OELs 6

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

Final report V3

Methodological note and

consultation synopsis

November 2024

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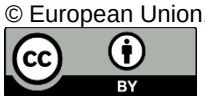

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LIST OF ABBREVIATIONS AND ACRONYMS

ACSH	Advisory Committee for Safety and Health at Work
BAT	Best Available Technique
BLV	Biological Limit Value
CAREX	Carcinogen Exposure
CAD	Chemical Agents Directive
CAS	Chemicals Abstracts Service
CBA	Cost Benefit Analysis
CBR	Cost Benefit Ratio
CEA	Cost Effectiveness Analysis
CEN	European Committee of Standardization
CLH	Harmonised Classification and Labelling
C&L	Classification and Labelling Inventory
CMD	Carcinogens and Mutagens Directive
CSR	Chemical Safety Report
DALY	Disability Adjusted Life Years
DG	Directorate General
DNEL	Derived No-Effect Level
DRR	Dose Response Relationship
EC	European Commission
ECHA	European Chemicals Agency
EIG	Employers Interest Group
ERR	Exposure Risk Relationship
ESENER	EU-OSHA's European Survey of Enterprises on New and Emerging Risks
EU	European Union
EWCS	Eurofound's European Working Conditions Survey
FBD	Future Burden of Disease
FoBiG	Forschungs und Beratungsinstitut Gefahrstoffe
GIG	Government Interest Group
IA	Impact Assessment
IARC	International Agency for Research of Cancer
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
LOQ	Limit of Quantification
MCA	Multi-Criteria Analysis
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne" or the Statistical Classification of Economic Activities in the European Community
OEL	Occupational Exposure Limit
OSH	Occupational Safety and Health
PPE	Personal Protective Equipment
PV	Present Value
RAC	Committee for Risk Assessment
QALY	Quality Adjusted Life Year
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RPA	Risk & Policy Analysts Ltd

RPE	Respiratory Protective Equipment
SEG	Similar Exposure Group
SLIC	Senior Labour Inspectors Committee
SME	Small and Medium-sized Enterprise
STEL	Short-Term Exposure Limits
TWA	Time Weighted Average
VCM	Value of Cancer Morbidity
VSL	Value of Statistical Life
WIG	Workers Interest Group
WPC	Working Party on Chemicals

1 INTRODUCTION

1.1 This methodological note and data collection synopsis

This methodological note and data collection synopsis summarises the methods used and data collected in the project '*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'*.

This note builds on similar documents developed in the framework of three previous OEL studies[1] undertaken for DG Employment, Social Affairs and Inclusion by RPA (Risk & Policy Analysts), COWI, FoBiG (Forschungs- und Beratungsinstitut Gefahrstoffe), and EPRD. Parts of the text have been extracted verbatim from reports previously published by RPA, COWI and FoBiG.

However, the methods used for previous studies have been further developed to reflect the experiences obtained in past projects carried out by the same study team and accommodate the specificities of the substances subject to this study. The areas developed as a result of experience in previous studies are:

- Air monitoring and administrative burden – this is a subject of considerable debate within the study team and the steering group; it is not specifically required by the CMRD, but the study team believes it is difficult to assess risk without including air monitoring. In some Member States such as Denmark, air monitoring is rare, whereas in others such as France and Poland is much more common. In addition, the study team is aware that even in these two Member States, few small companies undertake air monitoring. Therefore, the amount of monitoring has been reduced compared with the OELs4 and OELs5 studies, but there are still costs involved. The revised methodology is in section 7.2

The areas specifically required for the first time for this study are:

- Approach to welding fumes, see section 6;
- Biomonitoring and health surveillance, and associated administrative burden, see section 7.3;
- Approach to market effects, see section 8; and
- Approach to assessing the environmental impacts, see section 9

This document complements the five substance-specific reports produced under the same contract for:

- Welding fumes;
- Polycyclic aromatic hydrocarbons (PAH);
- Isoprene;
- 1,4-dioxane; and

[1] Socio-economic analysis collecting most recent information for a certain number of substances with a view to analyse the 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 or mutagens at work", OELs 3 (2017-18), OELs4 (2019-2020) and OELs 5 (2020-2021).

- Cobalt and inorganic cobalt compounds.

This note should be read in conjunction with the substance-specific reports – for some aspects, a more detailed description of the relevant methods is provided in the substance-specific reports; for other aspects, a more detailed account of the methods, data, and assumptions is provided in this report.

1.2 Objectives

European Commission by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe Prague (Czech Republic), RPA Europe (Italy), COWI A/S (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), Forcetechnology (Denmark) and EPRD Office for Economic Policy and Regional Development (Poland) has completed the following six reports:

- Methodological note;
- Report for 1,4-dioxane;
- Report for isoprene;
- Report for polycyclic aromatic hydrocarbons (PAH);
- Report for welding fumes; and

Report for cobalt and inorganic cobalt compounds.

The specific objective of this report is to set out the methods that underpin the assessment in the substance-specific reports, and to summarise the consultation exercise.

1.3 Previous studies

The study team has worked on several significant projects of particular relevance to this study, which are referred to throughout this report. These are:

- OELs3 - Study for DG Employment to collect information for substances with the view to analyse the 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 or mutagens at work. The six chemical agents were: cadmium and inorganic cadmium compounds, beryllium and inorganic beryllium compounds, arsenic acid and its salts, formaldehyde, chromium (VI) compounds and 4,4'-Methylene-bis(2-chloroaniline) (MOCA). The study involved extensive stakeholder consultation in all EU Member States and desk-based research. (2018a and 2018b RPA, COWI and FoBiG and EPRD);
- OELs4 - Study for DG Employment to collect information for substances with the view to analyse the 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 or mutagens at work. The four chemical agents were: acrylonitrile, benzene, nickel compounds and lead. The study involved extensive stakeholder consultation in all EU Member States and desk-based research. (2019, COWI, RPA, FoBiG and EPRD); and
- OELs5 - Study for DG Employment on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos). The three chemical agents were: asbestos, lead and its compounds, and

diisocyanates. The study involved extensive stakeholder consultation in all EU Member States and desk-based research (2021, RPA, COWI, FoBiG and EPRD).

1.4 Structure of the report

The report is organised as follows:

- Chapter 2 describes the approach to the assessment of all impacts;
- Chapter 3 describes how the Exposure Risk Relationships (ERRs) and Dose Response Relationships (DRRs) for estimating health impacts on workers were derived;
- Chapter 4 sets out the model used to estimate the incidence of ill health under the different scenarios and monetise the savings from avoided ill health (the assessment of the "benefits");
- Chapter 5 sets out the key features of the model for the assessment of the costs of OELs for all relevant substances except welding fumes;
- Chapter 6 sets out the key features of the model used for the estimation of the costs of OELs for welding fumes;
- Chapter 7 summarises the methodology for calculating the costs of air monitoring, biomonitoring and health surveillance, and the administrative burdens of these activities;
- Chapter 8 sets out the approach to assessing the market effects;
- Chapter 9 sets out the approach to assessing the environmental impacts;
- Chapter 10 provides the references; and
- Chapter 11 contains the annexes describing the consultation activities undertaken within the framework of this study.

2 APPROACH TO THE ASSESSMENT OF ALL 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 list is based on key impacts listed in the Better Regulation Toolbox, Tool #18.

The impacts considered by the study team to be the most significant are indicated with a "Yes" and a reference to the section in the substance-specific reports where the impacts are further analysed. The screening concern impacts of establishing an OEL for the substances/substance groups covered by the study or the inclusion of a substance into Annex 1 of the CMRD.

For each impact category with a No, a short remark describes the reasoning for determining that the impact is not among the most significant. For each impact category with a Yes, a reference is made to the relevant section and the reasoning is not further described in the table.

Table 2-1 Screening of potential key impacts of establishing an OEL at EU level for the substances and substance groups concerned

Impact category	Yes/No	Section in substance reports
Climate	N	No impacts expected
Quality of natural resources (water, soil, air etc.)	Y	7 Environmental impacts
Biodiversity, including flora, fauna, ecosystems, and landscapes	N	No impacts expected
Animal welfare	N	No impacts expected
Working conditions, job standards and quality	Y	3.3 Exposure concentrations
Public health & safety and health systems	Y	6.5 Benefits to public administrations
Culture	N	No impacts expected
Governance, participation, and good administration	N	No impacts expected
Education and training, education, and training systems	N	No impacts expected
Conduct of business	Y	8 Market effects
Position of SMEs	Y	8.4 SME competitiveness 11.2 SMEs
Administrative burdens on business	Y	7.2.11 Cost to companies of administrative burden 8 Market effects 11.1 Businesses

Impact category	Yes/No	Section in substance reports
Sectoral competitiveness, trade, and investment flows	Y	8.3 Single market 8.4 Competitiveness of EU business
Functioning of the internal market and competition	Y	8.3 Single market
Public authorities (and budgets)	Y	11.5 Taxpayers/public authorities
Sustainable consumption and production	N	No impacts expected
Efficient use of resources renewable & non-renewable	N	No impacts expected
Land use	N	No impacts expected
The likelihood or scale of environmental risks	Y	7 Environmental impacts
Employment	Y	8.5 Employment
Income distribution, social protection, and social inclusion of particular groups)	N	No impacts expected
Technological development / digital economy	Y	10.3 Impacts on digitalisation
Consumers and households	Y	11.4 Consumers
Capital movements; financial markets; stability of the euro	N	No impacts expected
Territorial impacts (specific (types of) regions and sectors)	Y	11.6 Specific Member States/regions
Innovation (productivity and resource efficiency); research (academic and industrial)	Y	8.2 Research and innovation
Fraud, crime, terrorism, and security, including hybrid threats	N	No impacts expected
Resilience, technological sovereignty, open strategic autonomy, security of supply	N	No impacts expected
Transport and the use of energy	N	No impacts expected
Food safety, food security and nutrition	N	No impacts expected
Waste production, generation, and recycling	N	No impacts expected
Third countries, developing countries, and international relations	N	No impacts expected

Impact category	Yes/No	Section in substance reports
Sustainable development	Y	9.4 Indirect impacts on the environment and environmental legislation 10.4 Contributions to the UN sustainable development goals
Fundamental rights	Y	10.2 Impacts on fundamental rights, including equality
Subsidiarity and proportionality principles	Y	14.5 Compliance with subsidiarity and proportionality principles

Source: Key impacts listed in the Better Regulation Toolbox, Tool #18

2.1 2019-2020 prices

All baseline estimates are for 2023 and the most recent data is used to derive estimates for 2023. However, the costs and benefits are calculated at approximately 2019-2020 prices. This is because the data being taken from Eurostat is for 2020 (or an average of 2018 and 2019, if 2020 data is poor or unavailable). Prices in the years up to 2020 were stable with minimal inflation. Prices have risen since 2020, sometimes significantly, particularly construction costs, but they are also now stabilising and sometimes dropping. As the ratio of costs to benefits is more important than their actual financial value, the study team has decided that it was better to use 2019-2020 values, than attempt to find 2023 values.

This means that the estimated values of both costs and benefits may be lower than reality. However, the relationship between them should be more robust than if the study team had taken 2023 prices, where available, adjusted other prices with factors that vary significantly between sectors, and in some cases attempted to adjust prices in areas where they are now falling.

2.2 Inflation

When adjusting financial values for inflation, the study team used the Bank of England for calculating the inflation (Bank of England, no date) and an average exchange rate for 2020, which was 1.1248 EUR (Exchange Rates, no date). Values over €1,000 are rounded to the nearest hundred euro.

2.3 Assessment period

The assessment period for this study is 40 years. Whatever the chosen assessment period, the potential ill-health endpoints due to exposure to a substance during the assessment period are included in the calculations of the cases and costs, even if latency, see section 4.3.1.3, means that the endpoint occurs many years after the assessment period. For example, if the assessment period is 40 years and the latency of lung cancer is 30 years, cases of lung cancer occurring for the next 70 years are included in the calculations.

For practical reasons, the assessment period should be a multiple of 20 years, because the investment cycle in the cost model is assumed to be 20 years. This means that investments in major industrial equipment, for example risk management measures (RMMs) such as closed systems, are assumed to take place every 20 years. If these RMMs require major investment at the start of the assessment period, the assumption is that they will require similar major additional investment when they are replaced or renovated in 20 years' time.

If company discontinuations are predicted, see section 5.5.1, all of these costs fall at the start of the assessment period with no repeat investment cycles. In these cases, the benefits will nevertheless continue for many years, so the longer the assessment period, the lower the cost to benefit ratio (CBR).

These facts mean that the choice of the assessment period is a balance: a shorter period leads to a higher CBR as fewer benefits are included, but all of the initial costs. A longer assessment period of say 60 years has a lower CBR, but with discount factors, the value of the benefits at 90 years if, for example, the latency was 30 years, becomes insignificant.

For the studies OELs1 to OELs4, the assessment period was set to 60 years. During OELs5, the assessment period was changed to 40 years with the agreement of DG Employment and the study's steering group, which included representatives of the Employers Interest Group (EIG), Government Interest Group (GIG), Workers Interest Group (WIG), of the Working Party on Chemicals (WPC). The decision to change the assessment period was taken for two reasons:

- It is a better compromise as there is little difference in CBRs between 40 years and 60 years due to the discount factors; and
- A 40 year assessment period was felt to be more in tune with the average working life, which is also taken as 40 years.

The study team believes that 40 years is a sensible assessment period for this study and its continued use enables figures from OELs6 to be directly compared with OELs5.

3 DERIVATION OF THE ERRS AND THE DRRS

3.1 Introduction

One of the criteria for the selection of a limit value (OEL or BLV) for a specific substance is the estimated impact on occupational health. Therefore, a method for the estimation of the 'health impact' is required, where this term is defined as the number of people ("cases") either suffering from cancer and/or non-cancer health effects due to occupational exposure to the relevant substance.

This section deals with the principles of this estimation procedure. A detailed explanation of how the specific inputs such as the dose response relationships were derived is given in each of the substance-specific reports in the sections:

- 2.1 Summary of epidemiological and experimental data; and
- 2.2 Deriving an Exposure Risk Relationship (ERR) for carcinogenic effects and a Dose Response Relationship (DRR) for non-carcinogenic effects.

The excess health risk at different potential OEL or BLV levels is based on:

- Exposure Risk Relationship (ERR) for cancer risk; and
- Dose Response Relationship (DRR) for non-cancer effects.

A specific excess risk of ill health is then estimated for specific OEL or BLV values based on the ERR/DRR and the actual/predicted exposure for each exposure scenario. The health effects are subsequently monetised for the purposes of a Cost Benefit Analysis (CBA).

The respective methodologies to derive (and to apply) the ERRs and DRRs are summarised in this section.

The following restrictions should be borne in mind:

- Existing toxicological and epidemiological data in regulatory toxicology have usually not been generated and prepared to enable researchers to estimate impacts for a range of exposure levels across multiple health effects. Often, the focus of the analysis of toxicological data is to provide only one point estimate for a *safe* (or *low risk*) level of exposure based on one critical health effect. Usually, at this level the national OEL or BLV is set and no "cases" of health impairment are assumed to occur if the limit is observed; and
- Some dose response or exposure risk relationship data are, in fact, considered by the respective assessors, but those are usually only provided for a single scenario and often can only be derived from experimental animal study data. In the course of extrapolating to the relevant occupational exposure scenario, such existing dose response data are usually not transformed and adapted to a range of target scenarios. Once a 'safe' OEL/BLV has been determined, the effects at levels well above that OEL/BLV are rarely discussed. For example, if a toxicologist finds respiratory irritation in an animal study as the critical (lowest) adverse effect and they also find neurotoxicity and immunological impairments at an, e.g., ten times higher level of exposure, they would typically focus on the safe level for respiratory irritation effects to quantitatively determine the most appropriate OEL and complement this with a qualitative discussion of the neurotoxic and immunological effects at higher exposure levels. In addition, the dose response curve for respiratory irritation from

experimental animal data is typically not systematically transformed into a DRR for a worker at exposure levels above the 'safe level' OEL.

As a result of these limitations, this study (and the previous OEL studies carried out for DG Employment, Social Affairs and Inclusion by this consortium) had to develop methods to estimate health impact for a range of relevant health effects identified by Committee for Risk Assessment (RAC), this includes both cancer (one or several cancer sites) and non-cancer effects, including dose response relationships for the relevant exposure range above a threshold for effects. Due to the limited quantitative dose response input data in many cases, these should be treated as indicative of the "true" health impact rather than as precise estimates.

In conclusion, the study team:

- Applies the ERR on the most critical cancer sites, which are given by the assessment of the European Chemicals Agency / Committee for Risk Assessment (ECHA/RAC), and only comment qualitatively on further cancer sites, which may be linked to exposure to the respective substance, but are expected to contribute less to the overall excess cancer risk from this substance;
- Refers to the most critical non-cancer effects quantitatively to derive DRRs; for this, the effects, which were regarded as the most critical ones by RAC in the relevant range of workplace exposures are selected and only qualitative comments are given on further non-cancer effects, which may be linked to exposure to the respective substance at higher exposure levels only or which might be of unclear health significance; and
- As there is even less scientific consensus on the increase of effect severity with increasing exposure concentration and the respective data are often not adapted to the workplace exposure scenario, the study team focuses on the *fraction of workers affected* at the different exposure levels when a DRR is established, without taking into account the increase of severity of effects. The potential severity of these effects is subsequently taken into account in the process of monetisation of their incidence estimated on the basis of the DRR.

These limitations suggest that the health impacts estimated in this study are only an approximation of the 'real' health impacts which may underestimate the full impact of the occupational exposure to the respective substances. However, as shown in the sensitivity analyses, there are also uncertainties that may result in overestimation of these impacts. In addition, a further complication is the 'number of cases' for multiple health effects, as there may be many individuals, which will suffer from more than one health effect due to occupational exposure simultaneously. Therefore, an additivity assumption for the number of cases would not be correct (significant overestimate).

Despite these limitations, it is expected that the health impacts estimated in this study do not lead to a systematic bias in the final selection of an OEL or BLV.

3.2 Methods to derive the ERRs and DRRs

3.2.1 Data bases and approaches used

In this project, 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 the 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 and RAC focussed on the non-cancer endpoints for the derivation of an OEL. This is due to the fact that 1,4-dioxane-mediated carcinogenicity is only relevant above the saturation level of metabolism, which is above 180 mg/m³ in humans. 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 scope for the current study.

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

Work on welding fumes focussed on the policy option of including this process-generated mixture into Annex I of the CMRD. Discussing options for setting an OEL was not intended in the frame of this study. No RAC opinion was available. 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. Due to this differing focus and the absence of reliable dose response data for cancer and non-cancer health effects neither ERRs nor DRRs were 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 included in the meta-analysis.

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. Human relevance means that existing information makes it likely that effects might occur in humans at exposure levels relevant to the policy options considered in this study. Human data are preferred over experimental animal data. Experimental data are used as supportive information only where insufficient human dose response information is available to derive a DRR.

Data from original toxicological and epidemiological studies, referenced by RAC or national committees as being qualified and demonstrating a dose response, have been examined for effect levels linked to a specific fraction of the exposed humans (or animals). If not contradicted by the overall weight of evidence, this slope reported in such a study is adopted for the DRR. If effects are reported on a continuous scale, this needs to be transformed to quantal data (i.e., the incidence of effects in the exposed population), which often requires certain assumptions.

As the threshold for non-cancer effects can be different to that for cancer effects, the starting point for the DRR may be different from the starting point for the ERR.

For each substance and endpoint, specific starting points (associated with zero risk) were identified for the DRRs. By definition, the starting points cannot be lower than the OEL proposed by RAC. These starting points were typically based on a NOAEL for the respective endpoint. Adaptations to the workplace scenario and assessment factors as recommended for the derivation of DNELs and OELs (according to ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.8) were applied to derive an effect specific "DNEL" (for example a DNEL for developmental toxicity).

For determining the effect size associated with concentrations above this starting point dose response data reported in the key studies were used. Again, adaptations to the workplace scenario, as well as time extrapolation factors (if needed, due to insufficient study duration) and allometric scaling factors (in case of animal data) were applied. However, no interspecies (for considering potential but unknown additional species differences) and no intraspecies assessment factors were applied. This is because the objective in this step is to estimate the fraction of affected workers at a certain exposure concentration. Applying an intraspecies factor would lead to a concentration where the most sensitive individuals would experience effects but not the whole worker population, for which the fraction affected is sought.

The scientific basis for the substance-specific ERRs and DRRs, and reference to ERRs and DRRs derived by various scientific bodies, are described in detail in each of the substance-specific reports in section 2.2, "Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)"

3.2.2 Time to tumour and latency

The slope of the ERR presented may implicitly be influenced by latency. However, there is no explicit "risk/time to tumour-relationship" considered in the toxicological part of this study. Some tumours may occur early within the exposure period of a worker or may occur late – even some time after the potential 40 years of employment (i.e. after retirement). Latency depends on the target organ, exposure concentration and the mode of action. If available, latency information is documented in the respective substance report, but note that this information is rarely available in sufficient detail (e.g., distribution data of latency within the population are usually not available).

However, time to tumour and latency influences the point in time in future when reduction in exposure resulting from a new OEL/BLV/STEL translates into a reduction in excess cancer risk (at population risk level). Therefore, separately from the toxicological input, the calculated baseline (number of cases presently) and assumptions on the return of benefits and costs in future time, if an OEL, BLV or STEL is set this year or later in future, may need some assumptions about latency. Unless stated otherwise in the relevant substance report, these latency assumptions are general default values also used in the previous OEL studies carried out by the study team (e.g. 10-50 years for solid tumours, average: 30 years).

For simplicity, it is assumed that tumour induction is linearly linked to exposure duration, which is, in reality only true for carcinogens with strictly accumulating risks. Even then, no strict linearity will be observed: some short exposure duration may not be sufficient to develop tumours at all. On the other hand, few exposure years may already be decisive to result in an identical excess tumour risk as if one is exposed over their entire working life. However, correlation of exposure duration with tumour risk is substance-specific and not further considered within this study due to the complexity of assumptions necessary for subsequent impact calculations.

If substance-specific information is available, the estimated latency for each of the substances is described in the substance-specific reports in section 2.2, "Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)".

4 ESTIMATION AND MONETISATION OF THE HEALTH IMPACTS

4.1 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.

This methodology section deals with the principles of this estimation procedure. The specific procedures used for the derivation of the parameters used for each of the substances are described in each of the substance-specific reports.

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

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

Table 4-1 BR Toolbox on health impacts

Aspect	Guidance
Health impacts	Direct impacts Indirect impacts: does the policy option influence the socio-economic environment that can determine health status? To assess direct and indirect health impacts monetary and non-monetary methodologies can be used. Non-monetary approaches: Quality adjusted life years (QALYs), Disability adjusted life years) (DALYs), Healthy life years (HLYs). Monetary approaches: preference-based approaches Willingness to pay (WTP), Willingness to accept (WTA) -> Value of Statistical Life (VOSL), Value of Life-Year (VOLY), accounting-style approaches (cost of illness method=only medical expenses, human capital method=loss of future earnings in case of disability or premature death)

Source: Better Regulation (BR) Toolbox for health impacts (BR Tool #31)

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

- **Direct costs:** These are the costs of healthcare, in other words, 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 (taxpayers) may also bear the costs of any disability/social security payments and will also suffer losses through foregone tax receipts; and

- **Intangible costs:** These include the non-financial 'human' losses associated with cancer, e.g. reduced quality of life, pain, suffering, anxiety and grief.

This note focuses on the methods used to estimate the cost savings (benefits) from reduced ill health. Other indirect benefits included the avoided cost of a Member State implementing a limit value on its own, see section 4.7. Some indirect benefits are specific to the substance and are described in the substance specific reports.

4.1.2 The model

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

Table 4-2 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 Bladder cancer*	Developmental toxicity Male reproductive toxicity (infertility)
Welding fumes	Lung cancer	
1,4-dioxane	None	Kidney effects Liver effects Local irritation: effects in nasal cavity

Source: Analysis by RPA, COWI & FoBiG
*Notes * only analysed in sensitivity analysis*

The primary ill-health effects of these endpoints are shown in the following table.

Table 4-3 Primary ill-health effects from each endpoint

Carcinogenic endpoints	Non-carcinogenic endpoints
Lung cancer	Mortality, lethargy, breathlessness, loss of appetite/weight loss
Liver cancer	Mortality, lethargy, loss of appetite/weight loss, feeling tired/unwell
Bladder cancer*	Mortality, lethargy, loss of appetite/weight loss, feeling tired/unwell
Restricted lung disease	Dyspnoea, increased difficulty breathing
Upper airway irritation	Running or itching nose, sore throat, irritated eyes

Carcinogenic endpoints	Non-carcinogenic endpoints
Degeneration of olfactory epithelium	Loss of sense of smell
Degeneration of spinal cord white matter	Mild Parkinson's disease is taken as a proxy: mild tremors, sleep problems, loss of sense of smell
Developmental toxicity	Miscarriage or stillbirth in pregnancy
Male reproductive toxicity (infertility)	Reduced sperm motility resulting in lower chances of conception
Kidney effects	Acute Kidney Injury (AKI) Stage 1, potentially some of the following: feeling sick or being sick, diarrhoea, dehydration, reduced urination, confusion, drowsiness
Liver effects	No specific symptoms but indicative of adverse changes in the liver
Local irritation: effects in nasal cavity	Running or itching nose

Source: Analysis by RPA, COWI & FoBiG
*Notes * only analysed in sensitivity analysis*

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 4-4 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: Analysis by RPA, COWI & FoBiG

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 below.

Table 4-5 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: Analysis by RPA, COWI & FoBiG

The model provides an approximation of the order of magnitude of the expected impacts and the core calculations are supported by sensitivity analysis. The outputs of the model include:

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

4.2 Inputs

4.2.1 Dose/exposure risk relationship

The risk of developing the relevant effect is estimated by combining exposure concentrations with:

- For cancer: Exposure Risk Relationship (ERR), i.e. excess risk of developing cancer due to lifetime occupational exposure to a substance (40 years); or
- For non-cancer endpoints: Dose Response Relationship (DRR), i.e. the proportion of workers that will develop an endpoint when exposed to a certain level of exposure. The DRR typically is defined for the health endpoint as it occurred in the underlying study and does not provide an indication for progression of disease severity. This is taken into account in the course of monetisation of the cases estimated by the model.

4.2.2 ExW: exposed workforce

The sources of data and assumptions used to estimate the numbers of workers exposed to the relevant substance are detailed in the substance-specific reports, together with the expected future trends.

As a default value, in the previous OEL studies 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.

The study team believes 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 study, the default staff turnover of 5% per year used in the previous studies is retained for purposes of consistency.

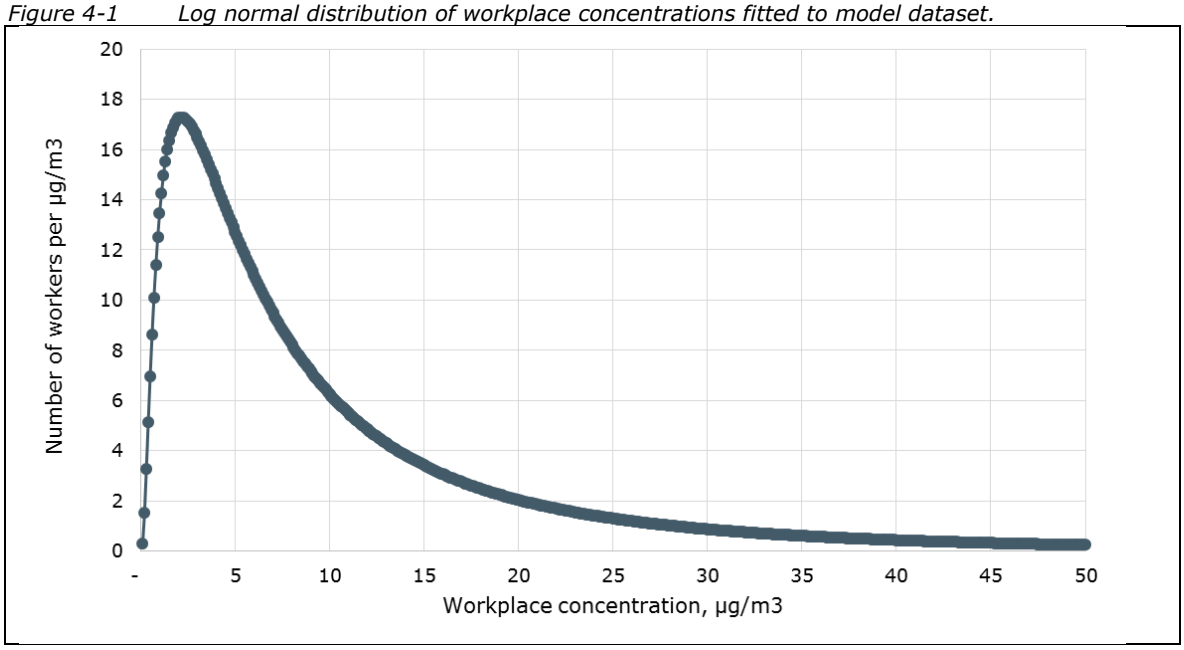
In a meta study of exposure in the hard-metal industry covering 32,354 workers, Marsh et al. (2017) reported that 30.4 % were employed for less than 1 year, 24.4% had an employment duration of 1-4 years, 26.7% had 5-19 years and 18.4% at least 20 years. If it is assumed that the fourth group covers the 20-40 years period, the average exposure time would be about 12.5 years. Moulin et al. (2000) studied a cohort of workers in the French stainless steel industry. The cohort comprised 4,897 subjects with a mean duration of employment of 17 years.

4.2.3 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 OEL and BLV 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 50^{th}, 75^{th}, 90^{th} and 95^{th} percentiles are estimated (please note that these parameters may differ between substances). An example of a log-normal distribution of exposure concentrations is given below.

Figure 4-1 Log normal distribution of workplace concentrations fitted to model dataset.



Source: Analysis by RPA, COWI & FoBiG

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.

Where such information is available, the study team has tried to establish for all reported data whether these are a result of personal or stationary sampling and whether they reflect exposure with or without wearing personal protective equipment (PPE).

Exposure concentration estimates 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.

4.2.4 Values used in the benefits and costs models

In both the benefits and costs models, the enterprises with exposed workers are split into five percentile groups. The exposure level assumed to be experienced by each group is calculated as shown in Table 4-6.

Table 4-6 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

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for mod-elling
91 - 95	5%	Arithmetic mean of 90th and 95th percentiles
96 - 100	5%	Geometric mean of 95th and 100th percentiles

Source: Study team

4.2.5 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 Box 4-1.

Box 4-1 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 OEL, 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: 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 in this study as follows:

- The 95th percentile of the current exposure distribution (air or biomonitoring concentrations) is compared with the policy option (OEL and/or 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; and
- 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.

4.3 Assumptions

4.3.1 Onset of the disease

4.3.1.1 MinEx & MaxEx - The minimum and maximum exposure duration required to develop the endpoint

No cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has been reached (see Table 4-7 below). No further increase in risk is assumed to arise with increasing exposure time after exceeding the MaxEx.

The basis for estimation of MinEx and MaxEx for each of the substances is described in the substance-specific reports. The default MinEx is two years for cancer, a standard assumption for a chronic condition. However, for practical reasons, the risk of developing cancer is assumed by the model to start in the first year of exposure and accumulate in a linear fashion up to a full risk estimated on the basis of the ERR after 40 years of exposure – this may lead to a slight overestimation of the risk. The minimum exposure (MinEx) periods in the table below have been derived using a precautionary approach that maximises worker protection.

The MaxEx reflects the time needed to reach the maximum risk estimated on the basis of the ERR/DRR and exposure concentration or biomonitoring. MaxEx is either based on the situation in the key studies used to derive the DRR (if workers were exposed for ten years in that study, it has been proposed that MaxEx is ten years because this was the exposure time leading to the effect size used for the DRR) or converted to a full working life (40 years).

If the exposure required to trigger the endpoint is low and the ill-health effect is permanent, such as the loss of the sense of smell (degeneration of olfactory epithelium), MaxEx is set to one year. If the exposure required to trigger the endpoint is low and the ill-health effect is not permanent, but could repeatedly occur, such as most forms of irritation, then MaxEx is set to zero to enable the benefits model to handle this differently.

Table 4-7 Minimum and maximum exposure duration to develop a condition (MinEx and MaxEx)

Substance	Endpoint (ERR or DRR)	MinEx (years)	MaxEx (years)
	Lung cancer	0	40

Substance	Endpoint (ERR or DRR)	MinEx (years)	MaxEx (years)
Cobalt and inorganic cobalt compounds	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 fumes	Lung cancer	0	40
1,4-dioxane	Kidney effects	0	1
	Liver effects	0	1
	Local irritation: effects in nasal cavity	0	0

Source: Analysis by RPA, COWI & FoBiG

4.3.1.2 Dist - the distribution of cases over time

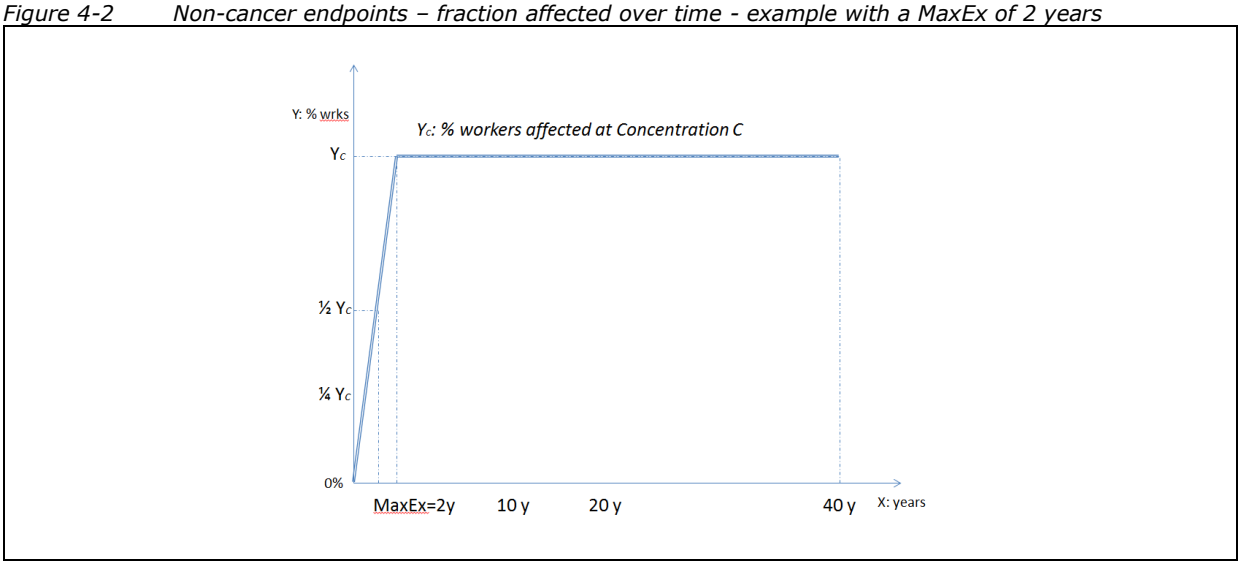
Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over the period between MinEx and MaxEx are assigned to specific years.

The distribution of cases between the 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).

For reasons of simplicity, the following approach is used to distribute the total **risk** (i.e. not incidence since incidence is delayed due to latency) over the 40 period assessed in this study. As noted above, although in theory no risk arises until the MinEx of two years has expired, for practical reasons, the models used for this study adopt a conservative approach and assume that risk arises from Year 1. 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 4-2 Non-cancer endpoints – fraction affected over time - example with a MaxEx of 2 years



Source: Analysis by RPA, COWI & FoBiG

4.3.1.3 Lat - Latency

The estimated risk is combined with latency to estimate the specific year of diagnosis of a case.

Cancer endpoints

By way of simplification, default latency values are used unless more detailed estimates exist for the specific substance. According to Rushton et al. (2012), all solid tumours are expected to have a latency of 10-50 years, meaning that the average latency is 30 years, however the latency for liver cancer is lower with a range of 10-25 years (Bevan et al., 2012), giving an approximate average latency of 18 years.

Latency periods for the cancer endpoints are shown in the table below. The information about latency for each of the substances is described in section 3.13.2 of the PAH report and section 3.13.2 of the cobalt report.

Table 4-8 Latency (Lat) periods of cancer endpoints

Substance	Endpoint	Latency (years)
Cobalt and inorganic cobalt compounds	Lung cancer	30
Polycyclic aromatic hydrocarbons (PAHs)		
Welding fumes		
Isoprene	Liver cancer	18

Source: Analysis by RPA, COWI & FoBiG

Non-cancer endpoints

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

Table 4-9 Latency (Lat) 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
Polycyclic aromatic hydrocarbons (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: Analysis by RPA, COWI & FoBiG

4.3.1.4 Summary

By way of summary, the method used in the model to estimate the incidence of disease and the relevant costs over time is shown graphically below.

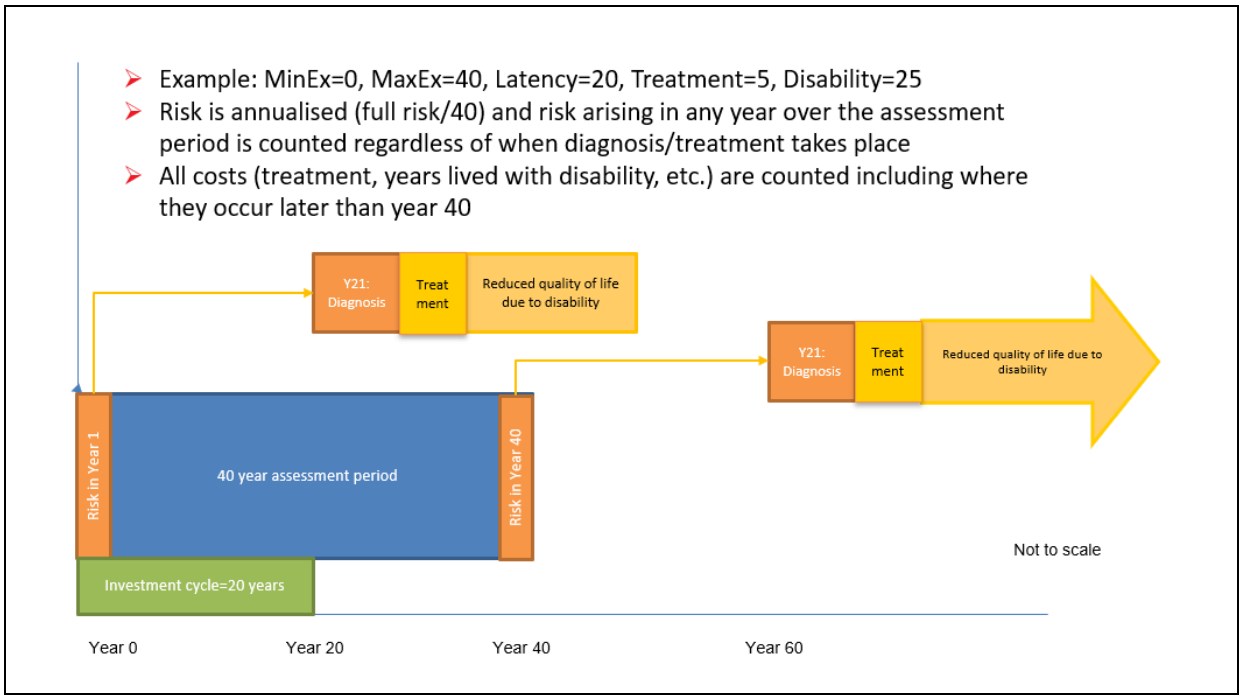


Figure 4-3 Incidence and costs of disease over time

Source: Analysis by RPA, COWI & FoBiG

4.3.2 The effects of the disease

4.3.2.1 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.

The mortality rate for lung cancer is derived from two sources in the USA and UK

> *The five-year survival rate for lung cancer is 56 percent for cases detected when the disease is still localized (within the lungs). However, only 16 percent of lung cancer cases are diagnosed at an early stage. For distant tumors (spread to other organs) the five-year survival rate is only 5 percent. (SEER Cancer Statistics Review, 1975–2015)*

> *Generally, for people with lung cancer in England: around 40 out of every 100 people (around 40%) survive their cancer for 1 year or more; around 15 out of every 100 people (around 15%) will survive their cancer for 5 years or more; and 10 out of every 100 people (10%) will survive their cancer for 10 years or more (Cancer UK, no date a)*

From these values, the mortality rate for lung cancer is broadly estimated at 80% for all stages at which it is detected.

The mortality rate for liver cancer is derived from two sources in the USA and UK

> *The five-year survival rate for liver cancer is 36 percent for cases detected when the disease is still localized (within the liver). However, only 13 percent of liver cancer cases are diagnosed at an early stage. For distant tumors (spread to other organs) the five-year survival rate is only 3 percent. (SEER Cancer Statistics Review, 1975–2015)*

> *40 out of 100 people (40%) will survive liver cancer for 1 year or more after diagnosis; and almost 15 out of 100 people (almost 15%) will survive liver cancer for 5 years or more after they are diagnosed (Cancer UK, no date b)*

From these values, the mortality rate for liver cancer is broadly estimated at 90% for all stages at which it is detected.

The mortality rate for bladder cancer is derived from two sources in the USA and UK

> *The five-year survival rate for liver cancer is 96% and 70% for percent for cases detected when the disease is still in-situ alone and localised, respectively. In the case of regional tumours, the survival rate drops to 39% and for distant tumours (spread to other organs) the five-year survival rate is only 8%. (SEER Cancer Statistics Review, 1975–2015)*

> *75 out of 100 people (75%) will survive bladder cancer for 1 year or more after diagnosis; almost 55 out of 100 people (almost 55%) will survive bladder cancer for 5 years or more after they are diagnosed; and around 45 out of 100 people (around 45%) will survive bladder cancer for 10 years or more after diagnosis (Cancer UK, no date c)*

From these values, the mortality rate for bladder cancer is broadly estimated at 50% for all stages at which it is detected.

Table 4-10 Mortality rate (MoR) over five years

Substance	Endpoint	Mortality rate
Cobalt and inorganic cobalt compounds	Lung cancer	80%
	Restricted lung disease	0

Substance	Endpoint	Mortality rate
	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 fumes	Lung cancer	80%
1,4-dioxane	Kidney effects	0
	Liver effects	0
	Local irritation: effects in nasal cavity	0

Source: SEER Cancer Statistics Review, 1975–2015, Cancer UK, no date a (based upon NHS England (2021) and ONS (2018)), Cancer UK, no date b (based upon NHS Digital (2020)), Cancer UK, no date c a (based upon NHS England (2021) and ONS (2018)) and analysis by RPA, COWI & FoBiG
*Notes * only analysed in sensitivity analysis*

4.3.2.2 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.

The five year survival period for cancer is also important as costs for cancer treatment are often given over five years. The endpoints with treatment periods of one year are usually endpoints that only have a short treatment period, one year is the minimum that the model can allocate costs against. These endpoints could recur. Miscarriages are taken as having a treatment period as 20 years because the effect is long term and the worker could continue having miscarriage over a long period.

Table 4-11 Treatment period

Substance	Endpoint	Treatment period (years)
Cobalt and inorganic cobalt compounds	Lung cancer	5
	Restricted lung disease	1
	Upper airway irritation	1

Substance	Endpoint	Treatment period (years)
Isoprene	Liver cancer	5
	Degeneration of olfactory epithelium	1
	Degeneration of spinal cord white matter	1
Polycyclic aromatic hydro-carbons (PAHs)	Lung cancer	5
	Bladder cancer*	3
	Developmental toxicity (miscarriage)	20
	Male reproductive toxicity (infertility)	1
Welding fumes	Lung cancer	5
1,4-dioxane	Kidney effects	1
	Liver effects	1
	Local irritation: effects in nasal cavity	1

Source: Analysis by RPA, COWI & FoBiG

*Notes * only analysed in sensitivity analysis*

4.3.2.3 Monetary value of the relevant endpoint

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

Table 4-12 Cost saving framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemother-apy/immunotherapy, etc.
	Informal care[2]	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 ab-sence 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	

[2] 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.

Category	Cost	Notes
	Approach 1 WTP: Morbidity	A monetary value of the impact on quality of life of affected workers
	Approach 2 DALY: Mortality	
	Approach 2 DALY: Morbidity	

Source: Analysis by RPA, COWI & FoBiG

All of the costs in the table above have been quantified to ensure that the study can estimate the impacts on individual stakeholder groups. The approach to the derivation of the costs for each of the cost categories above is set out below.

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

- Method 1: Application of WTP (Willingness to pay) values to each case (differentiating between mortality and morbidity); and
- 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.

4.3.2.3.1 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 (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 Box 4-2 below. Value of morbidity required for non-cancer endpoints by Method 1 are summarised in Table 4-13.

Box 4-2 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. The mid-point (€4,250,000) is used, 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 (ECHA 2016). This figure has been updated to 2021 prices: **€455,000.**

Source: Based on ECHA's WTP reference values mentioned in Better Regulation Tool#32
Note: Eurostat's GDP deflator (Dataset: GDP and main components (output, expenditure and income) [namq_10_gdp]) which provides the following result: 2021/2012: 1.108.

Table 4-13 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 (ECHA 2016)	€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 (Sturkenboom et al, 2015) Five WTP thresholds for a QALY gained were used: 0, 20,000, 40,000, 60,000, and 80,000 euro. 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 (ECHA 2017). This value covered early and later miscarriages and stillborns, and was therefore reduced by two thirds, and adjusted for inflation.	€9,600
Male reproductive toxicity (infertility)	Based on WTP of couples with infertility problems to conceive of €22,000 at 2012 (ECHA 2017), adjusted for inflation.	€30,000
Kidney effects	Based on WTP for temporary kidney effects €532 in 2012, taken as €1,000 for 2021, as	€1,000

Endpoint	Comment	Value of morbidity - VM
	unclear just how temporary these effects are (ECHA, 2016)	
Liver effects	Liver effects (temporary) taken as being the same as kidney effects (ECHA, 2016)	€1,000
Local irritation: effects in nasal cavity	Based upon WTP for skin irritation, twice a year for 10 years, €447 (ECHA, 2016)	€500

Source: ECHA, 2016 and ECHA, 2017, with analysis by RPA, COWI & FoBiG

Method 2 is summarised below.

Box 4-3 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: Analysis by RPA, COWI & FoBiG based on Better Regulation Tool #31

4.3.2.3.2 Years of life lost due to premature mortality

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.

4.3.2.3.3 Average disease duration after treatment

The average disease duration after treatment is given below.

Table 4-14 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 fumes	Lung cancer	5
1,4-dioxane	Kidney effects	1
	Liver effects	1
	Local irritation: effects in nasal cavity	1

Source: Analysis by RPA, COWI & FoBiG

*Notes * only analysed in sensitivity analysis*

4.3.2.3.4 Disability weight

There are two main sources of disability weights. The first is taken from the WHO Global Burden of Disease (GBD) study (WHO 2015) which was updated in 2015. The second set of weights are taken from the European Disability Weights Project (2015) conducted by the European Centre for Disease Prevention and Control (Haagsma 2015).

For this study, the disability weights derived in the GBD 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.

Table 4-15 Disability weights used in this study

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

Endpoint	During treatment	After treatment
Liver effects	0.016	0
Local irritation: effects in nasal cavity	0.006	0
Lung cancer	0.265	0.515
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: Analysis by RPA, COWI & FoBiG

*Notes * only analysed in sensitivity analysis*

An issue with the use of DALYs is that they measure health loss, rather than welfare loss and so the weights derived through these studies do not necessarily reflect the welfare losses suffered through illness. This may have consequences for their use in this study, as they may underestimate the true welfare losses from an illness for an individual. Haagsma et al. (2014) also note that valuations can vary significantly across countries, due to clear contextual differences in the ways people perceive health problems and how they affect their lives.

Box 4-4 Valuing a DALY

Valuing a DALY

To obtain the value of a DALY, the Value of a Statistical Life must be divided by the number of DALYs corresponding to a premature death. This number varies and is a function of the age at which death occurs, which itself depends on the nature of the risk considered (here, chemical exposure health impacts).

From the brief review conducted, there are several valuations for DALYs presented in the literature. For example, Stassen et al. (2007) estimate that the cost of a DALY for severe morbidity health effects is €87,000. A study by Highfill and Bernstein (2014) values a DALY averted as the value of a year of life in full health and sets this as being in the range of $100,000 to $200,000. This is equivalent to a range between €63,500 and €127,000. However, the study recommends the use of the lower estimate.

Source: Analysis by RPA, COWI & FoBiG and the sources mentioned in the box

The value of a DALY used in this study is €100,000.[3]

4.3.2.3.5 Cost savings for employers

Introducing OELs have 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 occupational illness. Such cost savings include:

[3] Although the same value was also used in previous Impact Assessments of OELs elaborated for DG Employment (starting in 2017/18: https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8224&furtherPubs=yes), a decision was taken not to adjust this value for inflation since the value used originally was an approximation of the order of magnitude rather than a precise estimated and was already rounded up.

- 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:

- Reduced productivity of the injured employee after re-employment;
- Costs of a replacement (difference in salary, reduced productivity);
- Overtime of colleagues to compensate;
- Rehabilitation costs (those paid by employer);
- Medical costs (those paid by employer);
- Administrative follow-up;
- Reorganising the work; and
- Training the replacement (time of the trainer).

The study collected data on these cost categories as well as compiling information about 400 cases of worker accidents and ill health. These cases were from 13 sectors including construction, transport and the chemical sector, though the numbers of cases linked to the latter were limited.

Although there are reasons for caution in interpreting this result[4], this estimate has been updated to 2021[5] resulting in **€13,200** being the value to employers of avoiding a single case of a high-severity accident or disease – this value was used in the 'cost saving/benefit' model for all substances. The method of summing up the different cost savings (benefits) is set out in Section 3.4 of this report.

No values of cost savings for employers are available for non-cancer endpoints, but the study team believes that there would 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

[4] The study only considered a small sub-set of health endpoints and so the costs estimated may be too generic and are likely to underestimate the costs to the employer of the most severe endpoints such as occupational cancer.

[5] 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.

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/reputational 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.

4.3.2.3.6 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. (2013) developed estimates of the magnitude of such costs by Member States 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 (Vencovsky, 2020, table 3.3).

4.3.2.3.7 Cost savings for the public sector - cost of healthcare

Cancer

Each lung cancer patient costs the UK healthcare system £9,071 annually (Cancer UK, 2012). 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 (Cullen, 2023). 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 £5,000 per year (Cox et al. 2020), which converted to euros the cost would be roughly €5,600.

Table 4-16 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: Cancer UK, (2012), Cox et al. (2020) and Cullen (2023)

*Notes * only analysed in sensitivity analysis*

Non cancer

A mild Parkinson's disease is used as a proxy for degeneration of spinal cord white matter. According to Weir et al. (2018), 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 (Tommys, 2022) and an academic paper modelling the economic costs of stillbirth (NIHR, 2021). 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 stillbirth and miscarriage, which have varying degrees of severity and, therefore, 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 4-17 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
Developmental toxicity – women – miscarriage	€3,500
Male reproductive toxicity - infertility	€1,400

Source: Analysis by RPA, COWI & FoBiG

4.3.3 Summary of the monetary values used

The unit costs used for monetisation are summarised below. Please note that some of the costs set out in the preceding sections have been rounded.

Table 4-18 Unit costs used for monetisation of ill health caused by occupational exposure

Endpoint	Direct costs			Indirect costs		Intangible costs		
	Healthcare	Informal care	Costs for employers	Mortality – productivity loss	Morbidity – lost working days	Approach 1 WTP: Mortality	Approach 1 WTP: Morbidity	Approach 2 DALY: Morbidity
Lung cancer	€11,500	€3,000	€13,200	€5,000	€1,000	€4,710,000	€455,000	€100,000
Liver cancer	€5,500	€3,000	€13,200	€5,000	€1,000	€4,710,000	€455,000	€100,000
Bladder cancer*	€5,600	€3,000	€13,200	€5,000	€1,000	€4,710,000	€455,000	€100,000
Kidney effects	€1,000					€4,710,000	€1,000	€100,000
Liver effects	€500					€4,710,000	€1,000	€100,000
Restricted lung disease	€1,000					€4,710,000	€3,300	€100,000
Upper airway irritation	€500					€4,710,000	€700	€100,000
Local irritation: effects in nasal cavity	€500		€500		€500	€4,710,000	€500	€100,000
Degeneration of olfactory epithelium	€500					€4,710,000	€32,000	€100,000
Degeneration of spinal cord white matter	€3,100	€1,000	€5,000		€1,000	€4,710,000	€1,000	€100,000

Endpoint	Direct costs			Indirect costs		Intangible costs		
	Healthcare	Informal care	Costs for em-ployers	Mortality – productivity loss	Morbidity – lost working days	Approach 1 WTP: Mortality	Approach 1 WTP: Morbidity	Approach 2 DALY: Morbid-ity
Developmental toxicity – women – mis-carriage	€3,500				€2,800	€4,710,000	€9,600	€100,000
Male reproduc-tive toxicity - infertility	€1,400					€4,710,000	€30,000	€100,000

Source: Analysis by RPA, COWI & FoBiG

*Notes * only analysed in sensitivity analysis*

4.4 Bringing it all together

The cost savings (benefits) that have been estimated for each substance are summarised below.

Table 4-19 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

Source: Analysis by RPA, COWI & FoBiG

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.

Methods 1 and 2 rely on two different approaches to the monetisation of ill health. Both approaches monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption costs to employers) and indirect (productivity/lost earnings[6]) impacts. However, they rely on different approaches to assign monetary values to intangible effects such as reduced quality of life, pain, suffering, anxiety and grief. Under Method 1, published or estimated Willingness-to-Pay (WTP)[7] values are used to monetise the intangible benefits. Method 2 relies on published or estimated disability weights[8] for specific diseases to estimate the avoided Disability-Adjusted Life Years (DALYs) and subsequently monetises these using a generic monetary value for a single DALY (€100,000 in this study). Methods 1 and 2 are not only different approaches but their use in this study relies on different sources of data. The two approaches are not intended to produce the same estimate or provide a lower and upper bound of a potential range. The results of both approaches should be considered together as indicative of the order of magnitude of the relevant impacts.

As noted above, the two methods rely on different approaches to the estimation of intangible costs of ill health. As a result, they rely on different data inputs and these are not consistently

[6] This is not the case where lost earnings are already taken into account in the Willingness to Pay estimate in published literature.

[7] Willingness-to-pay values measure an individual's willingness to pay to avoid a case of a disease.

[8] Disability weights measure the reduction in quality of life of a person that suffers from a specific disease.

available from the same source, meaning that neither of the two methods consistently results in a greater estimate than the other one. In some instances, the methods result in similar estimates but this is a coincidence.

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 4-20 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)[9]
Employers	Ce, Cp	CtotalEmployer=Ce+0.8*Cp

Source: Analysis by RPA, COWI & FoBiG

4.5 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.

Additional information is available in the substance specific reports in section 3.12.3.

4.6 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

[9] Assumes 20% tax.

- 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 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.

Additional information is available in the substance specific reports in section 4.9.

4.7 Indirect benefits

Member States may gain indirect benefits from not having to define their own national OEL, STEL or BLV, as a result of the introduction of an EU OEL. 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/or STEL and BLV is the sum of both costs: there is no economy of scale for introducing both together.

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

5 THE COST MODEL FOR ESTIMATING COMPLIANCE COSTS FOR COMPANIES

The cost framework used for the assessment is described in section 7 of each of the substance reports considering the impact of an OEL. The following description focusses on the general features of the model for estimating compliance costs for companies.

5.1 Introduction

5.1.1 Identification and screening of economic impacts

In line with the more general Impact Assessment requirements of BR Tool #18, the assessment first involves determining which of the potentially relevant impacts are expected to be significant and should thus be subject to a detailed cost assessment. There might be specific issues that are more relevant for one substance compared to another.

Taking into account the direct and indirect behavioural changes as well as potential ultimate impacts, the most relevant impacts were selected on the basis of the following factors:

- The relevance of the impact within the intervention logic;
- The absolute magnitude of the expected impacts;
- The relative size of expected impacts for specific stakeholders (such as impacts which may be small in absolute terms but may be particularly significant to specific types of companies, regions, sectors, etc.); and
- The importance of the impacts for the Commission's horizontal objectives and policies.

Table 5-1 below summarises the impact categories that could be significant and are thus assessed in this report.

Table 5-1 Assessment of the most significant economic impact categories

Impact category	Key impacts
Quality of natural resources (water, soil, air etc.)	• Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc.)? • Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges or sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources? • Does the option affect acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?
Working conditions, job standards and quality	• Does the option affect wages, labour costs or wage setting mechanisms? • Does the option affect employment protection (the quality of work contracts, risk of false self-employment?

Impact category	Key impacts
	• Does the option affect undeclared work? • Does the option affect work organisation? • Does the option affect occupational health and safety? • Does the option affect the exercise of labour standards? • Does the option affect social dialogue? • Does the option affect access to vocational training and career development advice? • Does the option affect participation, information, and consultation schemes for employees?
Public health & safety and health systems	• Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on socio-economic environment (working environment, income, education, occupation, nutrition)? • Does the option increase or decrease the likelihood or health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise, air, water or soil quality? • Will the option affect health due to changes in waste disposal? • Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs? • Are there specific effects on particular risk groups (determined by age, gender, disability, minority of ethnic or racial background, social group, mobility, region, etc.)? • Does the option affect the cross-border provision of health services, referrals across-borders and cooperation in border regions?
Conduct of business	• Will it impose additional costs on businesses? • How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of product limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? • Will it lead to creating new or closing down businesses? • Are some products or businesses treated differently from others in a comparable situation? How are individual Member States affected?
Position of SMEs	• What is the impact (positive or negative) of the option on the operation and competitiveness of SMEs and micro-SMEs in particular?
Administrative burdens on business	• Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)?

Impact category	Key impacts
Sectoral competitiveness, trade, and investment flows	• What impact does the option have on the cost of doing business which includes the costs of intermediate inputs (e.g. energy) and production related factors such as labour and capital? • What productivity effects does the option have? • What impact does the option have on a business' capacity to innovate i.e. its ability to produce more/higher quality products and services that meet customers' expectations? • What impact does the policy option have on a business' market share and comparative advantage in an international context (e.g. imports, exports, investment flows, trade barriers, regulatory convergence, etc.)? • How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? • How will investment flows be affected and the trade in services? • Will the option give rise to trade, customs, or other non-trade barriers? • Will the option affect regulatory convergence with third countries? • Have international standards and common regulatory approaches been considered?
Functioning of the internal market and competition	• What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and services providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation etc.?
Public authorities (and budgets)	• Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national regional, local), both immediately and in the long run? • Does it bring additional administrative costs on public authorities? • Does the option require the creation of new restricting of existing public authorities?
The likelihood or scale of environmental risks	• Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms? • Does the option affect the development in the insurance markets?
Employment	• To what extent are new jobs created or lost? • Are direct jobs created or lost in specific sectors, professions, regions or countries? Which specific social and / or age groups are affected, including groups determined by gender, disability, migrant, or minority of ethnic or racial background? • Are there significant indirect effects which might change employment levels? • Are there any factors that would prevent or enhance the potential to create jobs or prevent job losses? • To what extent does the option influence opportunities and incentives of workers/specific groups to work (i.e. supply of labour through labour market participation or mobility)?

Impact category	Key impacts
	• Does the option have overall consequences for economic growth and employment?
Technological development / digital economy	• Does the option affect processes that could be simplified or even automated? • Does the option potentially create synergies with existing digital policies? • Does the option affect one of several existing digital ecosystems and actors and/or the exchange of data between different actors and systems (including across sectors and borders)? • Does the option consider the reduction of burden and costs for businesses and citizens through the use of digital technology? • Does the option affect the pace of the digital transformation of economic or social sectors, including public services and the take-up of innovative digital technologies? • Does the option affect the digital accessibility or digital gap?
Consumers and households	• Does the option impact consumers' ability to benefits from the internal market or to access goods and services from outside the EU? • Does the option affect the prices, quality, availability or choice of consumer goods and services? • Does the option affect consumer information, knowledge, trust or protection? • Does the option impact the safety or sustainability of consumer foods and services? • Does the option impact vulnerable consumers?
Territorial impacts (specific (types of) regions and sectors)	• Does the option affect economic activity, environment, or people living in cities, rural, cross-border, insular, mountainous, or sparsely populated areas and in the EU outermost regions to a significantly different extent than elsewhere in the EU? • Is the problem concentrated in certain areas (e.g. rural), regions, or Member States? • Does the initiative address regions differently according to their traits/endowments and thus lead to uneven territorial development? • Does one or the other option distort the principle of territorial cohesion as one of the founding principles of the EU? • Does the initiative have an effect on the EU outermost regions taking into account their constraints (as per art. 349 TFEU) and on other island, cross-border and mountain regions taking into account their characteristics (as per art. 174)?
Innovation (productivity and resource efficiency); research (academic and industrial)	• Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production, methods, technologies, and products? • Does it promote or limit academic or industrial research? • Does it promote greater productivity/resource efficiency?
Fundamental rights	• Does the option impact on any of the fundamental rights endorsed by the EU Charter of Fundamental Rights

Source: Better Regulation (BR) Toolbox (BR Tool #18)

This note sets out the key features of the models developed to estimate the costs of the OEL/STEL/BLV policy option incurred by industry due to the need to implement more effective Risk Management Measures (RMMs). Costs relating to monitoring, biomonitoring and health surveillance and their associated administrative burden are covered in section 7. Other costs have been considered in the substance specific reports including the costs of monitoring for companies and the costs of transposition for Member State authorities – the methods used for the estimation of these costs are often substance-specific and are not set out in this note.

Indirect costs could arise in terms of the availability of products, the choice and quality of products, as well as possible ripple effects through the value chain; these types of costs are also discussed in more detail in section 8 on Market Effects in each substance reports.

5.1.2 Key features of the compliance cost model

The key impacts are the compliance costs for industry. These are estimated by means of a compliance cost model. This is a spreadsheet model that considers the RMMs currently in place and estimates the additional Risk Management Measures (RMMs) needed to reduce the air exposure levels from the actual levels to the target level, which is determined by suitability, effectiveness, and cost. The model then calculates the costs for a group of similar companies to implement these RMMs.

The output is the cost of implementing the OEL/BLV split by:

- Sector;
- Company size: small, medium and large; and
- One-off costs, recurrent costs and discontinuation costs.

This model was used to estimate the costs of compliance with the different policy options.

5.2 Key model inputs and assumptions

5.2.1 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 sector.

Some of these inputs are explained in the substance specific reports (such as the OEL/BLV options). More generic explanations are provided in this section.

5.2.2 Current exposure concentrations

The key input into the model is the distribution of exposure concentrations in each relevant industry sector. This involves dividing exposures into several (typically five) 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.

5.2.3 OEL/BLV policy options

The OEL/BLV and STEL policy options are summarised in Section 3 of each of the substance-specific reports.

5.2.4 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 5.2.4.

5.2.5 Number of enterprises in each exposure band

One of the key inputs into the model 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, for example where 10% of exposure measurements are over a certain level, 10% companies have exposure over that level.

The data sources and methods of estimating the numbers of relevant enterprises are specific to each of the substances – see each of the substance-specific reports.

5.2.6 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.

The methods and data sources used for estimating the average number of exposed workers and workstations in each company are specific to each of the substances – see the substance specific reports.

5.2.7 Discount rates

Costs and benefits are discounted over 40 years and therefore a 1% difference in rate can make a significant difference to the present value (PV) over 40 years. The impact is greatest when costs or benefits fall heavily at either the start or end of the 40 year period. If the costs are predominantly at the beginning of the period, they are less discounted and thus higher: this is often the case if the costs involve major one-off costs, such as installing a closed system. If the costs are predominantly at the end of the period, they are more discounted and thus lower: this is often the case with benefits that are due to endpoints like cancer that have high latency. A case of lung case does not occur until 30 years after exposure on average. The Better Regulations Tool #32 on non-monetary quantitative methods explains these impacts and also refers

indirectly to EUnetHTA 2015, for further details. Based upon the Better Regulation Toolbox, Tool #64 recommends a social discount factor off 3% for EU policies.

As the impact of the discount rates can be significant, the study team considered the following aspects:

- Using equal or differential discounting - equal discounting means using the same discount rates for both costs and benefits and differential discounting means using different discount rates, usually lower for benefit compared to costs;
- Using static or declining discount rates; and
- The best value for discount rates.

Williams et al. (2022) looks at healthcare systems across the world and considers whether they use equal or differential discounting. It finds that 80.7% of countries, including fifteen EU Member States, use equal discounting and 9.6% use differential discounting, including four Member States. Gravelle et al. (2000) also concludes that "*When health effects can be valued in monetary terms, as in CBA, they should be discounted at the same rate as costs*." The discounting approach in Member States and other major countries is shown in Table 5-2.

Table 5-2 Discounting approach by country and discount rates used for costs and benefits

Country	Year of publication	Discounting approach	Discount rate for costs	Discount rate for benefits	Discount rate for sensitivity analysis
Member States					
Austria	2012	Equal	3%	3%	0, 5 and 10%
Baltic (Latvia, Lithuania and Estonia)	2002	Equal	5%	5%	None stated
Belgium	2012	Differential	3%	1.50%	0 or 5% for costs and outcomes
Croatia	2011	Equal	5%	5%	Between 3 and 10%
Czech Republic	2016	Equal	3%	3%	0 and 5%
Denmark	2001		None stated	None stated	None stated
France	2012	Equal	4%	4%	3 to 6% [1]
Finland	2019	Equal	3%	3%	None stated
Germany	2009	Equal	3%	3%	0, 5, 7 and 10%
Hungary	2021	Equal	3.70%	3.70%	None stated

Country	Year of publication	Discounting approach	Discount rate for costs	Discount rate for benefits	Discount rate for sensitivity analysis
Italy	2020	Equal	3%	3%	Between 0 and 5%
Ireland	2020	Equal	4%	4%	0 and 10%
Poland	2016	Differential	5%	3.50%	0% for both
Portugal	1998	Equal	5%	5%	5%
Slovak Republic	2011	Equal	5%	5%	None stated
Slovenia	2013	Differential	3 to 5%	3%	Cost: 0–8%;
The Netherlands	2016	Differential	4%	1.50%	None stated
Europe	2015	Equal	3–5%	3–5%	None stated
Global					
Australia	2016	Equal	5%	Equal	5%
Brazil	2014	Equal	5%	Equal	5%
China	2020	Equal	5%	Equal	5%
Canada	2017	Equal	2%	Equal	2%
Japan	2022	Equal	2%	Equal	2%
South Korea	2021	Equal	5%	Equal	5%
Switzerland	2011		No values stated		No values stated
USA	2016	Equal	3%	Equal	3%
UK	2013	Equal	4%	Equal	4%
Global [3]	2003	Equal	3%	Equal	3%

Source: Williams et al. (2022), EUnetHTA (2015), European Commission (2021)

Note: 1 If time horizon is >30 years, then discount costs and benefits at 2%.

EUnetHTA (2015) says "*Most countries use a discount rate between 3 to 5 percent for both costs and effects. It is recommended that both costs and effects are discounted in the base case analysis with the same rate. Furthermore, sensitivity analyses that explore the effect of varying the discount rate and differential discount rates (that is a lower discount rate for benefits than costs) should be performed; setting both discount rates to zero is also recommended.*"

European Commission (2021) says: "*The social discount rate can decline over the reference period in projects with very long-term impacts. In the economic literature, there is some empirical support for the view that constant discounting is inconsistent with consumers' preferences. That is, in facing the decision between a smaller reward soon and a larger reward later, individuals would apply a lower discount rate in the long term. Time-inconsistent preferences would therefore justify using an SDR that declines over time. While the rationale for such an assumption is clear, the approach suggested here is that the SDR remains stable over the reference period. In most cases, the benefits and the costs arise during a limited number of years. That is, the reference period is 'short' enough to justify the use of a single SDR and to calculate the economic net present value (ENPV) with a negligible margin of error. Only projects with very long-term impacts (e.g. beyond 50 years), involving intergenerational equity considerations, should adopt declining discount rates.*"

Based upon the discount rates used in other Member States, the study team believes that equal discounting of costs and benefits and a static discount rate is the most appropriate approach, and that a static discount rate of 3% over the 40-year period represents the general consensus.

For substances that have significant health benefits from endpoints with latency (cancer), alternative discount rates and different discount rate approaches (differential and/or declining) are considered in the sensitivity analysis.

5.2.8 Current RMMs

The breakdown of RMMs currently used by the relevant companies, differentiated by enterprise size and sector was estimated for each substance. The data sources and methods of estimation are described in each of the substance-specific reports.

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 and 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 RPE, 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.

Table 5-3 RMMs considered in the model

RMM type	Levels
Substitution (SUB)	Substitution of the substance
Rework (RWK)	Rework/redesign of the production process
Local Exhaust Ventilation (LEV)	LEV3 Full enclosure LEV2 Partial enclosure LEV1 Open hood
Worker Enclosure (WE)	WE2 Pressurised or sealed worker enclosure WE1 Simple enclosed cabin
Respiratory Protective Equipment (RPE)	RPE3 Breathing apparatus RPE2 HEPA filter/half or full-face negative pressure respirator or similar RPE1 Simple mask/FFP mask or similar
Organisational and Hygiene measures (OH)	Organisational and hygiene measures
General dilution ventilation (GDV)	General dilution ventilation

Source: Analysis by RPA & COWI

For each sector, the proportion of companies that use these RMMs as their primary means of controlling exposure is estimated, with a combination of primary RMMs always totalling 100%, e.g. no RMM 0%, RPE1 20%, LEV2 80%.

The model is a simplification of reality and focuses on the primary RMM currently used to control exposure. It is recognised that in reality a combination of RMMs may be used by a single company to control exposure. A further simplification is that current RMMs are defined at sectoral rather than company level – all companies in a certain sector are thus assumed to have the same RMMs in place. Again, it is recognised that this is a simplification which may not be the case in real life.

5.2.9 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 5-4 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%

Type of RMM	% reduction
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: Analysis by RPA & COWI

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. The costs of discontinuation depend on the size of the company – for more information, see each of the substance-specific reports.

5.2.10 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 5-5 RMM unit costs

RMM	One-off costs	Recurrent costs	Lifespan
LEV3: Full enclosure	Based on IOM (2011) – high end of costs	10% based on one-off costs as recommended by US-OSHA (1992) (most likely electricity, maintenance and repairs) US-OSHA (1992) is no longer available, and no further studies giving an indication of the cost of recurrent costs have been found. The study team believes that the value of 10% is a reasonable assumption.	
LEV2: Partial enclosure	Estimated reported in literature which range from €60,000 to €120,000 per company	10% based on US-OSHA (1992) (most likely electricity, maintenance & repairs, compensation air, heating)	

RMM	One-off costs	Recurrent costs	Lifespan
LEV1: Open hood or add-on	Estimates reported in published literature which range from €1700 to €15,500	10% based on US-OSHA (1992) (most likely electricity, maintenance & repairs, compensation air, heating)	
WE2: Pressurised or sealed cabin	Assumed the same as LEV2	Assumed the same as LEV2	Assumed the same as LEV2
WE1 : Simple enclosure	Assumed the same as LEV1	Significantly lower than LEV1, assumed 3%	Assumed the same as LEV1
RPE3: 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 and refill) If used every working day for 1 hour, 1,000% of one-off costs	Assumed 2 years
RPE2: Half or full face negative pressure respirator/ Mask with HEPA filters or similar	Hakimian et al. (2015): €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. (2015): €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
RPE1: FFP mask/ simple mask or similar	Hakimian et al. (2015): €1 per disposable mask Assumed a new mask is required every workday, resulting in an annual cost of €260 per worker	Not relevant but one-off costs incurred every year	
OH1: Organisational & hygienic measures	Some data provided through consultation for Cd (International Cadmium Association, ICdA) as part of CMD 3, also consistent with IOM (2011) A large range of measures with different costs Assumed €1,000 per worker	Some data provided through consultation for Cd (ICdA) for CMD 3 (Ok, et al. 2008): 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. (2015): €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	Hakimian (2015): Approx. 30% of one-off costs (Ok, et al. 2008): 30% but this is for 24hr operation Figure used: 30%	20 years

RMM	One-off costs	Recurrent costs	Lifespan
	Assumed cfm required: Small: 300 cfm, Medium: 2,000 cfm, Large: 5,000 cfm		

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 workstations in the different size bands.

The costs of implementing each of the RMMs in a specific company depends on the number of exposed workers or workstations using the relevant substance. The costs may thus differ between companies in different sectors for which different average company sizes have been estimated (see section 4.2.6). Examples of these costs for three theoretical company sizes are given in Table 5-6.

Table 5-6 Cost 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 exposed 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		
LEV3: 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%
WE2: Pressurised or sealed	30,000	20	10%	240,000	20	10%	650,000	20	10%
WE1: Simple enclosed cab	7,000	20	3%	90,000	20	3%	260,000	20	3%
RPE3: 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%
RPE1: 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
OH1: Organisational measures	4,000		50%	54,000		50%	150,000		50%
GDV1: General dilution ventilation	6,000	20	30%	40,000	20	30%	100,000	20	30%

Source: Analysis by RPA & COWI

5.2.11 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 other form 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 substance. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, worker enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely, causing exposure to workers beyond the area where the substance is being handled. This means that administrators, managers and sales staff may be exposed.

The proportion of activities characterised by different duration of exposure, forms of the substance and extent of spread has been estimated for each relevant sector in the substance specific reports.

In the table below, the types of RMM that are suitable or not for each amount of exposure, form of substance and extent of spread are shown. These values were built into the cost model.

Table 5-7 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
RWK: Rework	Y	Y	Y	Y	Y	Y	Y
LEV3: Full enclosure	Y	Y	Y	Y	Y	Y	Y
LEV2: Partial enclosure	Y	Y	Y	Y	Y	Y	Y
LEV1: Open hood	Y	Y	Y	Y	Y	Y	Y
No LEV	Y	Y	Y	Y	Y	Y	Y

Type of RMM	<1h	>1h	Dust	Gas	Local	Diffuse	Periph-eral
WE2: Pressurised or sealed	N	Y	Y	Y	N	Y	Y
WE1: Simple enclosed cab	N	Y	Y	Y	N	Y	Y
No enclosure	Y	Y	Y	Y	Y	Y	Y
RPE3: Breathing appa-ratus	Y	N	Y	Y	Y	Y	Y
RPE2: Neg. pressure respirator	Y	N	Y	Y	Y	Y	Y
RPE1: FFP mask	Y	N	Y	Y	Y	Y	Y
No mask	Y	Y	Y	Y	Y	Y	Y
OH1: Organisational measures	Y	Y	Y	N	Y	Y	Y
No organisational measures	Y	Y	Y	Y	Y	Y	Y
GDV1: General dilution ventilation	N	Y	N	Y	N	Y	Y
No general ventilation	Y	Y	Y	Y	Y	Y	Y

Source: Analysis by RPA & COWI

5.3 Calculation of the risk management measures required for each policy option

5.4 How does the estimation model work?

The assumptions on the effectiveness and suitability of individual RMMs are used to determine whether a specific RMM is suitable to reduce exposure in a specific sector by the required degree. If several RMMs are suitable and effective enough, the cheapest one is selected. RMMs that companies already have in place are taken into account and a more effective RMM is chosen.

The logic process underpinning each company level decision is illustrated in the figure below.

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

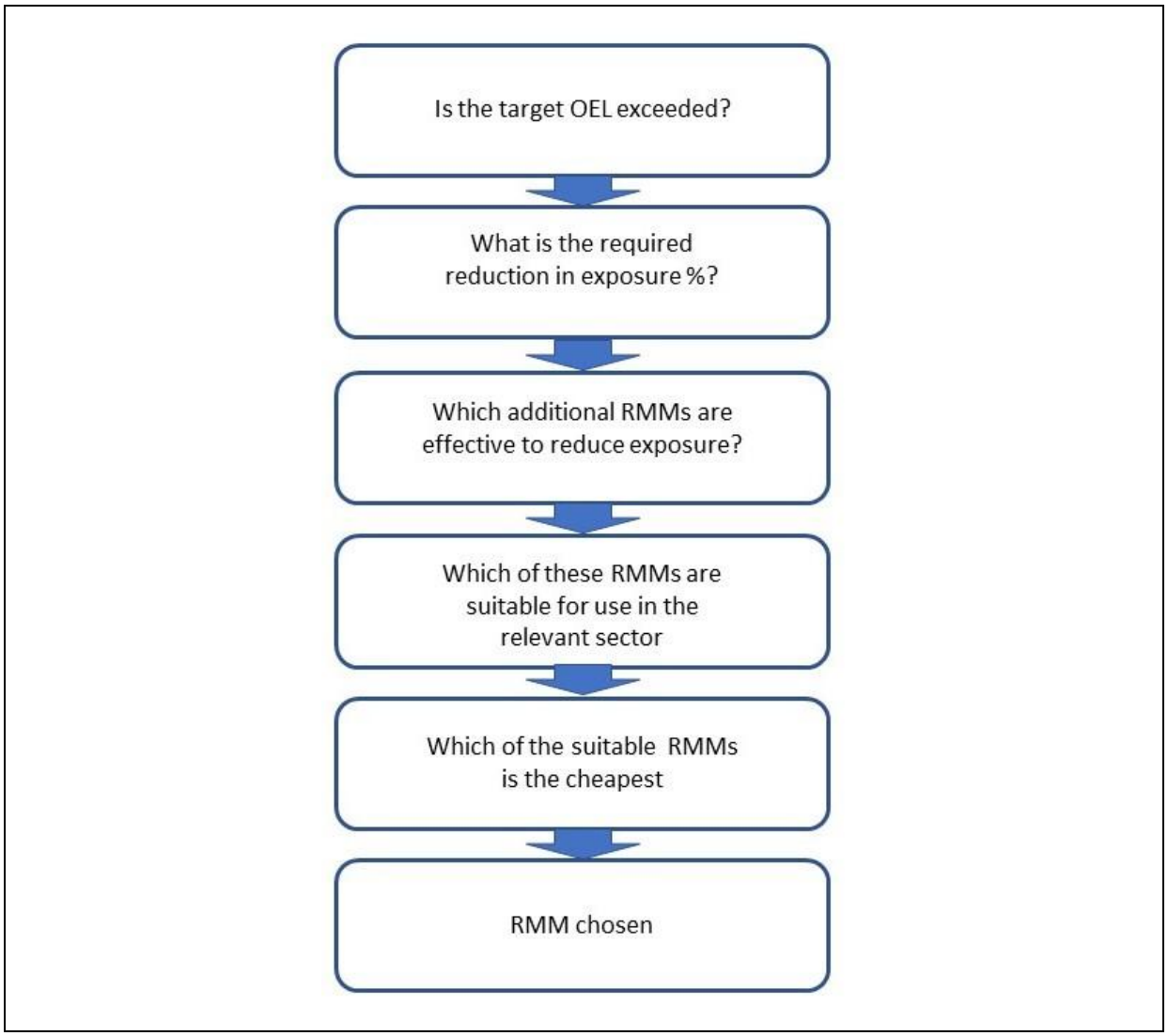


Figure 5-15-2 Decision making process in the cost estimation model (estimated for each company)

Source: Analysis by RPA & COWI

5.5 Selected issues requiring further explanation

5.5.1 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 calculated). 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/STEL/BLV policy option. As the model knows the number of companies by size for every scenario where discontinuation is the only option, the number of discontinuations by company size and sector can be derived.

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.

If the sector is entirely based on the substance, it is possible that 100% of large companies would also be forced to close: this is described in the substance report, if applicable, in section 8.3.1.2.

The discontinuation cost is taken as the loss of profit[10] 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.

In line with the logic set out above, for SMEs shutting down, the lost profit is assumed to be 10% of annual turnover for 20 years discounted for small and medium sized companies. For large companies shutting down, only part of the business is assumed to close and the lost profit is assumed to be 1% of annual turnover for 20 years discounted. All the workers in the small and medium sized companies and all the workers in the division (10%) of a large company are assumed to lose their jobs. The unemployment costs are discussed further in section 8.3.

The average turnover of small, medium and large companies is estimated taking the Eurostat activity categories (which do not always correspond to the relevant sectors where exposure occurs), stakeholder consultation and internet searches into account.

Discontinuation costs are estimated per company differentiating by size and sector and subsequently applied to the numbers of companies in the relevant sector; the number of companies in a sector thus has a significant impact on the total cost of all discontinuations.

Comparing the cost of discontinuations with the total compliance costs, it can be seen that they comprise a significant part of the compliance cost for some OEL/STEL/BLV policy options. The data should be interpreted with care, as companies may try to find other means of achieving compliance without the need to close. The discontinuation costs can also be seen as a proxy for high risk management measure compliance costs, that the model cannot estimate as they are complex and specific to the particular business. The discontinuation costs can also be considered as a proxy for other costs the business could face in closing down some or all of its operations, such as relocating and/or retraining staff for other work, and redundancy payments. Also, it is difficult to model the potential to substitute the substance or keep the business alive by reorientating to different products or services. Such other possibilities cannot be reflected in sufficient detail in the cost model, but they are likely to be significant costs.

Although the estimated number of discontinuations is based on a mathematical formula of the cost model which only predicts discontinuation where a sufficiently effective RMM is unavailable, these predictions are checked against consultation responses. For example, the questionnaire

[10] 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."

included a question on stakeholders' views on the lowest technically possible limit value, as well as the one-off and recurring costs of the different OEL/STEL/BLV policy options.

As the estimated number of discontinuations is based on a mathematical formula within the cost model, with many assumptions, the outcomes are typically not whole numbers. The study team rounds these numbers up, but occasionally the numbers are low and less than one. The study team believes that these fractions should still be included in the calculations, and therefore sometimes discontinuations are predicted for part of a company.

The discontinuations due to the OEL/STEL/BLV policy options are in addition to the normal rate of bankruptcies. Data on insolvencies suggest that a natural insolvency rate is around 1% per year.[11] However, it may not be appropriate to compare discontinuations resulting from the OEL/STEL/BLV policy options with the 'natural' bankruptcy rate due to the fact that the nature of these outcomes differs significantly – in cases of natural insolvencies, a company going out of business can be replaced by a competitor or a new market entrant. However, the discontinuations modelled in this study may entail a permanent loss of revenue generating activities in the EU, especially in instances where it is not technically feasible to meet the OEL/STEL/BLV policy option.

5.5.2 Negative recurring costs

The estimated recurrent compliance costs, when compared with the same costs under the baseline, can be both positive or negative. Negative costs (i.e. cost savings) occur, for example, when companies primarily use respiratory protective equipment (RPE), and these companies move to local exhaust ventilation (LEV) such as closed systems or partially closed systems. RPE tends to have a small one-off cost, but a high recurrent cost, whereas LEV has high one-off costs and lower recurrent costs. This negative value shows that in this instance, over 40 years, the cost of operating RPE is higher than installing and running LEV. Although it can be questioned whether relying on RPE is a rational allocation of resources, companies may prefer to pay more over 40 years, rather than face a substantial one-off sum: in particular, small companies may find it difficult to afford or borrow the funds for the investment. It is thus possible that, under the baseline, companies are not always operating the most cost-effective RMM. However, the cost model selects the most appropriate RMM on the basis of the overall cost (PV sum of one-off and recurring costs over 40 years) and thus assumes that companies opt for the RMM with the greatest overall cost-effectiveness regardless of any potential access to finance issues.

Negative values can also occur when a company using closed systems has to discontinue – the cost model treats all discontinuation costs as a one-off cost and, as a result, the overall recurrent costs can appear negative.

5.5.3 Annual costs estimated from PV40 values

According to Better Regulation Tool #63, net present value (NPV) is a useful method for comparing costs and benefits that have different timeframes. This study already takes the different timeframes into account in the cost and benefit models and the costs and benefits (cost

[11] Data on insolvencies are available for approximately half of EU Member States from https://www.creditreform.cz/fileadmin/user_upload/CR-International/local_documents/cz/documents/2021-05-20_AY_OE_Analyse_EU-2020_englisch_international.pdf. These data were compared with Eurostat enterprise statistics for 2018. Please note that the insolvency rate given above may overestimate the natural insolvency rate since financial services are not included in the Eurostat dataset for numbers of enterprises used for the calculation presented above.

savings) presented in sections 6, 7 and 14 of the substance reports are expressed as present value PV40 and are directly comparable allowing this study to derive Cost Benefit Ratios.

Present value (PV) is also used within the framework of ECHA restrictions and authorisations. The ECHA restriction guidance (ECHA, 2008), for example, sets out an PV formula that relies on both the number of years and discount rates. However, these methods are not used in this study because a) they are often used for a different reason, i.e. to annualise capital investment incurred in year 1 by spreading it over the lifetime of the equipment, and b) ECHA's Committee for Socio-economic Analysis (SEAC) appears (in the experience of the study team) to be moving towards PV by means of simple division by the number of years (at least within the context of Socio-Economic Assessments for REACH authorisations).

6 APPROACH TO WELDING FUME

6.1 Introduction

The methodology for calculating the benefits and costs of policy option 2 (Annex I) for welding fumes are different to those used for limit values, because there are no data available covering welding fumes exposure levels.

The costs and benefits of policy option 2 (Annex I) equate to zero, because they relate to risk mitigation measures (RMMs) that companies should already be implementing. However, the study team was asked to estimate the costs and benefits of additional companies applying already required RMMs, assuming that policy option 2 would result in increased awareness of the risks and better supply and use of RMMs.

6.2 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 fumes, the methodology is explained in detail in section 6.1 of the substance report. 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 fumes and an Exposure Risk Relationship (ERR) cannot 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 asked their opinion of the future trend for excess risk; and
- The impact of the policy option 2 (Annex I) is assumed to reduce the excess risk by a further 1% 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.

6.3 Costs

The costs model used to calculate the cost of RMMs 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, and the methodology is explained in detail in section 6.2 of the substance report. The approaches are:

- Bottom up - this is based upon 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 (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 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; 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 two (Annex I) can be calculated.

These two methods are initially calculated for a single estimated value and then for a range of values. The range of values for each cost method is then compared with a range of values for both benefits estimates, Method 1 and Method 2, together with their cost benefit ratios, see section 6.3 of the welding substance reports.

6.4 Assumptions

There is little data available to build estimates of costs and benefits, and details of the data available and levels of uncertainty are explained in section 6 of the substance report. As the estimates for benefits and costs are developed in this study, many assumptions are made by the study team, often with limited evidence, drawing from the expertise and experience of the study team. To validate these estimates, the study team held six interviews with key stakeholders presenting the assumptions, calculations and estimates and asking their opinions about them (three EU level and three Member State level stakeholders: a mix of welding associations, labour inspectorates, welding training organisations, trade unions and companies employing large numbers of welders). Generally, the consensus was that the study team's estimates were a reasonable guess. In a few cases, one or more stakeholders felt that an assumption was too high or too low, and this is indicated where applicable in the substance report.

6.5 Methodology for establishing Member States already defining welding fume as a process generated substance

6.5.1 Overview

Welding fumes are Process Generated Substances (PGS) generated during welding processes. The constituents of welding fumes are complex and highly heterogenous.

There were two parts to the investigation:

- Asking the Member State authorities directly (by targeted email survey); and
- Study team searches of Member State legislation.

6.5.2 Member States' input

As part of the main consultation, twenty Member States had previously responded to the online survey (13[12]) or were interviewed (5). None of the previous information obtained was sufficient to answer the question from DG Employment, see section 2.1. Therefore, these twenty individuals, together with the contact details held for the remaining seven Member States, were asked the following follow up question by email in December 2023:

> "In your transposition of the CMRD, do you have any provision specifically for welding fumes?
>
> The European Commission is considering adding the following entry into Annex I of the CMRD (from the ACSH opinion of 22 September 2023)
>
> 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

[12] They replied to the MSA survey in the main consultation but did not necessarily answer the questions about welding.

> 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)
>
> Do you have any similar provisions within your legislation that transposes the CMRD?
>
> If you do, please could you provide a link to the document and indicate the relevant section/article/page?"

Ten Member States responded to this email, and these are shown in Table 2 1.

6.5.3 Study team searches

The study team undertook searches of Member State legislation, to check, complement or fill the gaps where no information had been received from Member States. Up to three legal documents relating to transposition of the CMRD were identified in each Member State, depending upon how their legislation is presented. Some Member States transpose the whole of the CMRD in just one document, others have the limit values listed in a separate document, and a few have the Annex I element of the CMRD in a further document.

The search started with the webpage named as the source of the limit values in Table 3-1 of the welding report. If this did not include the latest amendments to the CMRD, further searches based on the naming of the first document were made to see if a later version has been issued. If this webpage did not include all three components, more searches were made of the document to see if any pointers could be found to the other documents.

The element that proved the most difficult to locate was the transposition of Annex I of the CMRD. If this was not within the list of limit values or the transposition of the main body of the CMRD, the study team went to the Google site for the Member State (such as google.it for Italy) and searched for words like auramine, cupro-nickel mattes, or isopropyl alcohol, combined with carcinogen, all translated. Auramine, cupro-nickel mattes, or isopropyl alcohol were chosen because these three substances are only mentioned in Annex I of the CMRD: the other items in Annex I of the CMRD have an OEL or skin notation.

The study team looked for any use of the words "weld", "welding", "fume" and "smoke" in all documents to find any instances of the legislation defining welding as a process generated substance with associated restrictions. Initially, this was done in English translations, but if these were unavailable or an English search found nothing, it was repeated using translations.

Terms were translated using two methods:

- The translation of the CMRD into all languages[13] ; and
- Google translate.

In the majority of cases, the only instances where the word "weld" occurred were associated to chromium VI in Annex III of the CMRD[14]. In the remainder of cases "welding" was either

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20220405

[14] Annex III of the CMRD has the following transitional measures for Chromium VI compounds: Limit value 0,010 mg/m3 until 17 January 2025. Limit value: 0,025 mg/m3 for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025

mentioned or the study team was unable to find any mention of "welding" (as noted below in section 2.4).

In some cases, only the first five or six items in Annex I of the CMRD were found: sometimes this reflected an old version of legislation, sometimes the Member State does not yet appear to have transposed the latest updates of the CMRD. Further searches were then made to try and find later versions of legislation which includes all eight items.

The study team worked hard to find the most recent version of transposition of the Annex I list of processes, but this was challenging. Sometimes, the Member State document referred to from the main legislation transposing the CMRD was not the latest version of the document. If some of the Annex I items in the CMRD are missing from the transposed Member State list, the study team looked hard for later versions. However, sometimes these cannot be found because they have not yet been transposed, and thus do not exist. However, it is possible that some do exist, but could not be found in a reasonable time.

7 ESTIMATION OF THE COSTS OF MONITORING, BIOMONITORING, HEALTH SURVEILLANCE AND ADMINISTRATIVE BURDEN

7.1 Introduction

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. The administrative cost is part of the administrative burden and is outlined in 7.4.

The administrative burden also includes the administrative costs borne by the Member State Authorities, which are outlined in section 7.5.

7.2 Air monitoring costs

Monitoring costs may constitute a significant part of the total costs of compliance with a new OEL. The extent to which demonstration of compliance with an OEL involves actual measurements in the workplaces differs by Member State and size of the enterprise, and consequently the estimate of total monitoring costs for air concentrations is subject to high uncertainty.

The experience from previous OEL impact assessments, is that monitoring costs for small companies may account for a major part of the total costs of complying with an OEL/STEL/BLV but it is uncertain to what extent micro and small-sized companies actually undertake monitoring.

7.2.1 Monitoring requirements of the CMRD and national legislation

According to Article 3 (2) of the CMRD, "*In the case of any activity likely to involve a risk of exposure to carcinogenic, mutagenic 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. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to the carcinogenic, mutagenic or reprotoxic substances.*"

In addition, in Article 5 (4) of the CMRD, "*Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III*".

The CMRD does not mandate measurements of workplace concentrations. The risk assessment must be renewed regularly, but the CMRD does not require regular monitoring if major changes in the conditions which may affect workers' exposure to the substances do not occur.

However, to determine the degree of exposure it is often necessary to measure the workplace concentrations, unless the degree can be estimated on the basis of experience with similar exposure situations, for example collected at a sector level.

The European standard EN 689:2018+AC:2019 (European Standard, 2019) specifies a strategy to perform representative measurements of exposure by inhalation to chemical agents to demonstrate the compliance with occupational exposure limit values (OELs). The use of the standard for compliance demonstration is not mandated by the CMRD but about half of the Member States have replied that compliance was tested in accordance with EN

689:2018+AC:2019. Regarding the frequency of measurements, section 7 of the standard "Periodic reassessment" specifies that:

> "*In general, an annual interval is recommended for reassessment, whatever method used.*"

It further specifies:

> "*Reassessment of exposure can be done with exposure measurements or other method.*"

Therefore, periodic measurements are not mandated, but measurements can be selected as a method for reassessment. In this case, the standard specifies:

> "*When reassessment is conducted with exposure measurements, periodic intervals for measurements are proposed in Annex I.*"

Annex I only applies if measurements are selected for the reassessment. Other methods for reassessment listed include reasonable worst case measurements, measurements of technical parameters (e.g. air velocity and air change), calculation of exposure (using appropriate models and algorithms), comparison with other workplaces, in the same enterprise or in other enterprises, and good practice guidance for defined branches and tasks.

For the OELs5 study, 12 Member States provided information about the monitoring requirements (not asked for in OELs6 study). Of these, 11 answered that air exposure concentration were determined by measurements, while two (BE and DE) answered that air exposure concentration were also determined by estimates. One Member State (DK) answered that in general, measurements are rarely taken as a means to demonstrate compliance with an OEL while one Member State (CY) answered that companies only take samples when there is a complaint or when it is a requirement based on the safety case. Most of the Member States answered that sampling should be personal. Five Member States answered that measurements should be taken by external contractor, while six answered that use of external contractor was not mandatory, but half of these answered it was common to use an external contractor. About half of the Member States replied that compliance was tested in accordance with EN 689:2018, however the described methods in other Member States also applied quite similar test strategies.

The frequency of testing and whether introduction of an OEL would require testing depends on many factors and a few examples of answers from Member States are listed below.

Table 7-1 Frequency of testing and testing requirements by Member State

Member State	Testing requirements
Cyprus	They only take samples when there is a complaint or when it is a requirement based on the safety case.
Denmark	In general, measurements are rarely taken as a means to demonstrate compliance. The National Authority for the Working Environment may order that a business should perform measurements to demonstrate compliance.
Estonia	Pursuant to applying the measures to reduce the risk and the changes made in the work process technology, the concentration of hazardous chemicals in the air of work environment should be again tested.
Finland	If the employees' exposure to hazardous chemical agents cannot be reliably assessed in any other manner, the employer shall carry out measurements regularly and always when the

Member State	Testing requirements
	conditions change in a way that increases an employee's exposure. The closer the measurement results for airborne contaminants are to the limit values, the more often measurements shall be carried out.
France	Annual measurement obligation according to the decree of December 15, 2009 relating to technical inspections of occupational exposure limit values in workplaces and the accreditation conditions of bodies responsible for inspections.
Latvia	The time interval for the next periodical measurement shall be determined in accordance with the result obtained in the previous measurements. The maximum time interval up to the next periodical measurement shall be: • 104 weeks, if in the previous measurements, occupational exposure concentration is less than 50% of the occupational exposure limit value; • 52 weeks, if in the previous measurements, occupational exposure concentration is between a 50% and 75% of the occupational exposure limit value; or • 24 weeks, if in the previous measurements, occupational exposure concentration is more than 75% of the occupational exposure limit value.
Poland	The frequency of tests and measurements of chemical substances in the air at workplaces depends on the results of the last measurements and whether there are limit values established for the substance.
Slovenia	It is not clearly stated in the standard how often the measurements shall be taken. However, it could be concluded that the compliance should be verified as soon as possible (within one to two years), especially for workers with consistently high exposure.

Source: RPA OELs5 study

7.2.2 Framework for estimating air monitoring costs

The parameters used for estimating air monitoring costs are listed in the table below.

Table 7-2 Parameters for air monitoring cost model

Parameter	Assumption for monitoring cost model	Sources of input to the model
Total number of companies with worker exposure to the substance by size class		The basis for the estimated number of companies by size class is provided in section 3.11 of the substance reports
Number of samples per monitoring campaign	Varies by size of company (number of SEGs) and distance between OEL and median exposure levels Varies by number of parameters measured: Inhalable/respirable, OEL/STEL, specific compounds	Estimated by study team on the basis of the requirements of the standard EN 689:2018+AC:2019
Unit costs of sample media and analysis	Varies by required LOQ of analysis method and the parameters to be measured	International laboratories providing analysis for the substances concerned
Costs such as sampling, and reporting for each monitoring campaign	Unit costs for planning, sampling and reporting. Sampling costs varies by number of samples	Based on model of costs of monitoring programmes developed for OELs3 (RPA et al., 2018b)
Percentage of companies that already have to comply	Companies that already have to comply with an OEL comparable to	Based on list of current OELs in section 3.1 and distribution of

Parameter	Assumption for monitoring cost model	Sources of input to the model
with an OEL comparable to each policy option	each policy option would not need additional monitoring programmes	companies by Member State in section in section 3.10 of the substance reports
Percentage of companies currently undertaking monitoring frequently	Varies by size of enterprises and distance between national OEL and current exposure level	Estimated by study team on the basis of information collected from laboratories, Member States authorities, OSH experts and companies
Percentage of companies expected to undertake monitoring after introduction of an OEL before implementing RMMs	Varies by size of enterprises and distance between OEL and current exposure level	As above
Percentage of companies expected to undertake monitoring after implementation of RMMs	Varies by size of enterprises and distance between OEL and current exposure level	As above

7.2.3 Number of samples per monitoring campaign

It is assumed that the strategy for sampling is in accordance with the standard EN 689:2018+AC:2019 (European Standards EN689, 2019). As mentioned above, the majority of Member States say that this standard or similar strategies are used. In the consultation survey for diisocyanates, as part of the OELs5 study, 46% of the 181 respondents answered that they did compliance monitoring in accordance with EN 689 while 19% answered that they did not know. For the OELs6 study, 41% of 56 companies answering this question for cobalt answered that they did compliance monitoring in accordance with EN 689 while 46 answered don't know and 11% answered no. This result is biased as the majority of companies answering were large companies. According to the experts consulted, it is common for medium and large sized companies to follow EN 689 whereas for small companies fewer demanding strategies are often applied, for example, taking only one or a few indicative measurements.

The strategy described in EN 689:2018+AC:2019 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.

EN 689:2018+AC:2019 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 as shown in box 4.1 in section 4.2.5.

The **screening test** requires three to five exposure measurements on workers belonging to a SEG.

- 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**.

- 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; and
- 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.

7.2.4 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 7-3 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**

** Each "exposure measurement" may consists of more samples if more than one parameter is measured.*

*** Median of sector's exposure concentrations*

These numbers accord with information obtained from health and safety specialist companies undertaking sampling campaigns. For example, a specialist interviewed in the Netherlands indicated the number of samples as follows:

- Small sized companies zero samples;
- Medium sized companies three sets of four samples (12); and
- Large sized companies four sets of six samples (24).

The specialist indicated that some samples are personal samples, others are stationary.

A comparison with the number of measurements reported in France for three substances (chromium VI, wood dust and silica dust) with an established OEL under the CMRD, indicates that the assumptions used above may rather result in an overestimation of the actual number than an underestimation. The average number of measurements per monitoring campaign range from four to seven, which correspond to the assumption for small companies where the OEL / median is less than two.

The number of companies with exposure to the three substances is not reported or available from previous OEL studies, but the estimated total number of potentially exposed workers from the most recent SUMER survey (INRS, 2022) is indicated in the table below. Comparing number of measurements over a five-year period with the number of exposed workers indicate that the number of measurements is approximately at 1/10 of the number of exposed workers. As the requirements for monitoring are more stringent in France than in most (possibly any) other MS, a total number of measurements of 1/10 of the number of exposed workers may be taken as an upper limit and used in the sensitivity analysis.

Table 7-4 Number of measurements, interventions (campaigns) and companies reporting in France during 2017 to 2021 (INRS, 2022)

	Chromium VI	Wood dust	Silica dust
Number of measurements	9,819	35,932	34,299
Number of interventions	2,193	7,957	5,593
Number of companies reporting	794	2,860	1,905
Measurements per intervention	4	5	6
Measurements per company over the entire period	12	13	18
Interventions per company	2.8	2.8	2.9
Number of potentially exposed workers in France	112,100 *	444,200	358,400

Source: INRS 2022; Number of exposed workers: Matinet et al., 2020.

** Chromium except stainless steel*

7.2.5 Experience from Member States

The largest uncertainties are related to the assumptions regarding the percentages of the companies that would undertake monitoring; in particular for the small companies.

As part of this study, further information on current practice with regard to monitoring has been collected from the literature, laboratories, Member States authorities, OSH experts and companies.

7.2.5.1 France

As mentioned, no data are available on the number of companies in France , but a comparison may be made for formaldehyde. From 2020 to 2021, the number of measurements of formaldehyde (8-h TWA) reported to SCOEL increased markedly from 21 measurements in 2020 to 1,724 in 2021, probably as consequence of the introduction of the new OEL (data before 2020 are not available). The total number of companies reporting over the two years was 202. Data

are still not available for 2022 and the increase may have continued. The OELs3 assessment report for formaldehyde estimated the total number of enterprises in France with exposure to formaldehyde at 11,751, of which 1,586 were large enterprises (RPA, 2018a). The estimated number of exposed workers was 102,000, which corresponds with the number of exposed workers in France in the most recent SUMER assessment of 185,900 (Matinet et al., 2020). The comparison indicates that even in France with a high level of measurements, it may be assumed that only the part of the companies with exposed workers actually undertakes monitoring after introduction of an OEL.

7.2.5.2 Denmark

According to Aldrich et al. (2020), in a study for the Danish Working Environment Authority, the experience of laboratories in Denmark is that foreign companies and larger companies more often have measurement programmes at a specific frequency e.g. annually. Danish companies and smaller companies more often have stand-alone indicative measurements (one to a few samples). Large companies are often more proactive, i.e. they more often make measurements before problems arise or before they receive requests from the authorities, while smaller companies are more often reactive in their approach to air measurements and make measurements only when they suspect there is an exposure (Aldrich et al., 2020). The main sectors include car refinishers, demolition companies, refineries, heavy industry, pharmaceutical industry, plastic industry, foundries and hospitals.

For the current study, two contacted laboratories indicate that they have noticed a marked increase in the number of measurements of elemental carbon after the introduction of a new Danish OEL for diesel engine exhaust emission (DEEE) which is lower than the newly introduced OEL at EU level. The number of measurements reported from one laboratory was about 100 samples in a year, whereas the other laboratory informed that measurements have been undertaken for 4-5 companies. The total for Denmark is likely to be some 200-400 samples. The number of workers exposed to DEEE in Denmark is estimated at 84,400 – 221,000 (Lassen et al., 2020) indicating that the number of samples compared to the number of potentially exposed workers is low.

7.2.5.3 The Netherlands

Two leading OSH service organisations have been contacted in the Netherlands. They both indicate that most companies would not monitor as a response to introduction of an OEL. One of the interviewees stated that he and his colleagues have never experienced that changing OELs were the reason for measurements. Another interviewee indicates that several of the companies that are already actively dealing with exposure do some monitoring as a consequence of an OEL introduction. These are mostly the larger companies with high and complex risk characteristics that evoke frequent and active surveillance by inspectorates. Examples are large petrochemical sites that monitor exposure to benzene as they expect a stricter OEL, and several companies started measurement campaigns after a new OEL for DEEE was introduced. Also, the branch association of insulation technology companies initiated a measurement campaign in the context of a lower OEL for diisocyanates. The latter is an example of measurement campaigns at trade associations' branch level, which has also been undertaken for DEEE.

In general, monitoring is mainly undertaken by larger companies. One of the interviewees indicated that measurements are hardly or not carried out in SMEs and the relatively high costs of measurements are an important factor here. Monitoring mainly take place in sectors like steel production, petrochemical industries and plastic production. The sampling campaigns are for larger companies undertaken in accordance with EN 689. For smaller companies, this approach may be too expensive. In those cases, one of the interviewees described that the process starts

with one measurement; if the concentrations is below 25% of OEL the measurement is repeated after a half and a full year. If the concentrations is above 25% of OEL extra measurements are required straight away. One interviewee indicated that it is not uncommon that occupational hygienists advise companies to spend their money on effective measures instead of on measurements.

7.2.5.4 Poland

An OSH research institute which undertakes sampling campaigns indicated that, as defined in Polish regulations, employers have a legal obligation to undertake testing and monitor exposure. The frequency of monitoring is defined in the regulation. As the requirements to monitor OELs have been implemented for a long period in Poland for the four substances under the current OELs6 project, an introduction of new OELs will not result in a completely new monitoring activity for employers in Poland. In Poland, the new OEL value for DEEE has been binding from the 20 February 2023. The research institute has received a large number of enquiries related to the monitoring of the elemental carbon and the occupational health exposure assessment methods. The majority of these enquiries are from large and medium sized enterprises. According to the interviewees, 98% of all exposed workers work for small and micro businesses such as car repair shops, and car services shops. Such micro and small enterprises are not making enquiries and it can be assumed that they will not be conducting monitoring and exposure measurement activities. The interviewees' institute purchased the required equipment and implemented a monitoring method to monitor DEEE. There are many businesses willing to be monitored when these monitoring activities are offered for free or at a subsidised cost (below the real market value cost).

According to the interviewees, micro and small enterprises do not routinely undertake monitoring and are consequently non-compliant with the legal requirements. In relation to formaldehyde, the OEL in Poland changed in 2018 and it is today one of the most monitored substances.

According to the interviewees when it comes to the proposed new OELs for the four substances included in this project, the biological monitoring is the most challenging aspect.

7.2.6 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); and
- 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 currently monitoring, one monitoring campaign to be undertaken before the new RMMs are introduced to establish which RMMs are required; and

- For some of the companies, one further monitoring campaign to be undertaken after the introduction of the RMMs to demonstrate compliance if there is uncertainty as to whether the new RMMs will achieve compliance.

Many companies, especially larger companies or companies with varying exposure concentration (e.g. from fugitive emission[15]), measure air concentrations regularly and would probably continue to do so after the introduction of the new OEL. The number of annual measurements may be significantly higher than the numbers indicated for the campaigns in the previous sections, but these measurements are typically not undertaken to document compliance but are part of the companies' HSE management procedures. Any measurements beyond the two campaigns described are not considered to be a consequence of the introduction of the OEL but are measurements that would be undertaken anyway. The introduction of the additional RMMs and the resulting lower concentration in some companies may result in less monitoring in the future, as the introduction of the new RMMs lowers the risk to workers from the exposure.

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. Each substance report includes a table in section 7.2.10 showing the percentage of all companies in the EU with exposed workers that would not need additional monitoring because they already meet a national OEL at the same or lower level. For Germany, it is assumed that the companies should already meet the level of tolerable risk (the higher of the two risk levels). The percentage may differ by sector, but for simplicity the calculated percentage is subtracted from the calculated total costs for all sectors.

For some substances, PAHs in the current OELs6 and diisocyanates in OELs5 are particular examples, there are many OELs at Member State level for different compounds of the substance. For these substances, assumptions are required to arrive at an estimate of the percentage of companies with exposed workers that are operating at the levels above and below the OEL policy options.

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; and
- 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

[15] Fugitive emissions are leaks and other irregular releases of gases or vapours from a pressurized containment.

because the costs of monitoring would be significant in comparison with the costs of just implementing further RMMs.

The study team considered whether to exclude companies in Member States that mandate monitoring but decided not to proceed with this because the data on mandatory monitoring had not been systematically collected from all Member States, and because in some Member States it is mandatory only if previous monitoring has been over a threshold such as 50% of the OEL. These percentages in Table 7-5 were developed within the study team based upon knowledge about the behaviour of small, medium and large companies, and based upon the fact that different Member States have different legislation and different enforcement levels.

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 7-5 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: Study team.

7.2.7 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 7-6 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

	Number	Unit
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: Study team.

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 service 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.

7.2.8 Estimated costs per company of two monitoring campaigns

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 undertake monitoring, given the existing OELs in their Member State, size, and sector (higher or lower level of monitoring).

Table 7-7 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	3	4	1	4	6
Planning, man-hours	€67	€402	€402	€402	€402	€402	€402

Activity Unit cost	Unit cost	OEL / median > 2			OEL / median < 2		
		S	M	L	S	M	L
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: Study team.

7.3 Biomonitoring and health surveillance costs

The costs of monitoring (sampling and analysis) are estimated separately to the core cost model. This section describes the overall framework for calculating the biomonitoring and health surveillance costs, and background information for setting the various parameters used for the calculations.

Biomonitoring and health surveillance costs may constitute a significant part of the total costs of compliance with a new BLV.

7.3.1 Requirements of the CMRD and national legislation

According to Article 11 (2) of the CMRD, "*Where a biological limit value has been set in Annex IIIa, health surveillance shall be mandatory for working with the carcinogen, mutagen or reprotoxic substance in question, in accordance with the procedures laid down in that Annex. Workers shall be informed of that requirement before being assigned to the task involving the risk of exposure to the carcinogen, mutagen or reprotoxic substance indicated.*"

Article 15 (4) of the CMRD says "*Biological limit values and other health surveillance information are set out in Annex IIIa"* and Annex IIIa (1.1) says for lead "*Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,075 mg/m³, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 40 µg Pb/100 ml*

blood is measured in individual workers." For the substances with BLVs in this study, the study team assumes that the level at which medical surveillance is required is 50% of the OEL or 50% of the BLV.

Article 14 of the CMRD sets out the requirements for health surveillance saying *"The Member States shall establish, in accordance with national law or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety. The doctor or authority responsible for the health surveillance of workers may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned."*

Article 3 (2) of the CMRD says *"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.*

There is some confusion in the CMRD because throughout the Directive the term "health surveillance" is used but in Annex IIIa, the term "medical surveillance" is used, and medical surveillance is not defined or used anywhere else in the Directive. The study team assumes that two terms have the same meaning.

Exactly what measurements or tests are required by health surveillance is also uncertain as it could mean anything from a full medical examination by a medical doctor and a wide range of tests every year, to a supervisor asking a couple of questions once a month. The study team has assumed that health surveillance relating to the substances in this study involves an examination by medical doctor, but no further tests requiring external analysis are required.

Many companies currently using the substances covered by this study would not currently undertake health surveillance, as their risk assessments would not lead them to do this: their Member States either has no BLV or it is well above the level at which the company operates.

7.3.2 Framework for estimating biomonitoring and health surveillance costs

The parameters used for estimating biomonitoring and health surveillance costs are listed in the table below.

Table 7-8 Parameters for biomonitoring and health surveillance monitoring cost model

Parameter	Assumption for monitoring cost model	Sources of input to the model
Total number of workers with worker exposure to the substance by size class		The basis for the estimated number of companies by size class is provided in section 3.4 of the substance reports
Unit costs of sample media and analysis	Varies by required LOQ of analysis method and the parameters to be measured	International laboratories providing analysis for the substances concerned
Costs such as sampling, and reporting for each monitoring campaign	Unit costs for planning, sampling and reporting. Sampling costs varies by number of samples	Based on model of costs of monitoring programmes developed for OELs 3 (RPA et al., 2018b)

Source: Study team

7.3.3 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 bio-monitoring 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 a full health surveillance is required , as the worker will need to provide samples and will require a follow up meeting with a medical doctor to receive the results.

7.3.4 Experience from Member States

No relevant information has been found.

7.3.5 Frequency of biomonitoring and health surveillance campaigns

Some companies are already expected to conduct health surveillance 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% and explained in the substance reports, see section 7.2.10.2; and
- 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 currently monitoring, one monitoring campaign to be undertaken before the new RMMs are introduced to establish which RMMs are required;
- For some of the companies, one further monitoring campaign to be undertaken 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 BL;
- 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; and
- 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%.

7.3.6 Assumed costs of planning, sampling, 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. For some substances, such as diisocyanates in OELs5, the cost per sample went up for measurements below a certain

LOQ, so the monitoring cost can be higher for the lowest policy options. This applies to both PAH and 1,4-dioxane.

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 demand increases, 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 7-9 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: Study team.

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 have 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.

7.3.7 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 BLVs in their Member State, size, and sector (higher or lower level of monitoring).

Table 7-10 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: Study team.

7.4 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.

7.4.1 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 company size to set up the monitoring each year. As in the previous calculations of the cost of monitoring, the cost of a worker or manager is assumed to be €500/day.

Table 7-11 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: Study team.

7.4.2 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 company size to set up the biomonitoring and health surveillance each year. As in the previous calculations of the cost of biomonitoring and health surveillance, the cost of a worker or manager is assumed to be €500/day.

Table 7-12 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: Study team.

7.5 Costs for Member State Authorities

There are three types of direct costs for Member State Authorities:

- Transposition costs;
- Enforcement costs; and
- Administrative burden.

7.5.1 Transposition costs

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 States may require further 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, RPA (2012)). Whilst 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 developing (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 (2011) 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 study 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 study assumes €100,000 per Member State as an approximation of the general order of magnitude of the transposition costs for putting welding fumes into Annex I because this is

likely to be accompanied by other changes to the CMRD to correct some contradictions caused by adding welding fumes into Annex I, see section 5 of the welding fumes substance report.

Sometimes there are complicating factors, such as OELs, STELs or BLVs for certain compounds, or for mixtures, which need to be handled differently and this is described in section 7.4 of the substance reports. This may lead to higher costs of transposition and applies to PAH and cobalt.

7.5.2 Enforcement costs

The enforcement, monitoring, inspection and adjudication costs depend on the number of companies that will be covered by the policy option. In principle, Member State Authorities are supposed to inspect companies already as they have the general obligation to protect workers. However, there could be an additional cost due to the need to ensure compliance with the new legislation. These enforcement costs depend on the inspection regime in each Member State, however such costs for each Member State are unknown and not estimated in this study. Despite this some costs are expected for each Member State authority.

7.5.3 Administrative burden

Member State authorities (MSAs) incur administrative costs if, for example, more reporting back to the EU is required, for example, or there are other additional administrative burdens. No additional reporting is anticipated and any other administrative burdens for MSAs cannot be identified or quantified.

8 APPROACH TO OTHER ISSUES

8.1 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, the study team can identify all of the companies with exposed workers accurately. But usually, the numbers of workers and companies by sector and size are taken available 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. The study team then makes an estimate based on the substance, risk management measures expected to be in place, and the proportions in similar industries. Wherever possible, the study team validates these estimates in discussion with companies and trade associations, but often they either have no idea or disagree.

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 (25th, 75th, 90th, 95th), 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.

The study team gathers all the available information, manually evaluates, interprets and assembles the exposure distribution for each sector, and then runs the models. Both the exposure distributions and the costs and benefits are sanity checked by the study team, 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, see section 5.2.7. 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.

In each of the substance reports, (section 13 and section 6.9 for welding), 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. Table 8-1 brings together all of the limitations that are considered to be significant. There are no significant impacts for isoprene.

Table 8-1 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 5.2.7	U or O	U or O

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	

Source: Study team.

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. The study team believes that the use of non-EU data increases the robustness of the estimates.

Clearly, the estimates of costs and benefits are based on many large assumptions: the study team's focus is to attempt to estimate the order of magnitude of the numbers correctly. For example, this means that if a number is 500,000, then the study team believes the number is likely to be between 100,000 and 999,999 but not 50,000 or 5,000,000.

8.2 One off costs and first year costs versus turnover and operating surplus

The first year costs include 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 cannot find RMMs that will enable it to comply, but this cannot be modelled, and it is likely to be high in cost, see section 5.5.1. 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.

8.3 Unemployment

Under the proposed policy options, employment conditions and workers health are expected to improve. However, negative employment impacts are expected to result from companies being forced to cease operations involving the substance if they cannot comply with the limit values. The numbers of workers potentially impacted at the different OELs are presented in section 8.5 of each substance report.

There are many potential scenarios, some positive and some negative. Note that some of the positive effects will still have a cost, such as retraining. 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 be a major employer in an area and therefore the impacts could extend to the town/area itself;
- 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[16].

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, 2016) and adapted from (Haveman R, H. and Weimer, D., 2015) and (Duborg, 2016). The impacts include the following components:

- The value of output/wages lost during the period of unemployment;
- The costs of job search, hiring and dismissing 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)); and
- 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 (Duborg, 2016 Table A7) 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; and
- 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).

[16] The study team is aware of some sectors where the last scenario is possible for cobalt and inorganic cobalt compounds and is making an adjustment for unemployment in these sectors.

8.4 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.

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 will find it harder to comply.

For many 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 and we assume that enforcement authorities understand that if major changes are underway to enable the FOEL, that they will take a constructive view.

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%. The transitional periods for PAH only apply to some sectors and therefore the reduction of 8% in costs and benefits only applies to these sectors and thus the overall reduction in costs and benefits is less than 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, see section 8.1. 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.

8.5 Monitoring and evaluation – SMART indicators

Some potential SMART (Specific, Measurable, Achievable, Relevant, and Time-Bound) indicators to be used in the monitoring and evaluation of the impacts are given in Table 8-2.

Table 8-2 SMART indicators to monitor and evaluate impacts

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 through the adoption by employers of appropriate risk management measures	Reductions in exposure to the identified CMR substances in the workplace to levels which are deemed safe.	Rates of adoption of improved RMM. by businesses and increased coverage of workers Numbers of cases breaching limit values and actions taken.	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 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 periods	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 information on CMR substances and safe exposure levels are generated and utilised to inform 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 updated scientific data, time to revise/adopt	Reports on operations and functioning of scientific bodies. Commission reports on adoption of revisions. Revisions to CMRD.
Facilitating implementation and contributing towards a better level playing field for economic operators by adopting minimum requirements 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 in different Member States (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, and the differences in these for companies and authorities in different Member States. 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

Specific objective	Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators
			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 requirements within time set by revised Directive. Number of MS adopting standards in excess of minimum requirements. Comparisons of EU minimum requirements with those of competing countries. Member State transposition of revised CMRD Costs for companies operating across Member States (including familiarisation and standardisation.)	Member State legislation Research studies commissioned by EC and Member State Authorities.
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 five-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.

Source: Study team and DG Employment

9 APPROACH TO THE ASSESSMENT OF THE ENVIRONMENTAL IMPACTS

Potential changes in OELs for the substances considered in this study may subsequently lead to an environmental impact, as an improvement or deterioration. The overall approach to the assessment of the environmental impacts is based on the Better Regulation (BR) Toolbox for environmental impacts (BR Tool #36). Initially the key questions listed in section 3.3. of the BR Tool #36 have been screened for all substances to identify which questions are relevant for the introduction of an OEL and should be answered in section 9 of the substance reports. This screening is shown in Table 9-1.

Each substance report outlines the following:

- For each impact shown in Table 9-1, the impact is identified as direct or indirect;
- Current environmental exposure to the substance including the persistent, bio-accumulative, and toxic (PBT) assessment status, sources, and background exposure;
- Direct environmental impacts; and
- Indirect environmental impacts.

Table 9-1 Key questions to identify potential environmental impacts

	Cobalt	PAH	Isoprene	1,4-dioxane	Welding
Overarching questions					
Is there a market failure linked to externalities (so polluters do not pay for the damage they do)?	-	-	-	-	-
Is there a market failure linked to environmentally harmful subsidies that encourage pollution?	-	-	-	-	-
What is the role of environmental technology and innovation in the problem and solving it?	√	√	-	-	-
Are there issues related to implementation and enforcement of existing environmental legislation?	√	√	√	√	√
Climate change					
Does the policy contribute to the achievement of the 2030 climate target of at least 55% net greenhouse gas emission and the climate-neutrality objective by 2050?	√	√	√	√	√
Does the policy affect the emission of ozone depleting substances (CFCs, HCFCs etc.)?	-	-	-	-	-
Does the policy affect our ability to adapt to climate change? How does the policy affect our adaptive capacity, resilience, or vulnerability for climate change?	-	√	-	-	√
Does the policy allow us to increase carbon removals or preserve carbon stocks?	-	-	-	-	-

	Cobalt	PAH	Isoprene	1,4-di-oxane	Welding
Does the policy improve climate mainstreaming into other policy goals?	-	-	-	-	-
With a view to achieving climate neutrality, i.e. equalisation of emissions and removals of greenhouse gases by 2050, does the policy ensure that no additional carbon lock-in is created?	-	-	-	-	-
Does the policy create risks for climate resilience as referred to in Tool #14 (Risk assessment and management)	-	-	-	-	-
Air					
Does the policy have an effect on emissions of harmful air pollutants that might lead to deterioration in the environment (crop yields, soil, forests or rivers etc.), affect human health, and damage buildings and cultural heritage	√	√	√	√	√
Water quality and resources					
Does the policy decrease or increase the quality or quantity of freshwater and groundwater?	√	√	√	√	√
Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)?	√	√	√	√	√
Does it affect drinking water resources, and in particular their quality?	-	-	-	√	√
Biodiversity					
Does the policy affect natural capital and the ecosystem services?	-	√	-	-	√
Does the policy reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)?	-	-	-	-	-
Does it affect protected or endangered species or their habitats or ecologically sensitive areas?	-	-	-	-	-
Does it affect the integrity and the conservation measures of Natura 2000 sites and for example split the landscape into smaller areas or in other ways affect migration routes, ecological corridors, or buffer zones??	-	-	-	-	-
Does the policy affect the scenic value of protected landscape	-	-	-	-	-
Soil quality and land use change and degradation					
Does the policy affect soil quality and result in a loss of soil carbon stocks, decline of soil	√	√	-	-	√

	Cobalt	PAH	Isoprene	1,4-di-oxane	Welding
biodiversity, compaction, sealing, landslides, acidification, contamination, salinisation or erosion?					
Does it lead to loss of available soil (e.g. through building or construction works i.e. land sealing) or increase the amount of usable soil (e.g. through land decontamination)?	-	-	-	-	-
Does the policy lead to land use change, land take and bring new areas of land ('greenfield') into use for the first time?	-	-	-	-	-
Does it affect land designated as sensitive for ecological reasons?	-	-	-	-	-
Does it lead to degradation of land?	-	-	-	-	-
Waste production and recycling					
Does the policy affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of, or recycled?	√	√	-	-	√
Zero pollution and toxicity					
Is the product toxic? At what levels? Is it (bio)degradable? Does it accumulate in the bodymass?	√	√	-	-	√
What are the sectors? Are there any non-toxic substitutes?	√	-	-	-	-
Efficient use of resources (renewable & non-renewable)					
Does the policy affect the use of renewable resources (fish, etc.) and lead to their use being faster than they can regenerate?	√	-	-	-	√
Does it reduce or increase use of non-renewable resources (groundwater, minerals, etc.)?	√	√	-	-	√
Does the policy affect the energy intensity of the economy?	√	√	-	-	-
Is there a risk of a 'rebound effect' (e.g. improvement in resource efficiency is offset by an increase in consumption)?	√	-	-	-	-
Is there an impact on the supply chain for key resources?	√	√	-	-	-
Circular economy					
Does the policy aim at maintaining the value of products, materials, and resources (understood as durability, reparability, reusability, or recyclability) for as long as possible by returning them into the product cycle at the end of their use, while minimising the generation of waste?	√	-	-	-	√

	Cobalt	PAH	Isoprene	1,4-di-oxane	Welding
Does the policy lead to verifiable additional sustainable production and consumption?	√	-	-	-	-
Does the policy change the relative prices of environmentally friendly and unfriendly products?	√	√	-	-	-
Does the policy promote or restrict environmentally (un)friendly goods and services through changes in capital investments, loans, insurance services, etc.?	-	-	-	-	-
Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?	√	√	-	-	-
The likelihood and scale of environmental risks					
Does the policy affect the likelihood or prevention of fire, explosions, breakdowns, accidents, and accidental emissions?	-	-	-	-	-
Does it affect the risk of unauthorised or unintentional release or proliferation of organisms or products that might have an environmental impact (such as invasive species)?	-	-	-	-	-
International environmental impacts					
Does the policy have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?	√	√	-	-	√
Does the policy promote the EU's sustainability objectives in third countries (Green Deal diplomacy)?	-	-	-	-	-
Environment and fairness					
Is the environmental policy socially just?	-	-	-	-	-
Does the policy reduce social and regional inequalities with respect to environmental and health risks, and access to eco-system services?	-	-	-	-	-
Does the policy disproportionally burden certain citizens (e.g. low-income or rural)? Are the benefits of the policy evenly distributed?	-	-	-	-	-

Source: Based upon BR #36, section 3.3

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11 ANNEXES

11.1 Annex 1 Stakeholder consultation – synopsis report

This section provides a summary of the stakeholder consultation exercises undertaken as part of this study ('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').

11.1.1 Outline of consultation strategy

The primary aim of the consultation activities is to identify information not available via desk-based research. For example, although information on current OELs, STELs, BLVs and notations is available, there is limited information 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. There may also, for example, be complications regarding the specificities of different sites and environments in which workers may be exposed. Consultation activities therefore formed a valuable part of this study.

The consultation activities conducted to date have included:

- Targeted questionnaires, these included: substance specific questionnaires, Member State Authorities, OSH Experts, Trade Unions and a further short questionnaire for welding[17];
- 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[18] being analysed as part of this study. 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). The substance and national experts in turn were also supported by experts in cost benefit analysis and consultation via a consortium led by RPA which has worked on all five previous OELs studies.

Any contact made with stakeholders was logged so that progress could be monitored, and interview guides have been prepared for those conducting interviews to ensure that the approach to collecting data was thorough and consistent. These guides include information clarifying the

[17] Questionnaires for MSA, Trade Unions and the further welding questionnaire were often accompanied by interviews. The aim of these interviews was to fill in the questionnaire and this formed the basis of the interview questions.

[18] Cobalt and inorganic cobalt compounds, isoprene, polycyclic aromatic hydrocarbons, welding fumes and 1,4-dioxane

objectives of the study, the study approach and provide detailed information on the measures being assessed. They also include information on the role of the national experts and the specific data that needs to be collected via consultation, as well as the privacy statement and the confidentiality options.

The following important aspects of the consultation exercise should be mentioned:

- There has been no public consultation conducted as part of this study, although the survey has – through its submission strategy – aimed to reach out widely.
- The consultation focused on generating *evidence* to directly support the analyses. Views and opinions have also been provided and are presented here as well, but the approach towards this has not been as systematic.
- Much of the evidence gathered is of a confidential nature and is thus not presented here, however it has been used to support the calculations and assessments that result from the analyses.

The table below summarises the stakeholder groups targeted and the tools, interests and strategies applied:

Table 11-1 Consultation tools and strategies

Stakeholder type	Interests represented	Main consultation tools	Strategy
EU Associations and REACH Consortia	Industry	Online interviews Email requests	Previous work demonstrated that EU trade and professional associations are the best instrument for reaching out to manufacturers/users. Upon request, the EU associations thus forwarded the questionnaires to national associations and companies. Supplementary information e.g. on number of companies, numbers of workers exposed, market situation, etc. was collected through email requests and online interviews with the associations and REACH consortia and statistics from Eurostat.
Member State Authorities	Member State Authorities	Questionnaires Online interviews	Member State authorities were contacted with a questionnaire and responses were followed up with online interviews, where possible. Experience from supporting the OELs 3, OELs 4 and OELs 5 studies demonstrated that this is the most effective way of collecting the specific information across all Member States.
Manufacturers/users	Industry	Questionnaires Online interviews Email requests	Based on the experience from OELs 3, OELs 4 and OELs 5, questionnaires for manufacturers/users were mainly distributed via EU associations. The EU associations forwarded the questionnaire directly to companies or forwarded it to national industry associations which then forwarded it to their member companies. This strategy was deemed the most sensible as experience from the previous OELs studies shows that only a few companies answer the questionnaire unless encouraged to do so by

Stake-holder type	Interests represented	Main consul-tation tools	Strategy
			either their relevant EU association or their national industry associations. To increase the number of responses, questionnaires were refined and kept as short as possible, and focused on providing data on existing RMMs as well as RMMs (and costs) needed to comply with the various reference limits (options) Questionnaire responses were then, where possible/ necessary, followed up by interviews and site visits. Some companies have also been contacted directly (i.e. not via the associations) by phone by national experts who encouraged and assisted the companies in filling out the questionnaire and/or undertook telephone interviews. This additional approach was selected to ensure that answers are provided by companies situated in as many Member States as possible.
National industry associations	Industry	Online interviews Email requests	National industry associations were primarily contacted via the EU associations. Some national associations were contacted directly by phone by national experts and interviewed to collect information supplementary to the information from EU associations and identify relevant national companies to be approached by the national experts.
Trade Unions	Workers	Online interviews Email requests Working Party on Chemicals (WPC)	Based on previous experience, this study focused on obtaining a few more targeted telephone interviews and email correspondence, as well as collecting information from worker association representatives of the WPC.
Occupational Health & Safety Professionals	Contacted to obtain scientific information	Questionnaire Online interviews	Occupational health and safety professionals were contacted with a questionnaire. This is considered the most efficient way to collect specific information across all Member States.
Working Party on Chemicals (WPC)	Industry Workers Member State Authorities	Participation in workshop	The study team presented draft results to the Working Party on Chemicals in May 2023. Previously, this has proved to be an effective means of receiving feedback from representatives of industry, employers' associations, workers' organisations and Member State authorities.
Laboratories	In communication to obtain information on sampling and analysis	Online interviews Email requests	In the study supporting OELs 3, a large number of laboratories were contacted via email requests. Limited information was obtained, and it was only obtained when the email requests were combined with telephone contact. For previous OELs studies and this study, the approach has been to contact a small number of

Stake-holder type	Interests represented	Main consul-tation tools	Strategy
			laboratories by phone and email using direct contacts, and to dedicate efforts to following-up on these, to obtain detailed information on methods applied, standards, limits of quantification and prices.

Source: Analysis by RPA Ltd and COWI

Some stakeholders could not be reached. Substance experts wanted to contact specific national welding institutes, companies and trade unions. Efforts were made to contact these stakeholders but there was no response.

11.1.2 Documentation of formal consultation activity

The questionnaires for each substance and stakeholder group can be found in the annexes.

- Welding Questionnaire: Welding Report Annex 2
- PAH Questionnaire: PAH Report Annex 3
- Cobalt Questionnaire: Cobalt Report Annex K
- Isoprene Questionnaire: Isoprene Report Annex 3
- 1,4 Dioxane Questionnaire: 1,4 Dioxane Annex 2
- MSA Questionnaire: Annex 2
- OSH Questionnaire: Annex 3
- Trade Union Questionnaire: Annex 4
- Welding short interview questionnaire: Annex 5

11.1.3 Methodologies and tools to process data

The online questionnaires for this study were hosted on EU Survey. EU Survey allows for full control over the creation and design of the questionnaire and allows translations to be edited through the website tools. Once completed, the survey data was exported from EU Survey into Excel and cleaned to ensure that only genuine responses were analysed. Any test answers or irrelevant responses were removed[19]. This was then provided to substance experts for analysis once combined with information that had been obtained through internet research, interviews and other means.

A stakeholder log was also created to monitor and record contact with stakeholders. This included contact information, contact method, and survey completion.

Experts responsible for each substance were provided with all the information relevant for their substance (questionnaire responses, interview minutes, site visit reports, position papers, etc.). All information was analysed by the specific substance expert and, where considered robust and

[19] One response for PAH and two responses for welding fumes were removed as these were completed by industry associations rather than companies and were analysed separately.

relevant, used as the basis for the substance-specific analyses in conjunction with information obtained via desk-based research.

11.1.4 Results of consultation activities

The consultation activities being conducted as part of this study are explained in greater detail in the subsections below.

11.1.4.1 Targeted online survey

The online 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, which provided an overview of the study and a link to the RPA webpage explaining the consultation activities, with links to each of the questionnaires, the privacy statement, and an introductory letter from the Commission. 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 and an additional welding questionnaire:

- Companies - cobalt;
- Companies - PAH;
- Companies - isoprene;
- Companies -1,4 – dioxane;
- Companies - welding fumes;
- Member State Authorities;
- Occupational Safety and Health Experts;
- Trade Unions; and
- Welding short interview guide.

The questionnaires for companies 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 to the study team using the designated OELs 6 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 the study team 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 to fill in information gaps. Other consultation methods were used to probe further into respondents' answers and gain a more in-depth understanding of the topic and potential impacts.

National experts were used to contact MSAs for countries where there was no response from that country.

The Commission and the Working Party on Chemicals (WPC) were provided the opportunity to comment on the drafts of each questionnaire before they were launched, to ensure that they were relevant and user-friendly.

Some stakeholders however expressed difficulty in responding to the questionnaire due to the complexity of the study – this was particularly the case for welding fumes. Discussions were held with key industry associations and these stakeholders were provided with the opportunity to respond to the questionnaire via interview, where explanation could be provided for each question. Responses were also received from industry organisations.

It should also be noted that some industry associations had already carried out their own surveys or had contributed to discussions on the relevant occupational exposure limits prior to this study, which may have resulted in consultation fatigue for some substances.

Around **691** stakeholders were invited to take part in the questionnaire. Many of the stakeholders contacted were relevant for multiple substances. 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. Based on experience from previous studies, this has been a useful method to ensure a high response rate from companies. Efforts were also made during calls with industry associations to encourage their members to respond. Stakeholders were selected from the sectors that were identified as being relevant for each of the substances. The tables below provide a summary of the responses according to stakeholder type.

Table 11-2 Summary of numbers of stakeholders contacted directly by questionnaire type

Stakeholder type		Number contacted
Companies	Companies	15.91% (110 out of 691)
	Industry associations	61.07% (422 out of 691)
Member State Authorities		20.69% (143 out of 691)
Occupational Health and Safety Experts		2.32% (16 out of 691)
Trade Unions*		3 contacted
Welding (short interviews)*		20 contacted

*Source: Consultation. *These were accompanied by an interview and were undertaken in addition to the main questionnaires and thus are not included in the total number.*

Four reminders were sent out to stakeholders to prompt them to respond and update them on the extension to the survey deadline. Stakeholders that had completed the survey or indicated

to the study team that the substance was not relevant to them were removed from the mailing list.

Table 11-3 Breakdown of number of stakeholders contacted directly by questionnaire type

Stakeholder type	Number contacted
Company	15.63% (108 out of 691)
Education and Training	0.14% (1 out 691)
Industry associations	59.62% (412 out of 691)
Laboratories	0.14% (1 out of 691)
Public authority	20.69% (143 out of 691)
NGO	1.45% (10 out of 691)
OSH Professional	2.32% (16 out of 691)
Trade Unions	0% (0 out of 691)

Source: Consultation.

The table below provides an overview of the number of responses received to the questionnaires from those contacted. This number includes responses that were able to be analysed after the initial cleaning process. Most responses came from companies as this was the stakeholder group where there was the most engagement and requests for responses. At least one contact was approached for each Member State, however not all Member States provided a response to the targeted questionnaire. The study team used the national experts to conduct interviews with the Member State authorities that have not responded to the questionnaire. National experts were also tasked with contacting and getting responses from trade unions.

Table 11-4 Responses per questionnaire

Stakeholder type	Number of responses
Companies	78.4% (196 out of 250)
Member State Authorities	10% (25 out of 250)
Occupational Health and Safety Experts	6% (15 out of 250)
Trade Unions	2 responses
Welding (short questionnaire)	12 responses
Total	**250**

Source: Consultation.

A large number of responses were received for substances that are used in a wide variety of industries. A breakdown of the questionnaire responses per substance and by company size is presented in the tables below.

Table 11-5 Questionnaire responses per substance

Stakeholder type	Number of responses
Cobalt	30.1% (59 out of 196)
PAH	32.65% (64 out of 196)
Isoprene	4.59% (9 out of 196)
1,4 Dioxane	2.55% (5 out of 196)
Welding Fumes	30.10% (59 out of 196)
Total	**196**

Source: Consultation.

Table 11-6 Summary of numbers of stakeholders contacted directly by each questionnaire type

Company size (employees)	Cobalt	PAH	Isoprene	1,4 Diox-ane	Welding Fumes	Total
Micro (<10)	1	1	0	0	12	**14**
Small (10-49)	5	10	0	2	14	**31**
Medium (50-249)	18	16	3	3	12	**52**
Large (250<)	35	37	6	0	21	**99**
Total	**59**	**64**	**9**	**5**	**59**	**196**

Source: Consultation.

11.1.4.2 Online interviews

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. The study team aimed 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.

Interviews were obtained in a variety of ways. At the end of the questionnaire, respondents were asked if they would be willing to take part in an interview. However, some online interviews were arranged through making direct contact with key industry associations.

Consultees were given the opportunity to respond in their native language. In cases where this was required, the interview was carried out by the national expert.

Each online interview lasted approximately one hour. After the telephone interview, organisations/individuals were sent notes from the meeting by email and asked for comments. The study team made sure that all interviewees were happy with the notes as a record of the interviews.

National experts and substance specific experts conducted interviews with relevant stakeholders. 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.

A summary of the number of interviews carried out is presented in the table below. A total of 58 interviews were carried out.

Table 11-7 Breakdown of interviews per stakeholder type

Stakeholder type	Interviews conducted
Laboratories	3.45% (2 out of 58)
EU industry association	50% (29 out of 58)
Companies	27.59% (16 out of 58)
Member State Authorities	0% (0 out of 58)
Trade Unions	1.72% (1 out of 58)
Occupational health and safety experts	1.72% (1 out of 58)
Other	15.52% (9 out of 58)
Total	58

Source: Consultation

Table 11-8 Breakdown of interviews per substance

Stakeholder type	Number of responses
Cobalt	29.31% (17 out of 58)
PAH	44.83% (26 out of 58)
Isoprene	6.90% (4 out of 58)
1,4 Dioxane	5.17% (3[20] out of 58)
Welding Fumes	10.34% (6 out of 58)
Other	3.45% (2 out of 58)
Total	58

Source: Consultation

11.1.4.3 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

[20] Two of these interviews were extended email exchanges.

answers to the questionnaire, as well as making requests for additional information such as industry statistics.

Cobalt and inorganic cobalt compounds: constructive conversations have been carried out via email with the following stakeholders:

- Cobalt REACH Consortium / Cobalt Institute
- Inorganic Pigments (IP) Consortium
- Frit consortium
- ETRMA-European Tyre & Rubber Manufacturers' Association
- Eurofer
- Concawe
- FuelsEurope
- FEFAC
- European Dental Industry (FIDE)
- Verband der Deutschen Dental-Industrie
- Eurobat
- VOM
- RECHARGE AISBL
- Glass Alliance Europe
- British Glass
- The European Semiconductor Industry Association (ESIA)
- EFPIA
- Catalysts Europe
- European Rubber Chemicals Association (ERCA)
- Eurocolour
- Eurometaux
- The European Foundry Association
- The Welding Institute (TWI)
- DGUV, Germany
- INRS, France
- Companies in Germany; Sweden, Denmark, Luxembourg, Belgium, Austria, Spain
- Laboratories in Denmark and Germany

PAH: constructive conversations have been carried out via email with the following stakeholders:

- European Institute for Wood Preservation (WEI-IEO)
- Company, Germany
- The European Steel Association (EUROFER)

- Fuels Europe
- Community of European Railway and Infrastructure Companies (CER)
- European Salmon Smokers Association (ESSA)
- European Rubber Chemicals Association (ERCA)
- BWL Consulting (EAST) Limited
- The Finnish Institute of Occupational Health (FIOH)
- European Construction Industry Federation (FIEC)
- Verband Chemiehandel e.V. (VHC)
- European Garage Equipment Association (EGEA)
- European Precious Metals Federation
- Confederation of European Waste-to-Energy Plants (CEWEP)
- Timber Development UK
- European Association of Research & Technology (EARTO)
- Wood Protection Association (WPA)
- Airports Council International Europe (ACI EUROPE)
- European Association for Coal and Lignite aisbl (Euracoal)
- The Voice of Europe's Independent Fuel Suppliers (UPEI)
- Airlines 4 Europe (A4E)
- Istituto nazionale Assicurazione Infortuni sul Lavoro (INAIL)
- International Carbon Black Association (ICBA)
- Federation of European Fire Officers association (FEU)
- European Rail Infrastructure Managers (EIM)

Isoprene: constructive conversations have been carried out via email with the following stake-holders:

- Cefic
- ERCA
- Company, US
- The Polymer Processing Society (PPS)
- FEICA
- European Oleochemicals & Allied products Group (APAG)
- Company, Netherlands
- Company, US
- Company, Italy
- Company, US
- Company, Japan
- BASF

- OSHA
- Company, US
- Company, US
- Company, Germany
- Industry Association, UK

1,4 – Dioxane: constructive conversations have been carried out via email with the following stakeholders:

- Company, Spain.

Welding fumes: constructive conversations have been carried out via email with the following stakeholders:

- Deutscher Verband für Schweißtechnik (DVS)
- European Welding Association (EWA)
- European Welding Federation (EWF)
- International Institute of Welding (IIW)
- Arbo Advies Bureau Halm, Netherlands
- Berufsgenossenschaft Holz und Metall (BGHM)
- Syndicat National de La Chaudronnerie, de La Tôlerie et de La Tuyauterie Industrielle (SNCT)
- European Construction Industry Federation (FIEC)
- The Welding Institute (TWI)
- Community of European Railway and Infrastructure Companies (CER)
- Vocational training centre, UK
- Company, Germany
- Company, Germany
- Deutsche Gesetzliche Unfallversicherung (DGUV)
- Nederlands Instituut voor Lastechniek (NIL)
- Netherlands working group on welding fumes

11.1.4.4 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 members of the study team for a site visit. Companies to be visited were identified through the questionnaire or 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.

Table 11-9 Site visits per substance

Stakeholder type	Number of responses
Cobalt	4
PAH	3
Isoprene	0
1,4 Dioxane	0
Welding Fumes	2
Total	**9**

Source: Consultation.

Table 11-10 Summary of site visits per substance and size of enterprise

Company size (enterprises)	Cobalt	PAH	Isoprene	1,4 Dioxane	Welding Fumes	Total
Micro (< 10)	0	1	0	0	0	1
Small (10-49)	0	0	0	0	0	0
Medium (50-249)	0	0	0	0	0	0
Large (>250)	4	2	0	0	2	8
Total	4	3	0	0	2	9

Source: Consultation.

11.1.4.5 Consultation results by substance

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.

11.1.4.6 Summary of consultation statistics

The following tables provide breakdowns of the questionnaire responses, interviews and site visits carried out by company size, stakeholder type and substance.

The breakdown of questionnaire responses, interviews and site visits by company size are provided below. They show that the majority of the responses were received from large or medium-sized enterprises, with fewer responses from small and very small enterprises.

Table 11-11 Breakdown of questionnaire responses, interviews and site visits per company size (only for consulted companies and laboratories)

Company size (employees)	Questionnaire responses	Interviews	Site visits
Micro (<10)	7.14% (14 out of 196)	0% (0 out of 16)	11.11% (1 out of 9)
Small (10-49)	15.83% (31 out of 196)	0% (0 out of 16)	0% (0 out of 9)
Medium (50-249)	26.53% (52 out of 196)	12.5% (2 out of 16)	0% (0 out of 9)
Large (250<)	50.51% (99 out of 196)	87.5% (14 out of 16)	88.89% (8 out of 9)

Source: Consultation

The breakdown of questionnaire responses, interviews and site visits per substance are provided below. These results show that most questionnaire responses and site visits were provided in relation to PAH, welding fumes and cobalt, with relatively fewer responses for isoprene and 1,4-dioxane.

Table 11-12 Breakdown of questionnaire responses, interviews and site visits per substance (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)

Substance	Questionnaire responses[21]	Interviews	Site visits
Cobalt	28.15% (85 out of 302)	29.31% (17 out of 58)	44.44% (4 out of 9)
PAH	29.47% (89 out of 302)	44.83% (26 out of 58)	33.33% (3 out of 9)
Isoprene	5.63% (17 out of 302)	6.90% (4 out of 58)	0% (0 out of 9)
1,4 Dioxane	9.93% (30 out of 302)	5.17% (3 out of 58)	0% (0 out of 9)
Welding fumes	26.82% (81 out of 302)	10.34% (6 out of 58)	22.22% (2 out of 9)
Welding (short interviews)	12 responses	n/a	n/a
Trade Unions	2 responses	n/a	n/a
Other	0% (0 out of 302)	3.45% (2 out of 58)	0% (0 out of 9)

Source: Consultation

The breakdown of questionnaire responses, interviews and site visits per Member State are provided below. These results show a high number of questionnaire responses were received from Germany and a high number of interviews were from Belgium. It is not clear why these countries received high responses but the high responses from these countries occurred across all substances.

In the substance reports, the potential impact of the high number of responses from Belgium and Germany is referred to if the study team thinks that the results could be biased by this. Germany in particular has already implemented regulations relating to welding and has relatively low existing OELs for PAH, cobalt and isoprene. Overall, the unbalanced breakdown of

[21] The questionnaire responses are higher here as the MSA and OSH questionnaire had substance specific sections. Where these have been completed, they have been added as one response.

responses by Member States is taken into account by the study team, and the information is balanced by data from other stakeholders and sources, to ensure that the conclusions are not believed to be unduly influenced by the responses from Belgium and Germany.

Table 11-13 Breakdown of questionnaire responses, interviews and site visits per Member State (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)

Country	Questionnaire responses	Interviews	Site visits
Inside the EU			
Austria	3.2% (8 out of 250)	3.45% (2 out of 58)	-
Belgium	3.6% (9 out of 250)	33.3% (19 out of 58)	-
Bulgaria	0.8% (2 out of 250)	0% (0 out of 58)	-
Croatia	1.6% (4 out of 250)	0% (0 out of 58)	-
Cyprus	0.4% (1 out of 250)	0% (0 out of 58)	-
Czechia	2.4% (6 out of 250)	0% (0 out of 58)	-
Denmark	1.6% (4 out of 250)	5.17% (3 out of 58)	-
Estonia	1.6% (4 out of 250)	0% (0 out of 58)	-
Finland	2.8% (7 out of 250)	1.72% (1 out of 58)	-
France	6.4% (16 out of 250)	0% (0 out of 58)	-
Germany	32.4% (81 out of 250)	13.79 % (8 out of 58)	-
Greece	0% (0 out of 250)	1.72% (1 out of 58)	-
Hungary	1.2% (3 out of 250)	0% (0 out of 58)	-
Ireland	0.4% (1 out of 250)	0% (0 out of 58)	-
Italy	11.2% (28 out of 250)	5.17% (3 out of 58)	-
Latvia	0.4% (1 out of 250)	0% (0 out of 58)	-
Lithuania	0.4% (1 out of 250)	0% (0 out of 58)	-
Luxembourg	0.4% (1 out of 250)	0% (0 out of 58)	-
Malta	0% (0 out of 250)	0% (0 out of 58)	-
Netherlands	6% (15 out of 250)	1.72% (1 out of 58)	-
Poland	4.4% (11 out of 250)	0% (0 out of 58)	-
Portugal	0.8% (3 out of 250)	0% (0 out of 58)	-
Romania	0.4% (1 out of 250)	0% (0 out of 58)	-

Country	Questionnaire responses	Interviews	Site visits
Slovakia	0.4% (1 out of 250)	0% (0 out of 58)	-
Slovenia	1.2% (3 out of 250)	0% (0 out of 58)	-
Spain	4% (10 out of 250)	8.62% (5 out of 58)	-
Sweden	5.2% (13 out of 250)	3.45% (2 out of 58)	-
Multiple Member States	1.6% (4 out of 250)	6.90% (4 out of 58)	-
Other	-	5.17% (3 out of 58)	-
Outside the EU			
Iceland	0.4% (1 out of 250)	0% (0 out of 58)	-
Norway	1.2% (3 out of 250)	0% (0 out of 58)	-
South Korea	0.4% (1 out of 250)	0% (0 out of 58)	-
Switzerland	1.6% (4 out of 250)	0% (0 out of 58)	-
UK	0.8% (2 out of 250)	6.90% (4 out of 58)	-
US	0% (0 out of 250)	3.45% (2 out of 58)	-
Total	**250**	**58**	**9**

Source: Consultation

Notes: In some cases, the input for location was given as several Member States or a list of companies for the same response. In order to not inflate the numbers presented, if this was given as an answer, it is recorded this under 'multiple Member States'.

Site visits have been carried out, but the location cannot be disclosed due to confidentiality and the small sample size.

11.1.5 How the information gathered has been taken into account

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 in all of the Member States, for each of the relevant substances, from companies of varying sizes.

The information collected via consultation has enabled the study team to gain a more nuanced understanding of the likely impacts of modifying or introducing OELs, which could not have been obtained otherwise via desk-based research/literature reviews. 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.

The table below summarises how the responses in each questionnaire section are used in each report. The majority of the analysis is undertaken and discussed in each of the substance specific reports.

Table 11-14 Questionnaire sections mapped to relevant section in each substance report

Questionnaires and sections	Report section
Companies	
B	Exposure concentrations Exposed workforce Current risk management measures (RMMs)
C	Lowest technically possible and economically feasible option
D	RMMs needed to achieve compliance
E	Voluntary industry initiatives
F	Other benefits
G	Impact of the implementation of other OELs
H	Other comments
Member State Authority	Existing national limits Costs for public administrations Costs Market effects Environmental impacts Indirect benefits Employment
Occupational Health & Safety Experts	Current risk management measures (RMMs) Existing national limits RMMs needed to achieve compliance
Trade Unions	Voluntary industry initiatives Exposed workforce Benefits
Welding	(Welding only - short interviews) Definition of the problem Benefits

Source: Study team

11.1.5.1 Information and issues raised by stakeholders

During the stakeholder consultation, the Cobalt Institute submitted three reports prepared specifically for the purpose of providing information for this study.

No similar reports specifically for this study were submitted for the other four substances.

11.1.5.1.1 Cobalt

The Cobalt Institute submitted three reports as part of the stakeholder consultation prepared specifically for this study (in addition to several older reports):

- Impact Assessment: Binding Occupational Exposure Limits for cobalt metal and cobalt substances. Prepared by eftec for the Cobalt Institute, July 2013
- Study on the impact of potential OELs on EU Strategic Goals. Prepared by RPA for the Cobalt Institute, March 2023.
- Cobalt Workplace Particle Size Distributions & Calculation of a Human Equivalent Concentration (HEC). Prepared by EBRC consulting for the Cobalt Institute, February 2016. With an update EXCEL spreadsheet with exposure concentration data.

The results of the two first studies have been presented by the Cobalt Institute for the Working Party on Chemicals (WPC) at a videoconference August 2023. The results of the studies are presented and discussed in the substance specific report. The Cobalt Institute has not submitted a position paper, but 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.

The European Feed Manufacturers' Federation (FEFAC) have submitted three reports that have previously been submitted to ECHA to the stakeholder consultation for the restriction proposal for five cobalt salts. FEFAC did not provide any positions.

The European Container Glass (FEVE) industry have submitted a paper on "FEVE input to the questionnaires on cobalt uses and welding fumes in the container glass industry". The paper includes information on the use of cobalt in the sector and occupational exposure. FEVE did not provide any positions.

European Dental Industry (FIDE) has provided a statement from the Association of German Dental Manufacturers on cobalt alloys in dental alloys of 8 June 2021. The statement concerns alternatives and exposure of the patients to cobalt in implants. The statement does not concern occupational exposure or any impact of establishing an OEL.

Catalyst Europe has provided four papers of which three are indicated as confidential and consequently are not quoted in the report, but have been used by the study team as background information. The fourth report on catalyst handling best practice guide is quoted in the report. Catalyst Europe did not provide any positions.

Eurometaux has answered that they have not received input/information from companies/associations that would not be covered by the Cobalt Institute survey. This explains why a number of associations in the metal sector have not answered the request from the study team. Eurometaux did not provide any positions.

The Frit Consortium have provided a statement on "Frits, chemicals additional information" of 30 January 2023: "Considering that neither the tricobalt tetraoxide (EC 215-157-2), nor the substance "frits, chemicals" (EC 266-047-6) are within the scope of the CMRD, the position of the frit industry is that our industrial sector would be outside of the scope of OELs6 consultation."

Eurocolour has provided a statement of 27 April 2023 which mainly concerns which pigments would be within the scope and that Eurocolour fully supports the information given by the relevant consortia, IP Consortium and Frits Consortium.

One company in the hardmetal sector has provided a position paper of 5 June 2023. Besides describing the process and value chain, the company point at the need for making sure that the EU can still source cobalt independent from China by ensuring recycling within the EU. It notes that introduction of an OEL would heavily impact recycling and that part of the supply chain where powder is handled. According to the position paper, more than 50% of the company's jobs have to be moved outside the EU by introducing low limits. It is indicated that an OEL of 20 µg/m^3 for the inhalable fraction would require a full automation/robotization, dramatically increasing the production costs.

11.2 Annex 2 - Member State authority questionnaire

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe (Italy), RPA Europe Prague (Czech Republic) COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), EPRD (Poland) and Force Technology (Denmark) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limit values (OELs) or introducing a substance into Annex I.

The purpose of the study is to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances at work (the Carcinogens, Mutagens or Reprotoxic substances Directive, **CMRD**).

The substances being considered are:

- **Polycyclic aromatic hydrocarbons (PAH)**
- **Cobalt and inorganic cobalt compounds**
- **Isoprene**
- **1,4-dioxane**

New OELs are proposed for the four substances above under the CMRD. In addition, biological limit values (BLV) are proposed for PAH and 1,4-dioxane, and a 15-minute short-term exposure limit value (STEL) is proposed for 1,4-dioxane. In addition, 'skin sensitisation' and 'respiratory sensitisation' notations are proposed for cobalt and inorganic cobalt compounds, and 'skin' notations are proposed for isoprene, PAHs and 1,4-dioxane.

An amendment to include **welding fumes** in Annex I of the CMRD is also being considered.

The purpose of this questionnaire is to collect data and information that will underpin the assessment.

All responses to this questionnaire will be treated in the **strictest confidence** and will only be used for the purposes of this study. In preparing our report for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

This questionnaire is intended for **Member State authorities** that are responsible for setting and/or enforcing national OELs and/or would be able to provide any information, views, and data on the likely impacts of new limit values.
The questionnaire consists of six parts:

- Part A: About your organisation
- Part B: Enforcement of existing limit values
- Part C: Current limit values for the five substances
- Part D: Impacts of potential new OELs or inclusion in Annex I
- Part E: Other comments
- Part F: Further communication

The **deadline** for completion of the questionnaire is **3 March 2023**.

The questionnaire is in English. However, you are welcome to answer the questions in any official European language of your choice. If you prefer to be interviewed in your language, please contact OELs6@rpaltd.co.uk

Please **return** the completed questionnaire to OELs6@rpaltd.co.uk

Abbreviations and terms used in the questionnaire:

BLV	A 'biological limit value' (BLV) is 'the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect'

CMRD	Directive2004/37/EC on the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances at work (the Carcinogens, Mutagens or Reprotoxic substances Directive
OEL	The term Occupational Exposure Limit value (OEL) refers to the limit of the time-weighted average (TWA) of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours.
RAC	The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment.
RMM	Risk Management Measure
SMEs	Small and Medium-sized Enterprises. Companies with between 50 and 249 employees are medium-sized. Companies with between 10 and 49 employees are small (and less than 10 employees are micro enterprises). Companies with more than 250 employees are large companies. For further definitions, please refer to http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm
STEL	A short-term exposure limit is like an OEL but involves a shorter reference period (usually 15 minutes). The aim of this value is to prevent adverse health effects caused by peaks in exposure that will not be controlled by the application of an 8-hour TWA limit.
8 hour TWA	8 hour Time-Weighted Average, measured in parts per million (ppm) or milligrams per cubic metre (mg/m^3). The 8 hour TWA is an expression for the average exposure for a typical working day. It is calculated by summing up the concentrations (in ppm or mg/m^3) during different periods of a day (usually 8 hours). Each concentration is multiplied by its relevant duration and the total is divided by the entire length of the working day (usually 8 hours) such as in this example: 8h-TWA = (2 hours * 500 ppm + 5 hours * 100 ppm + 1 hours * 700 ppm) / (2 + 5 + 1 hours).

Examples of relevant PAH compounds:

Substance name	Cas Number
Benzo[e]pyrene	205-892-7
Benzo[j]fluoranthene	205-910-3
Benzo[e]acephenanthrylene	205-911-9
Benzo[k]fluoranthene	205-916-6
Chrysene	205-923-4
Benzo[def]chrysene	200-028-5
Dibenz[a,h]anthracene	200-181-8
Benz[a]anthracene	200-280-6
Dibenzo[b,def]chrysene; dibenzo[a,h]pyrene	205-878-0
Benzo[r,s,t]pentaphene	205-877-5

Examples of relevant cobalt and inorganic cobalt compounds:

Substance name	Cas Number
Cobalt carbonate	513-79-1
Cobalt oxide	1307-96-6
Cobalt	7440-48-4
Cobalt dichloride	7646-79-9
Cobalt sulphate	10124-43-3

Substance name	Cas Number
Cobalt dinitrate	10141-05-6
Cobalt lithium dioxide	12190-79-3
Cobalt molybdate	13762-14-6
Cobalt dihydroxide	21041-93-0
Cobalt titanite green spinel	68186-85-6
Olivine, cobalt silicate blue	68187-40-6
Cobalt lithium nickel oxide	-
Aluminum cobalt lithium nickel oxide	177997-13-6
Reaction mass of cobalt olivine and crystalline silicon dioxide	68187-40-6

Examples of relevant isoprene compounds:

Substance name	Cas Number
Isoprene	78-79-5

Examples of relevant 1,4-dioxane compounds:

Substance name	Cas Number
1,4-Dioxane	123-91-1

Examples of relevant welding fumes substances:

Substance name
Inhalable welding fumes
Respirable welding fumes
Welding fumes (generic)
Particulate matter (dust)
Carbon monoxide
Nitrogen monoxide (NO)
Nitrogen dioxide (NO2)
Nitrogen oxides (NOx)
Ozone
Aluminium compounds (Al)
Barium compounds (Ba)
Cobalt compounds (Co)
Chromium II or III compounds (Cr II/III)
Chromium VI compounds (CrVI)
Total chromium (Cr)
Copper compounds (Cu)
Iron compounds (Fe)
Magnesium compounds (Mg)
Manganese compounds (Mn)
Nickel compounds (Ni)
Vanadium compounds (V)

A) About your organisation

Please provide the following details.

Question	Answer
Name	
Organisation	

Country	
Email	
Telephone	

B) Enforcing national exposure limit values

A1) Please summarise how compliance with **binding OELs** needs to be demonstrated in your Member State.

Question	Answer
How is the air exposure concentration determined?	☐ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	
If **measured**, are there any rules on whether sampling must be personal or for the work area?	
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☐ No
If measured, how is compliance with the OEL determined? See an explanation in the box below.	

A2) Please summarise how compliance with **binding STELs** needs to be demonstrated in your Member State.

Question	Answer
How is the air exposure concentration determined?	☐ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	
If **measured**, are there any rules on whether sampling has to be personal or for the work area?	
If **measured**, does air sampling have to be carried out by an external contractor?	☐ Yes ☐ No
If measured, how is compliance with the STEL determined? See an explanation in the box below.	

A3) Please summarise how compliance with **binding BLVs** needs to be demonstrated in your Member State.

Question	Answer
How is the biological limit value determined?	☐ Measured ☐ Estimated
If **estimated**, please specify how:	
If **measured**, how many samples and how often do they need to be taken to demonstrate compliance?	
If **measured**, does sampling have to be carried out by an external contractor?	☐ Yes ☐ No
If measured, how is compliance with the BLV determined? See an explanation in the box below.	

Values based on measured samples can be derived using, for example, the following methods:

- A single sample or several individual samples
- A single value combining all samples:

- Arithmetic mean
- Geometric mean
- Median
- 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Mode

- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- IF other, please specify

A4) Please indicate whether your Member State holds any databases containing exposure data

Question	Answer
Are you aware of any national occupational exposure databases in your Member State?	☐ Yes ☐ No
If yes, please provide a link (or send via email to OELs6@rpaltd.co.uk).	

C) Current limit values for the five substances

C1) For which of the following substances does your Member State have OELs, STELs, BLVs or skin notations, either binding or indicative? Please tick all that apply.

☐ Polycyclic Aromatic Hydrocarbons
☐ Cobalt and inorganic cobalt compounds
☐ Isoprene
☐ 1,4-Dioxane
☐ Welding fumes

C3) Please provide the following information for **Polycyclic Aromatic Hydrocarbons (PAHs)**.

Question	Answer
*Please provide information about **OEL(s)** for PAHs*	
OEL or OELs (value, unit)	
Please state the PAH compounds/applications/occupations that are covered by the OEL(s)	
Please indicate if respirable, inhalable or total dust	
Please give details about OELs for all types of PAH if there are more than one	
Is the OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	

Question	Answer
Any other comments about the OEL	
*Please provide information about **BLV(s)** for PAHs*	
BLV or BLVs (value, unit)	
Please state the PAH compounds/applications/occupations that are covered by the BLV	
Please indicate if respirable, inhalable or total dust	
Please give details about all BLVs if more than one	
Is the BLV?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the BLV	
*Please provide information about **notations** for PAHs*	
Please give details about any notations for PAHs (skin, sensitisation, respiratory etc)	
*Please provide information about **further sources of information***	
Are there further national data/ assessment documents on this substance? Please note this would also include any national guidance on biomonitoring for this substance.	☐ Yes ☐ No
If yes, please provide a link to the document(s) (or send it/them via email to OELs6@rpaltd.co.uk). If possible, provide English translations.	
Is there a national expert available to explain background and details of national regulations for this substance	☐ Yes ☐ No
If yes, please give contact details	

C4) Please provide the following information for cobalt and inorganic cobalt compounds.

Question	Answer
*Please provide information about **OEL(s)** for cobalt and inorganic cobalt compounds*	
OEL or OELs (value, unit)	
Please state which for cobalt and inorganic cobalt compounds /applications/occupations are included within the OEL(s)	

Question	Answer
Please indicate if respirable, inhalable or total dust	
Please give details about all OELs if more than one	
Is the OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the OEL	
*Please provide information about **notations** for cobalt and inorganic cobalt compounds*	
Please give details about any notations for cobalt and inorganic cobalt compounds (skin, sensitisation, respiratory etc)	
*Please provide information about **further sources of information***	
Are there further national data/ assessment documents on this substance?	☐ Yes ☐ No
If yes, please provide a link to the document (or send it via email to OELs6@rpaltd.co.uk). If possible, provide an English translation.	
Is there a national expert available to explain background and details of national regulations for this substance	☐ Yes ☐ No
If yes, please give contact details	

C5) Please provide the following information for **isoprene**.

Question	Answer
*Please provide information about **OEL(s)** for isoprene*	
OEL or OELs (value, unit)	
Please state which isoprene applications/occupations are included within the OEL(s)	
Please indicate if respirable, inhalable or total dust	
Please give details about all OELs if more than one	
Is the OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	

Question	Answer
Any other comments about the OEL	
*Please provide information about **notations** for isoprene*	
Please give details about any notations for isoprene (skin, sensitisation, respiratory etc)	
*Please provide information about **further sources of information***	
Are there further national data/ assessment documents on this substance?	☐ Yes ☐ No
If yes, please provide a link to the document (or send it via email to OELs6@rpaltd.co.uk). If possible, provide an English translation.	
Is there a national expert available to explain background and details of national regulations for this substance	☐ Yes ☐ No
If yes, please give contact details	

C6) Please provide the following information for **1,4-dioxane.**

Question	Answer
*Please provide information about **OEL(s)** for 1,4-dioxane*	
OEL or OELs (value, unit)	
Please state which 1,4-Dioxane applications/occupations are included within the OEL(s)	
Please indicate if respirable, inhalable or total dust	
Please give details about all OELs if more than one	
Is the OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the OEL	
*Please provide information about **STEL(s)** for 1,4-dioxane*	
STEL or STELs (value, unit)	
Please state which 1,4-Dioxane /applications/occupations are included within the STEL(s)	
Please indicate if respirable, inhalable or total dust	
Please give details about all STELs if more than one	

Question	Answer
Is the STEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the STEL	
*Please provide information about **BLV(s)** for 1,4-dioxane*	
BLV or BLVs (value, unit)	
Please state the 1,4-dioxane compounds/applications/occupations that are covered by the BLV	
Please indicate if respirable, inhalable or total dust	
Please give details about all BLVs if more than one	
Is the BLV?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the BLV	
*Please provide information about **notations** for 1,4-dioxane*	
Please give details about any notations for 1,4-dioxane (skin, sensitisation, respiratory etc)	
*Please provide information about **further sources of information***	
Are there further national data/ assessment documents on this substance?	☐ Yes ☐ No
If yes, please provide a link to the document (or send it via email to OELs6@rpaltd.co.uk). If possible, provide an English translation.	
Is there a national expert available to explain background and details of national regulations for this substance	☐ Yes ☐ No
If yes, please give contact details	

C7) Please provide the following information for **welding fumes.**

Question	Answer
*Please provide information about **OEL(s)** for welding fumes*	
OEL or OELs (value, unit)	

Question	Answer
Please state which welding fumes/ processes/ applications/ occupations are included within the OEL(s)	
Please indicate if respirable, inhalable or total dust	
Please give details about all OELs if more than one	
Is the OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Any other comments about the OEL	
*Please provide information about **further sources of information***	
Are there further national data/ assessment documents on this substance?	☐ Yes ☐ No
If yes, please provide a link to the document (or send it via email to OELs6@rpaltd.co.uk). If possible, provide an English translation.	
Is there a national expert available to explain background and details of national regulations for this substance	☐ Yes ☐ No
If yes, please give contact details	
Additional questions for welding fumes	
Germany and Denmark have ranked welding and associated processes by health hazard for welders. Has your country ranked welding and associated processes by health hazard for welders (combining emission rates and hazardous substances present for example), in order to recommend control measures?	☐ Yes ☐ No
If yes, can you provide a link to a reference which explains the methodology for ranking the welding and associated processes?	
If yes, can you provide a link to a reference	
If yes, can you provide a link to the recommended control measures for each welding and associated process	
Are you able to share data collected to assess the risk of occupational exposure to different welding and associated processes?	☐ Yes ☐ No
If yes, please provide links to this data or contact details for access to the data.	

Question	Answer
Is data available on the occupational exposure risk to welders and to other exposed workers working in the vicinity of the welding activity?	☐ Yes ☐ No
If yes, please provide links to this data or contact details for access to the data.	

D) Impacts of potential new limit values or inclusion in Annex I

D1) What would be the impact of the following policy options for combined **OELs** and **BLVs** for **PAHs**?

Policy Option	BaP, ng/m³	3-OHBaP level, nmol/mol creatinine
1 This is the Median and Mode limit value (or equivalent) observed among Member States	2000	3.8 nmol/mol creatinine
2 This is equivalent to lung cancer excess risk of 4 per 1,000	700	1.5 nmol/mol creatinine
3 This is the lowest OEL (tolerable concentration in Germany, equivalent to lung cancer excess risk 4 per 10,000)	70	0.3 nmol/mol creatinine
4 This would be 10% of the lowest OEL for EU MS and equivalent to a lung cancer excess risk of 4 per 100,000	7	0.2 nmol/mol creatinine

Impact	OEL (ng/m³)	3-OHBaP level, nmol/mol creatinine	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐
Costs for public authorities	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐
Competitive-ness	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐
SMEs	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐
Occupational health	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐
Environment	2000	3.8	☐	☐	☐	☐	☐
	700	1.5	☐	☐	☐	☐	☐
	70	0.3	☐	☐	☐	☐	☐
	7	0.2	☐	☐	☐	☐	☐

D2) What would be the impact of the following policy options for combined inhalable and respirable **OELs** for **cobalt and inorganic cobalt compounds**?

Policy Option	**Level, µg Co/m³ Inhalable fraction measured as Co**	**Level, µg Co/m³ Respirable fraction measured as Co**
1 For the inhalable fraction, currently the OE used in most EU Member States	20	4.2
2 For the inhalable fraction, currently the lowest OEL in EU Member States	10	2.5
3 Intermediate level	5	1.25
4 Based on the Risk Assessment Committee's (RAC) opinion on the OEL	1	0.5

Impact	**OEL inhalable fraction (µg Co/m³)**	**OEL respirable fraction (µg Co/m³)**	**Significant negative impact**	**Moderate negative impact**	**No impact**	**Moderate positive impact**	**Significant positive impact**
Costs for companies	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐
Costs for public authorities	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐
Competitive-ness	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐
SMEs	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐
Occupational health	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐
Environment	20	4.2	☐	☐	☐	☐	☐
	10	2.5	☐	☐	☐	☐	☐
	5	1.25	☐	☐	☐	☐	☐
	1	0.5	☐	☐	☐	☐	☐

D3) What would be the impact of the following policy options for **OELs** for **isoprene**?

Policy Option	**Level, mg/m³**
1 This corresponds to a calculated excess cancer risk of 4:1,000	129.4
2 This is currently the median or mode OEL in EU Member States	40
3 This is based on the RAC opinion and the lowest observed OEL in the EU	8.5
4 This corresponds to a calculated excess cancer risk of 4:100,000	1.3

Impact	OEL (mg/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐
Costs for public authorities	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐
Competitiveness	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐
SMEs	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐
Occupational health	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐
Environment	129.4	☐	☐	☐	☐	☐
	40	☐	☐	☐	☐	☐
	8.5	☐	☐	☐	☐	☐
	1.3	☐	☐	☐	☐	☐

D4) What would be the impact of the following policy options for **OELs, STELs** and **BLVs** for **1,4-Dioxane**

The **OEL** Policy Options	Level, mg/m³
Current IOELV under the CAD	73 (20 ppm)
Likely median (the list of values needs to be confirmed: 10, 20, 35, 36, 37, 50, 73)	36 (10 ppm)
Lowest national OEL: Latvia (& the Netherlands?) (RAC opinion lists 10 mg/m³ in Hungary – to be confirmed, same as HU STEL and ppm for 36 mg/m³, also close to 7.3 mg/m³)	20 (5.5 ppm)
RAC recommendation	7.3 (2 ppm)

Impact	OEL (mg/m^3)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐
Costs for public authorities	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐
Competitiveness	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐
SMEs	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐
Occupational health	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐
Environment	73	☐	☐	☐	☐	☐
	36	☐	☐	☐	☐	☐
	20	☐	☐	☐	☐	☐
	7.3	☐	☐	☐	☐	☐

The **STEL** Policy Options	
Policy Option	**Level, mg/m^3**
Highest STEL in an EU Member State (Finland), also 146 mg/m^3 in Austria, Germany, Slovenia and 140 mg/m^3 in the Czech Republic and France	150 mg/m^3 (40 ppm)
Intermediate level at the mid point between 90 mg/m^3 and 150 mg/m^3	120 mg/m^3 (33 ppm)
Intermediate value, selected due to the fact that two Member States (Lithuania and Sweden) have a STEL of 90 mg/m^3	90 mg/m^3 (40 ppm)
RAC recommendation, also close to the lowest national STEL (72 mg/m^3 in Denmark)	73 mg/m^3 (40 ppm)

Impact	STEL (mg/m^3)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐
	73	☐	☐	☐	☐	☐
Costs for public authorities	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐

Impact	STEL (mg/m^3)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
	73	☐	☐	☐	☐	☐
Competitiveness	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐
	73	☐	☐	☐	☐	☐
SMEs	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐
	73	☐	☐	☐	☐	☐
Occupational health	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐
	73	☐	☐	☐	☐	☐
Environment	150	☐	☐	☐	☐	☐
	120	☐	☐	☐	☐	☐
	90	☐	☐	☐	☐	☐
	73	☐	☐	☐	☐	☐

The **BLV values** Policy Options	Level, (HEAA in urine/mg Creatinine, at the end of exposure or shift
Corresponds to an OEL of 73 mg/m^3 (20 ppm)	366
Corresponds an OEL of 36 mg/m^3 (10 ppm)	188
Corresponds to an OEL of 20 mg/m^3 (5.5 ppm)	108
RAC recommendation, corresponding to an OEL of 7.3 mg/m^3	45

Impact	HEAA in urine/mg Creatinine	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐
Costs for public authorities	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐
Competitiveness	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐
SMEs	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐
Occupational health	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐

Impact	HEAA in urine/mg Creatinine	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐
Environment	366	☐	☐	☐	☐	☐
	188	☐	☐	☐	☐	☐
	108	☐	☐	☐	☐	☐
	45	☐	☐	☐	☐	☐

D5) What would be the impact of including **welding fumes** in Annex I of the CMRD?

Impact	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for companies	☐	☐	☐	☐	☐
Costs for public authorities	☐	☐	☐	☐	☐
Competitiveness	☐	☐	☐	☐	☐
SMEs	☐	☐	☐	☐	☐
Occupational health	☐	☐	☐	☐	☐
Environment	☐	☐	☐	☐	☐

D6) If companies affected by these limit values or entry into Annex I of the CMRD, could not comply and had to cease trading, what do you believe would happen? Please tick all that apply.

	Cobalt & inorganic cobalt compounds	PAHs	Isoprene	1,4-dioxane	Welding fume
The majority of employees would find alternative work of a similar level and pay within six months	☐	☐	☐	☐	☐
The majority of employees would not find alternative work of a similar level and pay within six months, and the impact on the local area (town) would be severe.	☐	☐	☐	☐	☐
The majority of employees would not find alternative work of a similar level and pay within six months, and the impact on the local region (city or region) would be severe.	☐	☐	☐	☐	☐
Don't know	☐	☐	☐	☐	☐

D7) Do you think companies will benefit from any of these indirect benefits if an EU-wide limit values are introduced for the four substances or welding fumes is brought into Annex I of the CMRD? Please tick all that apply.

	Cobalt & inorganic com-pounds	PAHs	Isoprene	1,4-diox-ane	Welding fumes
Healthier staff	☐	☐	☐	☐	☐
Increased productivity of work-ers	☐	☐	☐	☐	☐
Improved public image	☐	☐	☐	☐	☐
Easier to recruit staff	☐	☐	☐	☐	☐
Easier to retain staff	☐	☐	☐	☐	☐
Reduced cost of recruitment	☐	☐	☐	☐	☐
Easier monitoring of exposure	☐	☐	☐	☐	☐
Savings because company cur-rently has multiple locations in different Member States with dif-ferent regulations or OELs	☐	☐	☐	☐	☐
Level playing field with competi-tors	☐	☐	☐	☐	☐
Other indirect benefits, please specify	☐	☐	☐	☐	☐
There will be no indirect benefits	☐	☐	☐	☐	☐

Part E: Other comments

Please provide any additional comments in the box below.

Additional comments

Part F: Further communication

Please specify the contact persons for further communication.

Part		Contact person	Email	Telephone num-ber
Part A: Enforcing national limit values				
Part B: Current limit values for the five substances				
Part C: Impacts of new limit values				
Other related topics	Voluntary measures by public organisations or in-dustry to reduce exposures			
	Exposure data			
	Any other contacts			

Thank you for your answers!

11.3 Annex 3 - Occupational Health and Safety Experts Questionnaire

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe (Italy), RPA Europe Prague (Czech Republic) COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), EPRD (Poland) and Force Technology (Denmark) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limit values (OELs) or introducing a substance into Annex I.
The purpose of the study is to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances at work (the Carcinogens, Mutagens or Reprotoxic substances Directive, **CMRD**).
The substances being considered are:

- **Polycyclic aromatic hydrocarbons (PAH)**
- **Cobalt and inorganic cobalt compounds**
- **Isoprene**
- **1,4-dioxane**

New OELs are proposed for the four substances above under the CMRD. In addition, biological limit values (BLV) are proposed for PAH and 1,4-dioxane, and a 15-minute short-term exposure limit value (STEL) is proposed for 1,4-dioxane. In addition, 'skin sensitisation' and 'respiratory sensitisation' notations are proposed for cobalt and inorganic cobalt compounds, and 'skin' notations are proposed for isoprene, PAHs and 1,4-dioxane.
An amendment to include **welding fumes** in Annex I of the CMRD is also being considered.

The purpose of this questionnaire is to collect data and information that will underpin the assessment.
All responses to this questionnaire will be treated in the **strictest confidence** and will only be used for the purposes of this study. In preparing our report for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

This questionnaire is for **occupational health and safety (OSH) professionals** working with companies to reduce workers' exposure to the relevant substances. As an OSH expert, we hope that you will help us to understand the risk management measures required to implement OELs, STELs, and BLVs and thus assess their technical and economic feasibility.
The questionnaire consists of six parts:

- Part A: About your organisation
- Part B: Enforcement of existing limit values
- Part C: Current limit values for the five substances
- Part D: Impacts of potential new OELs or inclusion in Annex I
- Part E: Other comments
- Part F: Further communication

The **deadline** for completion of the questionnaire is **3 March 2023**.

The questionnaire is in English. However, you are welcome to answer the questions in any official European language of your choice. If you prefer to be interviewed in your language, please contact OELs6@rpaltd.co.uk
Please **return** the completed questionnaire to OELs6@rpaltd.co.uk

Abbreviations and terms used in the questionnaire:

BLV	A 'biological limit value' (BLV) is 'the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect'
OEL	The term Occupational Exposure Limit value (OEL) refers to the limit of the time-weighted average (TWA) of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours.
RAC	The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment.
RMM	Risk Management Measure
SMEs	Small and Medium-sized Enterprises. Companies with between 50 and 249 employees are usually referred to as medium-sized. Companies with between 10 and 49 employees are usually referred to as small (and with less than 10 employees as micro enterprises). Companies with more than 250 employees are referred to as large companies. For further definitions, please refer to http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm
STEL	A short-term exposure limit is like an OEL but involves a shorter reference period (usually 15 minutes). The aim of this value is to prevent adverse health effects caused by peaks in exposure that will not be controlled by the application of an 8-hour TWA limit.
8 hour TWA	8 hour Time-Weighted Average, measured in parts per million (ppm) or milligrams per cubic metre (mg/m^3). The 8 hour TWA is an expression for the average exposure for a typical working day. It is calculated by summing up the concentrations (in ppm or mg/m^3) during different periods of a day (usually 8 hours). Each concentration is multiplied by its relevant duration and the total is divided by the entire length of the working day (usually 8 hours) such as in this example: 8h-TWA = (2 hours * 500 ppm + 5 hours * 100 ppm + 1 hours * 700 ppm) / (2 + 5 + 1 hours).

Examples of relevant PAH compounds:

Substance name	Cas Number
Benzo[e]pyrene	205-892-7
Benzo[j]fluoranthene	205-910-3
Benzo[e]acephenanthrylene	205-911-9
Benzo[k]fluoranthene	205-916-6
Chrysene	205-923-4
Benzo[def]chrysene	**200-028-5**
Dibenz[a,h]anthracene	200-181-8
Benz[a]anthracene	200-280-6
Dibenzo[b,def]chrysene; dibenzo[a,h]pyrene	205-878-0
Benzo[r,s,t]pentaphene	205-877-5

Examples of relevant cobalt and inorganic cobalt compounds:

Substance name	Cas Number
Cobalt carbonate	513-79-1
Cobalt oxide	1307-96-6
Cobalt	7440-48-4
Cobalt dichloride	7646-79-9
Cobalt sulphate	10124-43-3
Cobalt dinitrate	10141-05-6
Cobalt lithium dioxide	12190-79-3
Cobalt molybdate	13762-14-6
Cobalt dihydroxide	21041-93-0
Cobalt titanite green spinel	68186-85-6
Olivine, cobalt silicate blue	68187-40-6
Cobalt lithium nickel oxide	-
Aluminum cobalt lithium nickel oxide	177997-13-6
Reaction mass of cobalt olivine and crystalline silicon dioxide	68187-40-6

Examples of relevant isoprene compounds:

Substance name	Cas Number
Isoprene	78-79-5

Examples of relevant 1,4-Dioxane compounds:

Substance name	Cas Number
1,4-Dioxane	123-91-1

Examples of relevant welding fumes substances:

Substance name
Inhalable welding fumes
Respirable welding fumes
Welding fumes (generic)
Particulate matter (dust)
Carbon monoxide
Nitrogen monoxide (NO)
Nitrogen dioxide (NO2)
Nitrogen oxides (NOx)
Ozone
Aluminium compounds (Al)
Barium compounds (Ba)
Cobalt compounds (Co)
Chromium II or III compounds (Cr II/III)
Chromium VI compounds (CrVI)
Total chromium (Cr)
Copper compounds (Cu)
Iron compounds (Fe)
Magnesium compounds (Mg)
Manganese compounds (Mn)
Nickel compounds (Ni)
Vanadium compounds (V)

A) About your organisation

Please provide the following details.

Question	Answer
Name	
Please indicate any relevant qualifications held	
Please provide names of any relevant institutes for which you hold membership	
Organisation	
Country	
Email	
Telephone	

If you have experience with several substances, please complete a questionnaire for each substance.

For which substance are you completing this questionnaire?

☐ Polycyclic Aromatic Hydrocarbons (PAHs)
☐ Cobalt and inorganic cobalt compounds
☐ Isoprene
☐ 1,4-Dioxane
☐ Welding fumes

B) Use of Risk Management Measures (RMM)

B1) Please list the specific applications or activities for which you have experience of evaluating or reducing air concentrations of the substance in workers' environments?	
Application or activity 1	
Application or activity 2	
Application or activity 3	
Application or activity 4	

B2) If welding fumes, go to B3; this question is for all substances except welding fumes.

Please indicate which risk management measures are commonly used in these applications. Please tick all that apply.

	Application 1	***Application 2***	***Application 3***	***Application 4***
Restructuring operations/processes				
Reduced amount of substance used	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐
Rotation of workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction				
Closed systems	☐	☐	☐	☐
Partially closed systems	☐	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
PPE (personal protective equipment)				
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Safety spectacles, goggles	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Gloves with a cuff, gauntlets and sleeving that covers part or all of the arm	☐	☐	☐	☐
Safety boots and shoes	☐	☐	☐	☐
Rubber boots	☐	☐	☐	☐
Conventional or disposable overalls, boiler suits, aprons	☐	☐	☐	☐
Coveralls/hazardous materials suits	☐	☐	☐	☐
Organisational and hygiene measures				
Training	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐

Substitution or discontinuation in the past				
Partial substitution of substances used in this activity in the past	☐	☐	☐	☐
Discontinuation of part of the activity using substances	☐	☐	☐	☐
Other measures				
Other	☐	☐	☐	☐
If other, please specify				

B3) If any substance except welding fumes, go to section C — this section is for welding fumes only.

Please indicate which risk management measures are commonly used in these applications? Please tick all that apply.

	Application 1	***Application 2***	***Application 3***	***Application 4***
Partial substitution of welding or associated processes: TIG has lower emissions than MMA, MAG solid wire has lower emissions than MAG flux cored wire, automated welding with integrated extraction instead of conventional welding	☐	☐	☐	☐
Substitution of welding or associated processes with other joining processes such as gluing, folding or mechanical joining (screws, rivets)	☐	☐	☐	☐
Partial substitution of content base material and addition material such as low manganese materials	☐	☐	☐	☐
Substitution of content base material and addition material such as low manganese materials	☐	☐	☐	☐
Discontinuation of activity using welding or associated processes	☐	☐	☐	☐
Restructuring operations/processes				
Separate welding and associated processes with emissions from other activities in space or time	☐	☐	☐	☐
Temporary relocation of workers with health effects of welding fumes	☐	☐	☐	☐
Permanent relocation of workers with health effects of welding fumes	☐	☐	☐	☐

Reduced time spent on welding activity	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐
Ventilation and extraction				
Closed systems	☐	☐	☐	☐
Partially closed systems	☐	☐	☐	☐
Open hoods over equipment, tracking extraction elements or local extraction ventilation	☐	☐	☐	☐
Separate low volume or high-volume spot extraction with mobile individual station separators	☐	☐	☐	☐
Welding torch-integrated extraction system	☐	☐	☐	☐
General ventilation	☐	☐	☐	☐
Regular maintenance of extraction equipment	☐	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐	☐
Welding booth with a welding table and adjustable extraction element	☐	☐	☐	☐
PPE (personal protective equipment)				
Gloves, goggles, coverall (for additive manufacturing with metal powders)	☐	☐	☐	☐
Welding helmets with a separate air supply	☐	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐	☐
Fan-assisted welding helmets	☐	☐	☐	☐
Forced ventilation welding helmets	☐	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐	☐
Organisational and hygiene measures				
Training and education of workers	☐	☐	☐	☐

Formal/external mask cleaning and filter changing regime	☐	☐	☐	☐
Regular check of effectiveness of protective measures	☐	☐	☐	☐
Blood monitoring	☐	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Health surveillance in place for these process workers	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Other measures				
Other (please specify):	☐	☐	☐	☐

C) Current limit values

C1) Please provide some information about the OEL(s) for the substance (limits on air concentration expressed as an 8-hour TWA) for your Member State where you are based.	
OEL (value, unit) (If relevant, please indicate if respirable, inhalable or total dust.	
Is this OEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Please define the scope, occupations or which specific compounds included in the OEL?	
How is the compliance of the OEL determined?	☐ Estimated ☐ Measured
If measured, how many samples are taken?	
If measured, how often are samples taken?	
If measured, how is compliance with the OEL determined? Please see an explanation in box below.	
Any other comments about the OEL	

C2) Please provide some information about the STEL for the substance (limits on air concentration during a reference period of 15 minutes) for the Member State where you are based.	
STEL (value & unit) Please indicate if respirable, inhalable or total dust	
Is the STEL?	☐ Binding ☐ Indicative
What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Please define the scope, occupations or which specific compounds included in the STEL?	
How is compliance with the STEL determined?	☐ Estimated ☐ Measured
If measured, how many samples are taken?	
If measured, how often are samples taken?	
If measured, how is compliance with the STEL determined? Please see an explanation in box below.	
Any other comments about the STEL	

C3) Please provide some information about the BLV for the substance (e.g. mg/m³ HEAA in urine) for the Member State where you are based.	
BLV (value & unit)	
Is the BLV?	☐ Binding ☐ Indicative

What is the lowest level of quantification practically achievable?	
Please specify the protocol and analytical method needed for this.	
Please state the occupations or which specific compounds are included in the BLV?	
How is compliance with the BLV determined?	☐ Estimated ☐ Measured
If measured, how many samples are taken?	
If measured, how often are samples taken?	
If measured, how is compliance with the BLV determined? Please see an explanation in box below.	
Any other comments about the BLV	

To determine compliance, values based on measured samples can be derived using, for example, the following methods:

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

D) The impacts of potential new limits under the CMRD

This section looks at the potential to reduce exposure with the view to complying with new limit values for the substance, or in the case of welding fumes, complying with inclusion in Annex I.

D1) In which applications/activities is a further reduction of exposure concentrations possible?		
Application or activity	**Is it technically feasible to reduce exposure further?**	**Is it economically feasible to reduce exposure further?**
Application or activity 1	☐ Yes ☐ No	☐ Yes ☐ No
Application or activity 2	☐ Yes ☐ No	☐ Yes ☐ No
Application or activity 3	☐ Yes ☐ No	☐ Yes ☐ No
Application or activity 4	☐ Yes ☐ No	☐ Yes ☐ No

D2) If you answered "yes" to the technical or economic feasibility of implementation of further RMM in at least one application in the previous question, please indicate the three RMMs that you think are the most effective way for exposure reductions and specify in which applications or activities, 1, 2, 3 and/or 4.		
	Effective	Relevant for application/activity
Restructuring operations/processes		
Reduced amount of substance used	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Reduced number of workers exposed	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Rotation of workers exposed	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Redesign of work processes	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Ventilation and extraction		
Closed systems	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Partially closed systems	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Open hoods over equipment or local extraction ventilation	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
General ventilation	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Pressurised or sealed control cabs	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Simple enclosed control cabs	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
PPE (personal protective equipment)		
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Powered air-purifying respirators	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4
Half and full facemasks (negative pressure respirators)	☐	☐ 1 ☐ 2 ☐ 3 ☐ 4

Disposable respirators (FFP masks)	☐	☐ 1	☐ 2	☐ 3	☐ 4
Face screens, face shields, visors	☐	☐ 1	☐ 2	☐ 3	☐ 4
Safety spectacles, goggles	☐	☐ 1	☐ 2	☐ 3	☐ 4
Gloves	☐	☐ 1	☐ 2	☐ 3	☐ 4
Gloves with a cuff, gauntlets and sleeving covering part or all of arm	☐	☐ 1	☐ 2	☐ 3	☐ 4
Safety boots and shoes	☐	☐ 1	☐ 2	☐ 3	☐ 4
Rubber boots	☐	☐ 1	☐ 2	☐ 3	☐ 4
Conventional or disposable overalls, boiler suits, aprons	☐	☐ 1	☐ 2	☐ 3	☐ 4
Coveralls/hazardous materials suits	☐	☐ 1	☐ 2	☐ 3	☐ 4
Organisational and hygiene measures					
Training	☐	☐ 1	☐ 2	☐ 3	☐ 4
Cleaning	☐	☐ 1	☐ 2	☐ 3	☐ 4
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐ 1	☐ 2	☐ 3	☐ 4
Provision of separate storage facilities for work clothes	☐	☐ 1	☐ 2	☐ 3	☐ 4
Formal/external RPE cleaning and filter changing regime	☐	☐ 1	☐ 2	☐ 3	☐ 4
Continuous measurement to detect unusual exposures	☐	☐ 1	☐ 2	☐ 3	☐ 4
Creating a culture of safety	☐	☐ 1	☐ 2	☐ 3	☐ 4
Substitution or discontinuation in the past					
Partial substitution of substances used in this activity in the past	☐	☐ 1	☐ 2	☐ 3	☐ 4
Discontinuation of part of the activity using substances	☐	☐ 1	☐ 2	☐ 3	☐ 4
Other measures					
Other	☐	☐ 1	☐ 2	☐ 3	☐ 4
Welding specific RMMs					
Partial substitution of welding or associated processes: TIG has lower emissions than MMA, MAG solid wire has lower emissions than MAG flux cored wire, automated welding with integrated extraction instead of conventional welding	☐	☐ 1	☐ 2	☐ 3	☐ 4
Substitution of welding or associated processes with other joining processes such as gluing, folding or mechanical joining (screws, rivets)	☐	☐ 1	☐ 2	☐ 3	☐ 4
Partial substitution of content base material and addition material such as low manganese materials	☐	☐ 1	☐ 2	☐ 3	☐ 4
Substitution of content base material and addition material such as low manganese materials	☐	☐ 1	☐ 2	☐ 3	☐ 4

Separate low volume or high volume spot extraction with mobile individual station separators	☐	☐ 1	☐ 2	☐ 3	☐ 4
Welding torch-integrated extraction system	☐	☐ 1	☐ 2	☐ 3	☐ 4
Welding booth with welding table and adjustable extraction element	☐	☐ 1	☐ 2	☐ 3	☐ 4
Gloves, goggles, coverall (for additive manufacturing with metal powders)	☐	☐ 1	☐ 2	☐ 3	☐ 4
Welding helmets with a separate air supply	☐	☐ 1	☐ 2	☐ 3	☐ 4
If other, please specify					

D3) If you have any other comments, e.g. on voluntary measures reducing exposures, please provide them here.

E) Further communication

Please tick if you are happy for the study team to contact you for further clarification or discussion about your responses?	☐
If you prefer this contact to be via a different email or phone number from those you provided at the start of the questionnaire, please provide the details here.	

Thank you for your answers!

11.4 Annex 4 – Trade union questionnaire

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe (Italy), RPA Europe Prague (Czech Republic) COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), EPRD (Poland) and Force Technology (Denmark) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limit values (OELs) or introducing a substance into Annex I.

The purpose of the study is to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances at work (the Carcinogens, Mutagens or Reprotoxic substances Directive, **CMRD**).

The substances being considered are:

- **Polycyclic aromatic hydrocarbons (PAH)**
- **Cobalt and inorganic cobalt compounds**
- **Isoprene**
- **1,4-dioxane**

New OELs are proposed for the four substances above under the CMRD. In addition, biological limit values (BLV) are proposed for PAH and 1,4-dioxane, and a 15-minute short-term exposure limit value (STEL) is proposed for 1,4-dioxane. In addition, 'skin sensitisation' and 'respiratory sensitisation' notations are proposed for cobalt and inorganic cobalt compounds, and 'skin' notations are proposed for isoprene, PAHs and 1,4-dioxane.

An amendment to include **welding fumes** in Annex I of the CMRD is also being considered.

The purpose of this interview is to collect data and information that will underpin the assessment.

A supporting letter from the European Commission is available here and the privacy statement is here.

Abbreviations used:

BLV	Biological Limit Value
NACE	NACE Revision 2, statistical classification of economic activities in the European Community See https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF page 61 ff
OEL	The term Occupational Exposure Limit value (OEL) refers to the limit of the time-weighted average of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours (8-h TWA).
RMM	Risk Management Measure
RPE	Respiratory protective equipment
8-hour TWA	8-hour Time-Weighted Average, measured in parts per million (ppm) or milligrams per cubic metre (mg/m^3). The 8-hour TWA is an expression for the average exposure for a typical working day. It is calculated by summing up the concentrations (in ppm or mg/m^3) during different periods of a day (usually 8 hours). Each concentration is multiplied by its relevant duration and the total is divided by the entire length of the working day (usually 8 hours) such as in this example: 8h-TWA = (2 hours * 500 ppm + 5 hours * 100 ppm + 1 hours * 700 ppm) / (2 + 5 + 1 hours).

Publication privacy

Confidentiality status	☐Confidentiality Option A: free to quote any information in the minutes and attribute it to them ☐Confidentiality Option B: use information in the minutes on an anonymous basis and in a way that cannot be linked to their company ☐Confidentiality Option C: treat the information in the minutes as confidential and only use it to inform the study's findings and conclusions
By checking this box, it is confirmed that the interviewee has read the Privacy Statement (in full) and agrees with the processing of their personal data for the purposes stated therein. They acknowledge that their views could be shared with the European Commission and published with information concerning the type of organisation that they represent, to which they hereby give their consent.	☐
Approval status	☐Minutes have been agreed during the interview and do not need further approval ☐Draft minutes to be sent to interviewee for approval

A) About the organisation

A1) Please provide the following details	
Name of interviewer	
Name of interviewee(s)	
Organisation	
Email address(es) of contact person(s)	
Telephone number of contact person(s)	
Country	

B) Main Interview Questions

1. Has any of the relevant substances come to your attention as a particular problem in your Member State? For example, have you run any campaigns for these chemicals (PAH, cobalt, isoprene, 1,4-dioxane or welding fumes)?

2. Would the proposed limits or amendments deliver substantial benefits in your Member State?

3. At what levels would the limits have to be set to deliver such benefits?

4. Do you have any information on the numbers of workers currently exposed to the relevant substances in your Member State?

5. Are you aware of any relevant studies that we should review or stakeholders that we should interview?

6. Are you aware of any databases that would provide figures on numbers of workers with ill health resulting from working with any of the relevant substances?

11.5 Annex 5 – Welding short interview questionnaire

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), RPA Europe (Italy), RPA Europe Prague (Czech Republic) COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), EPRD (Poland) and Force Technology (Denmark) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limit values (OELs) or introducing a substance into Annex I into the Carcinogens, Mutagens and Reprotoxins Directive (CMRD).

This interview deals specifically with the proposed amendment to include welding+ fume into Annex I of the CMRD.

Many questions ask for rough estimates / guestimates to the best of your ability. We need your expert judgement.

All responses to this questionnaire will be treated in the strictest confidence and will only be used for the purposes of this study. In preparing our report for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

The purpose of this interview is to collect data and information that will underpin the assessment.

A supporting letter from the European Commission is available here, together with the privacy statement here.

Welding+ fumes is defined (by ECHA, 2022)	• Fumes from the following activities: • Fusion welding (gas welding, arc welding (MIG, MAG, SMAW, FCAW, SAW, ESW, SW), arc welding (TIG, PAW), beam welding, • Soldering (soft soldering, hard soldering) • Brazing (>450°C, Laser beam brazing, Brazing with an electric arc (MIG, TIG, plasma)) • Thermal cutting or gouging • Thermal spraying • Flame straightening • Additive production processes

Publication privacy

Confidentiality status

☐ Confidentiality Option A: free to quote any information in the minutes and attribute it to them

☐ Confidentiality Option B: use information in the minutes on an anonymous basis and in a way that cannot be linked to their company

☐ Confidentiality Option C: treat the information in the minutes as confidential and only use it to inform the study's findings and conclusions

Privacy

By checking this box, it is confirmed that the interviewee has read the Privacy Statement (in full) and agrees with the processing of their personal data for the purposes stated therein. They acknowledge that their views could be shared with the European Commission and published with information concerning the type of organisation that they represent, to which they hereby give their consent.

☐

Approval status

☐ Minutes have been agreed during the interview and do not need further approval

☐ Draft minutes to be sent to interviewee for approval

A) About the organisation

A1) Please provide the following details

Name of interviewer	
Name of interviewee(s)	
Role of the interviewee(s)	
Organisation	
Type of organisation	☐ Welding institute or professional association ☐ Trade union for industry with significant number of welders such as metal working ☐ Welding training organisation ☐ Company employing a significant number of welders ☐ Other, please specify
Number of welders represented as members, workers, students, etc (approx.)	
Email address(es) of contact person(s)	
Telephone number of contact person(s)	
Country	

B) Main Interview Questions

1. Are you concerned about your employees', members', or students' exposure to welding+ fume? If yes, please explain why.

2. Have you run any campaigns to explain the risks of exposure to welding fumes to your employees', members, or students? If yes, please give some details.

3. Are you aware of the Carcinogens, Mutagens and Reprotoxins Directive (CMRD)?
☐ Aware and confident that I understand it ☐ Aware ☐ Not aware

4. Are you aware that carcinogens, mutagens and reprotoxins (CMRs) might be present in welding fumes?
☐ Aware and confident that I understand the implications of CMRs in welding fumes

4. Are you aware that carcinogens, mutagens and reprotoxins (CMRs) might be present in welding fumes?
☐ Aware of CMRs in welding fumes ☐ Not aware of CMRs being in welding fumes

5. Approximately what is your estimate of the proportion of your employees, members or students that are aware of the Carcinogens, Mutagens and Reprotoxins Directive (CMRD)? – to the nearest 10%

6. Approximately what is your estimate of the proportion of your employees, members or students that are aware that carcinogens, mutagens and reprotoxins (CMRs) might be present in welding fumes? – to the nearest 10%

7. Describe the part of the welding industry that you believe that you understand well. This could be on the basis of Member State, region, industry, company, welding process, welding emission rates, base or filler substances or any other variable

8. For this part of the welding industry, describe the situations that cause the highest exposure to carcinogens, mutagens and reprotoxins (CMRs) such as chromium VI, nickel compounds and cobalt

9. For this part of the welding industry, describe the situations that cause the lowest (or no) exposure to carcinogens, mutagens and reprotoxins (CMRs) such as chromium VI, nickel compounds and cobalt

10. How good is your employees', members', or students' (in the future) access to and use of risk management measures to protect them from welding fumes containing carcinogens, mutagens and reprotoxins? Please give the percentage for each, summing to 100%.	
Best practice	
Reasonable practice	
Poor practice/none	
Total	100%

11. If welding fumes containing carcinogens, mutagens and reprotoxins was brought into Annex I of the CMRD[22], how would the percentages in Q11 change? Please give your estimate of the future percentages for each, summing to 100%.	
Best practice	
Reasonable practice	
Poor practice/none	
Total	100%

12. Do you have any further comments?

[22] If a substance, mixture, or process is listed in Annex I of the CMRD, in Article 2 (a) (ii) of the CMRD the substance, mixture or process is defined as being carcinogenic. The proposal is to bring only welding fumes containing CMRs into Annex I: this does not include welding fumes that does not contain CMRs.

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