facemasks (negative pressure respirators)**	**Powered air-purifying respirators**	**PPE is essential regardless of the OEL**	**Rubber boots**	**Safety boots and shoes**	**Safety spectacles, goggles**	**Self-contained breathing apparatus or airline respirators**	**Redesign of work processes**	**Reduced amount of substance-generating PAH used**	**Reduced the number of workers exposed**	**Rotation of workers exposed**	**Discontinuation of the activity generating PAH**	**Partial substitution of processes or activities generating PAH**	**Partial substitution of substances or materials generating**	**Substitution of processes or activities generating PAH**	**Substitution of substances or materials generating PAH**	**Installing closed systems**	**Installing enclosure with extraction**	**Installing general ventilation**	**Installing open hoods over equipment or local extraction**	**Installing partially closed systems**	**Installing pressurised or sealed control cabs**	**Installing simple enclosed control cabs**	**Other**
C19.10 Manufacture of coke oven products (7)																																					
Current		2	7	7	7	7	2	2	5	7	7	3	4	2	5	7	2	7	7				5	5						2	2	7	7	7	4	6	5
7 & 0.2																									5												
70 & 0.3																									5												
700 & 1.5																																					
2000 & 3.8																																					

Never	7	5					5	5	2			4	3	5	2		5			7	7	7	2	2	2	7	7	7	7	5	5				3	1	2
C19.20 Manufacture of refined petroleum products (47)																																					
Current		1	4	11	45	12		12		11	16	1	7		45		13	16	5		4		34						12	1	7	1	2				8
7 & 0.2	16														22					3				7	7					4							6
70 & 0.3	34				4			4			4		4		23		4	4		3		3	3														12
700 & 1.5	36				4			4			4		4		19		4	4																			5
2000 & 3.8	45														23																						2
Never	2	46	43	36	2	35	47	47	35	47	36	31	46	40	47	2	47	34	31	42	44	43	44	11	40	40	47	47	47	35	42	40	46	45	47	47	34
C20.13 Manufacture of other inorganic basic chemicals (16)																																					
Current			3	14	14	14		4	2		6	12	6	9		12	2	14	12				14	2						2		14	7	3			
7 & 0.2	1		1	2	2		1		2					7	3	1				3	1	2	2	1	1			2		4	4		4	2		2	
70 & 0.3	5			2	2				2		2		2	6	2			2		2			2	1		2				1	1		1	4			
700 & 1.5	11																																				
2000 & 3.8	11																																				
Never	5	16	12	2	2	2	15	12	13	16	10	4	10	3	13	3	14	2	4	13	15	14	2	14	15	14	16	14	16	10	12	2	6	9	16	14	16
C20.14 Manufacture of other organic basic chemicals (20)																																					
Current		14	14	20	20	20	6	2	16	6	10	20	2	13	2	8	5	20	19	5	2		2	6	1					12	3	10	7	1	7		7
7 & 0.2				4												6				4	2				13	5	1	1									2
70 & 0.3	5	3		3				3								6				3	4			3	6	4											8
700 & 1.5	11	1			1											6				1	2			1	4	2				1							2
2000 & 3.8	12				2		2									6									4												7
Never	8	6	6				12	15	4	14	10		18	7	18	12	15		1	11	16	20	18	11	7	13	19	19	20	8	17	10	13	19	13	20	8

C22.19 Manufacture of other rubber products (1)																																					
Current				1	1	1					1	1			1			1	1														1		1		
7 & 0.2																																					
70 & 0.3																																					
700 & 1.5																																					
2000 & 3.8																																					
Never	1	1	1				1	1	1	1			1	1		1	1			1	1	1	1	1	1	1	1	1	1	1	1	1		1		1	1
C24.42 Aluminium production (7)																																					
Current			3	7	7	7		3	1	1	2	4	5	6	4	2		7	5				1	2		1				1	2	2	5	3	5		
7 & 0.2	2							2					4	3	3			4	4										1	4	4	4	4	4	3	3	
70 & 0.3	2							2					4	1	3			3	4	2									1	4	4	4	4	4	3	3	
700 & 1.5	2							2					3	2	2	1		3	3											3	3	3	3	3	2	2	
2000 & 3.8	4			1	1				1			1	2	1	2	1		2	2							1		1		2	1	2	2	1	1	1	
Never	2	7	4				7	3	6	6	5	3	1	1	2	4	7		2	5	7	7	6	5	7	5	7	6	6	1	1	1	2	2	2	4	7
C24.5 Casting of metals (3)																																					
Current			1	3	3	3		1	1		2	1	2				1	2	2	1		1	1			1					1	2	1				
7 & 0.2															1					1		1															
70 & 0.3	1																					1															
700 & 1.5	2																																				
2000 & 3.8	2																																				
Never	1	3	2				3	2	2	3	1	2	1	3	2	3	2	1	1	1	3		2	3	3	2	3	3	3	3	2	1	2	3	3	3	3

F42.11 Construction of roads and motorways (22)																																					
Current		2		16	19	15		4		4		14	17	2				20	13		20		13	14		2						18	15		2	2	4
7 & 0.2	1		6	6	19	19	6	2	4			15	17	4	2			19	19		19	2	19	19				6	2	2	2	19	16	2	5	2	
70 & 0.3	10	6			6	6	6	6		6		6				6		6	6			2	4	6				4	2		2		6		2	2	
700 & 1.5	9	6			6		6	4		2		6		2	2			6	6			2		4			6	6			2	4	2		2	2	
2000 & 3.8	13				6		6	4		2		7		2	2			7	6			2		4			6				2	5	2		2	2	
Never	9	16	16	2	3	3	16	16	18	16	22	2	5	18	18	16	22	2	3	22	2	20	3	2	22	20	16	16	20	20	20	2	3	20	17	20	18
G45.20 Maintenance and repair of motor vehicles (3)																																					
Current				3	3							3	3	3					3		3	1	3	3		3						3					
7 & 0.2					3					3								3	3		1	1	3	3								3		3			
70 & 0.3					3					3		3				3		3	3		1	1	3	3								3		3			
700 & 1.5					3					3		3				3		3	3		1	1	3	3								3		3			
2000 & 3.8	3				3					3		3				3		3	3		1	1	3	3								3		3			
Never		3	3			3	3	3	3	3		3				3		3			3		2			3		3	3	3	3	3		3		3	3
Source: RPA (2024), stakeholder survey																																					

2.7. National limit value(s)

Table 88 - current OELs and STELs in EU Member States and selected non-EU countries

Country	OEL [mg/m³]	Specification of OEL	STEL [mg/m³]	Specification of STEL
EU countries				
Austria [1,2,3]	0.002	- B[a]P, TRK value#, Carc, Sd, Sk	0.008	- B[a]P, TRK value#, Carc, Sd, Sk
Belgium [1,4]	-	- PAHs mixtures, particularly those containing B[a]P, which are carcinogens within the meaning of 2004/37 Directive Carc, Sk	-	
Bulgaria [5]	0.00015 **	- B[a]P - PAHs mixtures, particularly those containing B[a]P, which are carcinogens within the meaning of 2004/37 Directive, Sk	-	
Croatia [6]	-	- PAHs mixtures, particularly those containing B[a]P, which are carcinogens within the meaning of 2004/37 Directive, Sk	-	
Cyprus [7]	-		-	
Czechia [8]	0.005 *	- B[a]P, Carc, Repro, S, Sk	0.025 *	- B[a]P, Carc, Repro, S, Sk
Denmark [1,2,9]	0.2 [1,2] ** - [9]	- PAHs - benzene soluble, Carc, Sk [1,2] - PAHs mixtures, particularly those containing B[a]P, Sk [9]	0.4 [1,2]	- PAHs - benzene soluble, 15 min average value, Carc, Sk [1,2]
Estonia [10]	0.002 *	- B[a]P, Carc, Repro, Sk	0.02 *	- B[a]P, Carc, Repro, Sk

	-	- PAHs mixtures, particularly those containing B[a]P, Carc, Sk		
Finland [1,2,11]	0.01 ^^ -	- B[a]P, Sk - PAHs mixtures, Sk	-	
France [1,12]	-	- PAHs mixtures, particularly those containing B[a]P, Carc, Sk	-	
Germany [1,2,13]	0.0007 (I) § * 0.00007 (I) $	- B[a]P as key component in defined PAH-mixtures, Sk	0.0056 (I) § *	- B[a]P as key component in defined PAH-mixtures, 15 min average value, Sk
Greece [14]	0.005 *	- B[a]P	-	
Hungary [1,2,15]	0.002 *	- B[a]P, Carc	-	
Ireland [16]	-	- PAHs mixtures, particularly those containing B[a]P, Carc, Sk	-	
Italy [1,17]	-	- PAHs mixtures, particularly those containing B[a]P, which are carcinogens within the meaning of 2004/37 Directive, Sk	-	
Latvia [1,2,18]	0.00015 **	- B[a]P* [+]	-	
Lithuania [19]	0.002 *	- B[a]P [##], Carc, S, Repro, Sk	0.02 *	- B[a]P [##], 15 min average value, Carc, Repro, S, Sk
Luxembourg [20]	-		-	
Malta [21]	-		-	
Netherlands [1,2,22]	0.00055 **	- B[a]P, same value also applies for PAHs derived from coal (as B[a]P), Sk	-	
Poland [1,2,23]	0.002 * *	- B[a]P, Sk	-	

	0.002 **	- For 9 carcinogenic PAHs**++23, same value applies for PAHs-benzene soluble [1,2], Sk		
Portugal [24]	-		-	
Romania [1,2,25]	0.2 [1,2]* - [25]	- PAHs - benzene soluble [1,2] - PAHs mixtures, particularly those containing B[a]P, Carc [25]	-	
Slovakia [27]	0.002 ** -	- Ba[a]P, TRK value#, Carc, Sk & - PAHs mixtures, particularly those containing B[a]P, which are carcinogens, Sk	0.008 **	- Ba[a]P, TRK value#, Carc, Sk &
Slovenia [27]	0.002 **	- Ba[a]P, TRK value#, Carc, Repro &	0.008 **	- Ba[a]P, TRK value#, Carc, Repro &
Spain [28]	0.2*	- Coal tar, benzene soluble, Carc, Repro &	-	
Sweden [1,2,29]	0.002 **	- B[a]P, Carc, Repro, Sk	0.02 ^ ^	- B[a]P, 15 min maximum value, Carc, Repro, Sk
European Union [30]	-	- IOELV, Sk	-	
RAC [2]	-	- Sk	-	
Candidate countries				
Albania [46]	-		-	
Bosnia and Herzegovina [47]	-		-	

Georgia [48]	-		-	
Moldova [49]	0.00015 *	- B[a]P, Carc	-	
Montenegro [50]		- Mixtures of polycyclic aromatic hydrocarbons, especially those containing benzo(a)pyrene, which are carcinogenic, Carc, Sk	-	
North Macedonia [51]	0.002 *	- B[a]P, B[d,e,f,]P, Carc, Repro, Sk	-	
Serbia [52]	-		-	
Turkey [41]	-		-	
Ukraine [53]	-		-	
Other countries				
Australia [31]	-		-	
Brazil [32]	-		-	
Canada, Ontario [1,33]	-		-	
Canada, Québec [1,34]	0.005 *** 0.2 ***	- B[a]P, Carc - particulate PAHs - benzene soluble, Carc	-	
China	-		-	
India [35]	-		-	
Japan, MHLW [36]	0.2 ***	- Coal tar, benzene soluble	-	
Japan, JOSH [37]	-	- Carc	-	
Norway [1,2,38]	0.04 ^ ^	- For sum of 21 PAHs***+++ collected as particulates [38], same value applies for PAHs-benzene soluble [1,2], Carc, Sk	-	
Russia [39]	-		-	

South Korea [1]	0.2 [%]	- PAHs - benzene soluble	-	
Switzerland [1,2,40]	0.002 * 0.2 (I) *	- B[a]P, Carc, Repro, Sk - PAHs from coal tar pitch, Carc	-	
United Kingdom [42]	-		-	
USA, ACGIH [43]	0.2 ^	- PAHs - benzene soluble, Carc	-	
USA, NIOSH [44,$$]	0.1 ^	- PAHs from coal tar pitch - cyclohexane soluble, Carc	-	
USA, OSHA [1,45]	0.2 *	- PAHs - benzene soluble [%], Carc	-	

Source: RPA (2024)

Notes:
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
(I) = inhalable fraction/aerosol
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
[%] According to (country-specific source) unclear if value is binding or indicative
[&] Information according to reply of member state authority on questionnaire
Carc = notation for carcinogenicity
Repro = notation for reproductive toxicity
Sk = skin notation assigned or danger of skin absorption
S = notation for sensitisation assigned. Where a more detailed notation for sensitisation was given, the following notations were reported:
Sd = skin/dermal sensitisation
- no value available
 # TRK value ("Technische Richtkonzentration", Technical Guidance Concentration), based on technical feasibility
B[a]P can be present together with other polycyclic aromatic hydrocarbons in smoke, dust or mist, such as from bitumen and asphalt, and in some oils and combustion products
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk

$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk
$$ For NIOSH recommended exposure limits (RELs), "TWA" indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek."; Online: https://www.cdc.gov/niosh/npg/pgintrod.html, accessed December 2022
**[+] Additional OELs are derived for coal tar and pitch sublimates with an average content of benzo[a]pyrene (CAS No. 50-32-8): less than 0.075% an OEL of 0.2 mg/m³; 0.075-0.15 % an OEL of 0.1 mg/m³, and 0.15-0.3% an OEL of 0.05 mg/m³.*
***[++] The nine PAHs are dibenzo[a,h]anthracene, benzo[a]pyrene, benzo[a]anthracene, benzo[b]fluoroanthene, benzo[k]fluoroanthene, indeno[1,2,3-c,d]pyrene, anthracene, benzo[g,h,i]perylene, and chrysene*
****[+++] Sum of the following 21 PAH compounds: Anthracene, benz[a]anthracene), benzo[a]fluorene, benzo[b]fluorene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, benzo[e]pyrene, benzo[ghi]perylene, dibenzo[a,h])anthracene, dibenzo[a,e]pyrene, dibenzo[a,h]pyrene, dibenzo[a,i]pyrene, dibenzo[a,l]pyrene, phenanthrene, fluoranthene, indenol((1,2,3-cd)pyrene, chrysene, pyrene, and triphenylene.*
$$ OSHA defines "coal tar pitch volatiles" as the fused polycyclic hydrocarbons that volatilize from the distillation residues of coal, petroleum (excluding asphalt), wood, and other organic matter and includes substances such as anthracene, benzo(a)pyrene (BaP), phenanthrene, acridine, chrysene, pyrene, etc

Sources:

1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/, accessed on 02.12.2022
2: RAC, Committee for Risk Assessment (2022) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace. European Chemicals Agency (ECHA), Helsinki, Finland. Available at: https://echa.europa.eu/documents/10162/7937606/annex1_rac_opi_oel_pah_en.pdf/8222f456-ee7f-bf3b-66b2-aebf39693bb9?t=1675065114197, accessed on 05.01.2023
3: Austria (2021) Grenzwerteverordnung 2021 – GKV. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418, accessed on 02.12.2022
4: Belgium (2021) List of limit values (Titel 1. – Chemische agentia. and Titel 2. – Kankerverwekkende, mutagene en reprotoxische agentia). Available at: https://werk.belgie.be/nl/themas/welzijn-op-het-werk/algemene-beginselen/codex-over-het-welzijn-op-het-werk, accessed on 02.12.2022
5: Bulgaria (2021) List of limit values and list of carcinogenic/mutagenic/reprotoxic substances. Available at: https://www.lex.bg/laws/ldoc/2135477597 and https://www.lex.bg/bg/mobile/ldoc/2135473243, accessed on 05.12.2022
6: Croatia (2021) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2021_01_1_10.html, accessed on 05.12.2022
7: Cyprus (2021) Legislation on chemical agents and legislation on carcinogenic-mutagenic agents. Available at: https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/E3237CC15BD91575C2257E030029E9FF?OpenDocument and https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/D74ACEE6A814B7EAC2257E03002A76C9?OpenDocument, accessed on 05.12.2022
8: Czechia (2022) List of limit values. Available at: https://www.tzb-info.cz/pravni-predpisy/narizeni-vlady-c-361-2007-sb-kterym-se-stanovi-podminky-ochrany-zdravi-pri-praci, accessed on 05.12.2022
9: Denmark (2022) List of limit values. Available at: https://www.retsinformation.dk/eli/lta/2022/1054, accessed on 05.12.2022
10: Estonia (2022) List of limit values. Available at: https://www.riigiteataja.ee/aktilisa/1120/3202/2025/VV_30m_lisa.pdf#, accessed on 05.12.2022
11: Finland (2020) List of limit values. Available at: https://julkaisut.valtioneuvosto.fi/handle/10024/162457, accessed on 05.12.2022
12: France (2022) List of limit values. Available at: https://www.inrs.fr/media.html?refINRS=outil65, accessed on 05.12.2022
13: Germany (2022) List of limit values for carcinogenic hazardous substances (TRGS 910). Available at: https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-910.html, accessed on 05.12.2022
14: Greece (2019) List of limit values. Available at: https://www.elinyae.gr/sites/default/files/2019-10/oriakes%20times%202019_L_0.pdf, accessed on 05.12.2022
15: Hungary (2022) List of limit values. Available at: https://net.jogtar.hu/jogszabaly?docid=a2000005.itm, accessed on 05.12.2022
16: Ireland (2021) List of limit values. Available at: https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf, accessed on 05.12.2022
17: Italy (2022) List of limit values and amendments. Available at: https://www.ispettorato.gov.it/it-it/strumenti-e-servizi/Documents/TU-81-08-Ed.-Agosto-2022.pdf, accessed on 06.12.2022
18: Latvia (2022) List of limit values. Available at: https://likumi.lv/doc.php?id=157382&from=off, accessed on 06.12.2022
19: Lithuania (2022) List of limit values. Available at: https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr, accessed on 06.12.2022
20: Luxembourg (2020) List of limit values (2018) and list of carcinogens and mutagens (2020). Available at: http://legilux.public.lu/eli/etat/leg/rgd/2018/07/20/a684/jo and http://legilux.public.lu/eli/etat/leg/rgd/2020/01/24/a37/jo, accessed on 06.12.2022
21: Malta (2021) List of limit values. Available at: https://legislation.mt/eli/sl/424.24/eng/pdf, accessed on 06.12.2022

22: Netherlands (2022) List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII, accessed on 06.12.2022
23: Poland (2021) List of limit values from 2018 and amendments in 2020 and 2021. Available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001286/O/D20181286.pdf, http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200000061, and https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210000325/O/D20210325.pdf, accessed on 06.12.2022
24: Portugal (2022) List of limit values. Available at: https://dre.pt/dre/legislacao-consolidada/decreto-lei/2012-115495237, accessed on 07.12.2022
25: Romania (2021) List of limit values. Available at: https://legislatie.just.ro/Public/DetaliiDocument/75978, accessed on 07.12.2022
26: Slovakia (2020) List of limit values. Available at: https://www.epi.sk/zz/2006-355, accessed on 07.12.2022 and https://www.slov-lex.sk/pravne-predpisy/prilohy/SK/ZZ/2006/356/20201001_5255550-2.pdf, accessed on 05.07.2023
27: Slovenia (2021) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252, accessed on 07.12.2022 and https://www.uradni-list.si/files/RS_-2007-053-02834-OB~P001-0000.PDF, accessed on 05.07.2023
28: Spain (2022) List of limit values. Available at: https://www.insst.es/el-instituto-al-dia/limites-de-exposicion-profesional-para-agentes-quimicos-2022, accessed on 07.12.2022
29: Sweden (2022) List of limit values and amendments. Available at: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/, accessed on 07.12.2022
30: European Union, Directive 2019/130 of the European Parliament and of the council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (second amendment). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019L0130&from=EN, accessed on 07.12.2022
31: Australia (2022) List of limit values. Available at: https://www.safeworkaustralia.gov.au/doc/workplace-exposure-standards-airborne-contaminants-2022, accessed on 07.12.2022
32: Brazil (2021) List of limit values. Available at: https://www.guiatrabalhista.com.br/legislacao/nr/nr-15-anexo-11.pdf, accessed on 07.12.2022
33: Canada, Ontario (2020) List of limit values. Available at: https://www.ontario.ca/laws/regulation/900833, accessed on 07.12.2022
34: Canada, Québec (2022) List of limit values. Available at: https://www.legisquebec.gouv.qc.ca/en/document/cr/S-2.1,%20r.%2013, accessed on 07.12.2022
35: India (2007) List of limit values. Available at: https://dgfasli.gov.in/en/book-page/permissible-levels-certain-chemical-substancesin-work-environment, accessed on 08.12.2022
36: Japan (2022) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 12.12.2022
37: Japan - JOSH (2022) List of limit values. Available at: https://www.sanei.or.jp/english/files/topics/oels/oel_en.pdf, accessed on 08.12.2022
38: Norway (2022) List of limit values. Available at: https://lovdata.no/dokument/SF/forskrift/2011-12-06-1358#KAPITTEL_8, accessed on 10.12.2022
39: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022, accessed on 10.12.2022
40: Switzerland (2022) List of limit values. Available at: https://www.suva.ch/de-ch/services/grenzwerte#gnw-location=%2F, accessed on 10.12.2022
41: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 10.12.2022
42: United Kingdom (2020) List of limit values. Available at: https://www.hse.gov.uk/pubns/priced/eh40.pdf, accessed on 10.12.2022
43: ACGIH, American Conference of Governmental Industrial Hygienists (2022), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.
44: USA, NIOSH (2022) List of limit values. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 10.12.2022
45: USA, OSHA (2022) List of limit values. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 10.12.2022
46: Albania (2014) Albania (2014) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/115604/ALB-115604.pdf; accessed on 26.03.2024
47: Bosnia and Herzegovina (2020) Law on protection at work - part one. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/112339/BIH-112339.pdf; accessed on 26.03.2024
48: Georgia (2014) List of permissible concentrations of metals in the air of the working area. Available at: https://matsne.gov.ge/ka/document/view/2198163?publication=0, accessed on 28.03.2024
49: Moldova (2013) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/97247/PDF.pdf, accessed on 26.03.2024
50: Montenegro (2023) List of carcinogens and mutagens. Available at: and https://www.gov.me/dokumenta/d41be940-6c22-499d-8c32-3619e0a6d332, accessed on 27.03.2024
51: North Macedonia (2010) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/94988/MKD-94988.pdf, accessed on 27.03.2024
52: Serbia (2018) List of limit values. Available at: http://www.socijalnoekonomskisavet.rs/cir/publikacije/propisi%20bzr.pdf, accessed on 28.03.2024
53: Ukraine (2020) List of limit values and amendments (2023). Available at: https://zakon.rada.gov.ua/laws/show/z0741-20#Text, accessed on 28.03.2024

3. 1,4-DIOXANE

3.1. Relevant sectors with exposed workers

Table 89 - relevant sectors with risk of exposure to 1,4-dioxane

NACE code	Short name for sector	NACE full name
N/A	Manufacture of 1,4-dioxane	Part of C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
C21.1 and C21.2	Pharmaceutical production (intentional use)	C21.1 Manufacture of basic pharmaceutical products C21.2 Manufacture of pharmaceutical preparations
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as a by-product in the chemicals sector	C20.1Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics C20.5 Manufacture of other chemical products
M72.1	Laboratories (intentional use as a solvent)	M72.1 Research and experimental development on natural sciences and engineering
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	C20.4 Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, excluding C20.42 Manufacture of perfumes and toilet preparations
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	C20.42 Manufacture of perfumes and toilet preparations
Source: RPA (2024)		

3.2. Estimated number of enterprises with exposed workers in the EU

Table 90 – estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Number of enterprises			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
Part of C20.1	Manufacture of 1,4-dioxane	0	0	2	2
C21.1 and C21.2	Pharmaceutical production (intentional use)	71	13	11	95
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	90	11	4	105
M72.1	Laboratories	1,441	32	7	1,480
C20.4 excl. C20.42	Surfactants – generation as a by-product in the production of detergents, soaps, etc.	49	3	1	53
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	65	4	1	70
Source: RPA (2024)					

3.3. Estimated number of exposed workers in the EU

Table 91 – estimated number of workers in the EU exposed to 1,4-dioxane

Sector		Number of exposed workers	Total number of workers in NACE code	% of all workers in NACE code
N/A (part of C20.1)	Manufacture of 1,4-dioxane	150	548,777	0.03%
C21.1 and C21.2	Pharmaceutical production (intentional use)	15,000	637,569	2%
C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector	5,450	869,517	0.6%
M72.1	Laboratories	7,400	505,291	1%
C20.4 excl. C20.42	Surfactants – presence as a minor constituent/impurity in the production of detergents, soaps, etc.	1,150	92,680	1%
C20.42	Cosmetics – generation as a by-product in the production of cosmetics	2,000	198,169	1%
Total		**31,150**	**2,852,003**	**1%**
Source: RPA (2024)				

3.4. Exposure concentrations by sectors

Table 92 - summary of exposure concentrations (in mg/m3) by sectors.

Sector		AM	Median	P75	P90	P95	Max
Part of C20.1	Manufacture of 1,4-dioxane						Significantly <7.3
C21.1 and C21.2	Pharmaceutical production (intentional use)						<3.6
		6.5					18

C20.1, C20.3 and C20.5	Industrial use as a solvent and generation as by-product in the chemicals sector		40				180 (but not 100% of the time) so 90 taken forward
							<3.2
							<2.9
							<18
							<0.008
M72.1	Laboratories						6.5
			5				25
			0.11		0.58		166
			<0.07		0.15		0.18
C20.4 excl. C20.42	Surfactants - presence as a minor constituent/impurity in the production of detergents, soaps, etc.		3.6				
							<3.6
							32 (but only if not ventilated)
						7.3	
C20.42	Cosmetics – generation as a by-product in the production of cosmetics						
Source: RPA (2024)							

3.5. Current risk management measures

Table 93 – Companies' use of RMMs for individual process

Measure	% of respondents that use the measure for at least one process with worker exposure to 1,4-dioxane
Reducing the amount of substance used	20%
Reducing the number of workers exposed	0%
Rotating the workers exposed	20%
Redesign of work processes	0%
Closed systems	100%
Partial hood enclosures	0%
Open hoods over equipment or local extraction ventilation	60%
General ventilation	80%
Pressurised or sealed control cabs	20%
Simple enclosed control cabs	20%
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	0%
Powered air-purifying respirators	0%
Half and full facemasks (negative pressure respirators)	20%
Disposable respirators (FFP masks)	0%
Face screens, face shields, visors	20%
Goggles	60%
Gloves	80%
Continuous measurement to detect unusual exposures	20%
Training and education	60%
Cleaning	20%
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	20%

Provision of separate storage facilities for work clothes	20%
Formal/external RPE cleaning and filter changing regime	0%
Continuous measurement of air concentrations to detect unusual exposures	0%
Creating a culture of safety	60%
Partial substitution of 1,4-dioxane used in this activity in the past	0%
Discontinuation of part of the activity using 1,4-dioxane	0%
PPE is essential regardless of the OEL	80%
Source: RPA (2024), stakeholder survey	

3.6. Risk management measures required to achieve compliance

Table 94: RMMs required to meet policy options, % of processes (in brackets: number of processes)

Measure	Currently in place	73 mg/m³	36 mg/m³	20 mg/m³	7.3 mg/m³
No action required as OEL already achieved		58% (7)	58% (7)	50% (6)	33% (4)
Organisational and hygiene measures: Cleaning	25% (3)				
Organisational and hygiene measures: Continuous measurement of air concentrations to detect unusual exposures					
Organisational and hygiene measures: Continuous measurement to detect unusual exposures	8% (1)				17% (2)
Organisational and hygiene measures: Creating a culture of safety	67% (8)				
Organisational and hygiene measures: Formal/external RPE cleaning and filter changing regime					
Organisational and hygiene measures: Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	25% (3)				

Organisational and hygiene measures: Provision of separate storage facilities for work clothes	25% (3)				
Organisational and hygiene measures: Training and education	67% (8)				
Other	17% (2)	25% (3)	25% (3)	25% (3)	42% (5)
PPE (Personal Protective Equipment): Disposable respirators (FFP masks)					
PPE (Personal Protective Equipment): Face screens, face shields, visors	8% (1)				
PPE (Personal Protective Equipment): Gloves	92% (11)				25% (3)
PPE (Personal Protective Equipment): Goggles	75% (9)				25% (3)
PPE (Personal Protective Equipment): Half and full facemasks (negative pressure respirators)	8% (1)				
PPE (Personal Protective Equipment): Powered air-purifying respirators					
PPE (Personal Protective Equipment): PPE is essential regardless of the OEL	92% (11)				
PPE (Personal Protective Equipment): Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)					
Restructuring operations/processes: Redesign of work processes		8% (1)	8% (1)	8% (1)	17% (2)
Restructuring operations/processes: Reducing the amount of substance used	8% (1)	8% (1)			
Restructuring operations/processes: Reducing the number of workers exposed		8% (1)	8% (1)	8% (1)	
Restructuring operations/processes: Rotating the workers exposed	25% (3)	8% (1)	8% (1)	8% (1)	

Substitution or discontinuation: Discontinuation of part of the activity using 1,4-dioxane					
Substitution or discontinuation: Discontinuation of process using the substance					17% (2)
Substitution or discontinuation: Partial substitution of 1,4-dioxane used in this activity in the past					
Substitution or discontinuation: Substitution of substance				8% (1)	
Ventilation and extraction: Closed systems	67% (8)	17% (2)	17% (2)	17% (2)	25% (3)
Ventilation and extraction: General ventilation	58% (7)	8% (1)	8% (1)	8% (1)	17% (2)
Ventilation and extraction: Open hoods over equipment or local extraction ventilation	33% (4)				17% (2)
Ventilation and extraction: Partial hood enclosures					
Ventilation and extraction: Pressurised or sealed control cabs	8% (1)				
Ventilation and extraction: Simple enclosed control cabs	8% (1)				
Source: RPA (2024), stakeholder survey					

3.7. National limit value(s)

Table 95 - current OELs and STELs in EU Member States and selected non-EU countries

Country	OEL (mg/m³)	Specification of OEL	STEL (mg/m³)	Specification of STEL
Austria [1,2,3]	73 *	- Carc, Sk	146 *	- Momentary value, Carc, Sk
Belgium [1,2,4]	73 **	- Sk	-	
Bulgaria [5]	73 **		20 **	
Croatia [6]	73 **		-	
Cyprus [7]	73 **		-	
Czechia [8]	70 *	- Sk	140 *	- Sk

Denmark [1,2,9]	36 (T) & **	- Carc, Sk	72 (T) & **	- 15 min average value, Carc, Sk
Estonia [10]	73 *		-	
Finland [1,2,11]	36 (I) & ^^	- Sk	150 (I) & ^^	- 15 min average value, Sk
France [1,2,12]	73 *	- Restrictive statutory limit values, Carc	140 ^	- Carc
Germany [1,2,13]	73 *	- Sk	146 *	- 15 min average value, Sk
Greece [14]	73 *		-	
Hungary [1,15]	73 *	- Sk	-	
Ireland [1,2,16]	73 ^^	- Sk	-	
Italy [1,17]	73 **	- Sk	-	
Latvia [1,2,18]	20 **		-	
Lithuania [19]	35 **	- Carc	90 **	- Carc
Luxembourg [20]	73 ***		-	
Malta [21]	73 %		-	
Netherlands [1,22]	20 (T) & **		-	
Poland [1,2,23]	50 (V) & **		-	
Portugal [24]	73 ^		-	
Romania [1,2,25]	73 *	- Carc, Sk	-	
Slovakia [27]	73 **		-	
Slovenia [27]	73 **	- Sk	146 **	- Sk
Spain [1,2,28]	73 **	- Carc, Sk	-	
Sweden [1,2,29]	35 **	- Carc	90 ^^	- 15 min average value, Carc
European Union [1,2,30]	73	- IOELV	-	
RAC [2]	7.3	- Sk	73	- Sk
EU candidate counties				
Albania [46]	73 ^	- Sk	20 ^	- Sk
Bosnia and Herzegovina [47]	-		-	

Georgia [48]	-		-	
Moldova [49]	73 *		10 *	
Montenegro [50]	-		-	
North Macedonia [51]	73 *	- Carc, Sk	-	
Serbia [52]	73 *		-	
Turkey [1,41]	73 [%]		-	
Ukraine [53]	-		-	
Other countries				
Australia [1,31]	36 ***	- Carc, Sk	-	
Brazil [32]	-		-	
Canada, Ontario [1,33]	20 ***	- value only given in ppm	-	
Canada, Québec [1,34]	72 ***	- Carc, Sk	-	
China	-		-	
India [35]	-		-	
Japan, MHLW [1,36]	10 ***	- value only given in ppm	-	
Japan, JOSH [1,37]	3.6 ^^^	- Carc, Sk	-	
Norway [1,2,38]	18 (T) [& ^^]	- Carc, Sk	36 (T) [& ^^]	- 15 min average value, Sk
Russia [39]	10 (V) [%]		-	
South Korea [1]	20 [%]	- value only given in ppm, Sk	-	
Switzerland [1,2,40]	72 *	- Carc, Sk	144 *	- Carc, Sk
United Kingdom [1,2,42]	73 *	- Sk	-	
USA, ACGIH [43]	20 ^	- value only given in ppm, Carc, Sk	-	
USA, NIOSH [1,2,44]	-		3.6	- ceiling limit value (30 min), Carc
USA, OSHA [1,2,45]	360 *	- Sk	-	

Source: RPA (2024)

Notes:

RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
(V) = vapour
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific source) unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire
Carc = notation for carcinogenicity
Sk = skin notation assigned or danger of skin absorption
- no value available

Sources:

1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/, accessed on 02.12.2022
2: RAC, Committee for Risk Assessment (2022) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for 1,4-dioxane at the workplace. European Chemicals Agency (ECHA), Helsinki, Finland. Available at: https://echa.europa.eu/documents/10162/073d44ca-5ad2-8128-fd15-8c74a4bdb126, accessed on 05.01.2023
3: Austria (2021) Grenzwerteverordnung 2021 – GKV. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418, accessed on 02.12.2022
4: Belgium (2022) List of limit values (Titel 1. – Chemische agentia. and Titel 2. – Kankerverwekkende, mutagene en reprotoxische agentia). Available at: https://werk.belgie.be/nl/themas/welzijn-op-het-werk/algemene-beginselen/codex-over-het-welzijn-op-het-werk, accessed on 02.12.2022
5: Bulgaria (2021) List of limit values and list of carcinogenic/mutagenic/reprotoxic substances. Available at: https://www.lex.bg/laws/ldoc/2135477597 and https://www.lex.bg/bg/mobile/ldoc/2135473243, accessed on 05.12.2022
6: Croatia (2021) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2021_01_1_10.html, accessed on 05.12.2022
7: Cyprus (2021) Legislation on chemical agents and legislation on carcinogenic-mutagenic agents. Available at: https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/E3237CC15BD91575C2257E030029E9FF?OpenDocument and https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/D74ACEE6A814B7EAC2257E03002A76C9?OpenDocument, accessed on 05.12.2022
8: Czechia (2022) List of limit values. Available at: https://www.tzb-info.cz/pravni-predpisy/narizeni-vlady-c-361-2007-sb-kterym-se-stanovi-podminky-ochrany-zdravi-pri-praci, accessed on 05.12.2022
9: Denmark (2022) List of limit values. Available at: https://www.retsinformation.dk/eli/lta/2022/1054, accessed on 05.12.2022
10: Estonia (2022) List of limit values. Available at: https://www.riigiteataja.ee/aktilisa/1120/3202/2025/VV_30m_lisa.pdf#, accessed on 05.12.2022
11: Finland (2020) List of limit values. Available at: https://julkaisut.valtioneuvosto.fi/handle/10024/162457, accessed on 05.12.2022
12: France (2022) List of limit values. Available at: https://www.inrs.fr/media.html?refINRS=outil65, accessed on 05.12.2022
13: Germany (2022) List of limit values (TRGS 900). Available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-900.html, accessed on 05.12.2022
14: Greece (2019) List of limit values. Available at: https://www.elinyae.gr/sites/default/files/2019-10/oriakes%20times%202019_L_0.pdf, accessed on 05.12.2022
15: Hungary (2022) List of limit values. Available at: https://net.jogtar.hu/jogszabaly?docid=a2000005.itm, accessed on 05.12.2022
16: Ireland (2021) List of limit values. Available at: https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf, accessed on 05.12.2022

17: Italy (2022) List of limit values and amendments. Available at: https://www.ispettorato.gov.it/it-it/strumenti-e-servizi/Documents/TU-81-08-Ed.-Agosto-2022.pdf, accessed on 06.12.2022
18: Latvia (2022) List of limit values. Available at: https://likumi.lv/doc.php?id=157382&from=off, accessed on 06.12.2022
19: Lithuania (2022) List of limit values. Available at: https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr, accessed on 06.12.2022
20: Luxembourg (2020) List of limit values (2018) and list of carcinogens and mutagens (2020). Available at: http://legilux.public.lu/eli/etat/leg/rgd/2018/07/20/a684/jo and http://legilux.public.lu/eli/etat/leg/rgd/2020/01/24/a37/jo, accessed on 06.12.2022
21: Malta (2021) List of limit values. Available at: https://legislation.mt/eli/sl/424.24/eng/pdf, accessed on 06.12.2022
22: Netherlands (2022) List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII, accessed on 06.12.2022
23: Poland (2021) List of limit values from 2018 and amendments in 2020 and 2021. Available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001286/O/D20181286.pdf, http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200000061, and https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210000325/O/D20210325.pdf, accessed on 06.12.2022
24: Portugal (2022) List of limit values. Available at: https://dre.pt/dre/legislacao-consolidada/decreto-lei/2012-115495237, accessed on 07.12.2022
25: Romania (2021) List of limit values. Available at: https://legislatie.just.ro/Public/DetaliiDocument/75978, accessed on 07.12.2022
26: Slovakia (2020) List of limit values. Available at: https://www.epi.sk/zz/2006-355, accessed on 07.12.2022
27: Slovenia (2021) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252, accessed on 07.12.2022
28: Spain (2022) List of limit values. Available at: https://www.insst.es/el-instituto-al-dia/limites-de-exposicion-profesional-para-agentes-quimicos-2022, accessed on 07.12.2022
29: Sweden (2022) List of limit values and amendments. Available at: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/, accessed on 07.12.2022
30: European Union, Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548946115483&uri=CELEX:32017L2398, accessed on 07.12.2022
31: Australia (2022) List of limit values. Available at: https://www.safeworkaustralia.gov.au/doc/workplace-exposure-standards-airborne-contaminants-2022, accessed on 05.01.2023
32: Brazil (2021) List of limit values. Available at: https://www.guiatrabalhista.com.br/legislacao/nr/nr-15-anexo-11.pdf, accessed on 05.01.2023
33: Canada, Ontario (2020) List of limit values. Available at: https://www.ontario.ca/laws/regulation/900833, accessed on 05.01.2023
34: Canada, Québec (2022) List of limit values. Available at: https://www.legisquebec.gouv.qc.ca/en/document/cr/S-2.1,%20r.%2013, accessed on 05.01.2023
35: India (2007) List of limit values. Available at: https://dgfasli.gov.in/en/book-page/permissible-levels-certain-chemical-substancesin-work-environment, accessed on 05.01.2023
36: Japan (2022) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 05.01.2023
37: Japan - JOSH (2022) List of limit values. Available at: https://www.sanei.or.jp/english/files/topics/oels/oel_en.pdf, accessed on 05.01.2023
38: Norway (2022) List of limit values. Available at: https://lovdata.no/dokument/SF/forskrift/2011-12-06-1358#KAPITTEL_8, accessed on 05.01.2023
39: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022, accessed on 10.12.2022
40: Switzerland (2022) List of limit values. Available at: https://www.suva.ch/de-ch/services/grenzwerte#gnw-location=%2F, accessed on 05.01.2023
41: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 05.01.2023
42: United Kingdom (2020) List of limit values. Available at: https://www.hse.gov.uk/pubns/priced/eh40.pdf, accessed on 05.01.2023
43: ACGIH, American Conference of Governmental Industrial Hygienists (2022), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.
44: USA, NIOSH (2022) List of limit values. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 05.01.2023
45: USA, OSHA (2022) List of limit values. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 05.01.2023
46: Albania (2014) Albania (2014) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/115604/ALB-115604.pdf; accessed on 26.03.2024
46: Bosnia and Herzegovina (2020) Law on protection at work - part one. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/112339/BIH-112339.pdf; accessed on 26.03.2024
48: Georgia (2014) List of permissible concentrations of metals in the air of the working area. Available at: https://matsne.gov.ge/ka/document/view/2198163?publication=0, accessed on 28.03.2024
49: Moldova (2013) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/97247/PDF.pdf, accessed on 26.03.2024
50: Montenegro (2023) List of carcinogens and mutagens. Available at: and https://www.gov.me/dokumenta/d41be940-6c22-499d-8c32-3619e0a6d332, accessed on 27.03.2024
52: North Macedonia (2010) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/94988/MKD-94988.pdf, accessed on 27.03.2024

52: Serbia (2018) List of limit values. Available at: http://www.socijalnoekonomskisavet.rs/cir/publikacije/propisi%20bzr.pdf, accessed on 28.03.2024
53: Ukraine (2020) List of limit values and amendments (2023). Available at: https://zakon.rada.gov.ua/laws/show/z0741-20#Text, accessed on 28.03.2024

4. Isoprene

4.1. Relevant sectors with exposed workers

Table 96 - relevant sectors with risk of exposure to isoprene

NACE code	Short name for sector	NACE description
C19.20	Manufacture of refined petroleum products	This class includes the manufacture of liquid or gaseous fuels or other products from crude petroleum, bituminous minerals or their fractionation products. Petroleum refining involves one or more of the following activities: fractionation; straight distillation of crude oil; and cracking.
C20.17	Manufacture of synthetic rubber in primary forms	This class includes: Manufacture of synthetic rubber in primary forms Synthetic rubber Factice Manufacture of mixtures of synthetic rubber and natural rubber or rubber-like gums (e.g. balata)
Source: RPA (2024)		

4.2. Estimated number of enterprises with exposed workers in the EU

Table 97 – estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Number of enterprises			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
C19.20	Manufacture of refined petroleum products	-	-	18	18
C20.17	Manufacture of synthetic rubber in primary forms	53	7	2	62
Source: RPA (2024)					

4.3. Estimated number of exposed workers in the EU

Table 98 – estimated number of workers in the EU exposed to cobalt and inorganic cobalt compounds

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers in companies	Number exposed per company	Percentage exposed in companies
C19.20	Manufacture of refined petroleum products	10,266	18	33,666	570	28%
C20.17	Manufacture of synthetic rubber in primary forms	273	62	2,726	4	10%
Total		**10,539**	**80**	**36,392**	**132**	

Source: RPA (2024)

4.4. Exposure concentrations by sectors

Table 99 - summary of exposure concentrations (in mg/m3) by sectors, without adjustment for the use of RPE.

Sector		AM	Median	P75	P90	P95	Max
C19.20	Manufacture of refined petroleum products	0.20	0.11	0.23	0.44	0.65	1.36
C20.17	Manufacture of synthetic rubber in primary forms	0.25	0.21	0.31	0.43	0.52	0.76
Source: RPA (2024)							

4.5. Current risk management measures

Table 100 – Companies' use of RMMs for individual process by sector

Measure	C19.20	C20.17
Substitution		
Discontinuation	14% (1)	60% (3)
Reduce use		
Reduce workers		
Rotate workers		
Redesign		
Closed systems	86% (6)	60% (3)
Partial hood		
Open hoods		40% (2)
General ventilation	71% (5)	80% (4)

Pressurised control cabs	57% (4)	20% (1)
Simple control cabs		
RPE	71% (5)	40% (2)
HEPA		
Masks		40% (2)
Goggles	71% (5)	60% (3)
Gloves	71% (5)	100% (5)
Continuous measurement to detect unusual exposures		
Training	71% (5)	100% (5)
Cleaning	71% (5)	60% (3)
Creating a culture of safety	71% (5)	60% (3)
Personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	71% (5)	60% (3)
Provision of separate storage facilities for work clothes	71% (5)	100% (5)
Total number of processes analysed in sector	7	5
Source: RPA (2024), stakeholder consultation		

4.6. Risk management measures required to achieve compliance

Table 101: RMMs required to meet policy options, % of processes (in brackets: number of processes)

RMMs required	No action required as OEL already achieved	Cleaning	Continuous measurement of air	Continuous measurement to detect	Creating a culture of safety	Formal/external RPE cleaning and filter	Measures for workers' personal	Provision of separate storage facilities for	Training and education	Other	Disposable respirators (FFP masks)	Face screens, face shields, visors	Gloves	Goggles	Half and full facemasks (negative	Powered air-purifying respirators	PPE is essential regardless of the OEL	Self-contained breathing apparatus	Redesign of work processes	Reducing the amount of substance used	Reducing the number of workers exposed	Rotating the workers exposed	Discontinuation of process using the	Partial substitution of Isoprene used in this	Substitution of substance	Closed systems	General ventilation	Open hoods over equipment or local	Partial hood enclosures	Pressurised or sealed control cabs	Simple enclosed control cabs

Sector (n) OEL: mg/ m³																															
C19.20 Manufacture of refined petroleum products (7)																															
Current		71% (5)			71% (5)		71% (5)	71% (5)	71% (5)	14% (1)		43% (3)	71% (5)	71% (5)	71% (5)		71% (5)	71% (5)					14% (1)			86% (6)	71% (5)			57% (4)	
129.4	14% (1)									57% (4)																					
40.0	14% (1)									57% (4)																					
8.5	29% (2)									57% (4)																					
1.3	14% (1)									57% (4)																					
C20.17 Manufacture of synthetic rubber in primary forms (5)																															
Current		60% (3)			60% (3)		60% (3)	100% (5)	100% (5)	60% (3)		40% (2)	100% (5)	60% (3)	40% (2)		60% (3)	40% (2)					60% (3)			60% (3)	80% (4)	40% (2)		20% (1)	
129.4	100% (5)																														
40.0	100% (5)																														
8.5	100% (5)																														

1.3	100% (5)								40% (2)																						

Source: RPA (2024), stakeholders survey

4.7. National limit value(s)

Table 102 - current OELs and STELs in EU Member States and selected non-EU countries

Country	OEL [mg/m³]	Specification of OEL	STEL [mg/m³]	Specification of STEL
Austria [3]	-	- Carc	-	
Belgium [4]	-		-	
Bulgaria [5]	40 **		-	
Croatia [6]	-		-	
Cyprus [7]	-		-	
Czechia [8]	-		-	
Denmark [9]	-		-	
Estonia [10]	-		-	
Finland [11]	-		-	
France [12]	-		-	
Germany [1,2,13]	8.4 *	- Carc	67.2 *	- 15 min average value, Carc
Greece [14]	-		-	
Hungary [15]	-		-	
Ireland [16]	-		-	
Italy [17]	-		-	
Latvia [1,2,18]	40 **		-	
Lithuania [19]	40 **	- Carc	-	
Luxembourg [20]	-		-	
Malta [21]	-		-	
Netherlands [22]	-		-	
Poland [1,2,23]	100 **		300 **	- 15 min average value
Portugal [24]	-		-	
Romania [25]	-		-	
Slovakia [26]	-		-	
Slovenia [27]	-		-	
Spain [28]	-		-	
Sweden [29]	-		-	
European Union	-		-	
RAC [2]	8.5		-	
EU candidate countries				
Albania [45]	-		-	
Bosnia and Herzegovina [46]	-		-	
Georgia [47]	-		-	
Moldova [48]	-		-	
Montenegro [49]	-		-	
North Macedonia [50]	-		-	
Serbia [51]	-		-	
Turkey [41]	-		-	
Ukraine [52]	-		-	
Non-EU countries				
Australia [30]	-		-	
Brazil [31]	-		-	
Canada, Ontario [32]	-		-	

Canada, Québec [33]	-		-	
China	-		-	
India [34]	-		-	
Japan, MHLW [35]	-		-	
Japan, JOSH [1,36]	8.4 ^^^	- Carc	-	
Norway [37]	-		-	
Russia [38]	40 (V) %		-	
South Korea	-		-	
Switzerland [1,2,39]	8.5 *	- Carc	68 *	- Carc
United Kingdom [41]	-		-	
USA, ACGIH [42]	-		-	
USA, NIOSH [43]	-		-	
USA, OSHA [44]	-		-	

Source: RPA (2024)

Notes:
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
(V) = vapour
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to report on OEL-deriving systems from 2018. Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018. Status was not checked since 2018.

% According to (country-specific source) unclear if value is binding or indicative
Carc = notation for carcinogenicity
- no value available

Sources:
1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/, accessed on 02.12.2022
2: RAC, Committee for Risk Assessment (2022) ANNEX 1 in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for isoprene at the workplace. European Chemicals Agency (ECHA), Helsinki, Finland. Available at: https://echa.europa.eu/documents/10162/d311e1fc-b625-7847-d946-d6510c0b5e1d, accessed on 05.01.2023
3: Austria (2021) Grenzwerteverordnung 2021 – GKV. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418, accessed on 02.12.2022
4: Belgium (2022) List of limit values (Titel 1. – Chemische agentia. and Titel 2. – Kankerverwekkende, mutagene en reprotoxische agentia). Available at: https://werk.belgie.be/nl/themas/welzijn-op-het-werk/algemene-beginselen/codex-over-het-welzijn-op-het-werk, accessed on 02.12.2022
5: Bulgaria (2021) List of limit values and list of carcinogenic/mutagenic/reprotoxic substances. Available at: https://www.lex.bg/laws/ldoc/2135477597 and https://www.lex.bg/bg/mobile/ldoc/2135473243, accessed on 05.12.2022
6: Croatia (2021) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2021_01_1_10.html, accessed on 05.12.2022
7: Cyprus (2021) Legislation on chemical agents and legislation on carcinogenic-mutagenic agents. Available at: https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/E3237CC15BD91575C2257E030029E9FF?OpenDocument and https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/All/D74ACEE6A814B7EAC2257E03002A76C9?OpenDocument, accessed on 05.12.2022
8: Czechia (2022) List of limit values. Available at: https://www.tzb-info.cz/pravni-predpisy/narizeni-vlady-c-361-2007-sb-kterym-se-stanovi-podminky-ochrany-zdravi-pri-praci, accessed on 05.12.2022
9: Denmark (2022) List of limit values. Available at: https://www.retsinformation.dk/eli/lta/2022/1054, accessed on 05.12.2022
10: Estonia (2022) List of limit values. Available at: https://www.riigiteataja.ee/aktilisa/1120/3202/2025/VV_30m_lisa.pdf#, accessed on 05.12.2022
11: Finland (2020) List of limit values. Available at: https://julkaisut.valtioneuvosto.fi/handle/10024/162457, accessed on 05.12.2022
12: France (2022) List of limit values. Available at: https://www.inrs.fr/media.html?refINRS=outil65, accessed on 05.12.2022
13: Germany (2022) List of limit values (TRGS 900). Available at: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-900.html, accessed on 05.12.2022
14: Greece (2019) List of limit values. Available at: https://www.elinyae.gr/sites/default/files/2019-10/oriakes%20times%202019_L_0.pdf, accessed on 05.12.2022
15: Hungary (2022) List of limit values. Available at: https://net.jogtar.hu/jogszabaly?docid=a2000005.tm, accessed on 05.12.2022

16: Ireland (2021) List of limit values. Available at: https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf, accessed on 05.12.2022
17: Italy (2022) List of limit values and amendments. Available at: https://www.ispettorato.gov.it/it-it/strumenti-e-servizi/Documents/TU-81-08-Ed.-Agosto-2022.pdf, accessed on 06.12.2022
18: Latvia (2022) List of limit values. Available at: https://likumi.lv/doc.php?id=157382&from=off, accessed on 06.12.2022
19: Lithuania (2022) List of limit values. Available at: https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr, accessed on 06.12.2022
20: Luxembourg (2020) List of limit values (2018) and list of carcinogens and mutagens (2020). Available at: http://legilux.public.lu/eli/etat/leg/rgd/2018/07/20/a684/jo and http://legilux.public.lu/eli/etat/leg/rgd/2020/01/24/a37/jo, accessed on 06.12.2022
21: Malta (2021) List of limit values. Available at: https://legislation.mt/eli/sl/424.24/eng/pdf, accessed on 06.12.2022
22: Netherlands (2022) List of limit values. Available at: https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII, accessed on 06.12.2022
23: Poland (2021) List of limit values from 2018 and amendments in 2020 and 2021. Available at: https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001286/O/D20181286.pdf, http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200000061, and https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210000325/O/D20210325.pdf, accessed on 06.12.2022
24: Portugal (2022) List of limit values. Available at: https://dre.pt/dre/legislacao-consolidada/decreto-lei/2012-115495237, accessed on 07.12.2022
25: Romania (2021) List of limit values. Available at: https://legislatie.just.ro/Public/DetaliiDocument/75978, accessed on 07.12.2022
26: Slovakia (2020) List of limit values. Available at: https://www.epi.sk/zz/2006-355, accessed on 07.12.2022
27: Slovenia (2021) List of limit values. Available at: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252, accessed on 07.12.2022
28: Spain (2022) List of limit values. Available at: https://www.insst.es/el-instituto-al-dia/limites-de-exposicion-profesional-para-agentes-quimicos-2022, accessed on 07.12.2022
29: Sweden (2022) List of limit values and amendments. Available at: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/, accessed on 07.12.2022
30: Australia (2022) List of limit values. Available at: https://www.safeworkaustralia.gov.au/doc/workplace-exposure-standards-airborne-contaminants-2022, accessed on 05.01.2023
31: Brazil (2021) List of limit values. Available at: https://www.guiatrabalhista.com.br/legislacao/nr/nr-15-anexo-11.pdf, accessed on 05.01.2023
32: Canada, Ontario (2020) List of limit values. Available at: https://www.ontario.ca/laws/regulation/900833, accessed on 05.01.2023
33: Canada, Québec (2022) List of limit values. Available at: https://www.legisquebec.gouv.qc.ca/en/document/cr/S-2.1,%20r.%2013, accessed on 05.01.2023
34: India (2007) List of limit values. Available at: https://dgfasli.gov.in/en/book-page/permissible-levels-certain-chemical-substancesin-work-environment, accessed on 05.01.2023
35: Japan (2022) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 05.01.2023
36: Japan - JOSH (2022) List of limit values. Available at: https://www.sanei.or.jp/english/files/topics/oels/oel_en.pdf, accessed on 05.01.2023
37: Norway (2022) List of limit values. Available at: https://lovdata.no/dokument/SF/forskrift/2011-12-06-1358#KAPITTEL_8, accessed on 05.01.2023
38: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022, *accessed on 10.12.2022*
39: Switzerland (2022) List of limit values. Available at: https://www.suva.ch/de-ch/services/grenzwerte#gnw-location=%2F, accessed on 05.01.2023
40: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 05.01.2023
41: United Kingdom (2020) List of limit values. Available at: https://www.hse.gov.uk/pubns/priced/eh40.pdf, accessed on 05.01.2023
42: ACGIH, American Conference of Governmental Industrial Hygienists (2022), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.
43: USA, NIOSH (2022) List of limit values. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 05.01.2023
44: USA, OSHA (2022) List of limit values. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 05.01.2023
45: Albania (2014) Albania (2014) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/115604/ALB-115604.pdf; accessed on 26.03.2024
46: Bosnia and Herzegovina (2020) Law on protection at work - part one. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/112339/BIH-112339.pdf; accessed on 26.03.2024
47: Georgia (2014) List of permissible concentrations of metals in the air of the working area. Available at: https://matsne.gov.ge/ka/document/view/2198163?publication=0, accessed on 28.03.2024
48: Moldova (2013) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/97247/PDF.pdf, accessed on 26.03.2024
49: Montenegro (2023) List of carcinogens and mutagens. Available at: and https://www.gov.me/dokumenta/d41be940-6c22-499d-8c32-3619e0a6d332, accessed on 27.03.2024
50: North Macedonia (2010) List of limit values. Available at: https://wwwex.ilo.org/dyn/natlex2/natlex2/files/download/94988/MKD-94988.pdf, accessed on 27.03.2024
51: Serbia (2018) List of limit values. Available at: http://www.socijalnoekonomskisavet.rs/cir/publikacije/propisi%20bzr.pdf, accessed on 28.03.2024
52: Ukraine (2020) List of limit values and amendments (2023). Available at: https://zakon.rada.gov.ua/laws/show/z0741-20#Text, accessed on 28.03.2024

5. WELDING FUMES

5.1. Relevant sectors with exposed workers

Table 103 - relevant sectors with risk of exposure to welding fumes

NACE code	Short name for sector	Description of activities with exposure to welding fumes containing CMR substances
C24	Manufacture of basic metals	Welding processes, cutting during manufacture of steel tubes, pipes etc.
C25	Manufacture of fabricated metal products (excl. machinery & equipment)	Welding processes, cutting, coating (spraying)
C26	Manufacture of computer, electronic & optical products	Welding processes, soldering
C28	Manufacture of machinery & equipment	Welding, cutting, coating (spraying)
C29	Manufacture of motor vehicles, trailers & semi-trailers	Welding, cutting, coating (spraying)
C30	Manufacture of other transport equipment	Welding, cutting, coating (spraying)
C31	Manufacture of furniture	Welding, cutting, coating (spraying)
C32	Other manufacturing	Welding, cutting, coating (spraying)
C33	Repair & installation of machinery & equipment	Welding, soldering
E38	Waste collection, treatment & disposal, materials recovery	Cutting up metal products for materials recovery.
F41	Construction of buildings	Welding processes
F42	Civil engineering	Welding processes
F43	Specialised construction activities	Welding processes, soldering electronics or soldering pipework.
G45	Motor trade & repair	Welding processes: resistance spot welding
Source: RPA (2024)		

5.2. Estimated number of enterprises with exposed workers in the EU

Table 104 – estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector	Eurostat employees				Estimated % of employees undertaking welding+ activities			Estimated exposed welders				Estimated distribution across sectors
	Small	Medium	Large	Total	Small	Medium	Large	Small	Medium	Large	Total	
C24 Basic metals	6,796	28,248	359,499	394,543	25%	10%	5%	1,699.00	2,826	17,975	22,500	1.8%
C25 Fabricated metal products	310,557	440,532	608,374	1,359,463	25%	10%	5%	77,640.00	44,055	30,418	152,113	11.9%
C28 Machinery & equipment	13,986	72,276	491,722	577,984	25%	10%	5%	3,497.00	7,228	24,586	35,311	2.8%
C29 Motor vehicles,	20,972	103,170	1,088,100	1,212,242	25%	10%	5%	5,243.00	10,317	54,405	69,965	5.5%
C30 Manufacture of other transport equipment	12,965	42,800	452,577	508,342	25%	10%	5%	3,241.00	4,280	22,629	30,150	2.4%
C31 Furniture	4,844	21,318	26,598	52,760	40%	10%	5%	1,938.00	2,132	1,330	5,400	0.4%
C32 Other manufacturing	4,255	16,104	30,767	51,126	40%	10%	5%	1,702.00	1,611	1,539	4,852	0.4%
C33 Repair & installation of machinery & equipment	124,320	117,306	250,452	492,078	40%	10%	5%	49,728	11,731	12,523	73,982	5.8%
E38 Materials recovery	16,420	22,470	50,320	89,210	40%	10%	5%	6,568	2,247	2,516	11,331	0.9%
F41 Construction of buildings	514,158	243,450	301,902	1,059,510	40%	10%	5%	205,663	24,345	15,095	245,103	19.2%
F42 Civil engineering	38,850	86,700	374,544	500,094	40%	10%	5%	15,540	8,670	18,727	42,937	3.4%
F43 Specialised construction activities	1,026,404	310,833	428,901	1,766,138	40%	10%	5%	410,562	31,084	21,445	463,091	36.2%
G45 Repair of motor vehicles & motorcycles	295,094	37,032	28,330	360,456	40%	10%	5%	118,037	3,703	1,417	123,157	9.6%
Total	**2,389,621**	**1,542,239**	**4,492,086**	**8,423,946**	**-**	**-**	**-**	**901,058**	**154,229**	**224,605**	**1,279,892**	**100%**
Source: RPA (2024)												

5.3. Estimated number of exposed workers in the EU

Table 105 – estimated number of workers in the EU exposed to cobalt and inorganic cobalt compounds

Sector		Estimated number of exposed workers	% of exposed workers distributed across sectors
C24	Manufacture of basic metals	22,500	1.8%
C25	Manufacture of fabricated metal products (excl. machinery & equipment)	152,113	11.9%
C28	Manufacture of machinery & equipment	35,311	2.8%
C29	Manufacture of motor vehicles, trailers & semi-trailers	69,965	5.5%
C30	Manufacture of other transport equipment	30,150	2.4%
C31	Manufacture of furniture	5,400	0.4%
C32	Other manufacturing	4,852	0.4%
C33	Repair & installation of machinery & equipment	73,982	5.8%
E38	Waste collection, treatment & disposal, materials recovery	11,331	0.9%
F41	Construction of buildings	245,103	19.2%
F42	Civil engineering	42,937	3.4%
F43	Specialised construction activities	463,091	36.2%
G45	Wholesale & retail trade & repair of motor vehicles & motorcycles	123,157	9.6%
Total		**1,279,892**	**100%**
Source: RPA (2024)			

5.4. Exposure concentrations by sectors

No data available.

5.5. Current risk management measures

Table 106 - RMMs used by the Manufacture of paper and paperboard (C17.12) and Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21) sectors

RMM	C17.12 Paper (1)		C21 Pharmaceuticals (1)			
	MAG (solid wire)	MIG solder	MAG (flux)	MIG solder	MMA	TIG
Organisational and hygiene measures						
Blood monitoring			1	1	1	1
Culture of safety	1	1				

Health surveillance	1	1	1	1	1	1
Regular check of RMM effectiveness	1	1	1	1	1	1
Training and education	1	1				
PPE (Personal Protective Equipment						
Face screens, face shields, visors	1	1	1	1	1	1
Gloves, goggles, coverall	1	1	1	1	1	1
Restructuring operations/processes						
Reduced number of workers exposed	1	1				
Separate welding from other activities	1	1				
Ventilation and extraction						
General ventilation			1	1		1
Open hoods	1	1	1	1	1	1
Source: RPA (2024), Stakeholder consultation 2023, 58 responses received.						

Table 107 - RMMs for the Manufacture of glass and glass products (C23.1) and the Manufacture of tubes, pipes, hollow profiles and related fittings of steel (C24.2) sectors

RMM	C23.1 Glass (1)		C24.2 Tubes & pipes (1)
	F Spray	MAG (flux)	MIG (solid wire, Ni)
Organisational and hygiene measures			
Blood monitoring	1		
Culture of safety	1	1	1
Health surveillance	1		1
Regular check of RMM effectiveness	1		1
Training and education	1	1	1
PPE (Personal Protective Equipment)			
Disposable respirators (FFP masks)	1		
Face screens, face shields, visors	1	1	
Fan-assisted welding helmets			1
Forced ventilation welding helmets			1
Gloves, goggles, coverall	1	1	1
Restructuring operations/processes			
Permanent relocation of workers with health effects of welding fumes			1
Redesign of work processes	1		1
Reduced number of workers exposed	1	1	1
Reduced time spent on welding activity	1	1	1
Rotation of the workers exposed			1
Separate welding and associated processes	1	1	
Temporary relocation of workers with health effects of welding fumes	1	1	1
Substitution with lower emission welding process	1	1	

Ventilation and extraction			
Closed systems			
General ventilation	1	1	1
Open hoods	1		1
Partially closed systems			1
Regular maintenance of extraction equipment	1		1
Separate low volume or high volume spot extraction	1		1
Welding booth with a welding table & adjustable extraction element		1	1
Source: RPA (2024), Stakeholder consultation 2023, 58 responses received.			

Table 108 - RMMs for Aluminium production (C24.42) and Casting of iron (C24.51) sectors

RMM	C24.42 Aluminium (2)			C24.51 Iron (2)			
	MIG (Al)	MIG/MAG	TIG	MIG/MAG	MMA	PC	TIG
Organisational and hygiene measures							
Blood monitoring				2	1	1	2
Culture of safety	1	1	2				
Health surveillance				2	1	1	2
Training and education	1	1	2	2	1	1	2
PPE (Personal Protection Equipment)							
Disposable respirators (FFP masks)			1	2	1	1	2
Face screens, face shields, visors	1	1	2	2	1	1	2
Gloves, goggles, coverall	1	1	2	2	1	1	2
Restructuring operations/processes							
Reduced number of workers exposed		1					
Reduced time spent on welding activity	1		2	2	1	1	2
Rotation of the workers exposed	1		1				
Separate welding and associated processes	1	1		2	1	1	2
Ventilation and extraction							
General ventilation		1		2	1	1	2
Open hoods		1		2	1	1	2
Regular maintenance	1	1	1	2	1	1	2
Welding torch-integrated extraction system	1						
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.							

Table 109 - RMMs used by the Manufacture of fabricated metal products sector (C25)

RMM	C25 Metal products (8)		
	3D printing	Auto flame cutting	Brazing
Organisational and hygiene measures			

Blood monitoring			1
Culture of safety			1
mask cleaning & filter changing			1
Training and education		1	2
PPE (Personal Protection Equipment)			
Disposable respirators (FFP masks)		1	3
Face screens, face shields, visors			2
Gloves, goggles, coverall		1	1
Half and full facemasks (negative pressure respirators)			1
Welding helmets with a separate air supply		2	2
Restructuring operations/processes			
Reduced number of workers exposed		1	
Reduced time spent on welding activity			1
Temporary relocation of workers with health effects of welding fumes			1
Partial substitution of content base material and addition material		1	
Substitution of welding+ processes with other joining processes (gluing, folding, screws, rivets etc)			1
Substitution with lower emission welding+ process	1		
Ventilation and extraction			
Closed systems	1	1	
General ventilation		2	1
Open hoods	1		1
Partially closed systems			1
Pressurised or sealed control cabs			
Regular maintenance of extraction equipment	1	1	1
Simple enclosed control cabs	1		
Welding booth with a welding table & adjustable extraction element	1		1
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.			

Table 110 - RMMs used by the Manufacture of fabricated metal products sector (C25) continued.

RMM	C25 Metal products (8)						
	F	MAG	MAG	MAG	MIG	MIG	MIG

	spray	(flux, shielding gas)	(flux)	(solid wire)	(aluminium materials)	(solid wire, Ni)	solder
Organisational and hygiene measures							
Blood monitoring		1			1		
Culture of safety	1	2	1	4	1	1	1
Mask cleaning & filter changing		1		3			
Health surveillance	1	2	1	3	1	2	
Regular check of RMM effectiveness	1	1	1	3		1	
Training and education	1	3	1	10	2	3	
PPE (Personal Protective Equipment)							
Disposable respirators (FFP masks)		1		4	7		
Face screens, face shields, visors	1	3	1	4		2	1
Fan-assisted welding helmets		1		2		1	
Forced ventilation welding helmets		1					
Gloves, goggles, coverall	1	1	1	7	1	2	1
Half and full facemasks (negative pressure respirators)				1			
Powered air-purifying respirators		1		1		1	
Welding helmets with a separate air supply		2		4		1	
Restructuring operations/processes							
Reduced time spent on welding activity				1			
Separate welding+ associated processes		1		2			1
Partial substitution of content base material and addition material		1					
Substitution with lower emission welding+ process				1	1		
Ventilation & extraction							
Closed systems		1		1	1		
General ventilation		2		8	2	2	1
Open hoods	1	2	1	7	2	1	
Partially closed systems	1	2	1	1		1	
Pressurised or sealed control cabs		1					

Regular maintenance of extraction equipment	1	3	1	4	2	3	
Separate low volume or high volume spot extraction		2		2		1	
Simple enclosed control cabs		1			1		
Welding booth with a welding table and & adjustable extraction element	1		1	1	1	2	
Welding torch-integrated extraction system		1			1		
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.							

Table 111 - RMMs used by the Manufacture of fabricated metal products sector (C25) continued.

RMM	C25 Manufacture of fabricated metal products (8)						
	MIG/MAG	MMA	Not specified	PC	Soft solder	SAW	TIG
Organisational and hygiene measures							
Blood monitoring	2			2		2	
Continuous measurement of air concentrations to detect unusual exposures							1
Culture of safety	2	2		5	1	4	4
Mask cleaning & filter changing	1	1		2		1	2
Health surveillance	2	2		2		1	3
Regular check of RMM effectiveness	1	2		2		2	1
Training and education	5	2		6		7	5
PPE (Personal Protective Equipment)							
Disposable respirators (FFP masks)	4	1		2		3	2
Face screens, face shields, visors	4	2	4	4	1	5	4
Fan-assisted welding helmets	1						1
Forced ventilation welding helmets							1
Gloves, goggles, coverall	2	1		4	1	6	3
Half and full facemasks (negative pressure respirators)	2			1		1	1
Powered air-purifying respirators	1					1	1
Welding helmets with a	3	1		3		1	1

separate air supply							
Restructuring operations/processes							
Permanent relocation of workers with health effects of welding fumes	1						
Reduced number of workers exposed				1		1	1
Reduced time spent on welding activity	1						1
Separate welding+ processes	1			1		2	2
Temporary relocation of workers with health effects of welding fumes				1		1	2
Substitution of content base material and addition material	1						
Substitution with lower emission welding+ process						1	
Ventilation & extraction							
Closed systems						7	1
General ventilation	4			6	1	7	5
Open hoods	3	2		3		7	2
Partially closed systems		1					
Regular maintenance of extraction equipment	3	2		4		2	3
Separate low volume or high volume spot extraction	1	1	4	1			2
Simple enclosed control cabs				1		1	
Welding booth with a welding table & adjustable extraction element	2	1					2
Welding torch-integrated extraction system	1						
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.							

Table 112 - RMMs used by the Manufacture of other general-purpose machinery (C25.2) and Manufacture of other fabricated metal products (C25.99) sectors.

RMM	C25.2 Other machinery		C25.99 Other metal products (1)		
	MAG (solid wire)	SAW	LB cutting	MAG (solid wire)	TIG

Organisational and hygiene measures					
Continuous measurement of air concentrations to detect unusual exposures			1	1	1
Culture of safety	1	1	1	1	1
Mask cleaning & filter changing	1	1			
Health surveillance			1	1	1
Regular check of RMM effectiveness			1	1	1
Training and education	1	1	1	1	1
PPE (Personal Protection Equipment)					
Face screens, face shields, visors				1	1
Forced ventilation welding helmets	1	1			
Gloves, goggles, coverall				1	1
Welding helmets with a separate air supply	1	1			
Restructuring operations/processes					
Redesign of work processes	1	1			
Separate welding and associated processes			1	1	1
Substitution or discontinuation					
Substitution of welding or associated processes with other joining processes (gluing, folding, screws, rivets)			1		
Substitution with a lower emission welding+ process			1		
Ventilation & extraction					
Closed systems			1		
General ventilation	1	1	1	1	1
Open hoods	1		1	1	1
Regular maintenance	1	1	1	1	1
Simple enclosed control cabs			1		
Welding booth with a welding table and adjustable extraction element			1		
Source: RPA(2024) Stakeholder consultation 2023, 58 responses received.					

Table 113 - RMMs used by the Manufacture of machinery and equipment (C28) sector.

RMM	**C28 Machinery & equipment (5)**					
	Brazing	**LB cutting (additional materials)**	**MAG (flux, shielding gas)**	**MAG (solid wire)**	**MIG (solid wire, Ni)**	**MIG/MAG**
Organisational and hygiene measures						
Blood monitoring	1		1			1
Continuous measurement of air concentrations to detect unusual exposures	1	1			1	3
Culture of safety	2				1	3
Mask cleaning and filter	1	1			1	3

changing						
Health surveillance	2		1	1	1	3
Regular check of RMM effectiveness	2	1		1	1	4
Training and education of workers	2	1	1	1	1	4
PPE (Personal Protective Equipment)						
Disposable respirators (FFP masks)		1		1		1
Face screens, face shields, visors	2	1		1		3
Fan-assisted welding helmets					1	1
Gloves, goggles, coverall	2			1	1	3
Powered air-purifying respirators	1				1	2
Welding helmets with a separate air supply		1	1			1
Restructuring operations/processes						
Redesign of work processes				1		1
Rotation of the workers exposed				1		
Separate welding and associated processes	1				1	3
Substitution or discontinuation						
Partial substitution of content base material and addition material					1	
Substitution of welding or associated processes with other joining processes (gluing, folding, screws, rivets)				1		1
Substitution with a lower emission welding+ process						2
Ventilation & extraction						
Closed systems						1
General ventilation	2			1	1	3
Open hoods	1	1		1	1	4
Partially closed systems		1				2
Pressurised or sealed control cabs						
Regular maintenance	2			1	1	3
Separate low volume or high volume spot extraction			1			1
Welding booth with a welding table and adjustable extraction element	2			1	1	3
Welding torch-integrated extraction system			1	1		1
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.						

Table 114 - RMMs used by the Manufacture of machinery and equipment (C28) continued, and by the Manufacture of motor vehicles, trailers and semi-trailers (C29) sectors.

RMM	C28 Machinery & equipment (5)			C29 Motor vehicles (2)		
	PC	SAW	TIG	Brazing	Gas fusion welding	LB cutting
Organisational & hygiene measures						
Blood monitoring	1		1	1		
Continuous measurement of air concentrations to detect unusual exposures	1	1	2		1	1
Culture of safety	1		3	2	1	1
Mask cleaning and filter changing	1	1	2	2		
Health surveillance	1		3	2	1	1
Regular check of RMM effectiveness	2	1	4	2	2	1
Training and education	2	1	5	2	2	1
PPE (Personal Protective Equipment)						
Disposable respirators (FFP masks)	1	1	1	2		
Face screens, face shields, visors	2	1	4	2	1	
Fan-assisted welding helmets			1	1		
Forced ventilation welding helmets					1	1
Gloves, goggles, coverall	1		4	2	2	1
Half and full facemasks (negative pressure respirators)				2		
Powered air-purifying respirators	1		2			
Welding helmets with a separate air supply	1	1		1	1	1
Restructuring operations/processes						
Redesign of work processes			1			
Reduced number of workers exposed					1	1
Rotation of the workers exposed			1			
Separate welding and associated processes with emissions from other activities in space or time	1		4	1	1	
Substitution or discontinuation						
Substitution of welding or associated processes with other joining processes (gluing, folding, screws, rivets)			2	1		
Substitution with lower emission welding+ process			2	1	1	
Ventilation and extraction						
Closed systems				1		
General ventilation	1		5	1	1	1
Open hoods	2	1	3	1	2	1
Partially closed systems	1	1	1	1		
Regular maintenance	1		3	2		
Separate low volume or high volume spot			1	1		

extraction						
Simple enclosed control cabs						
Welding booth with a welding table and adjustable extraction element	1		4	1		
Welding torch-integrated extraction system			1	1		
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.						

Table 115 - RMMs used by the by the Manufacture of motor vehicles, trailers and semi-trailers (C29) sector (continued).

RMM	C29 Motor vehicles (2)					
	LB cutting	MIG (Al)	MIG (solid wire, Ni)	MIG solder	MIG/MAG	PC	SAW
Organisational and hygiene measures							
Blood monitoring		1	1		1		
Continuous measurement of air concentrations to detect unusual exposures					1	1	
Culture of safety	1	3	1	1	4	1	1
Mask cleaning and filter changing		2	1	1	2		
Organisation and hygiene measures							
Health surveillance in place for these process workers		3	1	1	4	1	1
Regular check of RMM effectiveness	1	3	1	1	4	1	2
Training and education	1	3	1	1	4	1	2
PPE (Personal Protective Equipment)							
Disposable respirators (FFP masks)		1	1		1	1	
Face screens, face shields, visors		2	1	1	2		1
Fan-assisted welding helmets		3	1	1	2		1
Forced ventilation welding helmets					1		
Gloves, goggles, coverall		3	1	1	4		2
Half and full facemasks (negative pressure respirators)		2	1	1	3		1
Powered air-purifying respirators		1			1		1
Welding helmets with a separate air supply		3	1	1	3		1
Restructuring operations/processes							
Redesign of work processes		2		1	1		
Reduced number of workers exposed			1		1	1	
Reduced time spent on welding activity			1				
Rotation of the workers exposed		1					
Separate welding and associated processes		2		1	1		2

Substitution or discontinuation							
Substitution of welding or associated processes with other joining processes (gluing, folding, screws, rivets)		2	1	1	1		
Substitution with a lower emission welding+ process		2	1	1	2		
Ventilation and extraction							
Closed systems	1	2			1		
General ventilation		3	1	1	3	1	1
Open hoods		2	1	1	3	1	2
Partially closed systems		1					1
Regular maintenance	1	2		1	2		1
Separate low volume or high volume spot extraction		1			1		
Simple enclosed control cabs					1		
Welding booth with a welding table and adjustable extraction element		2	1	1	2		1
Welding torch-integrated extraction system		1	1		1		
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received.							

Table 116 - RMMs used by the by the Repair and installation of machinery and equipment (C33) sector

RMM	C33 Equipment repair & installation (3)						
	Gas fusion welding	MAG (flux)	MAG (solid wire)	Not specified	PC	SAW	TIG
Organisational and hygiene measures							
Blood monitoring	1			1			1
Continuous measurement of air concentrations to detect unusual exposures				1			
Creating a culture of safety	1			2			1
Mask cleaning and filter changing	1			2			1
Health surveillance	1			2			1
Regular check of RMM effectiveness	1	1	1	1	1	1	1
Training and education	1	1	1	2	1	1	1
PPE (Personal Protection Equipment)							
Disposable respirators (FFP masks)	1			1			1
Face screens, face shields, visors	1			1			
Fan-assisted welding helmets		1	1		1	1	
Forced ventilation welding helmets				1			
Gloves, goggles, coverall	1			2			1
Half and full facemasks (negative pressure respirators)	1			2			1
Powered air-purifying respirators	1			2			

Welding helmets with a separate air supply	1			2			1
Restructuring operations/processes							
Permanent relocation of workers with health effects of welding fumes	1			1			1
Redesign of work processes							
Reduced number of workers exposed			1	1	1	1	
Reduced time spent on welding activity	1			1			1
Rotation of the workers exposed	1			1			1
Separate welding and associated processes with emissions from other activities in space or time	1	1	1	2	1	1	1
Substitution or discontinuation							
Partial substitution of content base material and addition material such as low manganese materials				1			
Substitution of content base material and addition material such as low manganese materials				1			
Substitution with lower emission welding+ process	1			1			1
Ventilation and extraction							
Closed systems				1			
General ventilation	1	1		2			1
Open hoods over equipment, tracking extraction elements or local extraction ventilation	1		1	2		1	1
Partially closed systems	1				1		1
Regular maintenance				2			
Separate low volume or high volume spot extraction				2			
Welding booth with a welding table and adjustable extraction element				1			
Source: RPA (2024) Stakeholder consultation 2023, 58 responses received							

Table 117 - RMMs used by the Repair of fabricated metal products (C33.11), Repair of motor vehicles and motorcycles (G45.2) and Education (P85) sectors.

RMM	C33.11 Metal products repair (1)	G45.2 Automotive repair (2)		P85 Education (1)			
	TIG	MIG solder	MIG/MAG	Brazing	Gas fusion welding	MIG/MAG	TIG

Organisational and hygiene measures							
Blood monitoring	1						
Culture of safety	1		1	1	1	1	1
Mask cleaning and filter changing	1		1				
Regular check of RMM effectiveness	1		1				
Training and education of workers	1		1				
PPE (Personal Protective Equipment)							
Face screens, face shields, visors	1	1	2				
Forced ventilation welding helmets			1				
Gloves, goggles, coverall	1		1	1	1	1	1
Half and full facemasks (negative pressure respirators)	1						
Welding helmets with a separate air supply	1						
Restructuring operations/processes							
Redesign of work processes			1				
Reduced number of workers exposed			1				
Rotation of the workers exposed			1				
Ventilation and extraction							
General ventilation		1	2	1	1	1	1
Partially closed systems				1	1	1	1
Regular maintenance of extraction equipment				1	1	1	1
Welding booth with a welding table and adjustable extraction element				1	1	1	1
Welding torch-integrated extraction system			1				
Source: Stakeholder consultation 2023, 59 responses received.							

5.6. Welding processes, generated substances, indication of CMRs, and workers' exposure

Table 118 – Welding processes, generated substances, indication of CMRDs and worker exposure

		Hazardous substances generated	CMRs (1A/1B) or not	Presence of the hazardous substances is known/proven, possible or exceptional	Workers are likely to be exposed or not
1	**Fusion welding**				
	Gas welding	Metal oxides from the base and filler materials, nitrogen oxides	Yes, depending on the base and filler materials	Base and filler materials: mild steel (Fe, Mn), copper alloys (Cu, Ni, Zn), aluminium (fluorides from the flux)	Yes, usually manual process, but low particle emissions.
	Arc welding - consumable electrode (filler) (MIG, MAG, SMAW, FCAW, SAW, ESW, SW)	Metal oxides mostly from the filler material, nitrogen oxides, carbon monoxide (MAG), ozone (aluminium alloys)	Yes, depending on the filler material, carbon monoxide (MAG)	Base and filler materials: mild steel (Fe, Mn, fluorides), stainless steel (Fe, Mn, Cr(III), Cr(VI), Ni, Co, V, fluorides), cast iron (Fe, Mn, Cr(VI), Ni), nickel-based alloys (Ni, Cr(VI), Fe), copper alloys (Cu, Ni), aluminium alloys (Al, Mg, Mn, Zn, Cu)	Yes, mainly in the craft sector. Automated processes are often used in industrial applications.
	Arc welding - non-consumable electrode (TIG; PAW)	Metal oxides mostly from the filler material, ozone	Yes, depending on the filler material	Base and filler materials: mild steel (Fe, Mn), stainless steel (Fe, Mn, Cr(III), Cr(VI), Ni, Co, V), cast iron (Fe, Mn, Cr(VI), Ni), nickel-based alloys (Ni, Cr(VI), Fe), copper alloys (Cu, Ni), aluminium alloys (Al, Mg, Mn, Zn, Cu), titanium alloys (Ti, Al, V), zirconium alloys (Zr)	Yes, mainly in the craft sector. Automated processes are often used in industrial applications.
	Beam welding	Metal oxides from the base material	Yes, depending on the base material	Base materials: mild steel (Fe, Mn), stainless steel (Fe, Mn, Cr(III), Cr(VI), Ni, Co, V), cast iron (Fe, Mn, Cr(VI), Ni), nickel-based alloys (Ni, Cr(VI), Fe), copper alloys (Cu, Ni), aluminium alloys (Al, Mg, Mn, Zn, Cu), titanium alloys (Ti, Al, V), zirconium alloys (Zr)	Not directly as almost completely automated. However, fume extraction system required to protect workers in the vicinity.

		Hazardous substances generated	CMRs (1A/1B) or not	Presence of the hazardous substances is known/proven, possible or exceptional	Workers are likely to be exposed or not
2	**Soldering**				
	Soft soldering (90°C- 450°C)	Mainly tin and tin oxides (from filler material), aldehydes (from rosin) and hydrogen chloride, evaporating solvents (isopropanol) from fluxes.	No, as long as lead-free due to restriction	Filler materials: mainly tin-based solders (e.g. Sn99Cu1 or Sn95Ag4Cu1) Fluxes: natural resins (e.g. rosin), organic acids (e.g. adipic acid) and chlorides (e.g. zinc chloride or ammonium chloride)	Yes, in the craft sector. Automated processes are often used in industrial applications.
	Hard (silver) soldering (> 450°C, flame brazing)	Copper oxide, zinc oxide, silver oxide, chlorides and fluorides (hydrogen chloride and hydrogen fluoride)	No	Filler materials: brazing solders made of copper-zinc alloys with additives of silver	Yes, in the craft sector. Automated processes are often used in industrial applications.
	Brazing (> 450°C, Laser beam brazing, Brazing with an electric arc (MIG, TIG, plasma)	Copper oxide Exceptionally cadmium oxide	No, with specific exceptions	Filler materials: copper-based alloys (e.g. CuSi3, CuAl8 or CuSn6) Exceptionally in defence and aerospace applications and when used for safety reasons (brazing fillers with cadmium)	Yes, in the craft sector. Automated processes are often used in industrial applications.
3	**Thermal cutting or gouging**	Metal oxides from the base material, nitrogen oxides, ozone	Yes, depending on base materials (e.g. Cr(VI) and Ni)	Base materials: mild steel (Fe, Mn), stainless steel (Fe, Mn, Cr(III), Cr(VI), Ni, Co, V), cast iron (Fe, Mn, Cr(VI), Ni), nickel-based alloys (Ni, Cr(VI), Fe), copper alloys (Cu, Ni), aluminium alloys (Al, Mg, Mn, Zn, Cu), titanium alloys (Ti, Al, V), zirconium alloys (Zr)	Yes, in the craft sector. Automated processes are often used in industrial applications.
4	**Thermal spraying**	Metal oxides from the spray additive, nitrogen oxides	Yes, depending on the spray additives (e.g. Cr(VI), Ni, Co)	Spray additives: boron, cobalt, molybdenum, nickel, chromium, silicon, plastics,	Yes, in the craft sector. For large components open

		Hazardous substances generated	CMRs (1A/1B) or not	Presence of the hazardous substances is known/proven, possible or exceptional	Workers are likely to be exposed or not
		(depending on energy source)		copper, carbides (WC-12Co, WC-27NiCr, WC-14CoCr, WC/Ti-C-17-Ni, Cr_3C_2-25NiCr etc.), steel, aluminium, zinc, bronze (Cu, Sn), tin, Monel (Ni, Cu, Fe), oxide ceramics (Al_2O_3, Cr_2O_3, TiO_2, Y_2O_3, ZrO_2), tantalum	spraying, for small components in spray booths. Automated processes are often used in industrial applications.
5	**Flame straightening**	Nitrogen oxides	No	Nitrogen oxides occur	Yes, usually manual process.
6	**Additive production processes**	Metal powders	No, the substrates do not contain carcinogenic substances. Carcinogenic substances can be formed in the closed installation space (e.g. nickel oxide).	Metal powders, especially iron, titanium, nickel, chromium and aluminium alloys	No, construction occurs inside closed machines.

5.7. National regulatory framework

Table 119 – welding fumes mentioned as process-generated substance in Member States legislation relating to the CMRD

MS	MSA reply *	Conclusion	Confidence
BE	Yes	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I, despite Belgium having a specific OEL for welding fumes on 5 mg/m^3. Annex I of the CMRD is transposed into Annex VI.2-2 of the 2017 Codex on wellbeing at work: https://werk.belgie.be/sites/default/files/content/documents/Welzijn op het werk/Regelgeving/codex2017.pdf	Medium
BG	Yes	**No mention** The MSA says there is no specific legislation for welding fume, other than the OEL for Chromium VI. The relevant document is the Regulation No 10 of September 26, 2003 on the Protection of Workers from Risks Related to Exposure to Carcinogens and Mutagens at work: https://www.lex.bg/bg/mobile/ldoc/2135473243 The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. Annex I of the CMRD is transposed in Appendix 3 of the above Regulation.	High
CZ	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. Annex I of the CMRD is transposed into Appendix 2 of Government Regulation No. 361/2007 Coll: https://www.tzb-info.cz/pravni-predpisy/narizeni-vlady-c-361-2007-sb-kterym-se-stanovi-podminky-ochrany-zdravi-pri-praci	Medium
DK	Yes	**Yes, mentioned, process-related limit values for several welding+ processes** Study team interpretation: Denmark effectively defines welding fumes as process generated substances because there are process-related limit values for several welding+ processes. Also, there is a legal requirement to use a ventilation system to remove welding fumes. Requirements for welding are included in the Arbejdstilsynet (the Danish Working Environment Authority) guide 'Welding, cutting, etc. in metal': https://at.dk/regler/at-vejledninger/svejsning-skaering-metal-d-2-16/ Section C of BEK nr 1054 af 28/06/2022: https://www.retsinformation.dk/eli/lta/2022/1054 includes the list of Danish process-related limit values for welding processes. Substance specific limit values for metal fumes are included in Section A. There are many mentions of dust, including limit values for metal dusts. Annex I of the CMRD is transposed into Appendix 2 of BEK nr 1795 af 18/12/2015: https://www.retsinformation.dk/eli/lta/2015/1795.	High
DE	Yes	**Yes, mentioned, through OEL for dust and regulations for carcinogens in welding fumes** The study team interpretation of MSA comments and their findings: Germany does not specifically define welding fume as a process generated substance but effectively it does because of its OEL for dust and the extensive regulations (TRGS 528) around carcinogens in welding fumes.	High

		Annex I of the CMRD is directly transposed in section 2 of TRGS 906: https://www.baua.de/DE/Angebote/Regelwerk/TRGS/TRGS-906.html The relevant documents are TRGS 906, TRGS 910 which lists carcinogenic substances: https://www.baua.de/DE/Angebote/Regelwerk/TRGS/TRGS-910.html, TRGS 402 which covers risk assessments for welding fumes: https://www.baua.de/DE/Angebote/Regelwerk/TRGS/TRGS-402.html, TRGS 900 providing workplace limit values:https://www.baua.de/DE/Angebote/Regelwerk/TRGS/TRGS-900.html, and TRGS 528: https://www.baua.de/DE/Angebote/Regelwerk/TRGS/pdf/TRGS-528.pdf?__blob=publicationFile&v=1 providing detailed technical rules for hazardous substances for welding work specifically. The definition of welding fumes according to TRGS 528, Article 2 Definitions is "[fumes] *from welding work resulting in particulate substances*". 32 references to the carcinogenicity of aspects of welding fumes or how carcinogenicity is taken into account are made in TRGS 528, so the carcinogenic nature of welding fumes is definitely recognised in Germany. However, exposure to welding fumes is regulated in a risk-based way, rather than a blanket regulation of all welding fumes. Figure 1 illustrates the fact that the size of particles in fumes depends upon the process. The processes included in this diagram include welding, soldering, thermal cutting and gouging.	
EE	No	**No mention** Study team interpretation: there is no definition of welding fumes as process generated substances or carcinogen or equivalent in Annex I. The relevant document is the 2021: Occupational health and safety requirements for the use of hazardous chemicals and materials containing them and limit values for chemical hazards in the working environment, Number 105 of 15 December 2005, revised 21 December 2021: https://www.riigiteataja.ee/akt/121122022014. At the end of this document is a link to the Annex containing the current list of limit values https://www.riigiteataja.ee/aktilisa/1211/2202/2014/VV_132m_lisa.pdf Annex I of the CMRD: the study team is unable to establish where this is transposed into Estonian legislation. However, there is a guide written in for the strategy 2007 – 2015 called CANCER RISKS IN THE WORKING ENVIRONMENT Prevention of cancer risks in the work environment and a general guide to reduction, which contains elements of Annex I of the CMRD in paragraph 3. This includes in item 3 "soldering, welding or other thermal processing of materials containing copper and nickel, during which the dust and smoke of these metals are produced or aerosol" https://www.terviseamet.ee/sites/default/files/content-editor/vanaveeb/Tervishoid/tootervis/Vahiriskid_tookeskkonnas_eesti.k.pdf	Medium
IE	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Irish 2021 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019:	High

		https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/2021-code-of-practice-for-the-chemical-agents-and-carcinogens-regulations.pdf There are substance specific limit values for metal fumes and metal dusts that may be relevant to welding. Annex 1 of the CMRD is transposed in Schedule 4 of the 2021 Code of Practice.	
EL	No	**Unclear** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I (but it is hard to be sure.) The Government Gazette 50A 2020 https://elinyae.gr/sites/default/files/2020-03/50a_2020.pdf harmonises Greek legislation with the CMRD, and exposure limit values for chemical & biological agents 2019 (Greek legislation) https://www.elinyae.gr/sites/default/files/2019-10/oriakes%20times%202019_L_0.pdf is an older version of similar legislation, with many terms in English. Both documents are difficult to search, either because some or all of the documents cannot be searched, or because some or all of the documents cannot be copied. Annex I of the CMRD is directly transposed on page 2 of the Government Gazette 50A 2020 and does not mention welding.	Low
ES	Yes	**No mention** The MSA says there is no specific legislation for welding fumes and no definition of welding fume as a process generated substance. The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Royal Decree 665/1997, of May 12, 1997, on the protection of workers against risks related to exposure to carcinogens at work BOE-A-1997-11145 Royal Decree 665/1997 of 12 May <> on the protection of workers against the risks related to exposure to carcinogens at work. Annex I of the CMRD is partly transposed in Annex I of the above Royal Decree 665/1997 of 12 May 1997.	High
FR	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. There are non-specific generic dust limits (for inhalable and respirable dust respectively) which apply to welding fumes, but the study team was unable to find any mention of welding relating to generic dust. Annex I of the CMRD was transposed in Article 1 of the Order of October 26, 2020 establishing the list of carcinogenic substances, mixtures and processes within the meaning of the labour code, (Version in force since July 1, 2021, Article 1 was modified by an Order dated 3 May 2021): https://www.legifrance.gouv.fr/loda/article_lc/LEGIARTI000043483855/2021-07-01 A brochure on how to use OELs, called 'Methods of prevention:	Medium

		measurement and evaluation devices’: https://www.inrs.fr/dms/inrs/CataloguePapier/ED/TI-ED-6443/ed6443.pdf contains no reference to welding, or welding fumes, and only 2 references to fumes (fumées) in relation to the definition of an aerosol, and the definition of fumes. The definition of fumes is given as: ”dispersions in the air of very fine solid particles, possibly accompanied by gases and vapours, generated by thermal processes, either by condensation from the gas phase (sometimes accompanied by chemical reactions such as oxidation), or by incomplete combustion”.	
HR	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant documents are the original bylaw from 2018 on the protection of workers against exposure to dangerous chemicals at work, exposure limit values and biological limit value: https://narodne-novine.nn.hr/clanci/sluzbeni/2018_10_91_1774.html and updates to the 2018 bylaw are in this bylaw https://narodne-novine.nn.hr/clanci/sluzbeni/2021_01_1_10.html The transposition of Annex I is done as a separate update with each by-law only listing the updates to the original by-law. The list of substances in the Annex I of the CMRD do not appear to be listed together in one place.	Medium
IT	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Legislative Decree no. 9 of 2008 April 81 amended November 2023 includes the transposition of the CMRD. https://www.ispettorato.gov.it/files/2023/11/TU-81-08-Ed.-Novembre-2023.pdf Annex XLII of the above covers Annex 1 on page 157 and there is no mention of welding.	Medium
CY	No	**Unclear** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Safety and Health at work laws of 1996 to (No. 2) of 2015: https://www.mlsi.gov.cy/mlsi/dli/dliup.nsf/all/D74ACEE6A814B7EAC2257E03002A76C9/$file/KDP_282-2020.pdf According to the MSA response for the main consultation, Cyprus has an OEL for welding fumes. But the study team cannot find this. Neither can any documents be found that mention items from Annex I of the CMRD. All documents are difficult to search, either because they cannot be searched, or they cannot be copied.	Low
LV	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is Regulations of the Cabinet of Ministers No. 325: https://likumi.lv/doc.php?id=157382&from=off on the Labor protection requirements in contact with chemical substances in workplaces.	Medium

		Annex I of the CMRD is transposed into Annex 2 of the Cabinet of Ministers Regulations No. 803 of September 29, 2008: https://likumi.lv/ta/id/181871-darba-aizsardzibas-prasibas-saskaroties-ar-kancerogenam-vielam-darba-vietas	
LT	Yes	**Yes, mentioned, OEL for welding aerosols** Study team interpretation: the definition of welding aerosol provided by the MSA implies that aerosol is process generated and the toxicity of the substances present (with associated limit values) in the aerosol will depend upon the materials being welded and welding process being used. This provision was established before Lithuania joined the EU (not as a transposition of CMRD) The study team found that in Order HN 23:2011 https://www.e-tar.lt/portal/lt/legalAct/TAR.8012ED3EA143/asr on Lithuanian Hygiene Standards Occupational Exposure Limits for Chemicals., item 692 of Annex 1 of the Lithuanian Hygiene Standard HN 23:2011 referenced by the MSA was provides the definition and an OEL for welding aerosols. There is no other reference to welding fumes. The translation of the definition of welding aerosol is "the **entire respirable fraction** of a **suspension of solid, liquid or solid and liquid particles** in a gaseous medium. Depending on the composition of the welding alloy, the electrodes used and the welding process, ozone may be released into the environment (e.g. when welding aluminium, titanium and their alloys with an electric arc in a protective argon atmosphere), carbon monoxide (e.g. when welding alloy steel with an electric arc), metals (iron, manganese, chromium, nickel), fluorides (flux-coated and hollow electrodes are prepared with fluorides). Therefore, first of all, it is necessary to determine whether the individual limit values of the aerosol components are not exceeded. If there are no toxic substances in the welding electrode, the metal to be welded or its coating, and no toxic gases are formed during welding, it is sufficient to determine the total concentration of the welding aerosol." Annex 1 of the CMRD is transposed in https://www.e-tar.lt/portal/lt/legalAct/TAR.313208361D5D under Section VII Final provisions.	High
LU	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant documents are Regulation 37 of the 30 January 2020: http://legilux.public.lu/eli/etat/leg/rgd/2020/01/24/a37/jo and Regulation 684 of the 16 August 2018: http://legilux.public.lu/eli/etat/leg/rgd/2018/07/20/a684/jo Annex I of the CMRD is transposed into Annex 1 of the Grand-ducal regulation of November 14, 2016 concerning the protection of employees against the risks linked to exposure to carcinogens or mutagens at work: https://legilux.public.lu/eli/etat/leg/rgd/2016/11/14/n3/jo	Medium
HU	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, 5/2020 (II.6):	Medium

		https://net.jogtar.hu/jogszabaly?docid=a2000005.itm Annex I of the CMRD is transposed in EüM decree on protection against occupational carcinogens and the prevention of health damage caused by them, 26/2000 (IX 30): https://net.jogtar.hu/jogszabaly?docid=a0000026.eum, with no item relating to welding.	
MT	No	**Unclear** The study team was unable to find any mention of welding fumes, despite undertaking extensive searches but there may be other legislation which was not identified. The relevant documents were in a database of Maltese legislation https://legislation.mt/. The Maltese Legal Notice (LN) 227 of 2003 https://legislation.mt/eli/sl/424.24/eng/pdf , which contains the OELs, has since been amended by LN 198 of 2015, LN 57 of 2018 and LN 356 of 2021: these three Legal Notices were also searched. Annex I of the CMRD: the study team is unable to establish where this is transposed into Maltese legislation.	Low
NL	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant documents were "SZW list of carcinogenic substances and processes, mutagenic or for reproduction toxic substances, Ministry of Social Affairs and Employment" published on 3 January 2022 in the Government Gazette of the Kingdom of the Netherlands: https://zoek.officielebekendmakingen.nl/stcrt-2022-51.html The Netherlands Working Conditions Regulations (https://wetten.overheid.nl/BWBR0008587/2022-07-01#BijlageXIII) contain the generic dust limit value for welding fume for the Netherlands, but no other references to welding fume, welding and no reference to welding as a process generated substance. Annex I of the CMRD is transposed into a list of carcinogenic substances and processes which was published in Gazette entry mentioned above published on 3 January 2022.	Medium
AT	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Austrian Order Grenzwerteverordnung 2021 - GVK https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418 Annex I of the CMRD seems to have been transposed on a state-by-state basis. For example, in the Styrian state (second largest state in Austria) Annex I is transposed in the State law gazette, dated 13 October 2005, p414: https://www.ris.bka.gv.at/Dokumente/Lgbl/LGBL_ST_20051013_100/LGBL_ST_20051013_100.pdf	Medium
PL	Yes	**No mention** MSA says there is no definition of welding fumes as a process generated substance. The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent	High

		and to Annex I. The relevant documents are the list of limit values of 12 June 2018:https://sip.lex.pl/akty-prawne/dzu-dziennik-ustaw/najwyzsze-dopuszczalne-stezenia-i-natezenia-czynnikow-szkodliwych-dla-18733965 and 3 December 2021, Poz. 2235 https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20210002235/O/D20212235.pdf Annex 1 of the CMRD is transposed on page 6 of Poz. 2235 the regulation on chemical substances.	
PT	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant documents are the Decree-Law number 24/2012 of the 6 February 2012: https://dre.pt/dre/legislacao-consolidada/decreto-lei/2012-115495237 which lists limit values. Annex I of the CMRD is transposed into Article 3 of Decree-Law No. 35/2020, of July 13 2020: https://diariodarepublica.pt/dr/detalhe/decreto-lei/35-2020-137703603	Medium
RO	Yes	**No mention** MSA says there is no specific legislation for welding fume. The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is the Decision no 1093 of August 16,2006 regarding establishment of minimum safety and health requirements for the protection of workers against the risks related to exposure to carcinogenic or mutagenic agents at work https://legislatie.just.ro/Public/DetaliiDocument/74889. This document does not contain any reference to "welding" or "weld". Annex I of the CMRD: Annex 1 of the CMRD is transposed in Appendix 1 of the above Decision 1093/2006.	High
SI	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant source is "Rules on the protection of workers from risks related to chemical exposure at work" Official Gazette of the Republic of Slovenia No. 72/21, from the Minister of Labour, Family and Social Affairs and equal opportunities (2021): http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV14252#. Annex I of the CMRD is transposed on page 26 of Practical guidelines for limit values for hazardous chemical substances, : https://vzd.mddsz.gov.si/document-download/prakticne-smernice-za-mejne-vrednosti-za-nevarne-kemicne-snovi-2022-01-14-429.	Medium
SK	Yes	**Yes, mentioned, OEL for welding solid aerosols** MSA indicates that there is specific legislation for welding fumes, with an OEL. Welding solid aerosols have an OEL of 5mg/m^3. The relevant documents are the Slovak regulation 355/2006 or "Temporary version of the Regulation protecting the health of employees from risks related to exposure to carcinogenic and mutagenic factors at work, of 10 May 2006, effective from 01.10.2020": https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2006/356/	High

		Annex 1 of the CMRD is directly transposed in Annex 1 of the above regulation.	
FI	Yes	**Yes, mentioned, already in transposition of Annex 1 of the CMRD** MSA says, and study team confirms, that welding and thermal cutting of stainless steel has already been added to the Finnish equivalent of Annex I of the CMRD. The decree is the following: https://www.finlex.fi/fi/laki/alkup/2019/20191267 on page 4 is Annex I, in Finnish "Liite I", which includes carcinogenic work processes. Annex I includes: "*10. Ruostumattoman teräksen hitsaus ja polttoleikkaus*." This translates to: "Welding and thermal cutting of stainless steel". The relevant document is the Decree of the Government addressing the risk of work-related cancer, 1267/2019, of 12 December 2019: https://www.finlex.fi/fi/laki/alkup/2019/20191267	High
SE	No	**No mention** The study team cannot find any definition of welding fumes specifically as a process generated substance, as carcinogen or equivalent to Annex I. The relevant document is 2018:1 The Swedish Work Environment Authority's regulations and general advice on hygiene limit values in relation to the inhalable and respirable fractions of welding fume particles: https://www.av.se/arbetsmiljoarbete-och-inspektioner/publikationer/foreskrifter/hygieniska-gransvarden-afs-20181-foreskrifter/ This legislation contains many dust limit values for different substances, but not welding specifically. There is advice on the measurement of workplace dust and references to Swedish standards and a Swedish OSH method. Annex I of the CMRD is transposed into the Swedish Provisions and General Recommendations on Chemical Hazards in the Working Environment (AFS 2011:19, p21): https://www.av.se/globalassets/filer/publikationer/foreskrifter/engelska/chemical-hazards-in-the-working-environment-provisions-afs2011-19.pdf and amended by general advice on chemical work environment risks (AFS 2022:4) https://www.av.se/globalassets/filer/publikationer/foreskrifter/andringsforeskrift/afs-2022-4.pdf	Medium

ANNEX 7: ROUTE(S) OF EXPOSURE AND ADVERSE HEALTH EFFECTS

1. COBALT AND ITS INORGANIC COMPOUNDS

1.1. Routes of exposure and uptake

Relevant exposure routes are oral and inhalation. Inhalation absorption is highly dependent on the particle size of cobalt. As a metal cobalt is not metabolised in the body. Excretion after inhalation exposure is highly dependent on the solubility of the cobalt substance, the more soluble the substance is, the more rapidly it is eliminated via the lungs by transfer to the blood and excretion via urine and faeces.

1.2. Adverse health effects

Cobalt and several inorganic cobalt compounds have a harmonised classification for carcinogenicity according to Annex VI of the CLP Regulation (Canc. 1A or B). Numerous studies on carcinogenic effects of cobalt have been published. However, the epidemiological evidence can be considered as inconsistent mainly due to the presence of confounding factors or limitations of the studies. Experimental evidence of alveolar/bronchiolar adenomas and carcinomas (combined) in the lung of rodents was found in two chronic inhalation NTP studies with soluble cobalt sulphate heptahydrate and non-soluble cobalt metal. RAC considers carcinogenicity in animal studies and non-cancer related respiratory effects in exposed workers as the critical toxicological endpoints after cobalt exposure. For carcinogenicity they did not identify a threshold. However, RAC believes that a 'break point' for the carcinogenic effects can be established at 0.5 $\mu g/m^3$ and derived an ERR for lung cancer (RAC, 2022). This ERR is also applied in the present report.

The main critical non-cancer endpoints after inhalation exposure are respiratory effects observed in exposed workers.

RAC considers three occupational exposure settings in the context of the OEL derivation. These are:

- production and use of cobalt and cobalt compounds;
- production and use of hard-metal; and
- polishing of diamonds.

According to RAC exposure to cobalt is associated with diseases like asthma, whereas exposure to cobalt-containing hard-metal is an established cause of parenchymal lung disease. Parenchymal lung disease is also reported in workers from the diamond-polishing industry. Numerous studies from different industrial sectors describe decreased lung function and respiratory tract irritation in association with cobalt exposure.

Cobalt metal and several cobalt compounds also have a harmonised classification as Repr. 1B (H360F) or are notified by the registrants as Repr. 1B (H360) or Repr. 1A (H360) as significant effects on the male reproductive system can be observed. These classifications are based on animal data (e.g. reduced sperm motility) as no relevant epidemiological data are available investigation fertility or developmental toxicity effects.

Effects mainly observed after oral cobalt exposure or in non-occupational settings (cardiovascular diseases, thyroid-related, haematological and nervous/sensory effects) are not considered for the current assessment.

2. PAHs

2.1. Routes of exposure and uptake

Inhalation is the most relevant exposure pathway for PAH for workers. However, also dermal exposure both with regard to local tumorigenesis (PAH mixtures cause skin tumours after dermal exposure, see below) and systemic uptake is relevant. For the dermal exposure route absorption rates widely differ, depending on PAH components and model species. BaP is readily absorbed via inhalation, the oral and dermal route.

PAH are rapidly distributed via blood and lymph in the whole body. Biotransformation takes place predominantly via oxidative pathways by CYP enzymes (CYP1A1 and A2) in the liver. Initially formed epoxides are converted to dihydrodiol derivatives and phenols. Induction of the oxidative metabolising enzymes occurs via binding to the aryl hydrocarbon receptor AhR.

Glucuronide and sulphate conjugates of PAH metabolites are excreted in the bile and urine. Glutathione conjugates are further metabolized to mercapturic acids in the kidney and are excreted in the urine. A commonly measured urinary metabolite is 1-hydroxypyrene. Renal PAH elimination was reported with a half-life range between 6 to 35 hours after occupational exposure. Excretion half-lives in faeces and urine have been reported in animal studies as 22 hours and 28 hours, respectively.

2.2. Adverse health effects

The most important health effect of PAH is carcinogenicity, most prominently lung cancer but also in the bladder, and skin. The International Agency for Research on Cancer (IARC) classified the substance benzo[a]pyrene (BaP) and certain occupational activities (e.g. coal tar distillation) as carcinogenic to humans (group 1). Also, there is sufficient evidence for the carcinogenicity of BaP and some other PAH in experimental animal studies.

PAH show moderate to low systemic toxicity after short- or long-term exposure. The most relevant non-cancer endpoint of PAH is reproductive toxicity, which has been shown for BaP in several animal studies.

3. 1,4-DIOXANE

3.1. Routes of exposure and toxicokinetics

As reported in the REACH dossiers the occupational exposure is expected to occur via inhalation during production, processing and use of the substance[224]. The dermal route also contributes to the body burden (no quantification available; ECHA, 2022b). Adsorption after inhalation and oral exposure is rapid. Newer data (Dennerlein et al. 2015; RAC 2022a) also point to considerable adsorption after dermal exposure. Once absorbed 1,4-dioxane is evenly distributed and rapidly metabolised (CYP mediated) to HEAA (and 1,4-dioxane-2-one, which is in pH-dependent equilibrium with HEAA). Excretion takes place mostly in urine as HEAA (minor amount unchanged), but also to some degree in exhaled air (unchanged or CO2).

[224] Estimates range from 0.03 mg/m³ up to around 26 mg/m³

3.2. Adverse health effects

The substance is irritating to the eyes and respiratory tract and due to its defatting properties causes skin dryness and eventually skin cracking. The substance is not known to be a skin sensitiser from animal experiments and does not show reproductive and/or developmental toxic effects in available studies on rats and mice. The main target organs are the respiratory tract (e.g. nasal cavity), liver and kidney, especially after repeated exposure (ECHA, 2022b). With regard to carcinogenicity, there is only limited evidence from human epidemiological studies. However, based on results from experimental animal data 1,4-dioxane is considered carcinogenic in rodents, thus leading to harmonised classification as Carc. 1B (ECHA, 2022a).

4. Isoprene

4.1. Routes of exposure and toxicokinetics

Occupational exposure to isoprene may occur primarily via inhalation or dermal contact during the production and usage of isoprene or synthetic rubber at industrial sites (RAC, 2022a). The dermal uptake is regarded as negligible (RAC, 2022b). However, isoprene can also be found in the air as it is produced and emitted by vegetation (RAC, 2022a). Isoprene is endogenously formed in humans with an estimated rate of approx. 0.2 µmol/kg bw and necessary for the synthesis of steroids and terpenes (RAC, 2022a).

It is mainly in the liver (90%) that isoprene is metabolised to monoepoxides which can be further oxidised to a diepoxide. This diepoxide is mutagenic. Subsequently, isoprene epoxides are broken down and conjugated by enzymes which results in a loss of toxicity (Hartwig and MAK Commission, 2015, RAC, 2022a). Studies observed interspecies differences in enzyme activity and its effects on the formation of the toxic isoprene metabolite. It was observed that especially mice and rats are more susceptible to isoprene and its metabolism to the mutagenic diepoxide than humans (Peter et al., 1990; RAC, 2022a).

4.2. Adverse health effects

Isoprene has a harmonised classification for carcinogenicity (Carc. 1B) and mutagenicity (Muta. 2). There are no epidemiological studies on exposure to isoprene alone. However, a small database exists for rubber industry workers exposed to isoprene and other chemicals at the same time. There is sufficient evidence for the carcinogenic activity of isoprene from experimental animal studies. RAC considered the carcinogenicity of isoprene "[…] as the critical health effect." (RAC, 2022a).

The considerations in the RAC opinion report identified the increase in the number of cells in the spleen and increased cell growth of haemopietic cells in bone marrow as the most sensitive toxicity endpoints from chronic exposure. For these endpoints the Lowest Observed Adverse Effect Concentration (LOAEC) was 10 ppm (28 mg/m3).

Additionally, repeated exposure to isoprene has been found to cause adverse effects on several organ systems. Based on these adverse effects, the following endpoints were evaluated:

- Anaemia;
- Degeneration of olfactory epithelium;
- Degeneration of spinal cord white matter;
- Male fertility;
- and reduced birthweight.

5. Welding fumes

5.1. Routes of exposure and uptake

During welding, metal pieces are fused through coalescence by using heat (energy) and filler material (also containing metals). During the heating process metals vaporise and condense rapidly afterwards into fine particles (particulate matter/fumes). Depending on the base metals, the used filler material, and the heat source the composition of the fumes can vary widely. In addition to the particulate matter (welding fumes), gases such as carbon monoxide are present and might impact observed health effects. Inhalation is the most important route of exposure. Process-generated fumes from welding and similar processes ((soldering, thermal cutting or gouging, thermal spraying, flame straightening, additive production processes) are summarised by ECHA (2022) as welding fumes+.

5.2. Adverse health effects

A critical health effect is carcinogenicity. IARC (2018) concluded that there is sufficient evidence for increased lung cancer risks in humans due to exposure to welding fumes. Also, a weaker association was observed with kidney tumours.

Apart from carcinogenicity, welding fumes may cause several types of respiratory tract toxicity, after short-term as well as long-term exposure. Acute effects comprise acute irritation to the throat and larger airways in the lungs. Metal fumes fever is a (transient) flu-like condition. Further, welders show a higher risk to develop acute pneumonia (pneumococcal pneumonia).

Chronic effects consist of occupational asthma, chronic bronchitis (airway inflammation, with symptoms like coughing and mucus in the bronchiolar airways) and welder’s lung (also known as siderosis). Welder’s lung is an iron-particle induced benign pneumoconiosis, which is unlikely to proceed to interstitial fibrosis. It is characterised by deposition of metal particles in the lung, with no clear correlation to a decrease in lung function. The evidence for welding fumes deteriorating lung function and causing chronic obstructive pulmonary disease (COPD) is discussed, but the evidence so far is weak.

In addition to the respiratory effects, it is discussed that welding fumes exposure may lead to neurological disorders, possibly caused by manganese and nephrotoxicity (tubular dysfunction), due to the presence of cadmium in welding fumes. Further, reproductive toxicity caused by welding fumes is under discussion.

Annex 8: Process for setting binding limit values and associated provisions under the CMRD

Step 1: priority setting

It is not realistic to address every hazardous chemicals that may be used at the workplace. Instead it is appropriate to identify and target priority substances.

The selection of the substances to be addressed through this initiative was based on a consultative approach including stakeholder engagement at Member States and social partners 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 OEL, or other institutional priorities;

Considering the ill-health work-related 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 or other measures.

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

Step 2: scientific evaluation and public consultation

Article 16 of the CMRD state that scientific/feasibility data should be included in the basis on which binding OELs and BLVs are set, but the directives do not determine which scientific body should be the source of such data. However, based on a Service Level Agreement (SLA) signed by DG EMPL and ECHA, this Committee assists the Commission delivering scientific evaluations, upon request, on the toxicological profiles of each of the selected priority chemical substances in relation to their adverse health effects on workers. These scientific evaluations shall, where appropriate, include proposals for Occupational Exposure Limit values (OELs), biological limit values (BLVs)/biological guidance values and/or notations. This task shall be carried out on the basis of the latest available scientific and technical data and take into account the specific context of occupational exposures at the workplace.

Scientific information from other sources can also be taken into account as long as the data is adequately robust and is in the public domain (e.g. conclusions of national limit vlaue-setting science committees). RAC carries out scientific evaluation at EU level based on the methodology agreed withing the ECHA/RAC-SCOEL Joint Task Force and as a result publish an Opinion on scientific evaluation of occupational exposure limits for the selected priority chemical substances. RAC procedure for the adoption of an Opinion includes an external consultation of relevant stakeholders. This ensures scrutiny of the scientifc evidence and methodological approach used by RAC and ensures transparency of the process.

Step 3. Two-stage social partner 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 2023. Annex 2 provides further information on the outcomes of the consultation.

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 CMRD 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 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 limit value (OEL, STEL or BLV) for a substance is established, taking into account the views of representatives from the government, workers', and employers' interest groups.

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

The adopted ACSH Opinions include, where necessary, specific comments from the interest groups (government, employers and workers) which broadly reflect the principal points maintained by each interest group throughout discussions of the Working Party on Chemicals (WPC).

The ACSH has adopted opinions for the priority substances foreseen for this amendment of CMRD.

In practice, a limit value 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 the limit values exist within the broader context of the CMRD general obligations to prevent risks to workers' health (exposure elimination/reduction, process enclosure etc.), which establishes an appropriate and exceptionally high legal standard for workplace- and process-specific risk control.

Step 5: Impact assessment

Between 2022 and 2024, an external contractor evaluated, on behalf of the Commission, health, socioeconomic and environmental impacts of the proposed amendments to CMRD 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 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.

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

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

An option is retained if the ACSH opinion has been clear and consensual, there are no concerns about the 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.

A positive opinion 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 the legislative proposal which will be adopted following the ordinary legislative procedure. The adopted Directive will be published in the EU Official Journal and Member States will then transpose the limit values and any associated notation into their national legislation by the date set in the Directive.

The limit values 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 limit values.

Within the CMRD there are obligations for employers to apply the appropriate measures at the workplace to ensure that the exposure of workers to these substances do not exceed the limit values. The monitoring of the correct implementation of the national legislation that transposes the EU directives and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

ANNEX 9: DATA SUPPORTING THE SETTING OF POLICY OPTIONS

1. Cobalt and inorganic cobalt compounds

The policy options consist of pairs of OELs which are set independently based on the different health effects of the inhalable ('I') and the respirable fraction ('R'). The inhalable fraction OEL addresses non-carcinogenic effects and the respirable fraction OEL addresses carcinogenic effects.

In its scientific opinion[225], RAC derived the following pair of OELs from human and animal studies based on inflammatory effects: 1 µg/m³ (I) and 0.5 µg/m³ (R). The proposed OELs (option 1) are based on a mode of action-based threshold for the carcinogenicity of cobalt compounds. The risk associated with the respirable OEL is close to 4:100,000.

Following discussions within its WPC, the ACSH recommended in its tripartite opinion[226] to set the following pair of OELs for cobalt and its inorganic compounds: 10 µg/m³ (I) and 2.5 µg/m³ (R), 6 years after the entry into force of the initiative subject to this impact assessment. In the meantime, it recommended a transitional pair of OELs: 20 µg/m³ (I) and 4.2 µg/m³ (R). The risk associated with the respirable OEL is close to 4:1,000. Since those two pairs of options are supported by the relevant stakeholders, in particular the social partners and Member States authorities represented within the ACSH, they were also set as policy options 4 and 5.

Finally and given the relative gap between the RAC and the ACSH recommendations, a intermediate pair of OELs (5 µg/m³ (I) and 1.25 µg/m³ (R)) was set (option 3).

2. PAHs

In its scientific opinion[227], RAC concluded that it was not possible to derive an OEL under which there will be no expectation of a relevant residual cancer risk. For that reason, RAC did not recommend any OEL. Instead, it derived a cancer exposure-risk relationship (ERR) expressing the excess risk for lung cancer as a function of the air concentration of BaP (considered as a marker substance for carcinogenic PAHs). Therefore, the RAC opinion could not be used to set a policy option.

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[225] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for cobalt and inorganic cobalt compounds, available at: https://echa.europa.eu/documents/10162/7937606/final_rac_oel_opinion_cobalt_en.pdf/d96755b2-8bd0-afe7-ab94-0a2f263fc593?t=1675065309296

[226] ACSH (2023), Opinion on an EU BOEL and notations for cobalt and its inorganic compounds, Doc. 005/23, available at: ACSH Adopted opinion Cobalt and inorganic compounds 22.09.23-EN.pdf (europa.eu)

[227] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for polycyclic aromatic hydrocarbons, available at: 06454dd9-cadc-acef-a11b-439f2a0d8efa (europa.eu)

The ACSH recommended in its tripartite opinion[228] an OEL of 70 ng/m³ (measured as BaP), which was set as policy option 3.

On top of this policy option, the OELs corresponding to an excess risk of 4:100,000 and 4:1,000 were also retained: 7 ng/m³ (option 2) and 700 ng/m³ (option 4), respectively.

3. 1,4-dioxane

In its opinion[229], RAC recommended an OEL of 7.3 mg/m³ (2 ppm) for 1,4-dioxane. This OEL assumes a mode of action-based threshold for the carcinogenic effects of this substance.

The ACSH recommended in its tripartite opinion[230] the OEL of 7.3 mg/m³ (2 ppm) proposed by RAC. Since this option supported by the relevant stakeholders within the ACSH and by RAC, it was set as policy option 2.

Two additional options for OEL for 1,4-dioxane were retained for the purpose of this impact assessment. First, the lowest national OEL currently in place in Latvia and the Netherlands: 20 mg/m³ (5.5 ppm – option 3). The third policy option is 36 mg/m³ (10 ppm – option 4), which is the most common value of existing national OELs between 73 mg/m³ (current indicative OEL under CAD) and 20 mg/m³.

RAC also recommended a BLV of 45 mg 2-hydroxyethoxyacetic acid (HEAA)/g creatinine. A BLV is the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect.

RAC provides a relationship[231] between the mean urinary HEAA levels after the end of exposure (extrapolated to 8 hours) and the air concentration of 1,4-dioxane. Based on this correlation, the following policy options for BLVs corresponding to the retained options for OELs were set: 45 mg, 108 mg and 188 mg.

4. Isoprene

Despite the absence of significant CDB and FDB associated with occupational exposure to isoprene, several policy options were assessed, including the option unanimously recommended by stakeholders, in line with Better Regulation guidelines. Assessing policy options for limit values is

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[228] ACSH (2023), Opinion on an EU BOEL for polycyclic aromatic hydrocarbons, Doc. 003/23, available at: ACSH Adopted opinion PAHs 22.09.23-EN.pdf (europa.eu) & Addendum to ACSH opinion 003/23, available at: Addendum to ACSH opinion PAHs-EN.pdf (europa.eu)

[229] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for 1,4-dioxane, available at: 686365df-9485-c2ac-b342-289ec306d188 (europa.eu)

[230] ACSH (2023), Opinion on an EU BOEL, STEL, BLV and skin notation for 1,4-dioxane, Doc. 007/23, available at: ACSH Adopted opinion 1_4-dioxane 22.09.23-EN.pdf (europa.eu)

[231] Urinary HEAA level (in mg/g creatinine) at the end of exposure = 17.82 x (air concentration of 1,4 dioxane in ppm) + 9.58.

also in line with the obligation laid down in the CMRD and requiring that limit values should be established for all those carcinogens, mutagens or reprotoxic substances for which this is possible.

RAC recommended the following OEL: 8.5 mg/m³ (3 ppm)[232]. According to RAC, this value is in relative alignment with the natural variation of isoprene produced endogenously in humans. More information is available in the RAC opinion.

In its opinion, the ACSH supported the OEL recommended by RAC. Since this option supported by the relevant stakeholders within the ACSH, it was set as a policy option.

In addition, the following policy options for OEL were retained in this impact assessment:

- 40 mg/m^3, corresponding to the median value for existing national OELs within the EU; and
- 129.4 mg/m3, corresponding to a cancer risk level of 4:1,000[233].

5. Welding fumes

The evidence gathered indicates that some employers are not aware that their welding processes may contain carcinogens, mutagens or reprotoxic substances. This driver was supported by the tripartite ACSH in its opinion[234]. Consequently, and despite welding can be a relatively safe activity if all the safety and exposure control measures are in place, it remains a prominent concern that welders are at high risk from various diseases, including cancers[235].

According to ECHA[236] in its scoping study on welding fumes, an entry of welding fumes in Annex I would bring clarity about employers' duties and which measures have to be taken. With the legal clarity brought by this inclusion, employers would be aware that welding fumes might contain substances covered by the CMRD, and consequently the risk management measures provided by the CMRD must apply.

The policy option of an entry of welding fumes in annex I to the CMRD was supported in its opinion[237] by the ACSH. The three interest groups consider that an inclusion into annex I to the CMRD might indicate to stakeholders that more needs to be done to ensure that the RMMs are in place and will bring clarity about employer's duties on measures to be taken.

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[232] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for isoprene, available at: 11c4dd13-2117-8cd1-83d6-44fc9e591b8f (europa.eu)
[233] Based on the ERR derived by RPA in the absence of an ERR in the RAC opinion
[234] ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)
[235] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)
[236] ECHA (2022), op. cit.
[237] ACSH (2023), op. cit.

ANNEX 10: ACCOMPANYING MEASURES AND OPTIONS DISCARDED

1. Accompanying measures

1.1. STEL

STEL values, usually involving a 15-minute reference period, are used when adverse health effects are not adequately controlled by compliance with an 8-hour TWA OEL, e.g. for substances for which a critical effect is observed following a brief exposure (e.g. acute toxic substances, substances causing nuisance, irritation, central nervous system depression, sensitisation).

RAC recommended a STEL for 1,4-dioxane, only. No data are available for the costs of compliance with the STEL options. However, it can be assumed that compliance with the OEL option would also mean that the relevant companies would comply with a STEL at a higher level. The ratios between the STELs and OELs currently in place in the Member States that have both an OEL and a STEL are summarised below.

Table 120 - STEL/OEL factors (rounded)

Member State(s) or source	STEL/OEL ratio
AT, CZ, DE, DK, FR, SI	2
LT, SE	3
FI	4
RAC opinion	10
Source: RPA (2024)	

Although peak exposures may be significantly higher than the 8-hour TWA, the fact that several Member States have STELs at 2 to 4 times the value of the OEL lends some support to the contention that compliance with an OEL of 7.3 mg/m3 is likely to ensure compliance with a STEL at ten times this value, i.e. 73 mg/m3. This would mean that no additional costs would be expected from complementing an OEL of 7.3 mg/m3 with a STEL at least 10 times higher, with the exception of additional measurement costs in cases where companies are particularly concerned about specific high-exposure activities.

1.2. Notations

OELs, STELs and/or BLVs can further be annotated with appropriate indications of additional body burden resulting from non-inhalation routes such as:

- “Skin” notation where the dermal route of exposure is scientifically considered to be relevant.
- “Skin sensitisation” where the substance can cause sensitisation of the skin.
- “Respiratory sensitisation” where the substance can cause sensitisation of the respiratory tract.

In its scientific opinions, RAC recommended the following notations:

- “Skin sensitisation” and “respiratory sensitisation” for cobalt and inorganic cobalt compounds;
- “Skin” notation for 1,4-dioxane; and
- “Skin” notation for PAHs.

The notations are irrespective of the level of the limit values.

1.3. Possible revision of the SLIC guidance on welding fumes

On 7 May 2024, the SLIC adopted a new mandate for its specific working group on chemical agents (WG CHEMEX) for 2024-2027. This new mandate provides for an evaluation of the need for a revision of any previous produced documents by the WG CHEMEX. This task could result in the revision of the existing SLIC guidance document for national labour inspectors on addressing health risks from welding fume[238]. This guidance document, which was developed in 2018, for national labour inspectorates, aims to increase inspectors’ competences and confidence during enforcement activities related to health risks from welding fumes activities and exposure to welding fumes. In the absence of specific information on if and how this guidance document will be updated, the effects of this option could not be assessed and considered under this impact assessment. However, it is likely that an update of this guidance document will be complementary to the inclusion of welding fumes in the Annex I of the CMRD and result in better protection for workers.

2. Isoprene-related discarded option

This section outlines the baseline for isoprene and provides with a detailed assessment of the costs and benefits for the limit value recommended by the ACSH.

2.1. What is the baseline

[238] SLIC (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC

Around 10,500 workers are currently exposed to isoprene in the EU. These workers are divided in two sectors: manufacture of refined petroleum products (97%) and manufacture of synthetic rubber in primary forms (3%).

The refinery capacity in the EU is expected to decrease as a consequence of the ban of sale of new diesel and gasoline driven cars and vans from 2035. The evidence gathered[239] suggests that this decrease of the refinery capacity would be of 6% per year. The number of workers exposed to isoprene in this sector is assumed to follow the same trend. With regard to the synthetic rubber in primary forms manufacturing sector, based on the annual compound growth rate for this sector[240], it is expected that the number of exposed workers increase by 7% per year over the reference period. Overall, the number of exposed workers will decrease over that period since most of these workers are operating the manufacture of refined petroleum products. No forthcoming changes in national limit values or other relevant national legislation have been identified.

According to the evidence gathered[241], including the RMMs currently in place (see section 2 and annex 6) workers operating in those two sectors are exposed on average to levels of isoprene of 0.20 mg/m^3 and 0.25 mg/m^3, respectively. The maximum exposure levels recorded in the manufacture of refined petroleum products are higher than for manufacture of synthetic rubber in primary forms: 1.36 mg/m^3 vs 0.76 mg/m^3. The evidence gathered indicates that the limit value of 0.66 mg/m^3 for benzene (which will enter into force in April 2026) and the future limit value for PAHs is likely to impact downwards workers' exposure to isoprene in some activities (e.g. steam cracking and refining). However, as the exposure levels to isoprene in the EU are alrealy below the health-based limit value derived by RAC, their effects have not been factored into the baseline as they would not have any effects on the impacts assessed under section 6.

The exposure levels in both sectors are expected to keep stable over the reference period. The evidence gathered indeed suggest that in both sectors, RMMs are currently implemented to the most extent possible (i.e. closed systems and respiratory protective equipment (RPE) in high risks tasks such as maintenance).

According to the evidence gathered[242], the present workers' exposure levels are very low. As a result, the FDB is also expected to be very low or even 0.

The above assumptions and estimates should be treated with cautious due to limited availability of data, including exposure data.

Table 121: baseline scenario for isoprene over 40 years

Number of exposed workers	10,539
Change in exposure level	0%

[239] RPA (2024), op. cit.
[240] RPA (2024), op. cit., isoprene report, section 3.4.5.
[241] RPA (2024), op. cit.
[242] RPA (2024), op. cit.

Change in number of exposed workers	- -6% for petroleum products manufacturing - +7% for synthetic rubber manufacturing
Future disease burden (FDB) from current and future exposure – Number of cases over 40 years	0.03 - 0.03 (liver cancer) - 0 (degeneration of olfactory epithelium and spinal cord white matter)
Estimated deaths due to FDB cancer over 40 years	0
Monetary value FDB cancer over 40 years	- Method 1: €40,000 - Method 2: €50,000
Monetary value FDB other adverse health effects over 40 years	€0
Source: RPA (2024)	

2.2. Description of the policy option

Option 2 corresponds to the health-based limit value derived by RAC in its opinion and is also the limit value recommended by the ACSH, namely 8.5 mg/m³. This option also corresponds to the threshold limit value derived by RAC in its opinion. In the absence of problem for workers exposed to isoprene, no additional option than the OEL recommended by social partners and Member States authorities represented in the WPC/ACSH was originally retained for the purpose of this impact assessment.

2.3. What are the impacts of the policy option for isoprene

2.3.1. Social impacts

(a) Impacts on workers' health

No expected impact on workers' health, regardless of POs.

(b) Impacts on employment

No expected impact on employment, regardless of POs.

2.3.2. Economic impacts

(c) Impacts on businesses, including SMEs

While businesses are not expected to bear any **adjustment costs** (discontinuation costs and investment in RMMs) under PO 2, they would nevertheless face additional **monitoring and administrative costs**.

Although the current exposure levels are below PO 2, it is assumed that businesses operating in Member States with no or higher national limit value than PO 2 would need to show compliance with the new or revised limit value[243].

Overall, business will spend €190,000 under PO 2 over 40 years. About 70% of the total monitoring costs will be supported by large companies.

Table 122: total estimated costs of two additional air monitoring campaigns in € million over 40 years by policy option and size of company

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (8.5 mg/m³)	0.02	0.03	0.13	**0.19**
Source: RPA (2024)				

The administrative costs associated with the monitoring campaigns amount to €110,000 under PO 2 over 40 years. As for the monitoring costs, most of the administrative costs would be supported by larger companies.

Table 123: total estimated costs of administrative burden of additional air monitoring by policy option and size of company over 40 years

Policy options	Total costs (€ million)			
	Small	Medium	Large	**Total**
PO 2 (8.5 mg/m³)	0.01	0.01	0.09	**0.11**
Source: RPA (2024)				

Overall, businesses are expected to support compliance costs amounting to €160,000 under PO 2 over 40 years, which would represent €4,000 per company over the same period. Businesses would dedicate 0.002% of their turnover as compliance costs (scenario of small- and medium-sized enterprises operating in synthetic rubber manufacture sector under PO 2).

(d) Impacts on competitiveness

Given the negligible compliance costs, including compared to the turnover, no impact on competitiveness is expected, regardless of the PO.

(e) Impacts on the single market

The introduction of an EU-wide OEL for isoprene would result in less divergencies between Member States with regard to the national OELs, in particular given the low number of Member

[243] All Member States except DE under policy option 2.

States with an existing OEL. This more homogenous regulatory framework for isoprene would theoretically improve the functioning of the internal market by creating a more level playing field. However, this impact would be negligible given the current low levels of exposure for workers in all Member States.

(f) Impacts on public authorities/Member States

As only 5 Member States have a national OEL for isoprene, most of the Member States would have to bring changes in their national legislations in the event of an EU-wide OEL. Furthermore, some Member States will also need to adapt their existing OEL under PO 2 (BG, LT, LV and PL).

Assuming that modifying an existing OEL is less costly than introducing a new OEL, the **transposition costs** for PO 2 would account for €1.22 million.

While public authorities would not avoid **costs of ill health** under PO 2, they would not have to devote resources to setting their own national OEL (e.g. an impact assessment). The **avoided costs related the setting of an OEL** at national level would amount to €2.4 million under PO 2. However, these avoided costs are very theoretical as it is unlikely that Member States with no OEL for isoprene would devote resources for setting a national OEL given the expected absence of benefits for workers and businesses. Therefore, it is considered that there would be no avoided costs for public authorities.

As PO 2 is expected not to entail any costs to businesses, there would be no specific Member States that would be particularly impacted.

(g) Impacts on digitalisation

None of the POs are expected to impact sectors with exposed workers to isoprene. Therefore, and even if polyisoprene may be used in electronics (photoresists in semiconductor manufacturing[244]), no impact on digitalisation is expected, regardless of the PO.

2.3.3. Social impacts

No expected direct or indirect impact on environment, regardless of the PO.

2.4. How do the options compare?

Effectiveness: PO 2 would result in avoided ill-health cases compared to the baseline and its impact on workers' health is therefore zero compared to the baseline.

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[244] Fujifilm (2023), Fujifilm website "Negative (Polyisoprene-based)", https://www.fujifilm.com/uk/en/business/semiconductor-materials/photoresists/negative

Since only 5 Member States currently have a limit value for isoprene, introducing a limit value at EU level would theoretically contribute to a better playing field in the single market, however, the real impact is likely to be zero given the already very low levels of exposure for workers in the EU.

As PO 2 is fully consistent with the recommendation of the ACSH, this should theoretically have a positive impact on its effectiveness in terms of ill-health cases avoided. However, since it is expected that all workers in the EU are already exposed to safe levels of isoprene, businesses will not invest in additional RMMs. Therefore, the real impact of the full consistency with the ACSH opinion on the effectiveness is zero too.

Efficiency: the C/B ratio of PO 2 for isoprene could not be calculated in the absence of any benefits.

PO 2 is expected to entail monitoring and administrative costs for businesses, amounting to between €300,000 (€4,000 per company on average). These costs would not exceed 0.002% of the turnover, irrespective of the sector or the size of the company and are therefore and the negative impact is therefore very small compared to the baseline.

No discontinuation or job loss is expected under PO 2.

Coherence: In the absence of benefits, PO 2 would not contribute to Europe's Beating Cancer Plan. Furthermore, no impacts on the other key EU policies arising from PO 2 were identified.

Table 124 – Comparative scoring of the policy options for isoprene

	PO 2
Effectiveness	
Number of cancer and non-cancer cases avoided	0
Contribution towards a better level playing field	0
Consistency with the recommendation of the ACSH	0
Total effectiveness	***0***
Efficiency	
Costs/benefits ratio (C/B ratio)	NA
Costs compared to turnover	(-)
Number of discontinuations and job losses	0
Total efficiency	***(-)***
Coherence	
Coherence with Europe's Beating Cancer Plan	0
Coherence with other key EU policies (EU Green Deal, EU strategic autonomy, digital transition)	0
Total coherence	
Overall score	**(-)**

3. Options discarded at an early stage

3.1. Banning the use of the substances subject to this impact assessment

Substitution is the first option in the hierarchy of RMMs under the CMRD that an employer has to consider. This means that if it were technically feasible, employers should already have replaced use of the concerned substance with safer alternatives.

3.2. Directly adopting the most stringent national limit values

Wherever substitution is a suitable alternative for use of the chemical agents in question the CMRD already requires this, regardless of the existence of a limit value. As this legal standard already establishes that these substances should not be used in the workplace where safer alternatives are available, establishing a stricter prohibition in the form of a ban would constitute disproportionate measure with a strong negative impact on businesses and, in for some substances such as cobalt, on key EU objectives, such as the green transition. Further, it is not under the remit of the CMRD to ban substances.

For most of the carcinogens some Member States adopted limit values more stringent than some policy options considered in this impact assessment. It could be argued that such limit values 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. Furthermore, national economies can vary greatly among Member States, including regarding the representativity of different sectors. Therefore, the impacts resulting from some policy options can also be highly different between Member States.

3.3. Providing industry-specific scientific information without amending the CMRD

Another option could be for the Commission to collect and provide industry-specific scientific information to support employers in complying with the CMRD 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 CMRD, which provides for general exposure management requirements to be specifically supplemented by EU-wide minimum standard limit values;

- 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.

3.4. 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, mutagenic and reprotoxic substances and on the scope of the CMRD, such in the case of welding fumes. 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.

Regarding welding fumes, several guidance documents already exist at EU-level. In 2018, the Senior Labour Inspectorate Committee developed a European Guidance on addressing health risks from welding fumes[245]. Although this guidance was developed for inspectors, it is also fit for businesses. With this document, they can also ensure compliance with its requirements. This guidance includes background information such as health risks, types of welding the legal framework for regulation, typical control measures, health surveillance and key information. It also includes a welding fumes task sheets with specialised guidance on each welding activity including approaches to control welding fumes exposure, illustrative photographs, etc.

Another guidance document was developed by the European Welding Association (EWA). This guidance[246] includes different exposure scenarios and operational conditions, with recommended RMMs, with the aime of outlining how metals, alloys and metallic articles and mixtures can be safely welded with respect to exposure to welding fumes and gases.

Despite the existence of guidance at EU level, the evidence gathered shows that the welding fumes-related problem persists. Therefore, the development of a new guidance was not considered relevant to address the problem.

3.5. Setting a limit value for welding fumes

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[245] SLIC (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC
[246] EWA (2021), Welding Exposure Scenario – ENGL. Available at : WES-EWA-TCC-458-2021-05-English-002.pdf

With regard to welding fumes, the purpose of the initiative subject to this impact assessment is to improve clarity on the scope of the CMRD. The setting of a limit value for welding fumes would not have allowed for providing more legal clarity and cannot therefore be considered as an alternative to the inclusion of welding fumes in Annex I of the CMRD.

Currently, welding fumes have no EU-wide limit value covering all its fumes. However, for the majority of metals involved in the composition of these fumes, there is already an existing limit value in Annex III of the CMRD. Furthermore, the setting of a limit value in the CMRD require a scientific opinion from RAC. So far, the Commission only has a scoping study of ECHA to support a possible inclusion of welding fumes in Annex I, not a scientific opinion from RAC. Finally, the heterogeneous character of welding fumes makes it very difficult to establish a common OEL for all welding processes.

For all the above reasons, the establishment of a limit value covering all welding fumes was discared.

3.6. 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. Furthermore, applying less stringent rules to SMEs in the area of OSH would also negatively impact their ability to attract workers as the latter would favour better working conditions.

ANNEX 11: CONSISTENCY AND COMPLEMENTARITY WITH THE REACH REGULATION

Restrictions under REACH

1. COBALT

1.1. Restrictions

None of the substances within the scope of this impact assessment are subject to restrictions under REACH. For five cobalt salts, a restriction proposal was prepared by ECHA in 2018, but the proposal has been withdrawn by Commission Decision of 8th April 2022 on the termination of the restrictions process on cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) under REACH.

A number of arsenic, cadmium, nickel, lead, and inorganic ammonium substances subject to restrictions contain cobalt, but none of the substances are registered and consequently out of the scope of this study. The relevant entries in REACH Annex XVII are as follows: Arsenic compounds (entry 19), cadmium and its compounds (entry 23), nickel and its compounds (entry 27), lead and its compounds (entry 63), and inorganic ammonium salts (entry 65).

1.2. Authorisation

None of the substances within the scope of this impact assessment are subject to authorisation under of REACH.

1.3. Chemical Safety Reports (CSRs)

As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an exposure assessment and risk characterisation that address all the identified hazards of the substance. The CSRs include for all Worker Contributing Scenarios (WCS) a description of the operational conditions and the risk management measures. This CSRs provide key information for the risk assessments to be undertaken in accordance with the requirements of the CMRD.

1.4. Classification and Labelling Inventory (C&L Inventory)

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange

Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process.

1.5. Risk management option analysis

A risk management option analysis (RMOA) for five cobalt salts from 2017 concluded that follow-up regulatory action at EU level was needed and that a restriction would be the most appropriate for the five substances. The restriction process has later been terminated as described above and replaced by the policy option of establishing an OEL. For cobalt metal and other inorganic cobalt compounds no RMOA has been developed.

2. PAHs

The substances within the scope of the study are not subject to the requirements for registrations under REACH. Some PAH are manufactured industrial chemicals, but many are process generated and are not subject to REACH registration.

PAH occur almost always in mixtures of several PAH and are formed during incomplete pyrolysis or combustion and pyrolysis processes of organic materials, such as coal and wood. The composition of the mixture is varied and depends on the process that generates them as well as the materials involved.

Some substances contain PAH that are released upon use. For example, anthracene oil (EC 292-602-7) and pitch, coal tar, high temp. (CTPHT) (EC number 266-028-2). These may be subject to REACH registrations and other REACH processes.

2.1. CSRs

None of the substances are registered, however some substances known to contain PAH are registered. As part of the registration processes for these substances, companies have prepared CSRs which among others include an assessment of occupational exposure and environmental exposure.

Table 125 - list of substances containing PAH for which CSR have been obtained and used in the assessment

Substance	EC number
Pitch, coal tar, high-temp.	266-082-8

2.2. C&L Inventory

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. The carcinogenic PAHs have a harmonised C&L and therefore the inventory was not consulted for self-classifications.

2.3. Restrictions

The table below presents the current REACH restriction of PAH.

Table 126 - REACH restrictions on PAH

Entry	Substance	EC number	Restriction
50	Benzo[a]pyrene (BaP)	200-028-5	The restrictions concern the use of certain products that may contain one or more of the PAH substances mentioned. These include, amongst others: 1) Extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain: - more than 1 mg/kg (0,0001% by weight) BaP, or - more than 10 mg/kg (0,001% by weight) of the sum of all listed PAH; 2) Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001% by weight of this component) of any of the listed PAH; 3) Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005% by weight of this component) of any of the listed PAH; 4) Granules or mulches shall not be placed on the market for use as infill material in synthetic turf pitches or in loose form on playgrounds or in sport applications, if they contain more than 20 mg/kg (0,002 % by weight) of the sum of all listed PAH.
	Benzo[e]pyrene (BeP)	205-883-8	
	Benzo[j]fluoranthene (BjFA)	205-910-3	
	Benzo[a]anthracene (BaA)	200-280-6	
	Chrysene (Chr)	205-923-4	
	Dibenzo[a,h]anthracene (DBAhA)	200-181-8	
	Benzo[k]fluoranthene (BkFA)	205-916-6	
	Benzo[b]fluoranthene (BbFA)	205-911-9	
Source: REACH Annex XVII			

A Restriction proposal as well as related opinions by RAC and SEAC have been published in 2022 that limit the amount of PAH in clay shooting targets. The restriction is likely to be adopted this year.

In addition, creosote and creosote containing substances are included in REACH Annex XVII entry 31. The restrictions concern the use of these substances in wood treatment and specify that these substances shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market. A further restriction is being considered on the placing on the market, re-use and secondary use of wood treated with creosote or related substances (ECHA, 2022a).

2.4. Authorisation

None of the substances within the scope of this study are listed in Annex XIV of REACH. Substances containing PAH which are released during use, may be subject to REACH authorisations, these are anthracene oil (EC 292-602-7) and pitch, coal tar, high temp. (CTPht) (EC 266-028-2).

3. 1,4-DIOXANE

The substances within the scope of the study are subject to the requirements for registrations under REACH.

3.1. CSRs

As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an assessment of occupational exposure and environmental exposure.

3.2. C&L Inventory

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process.

3.3. Restrictions

There are currently no entries for 1,4-dioxane in Annex XVII of REACH. However, a call for evidence by the German Federal Institute for Occupational Safety and Health (BAuA) was open until 20 July 2023 on a potential Annex XV restriction on the manufacture, placing on the market and use of 1,4-dioxane in surfactants, motivated by the need to prevent environmental emissions of 1,4-dioxane. The expected date of submission of the restriction proposal is 2024.

3.4. Authorisation

In 2021, 1,4-dioxane was included in the Substances of Very High Concern (SVHC) Candidate List for Authorisation according to REACH Art. 57 (a) and 57 (f),with this triggering substitution and information requirements.

3.5. Risk management option analysis

A Risk Management Option Analysis (RMOA) was completed by Germany in 2020 to assess regulatory options following the change of harmonised classification from C2 to C1B. It was concluded that a potential identification as SVHC and a potential Annex XV restriction were to be considered. As regards occupational exposure, it was noted that: the currently valid IOELV turned out to be obsolete and should not be used from now on as basis for risk assessment. In light of the upcoming Carc. 1B classification the provisions of CMRD become relevant and a BOELV should be derived.

4. Isoprene

The substances within the scope of the study are subject to the requirements for registrations under REACH.

4.1. CSRs

As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an assessment of occupational exposure and environmental exposure. The CSRs have been a key information source for the current assessment.

4.2. C&L Inventory

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process.

4.3. Restrictions

Isoprene currently has no restrictions listed under the REACH regulation. Additionally, isoprene has one reported Assessment of Regulatory Needs (ARN) not relating to a proposed restriction and no restriction intentions in the Registry of restriction intentions (RoI). As such it can be expected that isoprene will not be restricted under REACH in the near future.

4.4. Authorisation

Isoprene is not currently included on the candidate list or authorisation list under the REACH regulation. As such there are no authorisation requirements for this substance.

4.5. Risk management option analysis

An intention for a risk management option analysis (RMOA) was submitted for Isoprene in 2016, on account of its CMR properties. Since this intention was submitted, no RMOA has been conducted. Therefore, introducing Occupational Exposure Limits for isoprene is the only suggested regulation for control of the risks posed by this substance at EU level.

5. WELDING FUMES

The substances in welding fumes are process generated, produced during the welding process. There is no requirement for process generated substances to be registered under REACH. According to ECHA the base metals can be considered to be part of an article whilst the filler materials could be either articles or mixtures (alloys are special mixtures), and although covered by REACH are not subject to REACH registration.

ANNEX 12: SME TEST

1. COBALT AND ITS INORGANIC COMPOUNDS

Table 127 – Cobalt and its inorganic compounds-related SME test

Identification of affected businesses

- 81% of the affected companies are small companies and 13% are medium sized companies.
- The share of SMEs is similar across all the most affected sectors (the sectors with highest number of exposed workers).

Consultation with SME stakeholders

- SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 37% in the stakeholder survey conducted for this study. While this share is lower than the share of SMEs in affected companies, SMEs are still well represented.
- SME stakeholders express concern that the two lowest OEL options, 1/0.5 µg/m³ and 5/1.25 µg/m³ will negatively affect their competitiveness.

Assessing the impacts on SMEs

One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. While there is no specific agreed benchmark for what significant impacts are, when the indicator is above 5%, then it will be considered significant in this study. The table presents how many sectors where the indicator is above 5% for small and medium companies. This indicates that it is only small companies that face more significant challenges for the lower OELs.

OEL	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
1 / 0.5 µg Co/m^3	37%	0%
5 / 1.25 µg Co/m^3	15%	0%
10 / 2.5 µg Co/m^3	7%	0%
20 / 4.2 µg Co/m^3	0%	0%

Minimising the negative impacts on SMEs

- The option proposed by the ACSH with a transitional period of 6 years before the option of the OEL 10 / 2.5 µg Co/m³ will be introduced allows companies to plan and finance their investments in RMMs over the six-year period. The is will be particular important for SMEs. It means that in all sectors, the SMEs will have to invest less than 1 % of turnover in RMMs each year of the transitional period.
- This is likely to mitigate the possible negative impacts on the SMEs.

2. PAHs

Table 128 – PAHs-related SME test

Identification of affected businesses
• 99.1% of the affected companies are small companies and 0.7% are medium sized companies. • The majority of sectors under review in the study are primarily made up of SMEs (>90% of all companies are SMEs) with the exception of the following sectors: C19.2 (refineries approximately half are SMEs), C20.13 (manufacturer of carbon black – around 80% are SMEs), C20.14 (coal tar distillation - approximately 45% are SMEs), C23.99b (graphite and carbon electrode manufacture - all are large enterprises), C24.42 (manufacture of aluminium – approximately one third are SMEs), and D35.11 (coal fired power plants - approximately 85% are SMEs). All of these sectors have a low number of operating enterprises in the EU indicating that the higher percentage of large companies refers to a small number overall.
Consultation with SME stakeholders
• SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 38% in the stakeholder survey conducted for this study. SME responses were only provided in regard to C19.2 (refineries), C20.13 (manufacture of carbon black), C20.14 (coal tar distillation), C24.42 (manufacture of aluminium), C24.5 (casting of metals), F42.11 (road paving) and may not provide a robust representation of these sectors. • SME respondents unilaterally believed that the most stringent policy options (7 and 70 ng/m^3) would have negative impact on EU competition. At 700 ng/m^3 SME respondents were split as to whether EU competition would be impacted (this was felt to be negative for C20.13 (approximately half of SME sector respondents) and C20.14. the remaining sectors believed there would be limited/no impact at this level. • All respondents believed 7 and 70 ng/m^3 would have negative impacts on global competition. At 700 ng/m^3 approximately half of the respondents believed there would be limited/no impact. Those that believed there would be negative impacts were in C20.13 and C20.14. • However, these results should be read with caution as they are not a representative sample of the sectors.
Assessing the impacts on SMEs
• One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. • At the lowest policy option, in approximately half the sectors, small and medium sized enterprises will experience high costs as a percentage of turnover. Sectors with high percentages for SMEs include C16.1 wood preservation, C19.2 petroleum refineries, C20.14 coal tar distillation, C23.2 manufacture of refractor products, C23.99a manufacture of bituminous products, C24.1 steel and iron foundries, C24.45 other non-ferrous metallurgy, C24.5 casting of metals, D35.11 coal fired power plants, E39 soil remediation, F42.12 welding of railroad tracks, and N81.22 chimney sweeps. Also coking plants (C19.1) are heavily impacted at this level due to 100% of companies discontinuing. • At the 70 ng/m^3 policy option SMEs are potentially disadvantaged, albeit to a lesser extent than at ng/m^3 in the following sectors: C16.1 wood preservation, C19.1 coking plants, C19.2 petroleum refineries, C23.2 manufacture of refractory products, C24.1 steel and iron foundries,

C24.45 other non-ferrous metallurgy, C24.5 casting of metals, D35.11 coal fired power plants, E39 soil remediation, and F42.12 welding of railroad tracks. • At 700 ng/m^3 and 2000 ng/m^3 SMEs may also have high costs as a percentage of operating surplus in C16.1 wood preservation, C23.2 manufacture of refractory products, C24.1 steel and iron foundries, and D35.11 coal fired power plants. • In terms of R&D, the introduction of OELs this may result in proportionally less R&D being performed by small and medium companies than large (albeit most companies would reduce their R&D regardless of their size) at the two lowest policy options. This may put SMEs at a disadvantage against large companies in the future; R&D is the means to develop novel methods to improve efficiency and reduce costs for companies. • Overall SME's may be at a competitive disadvantage compared with large enterprises as costs make up a higher proportion of their turnover than large companies which are more likely to absorb the costs.
Minimising the negative impacts on SMEs
• The policy option where a transitional period of 6 years before the option of the OEL 70 ng/m^3 will be introduced allows companies to plan and finance their investments in RMMs over the six-year period. The is will be particularly important for SMEs. • Based on first year costs as a percentage of turnover for sectors with a transitionary period, C19.1 and C20.14 are sectors with high first year costs for remaining SMEs, and a high proportion of discontinuations at 70ng/m^3. For C19.1 the majority of the sector is estimated to be made up of SMEs, and for C20.14 approximately half of all companies are SMEs. • The transitionary period is expected to reduce the number of SMEs discontinuing (and therefore unemployment) for SMEs in these sectors.

3. 1,4-DIOXANE

Table 129 – 1,4-dioxane-related SME test

Identification of affected businesses
• 95% of the affected companies are small companies and 3% are medium sized companies. • The share of SMEs is similar across all the most affected sectors (between 88% and >99%) with the exception of the sector that produces 1,4-dioxane.
Consultation with SME stakeholders
• SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 100% in the stakeholder survey conducted for this study (40% of responses are from small companies, 60% of responses are from medium-sized companies). SMEs are thus well represented. • SME stakeholders express concern that the lowest OEL option, two of the five respondents expect moderate or significant competitiveness impacts from the OEL option of 7.3 mg/m^3 (2 ppm).

Assessing the impacts on SMEs
One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. While there is no specific agreed benchmark for what significant impacts are, when the indicator is above 5%, then it will be considered significant in this study. The table presents how many sectors where the indicator is above 5% for small and medium companies. This indicates that it is only small companies that face more significant challenges for the lowest OEL or lowest OEL/BLV combination in the following sector: C20.1, C20.3 and C20.5 chemicals, where this indicator exceeds 14% for both lowest OEL or lowest OEL/BLV combination.

OEL	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
7.3 mg/m3	17% (1 sector)	0%
20 mg/m3	0%	0%

OEL	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
7.3 mg/m3 and 45 mg HEAA in urine/g Creatinine	17% (1 sector)	0%
20 mg/m3 and 108 mg HEAA in urine/g Creatinine	0%	0%

Minimising the negative impacts on SMEs
None of the policy measures have special provisions for SMEs.

4. ISOPRENE

Table 130 – Isoprene-related SME test

Identification of affected businesses
66% of the affected companies are small companies and 9% are medium sized companies. The share of SMEs is different between the two sectors in this analysis as no SMEs are associated with the C19.2 Manufacture of refined petroleum products sector.
Consultation with SME stakeholders

- SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 33% in the stakeholder survey conducted for this study. While this share is lower than the share of SMEs in affected companies, SMEs are still well represented.
- SME stakeholders expressed no concern for any of the policy options, in relation to their competitiveness.

Assessing the impacts on SMEs

One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. While there is no specific agreed benchmark for what significant impacts are, when the indicator is above 5%, then it will be considered significant. The table presents how many sectors where the indicator is above 5% for small and medium companies. This indicates that it is only small companies that face more significant challenges for the lower OELs.

Policy option	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
8.5 mg/m^3	0%	0%

Minimising the negative impacts on SMEs

None of the policy measures have special provisions for SMEs.

5. WELDING FUMES

Table 131 – Welding fumes-related SME test

Identification of affected businesses

- An estimate of the affected companies is that 97.6% are small companies and 1.9% are medium sized companies.
- The sectors with the highest numbers of exposed workers in SMEs are estimated to be F43, F41, G45, C25 and C33.

Consultation with SME stakeholders

- SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 64% of the stakeholder survey conducted for the purpose of this impact assessment. Although this share is lower than the share of SMEs in affected companies or SMEs as a share of enterprises with exposed workers, SMEs are still well represented.
- A large limitation is that there were no responses from the construction sector which is estimated to include approximately half of exposed workers employed by SMEs (F41, F43). Also 55% of the survey responses were from Germany, so the responses are unlikely to be representative of the EU27.
- The most common estimate by SMEs for the initial investment to comply with policy option 2 was €10,000 – 100,000, this compares with an equivalent estimate of more than €100,000 for large enterprises[247]. At the time of the survey, policy option 2 was not fully defined, so these estimates may not be accurate.
- However, key stakeholders interviewed (July 2023) identified that worker protection is often weaker in SMEs than in larger enterprises, and that there is likely to be a greater need for SMEs to invest in additional RMMs and/or use RMMs they already have more effectively to protect their workers.

Assessing the impacts on SMEs

SMEs have limited funds to invest in RMMs, so are more likely to need:

- To use their R&D budget to invest in RMMs;
- To pass on additional costs to consumers through price increases;
- To potentially consider options to avoid using CMRs in welding which could reduce the variety of products they sell; and
- To potentially avoid generating welding fumes by avoiding welding completely, which could reduce the quality (strength and robustness) of their products although this is considered unlikely.

Minimising the negative impacts on SMEs

The possible revision of the SLIC guidance on welding fumes might include specific provisions to support SMEs in complying with their obligations laid down in the CMRD.

[247] The study team believes this is due to large enterprises expecting to install factory-wide extraction systems.