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

Cobalt and inorganic cobalt compounds

November 2024

Written by Carsten Lassen and Michael Munk Sørensen (COWI); Klaus Schneider, Anne Bierwisch and Eva Kaiser (FoBiG).
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LIST OF ABBREVIATIONS AND ACRONYMS

AAS	Atomic absorption spectrometry
ASD	AeroSpace and Defence Industries Association of Europe
ACEA	European Automobile Manufacturers' Association
ACGIH	American Conference of Governmental Industrial Hygienists
ACSH	Advisory Committee of Safety and Health at Work
AGS	Ausschuss für Gefahrstoffe (German Committee on Hazardous Substances)
AI	Adequate Intake
AlNiCo	Aluminium-nickel-cobalt (magnet)
AM	Arithmetic mean
ANSES	French Agency for Food, Environmental and Occupational Health & Safety
APF	Assigned protection factor
ASA	Register of occupational exposure hazards and procedures in Finland
ATSDR	Agency for Toxic Substances and Disease Registry
BAT	Best Available Technique
BCF	Bio-concentration factor
BEV	Battery Electrical Vehicle
BGV	Biological Guidance Value
BLV	Biological Limit Value
(h)BMD_{10}	(Human) benchmark dose associated with 10% extra risk of adverse effect
(h)$BMDL_{10}$	(Human) lower confidence limit of the BMD_{10}
BOEL	Binding occupational exposure limit
BR	Better Regulation
BREF	Best available techniques reference document
BYD	Manufacturer of electric cars
C&L	Classification & Labelling (inventory)
CAD/CAM	Computer aided design (CAD) / computer aided manufacturing (CAM)
CAREX	Carcinogen Exposure (inventory)
CAS	Chemicals Abstracts Service
CBA	Cost Benefit Analysis
CBR	Cost Benefit Ratio
C_{Cobalt}	Concentration of cobalt in air
CDB	Current disease burden
CEN	European Committee of Standardization
CLH	Harmonised classification and labelling (registry)
CLP	Classification, Labelling and Packaging of substances Regulation
CMD	Carcinogens and Mutagens Directive (historic)
CMRD	Carcinogens, Mutagens and Reproductive substances Directive
Co	Cobalt
COLCHIC	French Occupational exposure to chemical agents database
CoRC	Cobalt REACH Consortium
CSR	Chemical Safety Report (under REACH)
DALY	Disability Adjusted Life Years
DG	Directorate General
DGUV	Deutsche Gesetzliche Unfallversicherung (German Social Accident Insurance)
DNEL	Derived no-effect level

DRR	Dose Response Relationship
ECHA	European Chemicals Agency
EDTA	Ethylenediaminetetraacetic acid
EEA	European Economic Area
EFSA	European Food Safety Authority
EPCIA	European Passive Components Industry Association
E-PRTR	European Pollutant Release and Transfer Register
ERTRAC	European Road Transport Research Advisory Council
ERCA	European Rubber Chemicals Association
ERR	Exposure Risk Relationship
ES	Exposure Scenario
ESIA	European Semiconductor Industry Association
ETAAS	Electrothermal Atomic Absorption Spectrometry
ETRMA	European Tyre & Rubber Manufacturers Association
EV	Electrical vehicle
FAAS	Flame Atomic Absorption Spectroscopy
FDB	Future disease burden from current and future exposure during the 40-years assessment period
FEF_{25-75}	Forced expiratory flow during exhalation of 25-75% of FVC
FEFAC	European Feed Manufacturers' Federation
FEV_1	Forced expiratory volume in 1 second
FEVE	European Container Glass Federation
FFP	Filtering facepiece
FIDE	European Dental Industry
FoBiG	Forschungs und Beratungsinstitut Gefahrstoffe
FTE	Full time equivalent
FVC	Forced vital capacity
GESTIS	Internationale Grenzwerte für chemische Substanzen (International limits for chemical substances)
GFAAS	Graphite furnace technique
GHG	Greenhouse gases
GM	Geometric mean
GTF	Grinding time fraction
GTL	Gas to liquid
HDS	High Demand Scenario
HDS	Hydrodesulfurization
HEPA	High-Efficiency Particulate Air (filter)
IA	Impact Assessment
IARC	International Agency for Research of Cancer
ICP-AES	Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IEA	International Energy Agency
IP	Inorganic pigment
IPA	Isophthalic acid
IPCS	International Programme on Chemical Safety
ISO	The International Organization for Standardization
IUPAC	International Union on Pure and Applied Chemistry
JEDEC	Joint Electron Device Engineering Council
JRC	Joint Research Centre
JSOH	Japan Society for Occupational Health
LCA	Life Cycle Assessment
LCO	Lithium-cobalt oxide (battery)
LDS	Low Demand Scenario
LEV	Local Exhaust Ventilation

LFMP	Lithium-iron-manganese-phosphate (battery)
LFP	Lithium iron phosphate (battery)
LIB	Lithium-ion batteries
LLN	Lower limit of normal
LOAEC	Lowest observed adverse effect concentration
LOQ	Limit of Quantification
LRTAP	UNECE Convention on Long-range Transboundary Air Pollution
MAG	Gas-shielded arc (welding)
MaxEx	Maximum Exposure time
MCA	Multi-criteria analysis
MDR	Medical Devices Directive
MEASE	Occupational Exposure Assessment Tool for REACH
MHLW	Ministry of Health, Labour and Welfare (Japan)
MMF	Maximum mid-expiratory flow
MS	Member State
MSA	Member State Authorities
n	Number (mainly for number of measurements)
NACE	'Nomenclature statistique des activités économiques dans la Communauté européenne' or the Statistical Classification of Economic Activities in the European Community
NAEC	No adverse effect concentration
Na-ion	Sodium-ion (battery)
NCA	Nickel cobalt aluminium oxide (battery)
Nd-Fe-B	Neodymium-iron-boron (magnet)
Ni-Cd	Nickel-cadmium (battery)
Ni-MH	Nickel metalhydride (battery)
NIOSH	National Institute for Occupational Safety and Health
NMC	Lithium-nickel-manganese-cobalt-oxide (battery)
NMRD	Non-malignant respiratory diseases
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOS	Newcastle-Ottawa Scale (for assessing the quality of nonrandomised studies in meta-analyses)
NTP	National Toxicology Program
OEL	Occupational Exposure Limit
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
OXO reaction	Hydroformylation of alkenes
P50	50% percentile = median
P75, P90, P95, P99	Percentiles
PAH	Polycyclic aromatic hydrocarbons
PBPK	Physiologically based pharmacokinetic
PBT	Persistent, bio-accumulative, and toxic
PEF	Peak expiratory flow
PGM	Platinum group metal
PoD	Point of departure
PPE	Personal Protection Equipment
PROC	Process category (under REACH)
PTA	Purified terephthalic acid
PV	Photovoltaics
PV	Present value
PVD	Physical Vapor Deposition
Q&A	Questions and answers
R&D	Research & Development

R&I	Research & Innovation
R:I	Respirable to Inhalable (ratio)
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RMOA	Risk management option analysis
ROS	Reactive oxygen species
RPA	Risk & Policy Analysts
RPE	Respiratory Protective Equipment
SBS	Structural Business Statistics (compiled by Eurostat)
SCL	Specific Concentration Limit
SCOEL	Scientific Committee on Occupational Exposure Limits
SCOLA	French Occupational exposure to chemical agents database
SEAC	Committee for Socio-Economic Analysis
SEG	Similar Exposure Group
SIREP	Italian Information System on Occupational Exposure to Carcinogens
SIEF	Substance Information Exchange Forum
SME	Small and Medium-sized Enterprise
STEL	Short term exposure limit
STOP	Substitution, Technical measures, Organisational and Personal protective equipment
SUMER	French Medical Monitoring Survey of Professional Risks
SVHC	Substance of Very High Concern
TRGS	Technical Rules for Hazardous Substances
TRK	Technische Richtkonzentrationen (Technical Guidance Concentrations) in Austria
TWA	Time Weighted Average
UN	United Nations
UNECE	United Nations Economic Commission for Europe
USA	United States of America
VDDI	Association of German Dental Manufacturers
VLEP	Valeurs limites d'exposition professionnelle (French OEL)
vPvB	Very Persistent and very Bio-accumulative
WCS	Worker Contributing Scenario
WHO	World Health Organization
WTP	Willingness to Pay
YLD	Years lived with disability
ZVO	Zentralverband Oberflächentechnik e.V.
3D	Three-dimensional
For chemicals and elements abbreviations, reference is made to the International Union on Pure and Applied Chemistry (IUPAC) periodic table of elements.[1]	

[1] https://iupac.org/what-we-do/periodic-table-of-elements/

ABSTRACT EN-FR-DE

EN: This study supports the European Commission's Impact Assessment of a potential Occupational Exposure Limit (OEL) value for cobalt and inorganic cobalt compounds under the scope of Carcinogens, Mutagens and Reprotoxic substances Directive (CMRD, Directive 2004/37/EC). This report estimates costs and benefits for a range of potential OELs for cobalt and inorganic cobalt compounds. The monetised impacts relate primarily to the compliance costs of achieving the OEL and the avoided costs of ill health for conditions including lung cancer and the two non-cancer endpoints (restrictive lung disease and upper airway irritation). Cobalt metal and inorganic cobalt compounds are used in downstream uses in numerous sectors and an estimated to around 113,000 workers are exposed to cobalt and inorganic cobalt compounds in the EU. Four reference policy options are assessed in the study: 1 / 0.5 µg Co/m³, 5 / 1.25 µg Co/m³, 10 / 2.5 µg Co/m³ and 20 / 4.2 µg Co/m³. The cost benefit ratios for all policy options indicate higher costs than benefits. Both benefits and costs are significant. The benefits are estimated in the order of € 30 million to € 150 million over a 40-year assessment period. The cost range have been estimated at € 180 million to € 9800 million over the same 40-year period. The assessment is subject to some uncertainty and the sensitivity assessment indicates that benefits could be 2-3 times higher.

FR: Cette étude appuie l'évaluation d'impact de la Commission européenne concernant une valeur limite d'exposition professionnelle (VLEP) potentielle pour le cobalt et les composés inorganiques du cobalt dans le cadre de la directive sur les substances cancérogènes, mutagènes et toxiques à la reproduction (CMRD, directive 2004/37/CE). Ce rapport estime les coûts et les avantages d'une série de VLEP potentielles pour le cobalt et les composés inorganiques du cobalt. Les impacts monétisés concernent principalement les coûts de mise en conformité afin d'atteindre la VLEP et les coûts évités des problèmes de santé, notamment le cancer du poumon et les deux paramètres non-cancérigènes (maladie pulmonaire restrictive et irritation des voies aériennes supérieures). Le cobalt métal et les composés inorganiques du cobalt sont utilisés en aval dans de nombreux secteurs et l'on estime qu'environ 113 000 travailleurs sont exposés au cobalt et aux composés inorganiques du cobalt au sein de l'UE. L'étude évalue quatre options de VLEP de référence : 1 / 0,5 µg Co/m³, 5 / 1,25 µg Co/m³, 10 / 2.5 µg Co/m³ et 20 / 4.2 µg Co/m³. Les ratios avantages-coûts de toutes les options politiques indiquent des coûts supérieurs aux avantages. Les avantages et les coûts sont tous deux significatifs. Les bénéfices sont estimés entre 30 et 150 millions d'euros sur une période d'évaluation de 40 ans. La fourchette des coûts a été estimée entre 180 et 9800 millions d'euros sur la même période de 40 ans. L'évaluation est entachée d'une certaine incertitude et l'évaluation de la sensibilité indique que les avantages pourraient être 2 à 3 fois plus élevés.

DE: Diese Studie unterstützt die Folgenabschätzung der Europäischen Kommission für einen möglichen Grenzwert für die Exposition am Arbeitsplatz (OEL) für Kobalt und anorganische Kobaltverbindungen im Rahmen der Richtlinie über krebserzeugende, erbgutverändernde und fortpflanzungsgefährdende Stoffe (CMRD, Richtlinie 2004/37/EG). In diesem Bericht werden Kosten und Nutzen für eine Reihe potenzieller OEL für Kobalt und anorganische Kobaltverbindungen geschätzt. Die monetarisierten Auswirkungen beziehen sich in erster Linie auf die Kosten für die Einhaltung der OEL und die vermiedenen Kosten für Gesundheitsschäden, einschließlich Lungenkrebs und die beiden nicht krebsbedingten Endpunkte (restriktive Lungenerkrankung und Reizung der oberen Atemwege). Kobaltmetall und anorganische Kobaltverbindungen werden in zahlreichen Sektoren in nachgelagerten Bereichen verwendet, und schätzungsweise 113.000 Arbeitnehmer in der EU sind Kobalt und anorganischen Kobaltverbindungen ausgesetzt. In der Studie werden vier Referenz-OEL-Optionen bewertet: 1

/ 0,5 µg Co/m³, 5 / 1,25 µg Co/m³, 10 / 2.5 µg Co/m³ und 20 / 4.2 µg Co/m³. Das Kosten-Nutzen-Verhältnis für alle Optionen zeigt, dass die Kosten höher sind als der Nutzen. Sowohl der Nutzen als auch die Kosten sind erheblich. Der Nutzen wird auf 30 bis 150 Mio. € über einen Bewertungszeitraum von 40 Jahren geschätzt. Die Kosten werden auf 180 Mio. € bis 9800 Mio. € über denselben 40-Jahres-Zeitraum geschätzt. Die Bewertung ist mit einer gewissen Unsicherheit behaftet, und die Sensitivitätsanalyse zeigt, dass der Nutzen 2–3-mal höher sein könnte.

EXECUTIVE SUMMARY

The Carcinogens, Mutagens and Reprotoxic Substances Directive (Directive 2004/37/EC), hereinafter the CMRD, protects workers from exposure to carcinogens, mutagens or reprotoxic substances at work. This study supports the European Commission's Impact Assessment (IA) of a potential Occupational Exposure Limit (OEL) for cobalt and inorganic cobalt compounds.

Cobalt metal and inorganic cobalt compounds are used in a large number of downstream sectors. In total 27 sectors and 2 cross-sectoral activities are analysed. Furthermore, 32 sectors or cross-sectoral activities, indicated in national databases, CSRs (Chemical Safety Reports) and the literature have been screened and excluded from the detailed assessment. The main factors considered in the exclusion of sectors from the analysis are that the available data indicate that the 95 percentile (P95) of the exposure concentrations is below the lowest assessed OEL and the assessment thereby would indicate no impact, or that the available data indicate that the application may not take place today. For cross-sectoral downstream applications, some sectors with limited use are excluded and the estimated number of workers exposed, and the number of companies are allocated to the main sectors for the application. As an example, sharpening of hardmetal tools may to some extent take place in many sectors, but this activity is in the analysis allocated to the sector C25.62 'Machining' which is considered to include those companies specialised in this activity. In addition, for some activities a detailed split between sectors where the alloys are used could not be obtained and the distribution of the activities between sectors is quite uncertain. This approach does not affect the overall costs and benefits but introduces some uncertainties in the distribution of the impacts between sectors. In total, the study has estimated that around 113,000 workers are exposed to cobalt and inorganic cobalt compounds.

The costs and benefits (relative to the baseline) estimated in this report for the policy options are summarised in Table 0.1. The benefits are shown for both Method 1 and Method 2. The costs are for the present value (PV) over 40 years with a static discount rate of 3%. They assume a 5% turnover in staff. The estimated costs exceed the benefits for all policy options: at the Committee for Risk Assessment (RAC) recommended OEL of 1 / 0.5 μg/m^3 the costs are between 63 to 68 times the benefits. For the other options: the costs exceed the benefits with a much lower ratio.

Table 0.1 Summary of monetised costs and benefits (static discount rate, additional to the baseline)

Policy option	1 / 0.5 μg Co/m³	5 / 1.25 μg Co/m³	10 / 2.5 μg Co/m³	Transitional option	20 / 4.2 μg Co/m³
Total benefits M1 in € million	€ 160	€ 140	€ 81	€ 70	€ 31
Total benefits M² in € million	€ 150	€ 130	€ 80	€ 70	€ 29
Total costs in € million	€ 9,800	€ 1,900	€ 640	€ 590	€ 180
Cost benefit ratio M1	63	14	8	8	6
Cost benefit ratio M2	68	15	8	8	6

*Notes: *Values relate to method 1 (Willingness to Pay, WtP values for mortality and morbidity) and method 2 (Disability Adjusted Life Year, DALY). ** The policy options represent the OEL for the inhalable and respirable fraction, respectively separated by a slash. Numbers may be rounded.*
Source: Study team

The multi-criteria analysis summarising both the monetised and qualitative impacts is shown in Table 0.2. The MCA table includes the option proposed by the ACSH. The option proposed by the ACSH includes a transitional period so that initially, the OEL will be 20 / 4.2 µg Co/m³ and then after 6 years, the OEL will be 10 / 2.5 µg Co/m³.

Table 0.2 Multi-criteria analysis (all impacts over 40 years and additional to the baseline) per policy option in € million

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Direct costs - adjustment						
Risk management measures - first year	Companies	€ 1,500	€ 710	€ 240	Cannot be monetised	€ 90
Risk management measures - recurrent	Companies	€ 2,200	€ 430	€ 110	Cannot be monetised	€ 20
Risk management measures - discontinuations	Companies	€ 6,000	€ 700	€ 230	Cannot be monetised	€ 20
Risk management measures - total	Companies	**€ 9,600**	**€ 1,800**	**€ 580**	**€ 530**	**€ 130**
Risk management measures -total per company (in '000 €)	Companies	€ 630	€ 120	€ 38	€ 35	€ 8
Risk management measures excluding discontinuation costs -total per continuing company (in '000 €)	Companies	€ 260	€ 80	€ 24	Cannot be monetised	€ 8
Monitoring (sampling and analysis)	Companies	€ 110	€ 90	€ 60	€ 50	€ 40
Direct costs - administrative						
Company cost of administration burden	Companies	€ 13	€ 9	€ 7	€ 6	€ 4
Direct compliance costs – total						
Adjustment, monitoring and administration burden costs	Companies	**€ 9,800**	**€ 1,900**	**€ 640**	**€ 590**	**€ 180**
Adjustment, monitoring and administration burden costs per company (in '000 €)	Companies	€ 640	€ 130	€ 42	€ 38	€ 12
Direct costs - enforcement costs						
Transposition costs	Public sector	€ 0.9	€ 0.9	€ 0.9	€ 0.9	€ 0.9
Enforcement costs	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.				
Indirect costs - other						
Firms exiting the market - No. of company closures	Companies	1,090	140	60	Cannot be quantified	10
Firms discontinuing at least a part of their business - %	Companies	7.1%	0.9%	0.4%	Cannot be quantified	0.1%

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	Up to 3% (small companies)	Up to 1% (small companies)	Up to 0.4% (small companies)	Cannot be quantified	Up to 0.2% (small companies)
First year compliance costs as % of annual turnover (excluding discontinuations)	Companies	Up to 29% (small companies), but up to 4% (medium companies)	Up to 10% (small companies), but up to 1.5% (medium companies)	Up to 5.8% (small companies), but up to 0.75% (medium companies)	Cannot be quantified	Up to 2.3% (small companies), but up to 0.3% (medium companies)
Employment – Jobs lost	Workers & families	25,850	2,760	1,120	Cannot be quantified	80
Employment – Social cost	Workers & families	€ 2,000	€ 220	€ 80	Cannot be quantified	€ 7
International competitiveness	Companies	Negative impacts	No significant impacts	No significant impacts	No significant impacts	No significant impacts
Consumers	Consumers	No impact	No impact	No impact	No impact	No impact
Internal market	Companies	Positive effects though not of significant importance.				
Research and innovation	Companies	Negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	Limited negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	No or limited negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)		No or very limited negative impact
Specific MSs/regions - MSs that would have to change OELs	Public sector	All	All	All	All	All
Regulation	Companies	€ 0	€ 0	€ 0	€ 0	€ 0
Direct benefits – improved well-being - health						
Reduced cases of ill health – lung cancer	Workers & families	71	51	23	23	12
Reduced cases of ill health – restrictive lung disease	Workers & families	4,370	4,370	2,840	2,840	1,000
Reduced cases of ill health – upper airway irritation	Workers & families	14,150	12,270	7,360	7,360	2,140
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 150 - 140 million	€ 130 - 120 million	€ 75 - 74 million	€ 69 - 68 million	€ 29 - 27 million
Direct benefits – improved well-being – safety						
Avoided costs	Companies	€ 2	€ 2	€ 1	€ 1	€ 0
Avoided costs	Public sector	€ 8	€ 7	€ 4	€ 4	€ 1
EU policy agenda	All	Contribution to the EU Green Deal: Chemical Strategy towards a toxic-free environment				
Direct benefits – improved well-being - environmental						
Environmental releases	All	Limited reduction of environmental release of cobalt. Changes to cobalt free alternatives will have positive impact whereas increased costs of some articles may have a negative. Increased costs of recycling may have a negative impact.				
Direct benefits – market efficiency						

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Level playing field	Companies	A harmonised OEL at EU level would help to ensure a level playing field between companies operating in different EU Member States.				
Indirect benefits						
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for companies with operations across multiple Member States.				
Synergy	Companies	Positive minor impact.				
Corporate Social Responsibility	Companies	Positive minor impact.				
Avoided cost of setting OEL[2]	Public sector	€ 0.5	€ 0.5	€ 0.5	€ 0.5	€ 0.5
Other impacts						
Recycling – loss of business	Recycling companies	Negative impacts due to compliance costs.	Negative impacts due to compliance costs.	Minor negative impacts.	Minor negative impacts.	Minor negative impacts.
Impacts on fundamental rights	All	Compulsory monitoring of cobalt levels will help to ensure that the fundamental right of workers to workplace environments which respect human health is reliably enforced.				
Impacts on digitalisation	Companies	No impacts on digitalisation are expected.				
Contributions to the UN sustainable development goals	All	In relation to the third sustainable development goal – "*good health and wellbeing - improved worker and family health*" – the above comment for impacts on fundamental rights also applies.				

Source: Study team
Note: May not sum to total due to rounding

The main uncertainties and issues to be considered in the decision-making process include:

- **Valuation of the non-cancer endpoints**: The valuation of the non-cancer endpoints is subject to uncertainty. A sensitivity assessment has been done where the high-end values for the disability weight of the relevant diseases have been used. The sensitivity assessment indicate that the benefits of the non-cancer endpoints could be in order of three times higher. This will change the cost benefit ratio to almost one-third of the values presented in Table 0-1.

- **Inhalable vs. respirable fraction**. The policy options consist of pairs of OELs which are set independently based on the different health effects of the inhalable and the respirable fraction, respectively. Furthermore, for the inhalable fraction the highest policy option is set based on the mode of nationals OEL in those Member States where an OEL is established. The ratio between the OEL for the respirable and the inhalable fraction differs between the policy option with a respirable to inhalable fraction ratio (R:I) of 1:2 for the 1 / 0.5 µg/m³ policy option and 1:4.7 for the 20 / 4.2 µg/m³. Based on data on respirable to inhalable fraction ratios for the different sectors, it is assessed that at the 1 / 0.5 µg/m³ policy option compliance with the inhalable fraction will be the most challenging for all sectors except for welding and similar high-temperature activities. At the 20 / 4.2 µg/m³ policy option, for some sectors using cobalt compounds, the OEL for the respirable fraction will

[2] This element of avoided cost might be an under estimation of the total avoided costs. It could be that some Member States with an existing OEL would want to revise it during the assessment period to increase worker protection. It is however not certain how many Member States would do that. This possible underestimation would be insignificant compared with the other benefits.

be the most challenging whereas for sectors using cobalt metal it will be the inhalable fraction which is the most challenging.

- **Level of adjustment costs.** The output data of the cost model should be interpreted with caution as the calculation is based on a number of assumptions and simplifications as outlined in section 6.3 and the Methodological Note. The assumptions have been made in consultation with the stakeholders from the ACSH WPC including representatives for workers, employers and Member States. Nonetheless, the data give an indication of the magnitude. Compared to companies' turnover, the adjustment costs are small for the majority of sectors and for all but the two lowest OEL. The adjustment costs for the two highest policy options are in an order below 0.5% of turnover. The levels of adjustment costs estimated by companies for the stakeholder consultation is significantly higher than calculated by the cost model except for the 1 / 0.5 µg/m^3 policy option. The main difference is assessed to depend on the differences in taking existing use of RPE into account. For the costs estimates for the current study, it is assumed that RPE may be used to bring the exposure below the OEL for some exposure situations where the use of RPE is in general accepted today and where the scope for further technical preventive measures for limiting workers' exposure has already been exhausted (e.g. some cleaning and maintenance operations); see Section 7.2.16 for a detailed discussion.

- **Recycling**. The introduction of an OEL may, at the two lowest policy option, decrease the percentage of cobalt in waste recovered within the EU because of the extra adjustment costs. A part of the cobalt in the waste may either be disposed of without recovery or be exported for recovery outside the EU. Increased recovery of cobalt within the EU is in accordance with the EU's Open Strategic Autonomy and the intentions and benchmarks of the European Critical Raw Materials Act even the Regulation proposal do not set up specific benchmarks for cobalt recovery. For batteries recovery targets are set in the new Regulation on batteries and waste batteries but for other waste categories it may be relevant to investigate how it is ensured that the introduction of an OEL does not make recovery of the cobalt within the EU unprofitable.

- **Critical raw material and green transition.** Cobalt is a critical raw material and is used for some of the key technologies in the green transition such as batteries for vehicles and storage and magnets in wind turbines. The adjustment costs for implementing the OELs may be passed on to the articles which may lead to higher costs of key technologies in the green transition. On the other hand, the introduction of an OEL may among other drivers push to the development of cobalt-free alternatives e.g. for some tools and batteries where alternatives already are on the market and make the EU less dependent on raw materials imported from a few countries outside the EU. It is only for the two lowest policy options where there could be an impact. For the two highest policy options, the adjustment costs would only result in such a small and marginal change in the price of the article that it would not impact on the green transition.

- **Impacts on SME**. The costs of compliance consisting of risk management measures, monitoring and administrative burden are relatively high for small and medium sized companies at all policy options. The impact varies by policy option. It is for the two lowest policy options where the main impacts could be expected. In sectors where the cost burden is high, the competitiveness of SMEs could be negatively affected under the two lowest OELs. For the two highest policy options the additional cost burden is not assessed to significantly affect the operation of SMEs in the majority of sectors. Note that the policy options transitional period will make it easier for companies to plan and finance the use of additional RMMs. This will be important for the SMEs. Hence, it therefore not expected that SMEs will be significantly affected under the policy option with transitional period.

- **Discontinuation and dislocation**. An OEL for cobalt and inorganic cobalt compounds is unlikely to be the only cause for companies to discontinue, which in reality, for many medium and large companies, may be relocating outside the EU whereas it for small companies may be discontinuation of the activities. EU’s competitor countries have OELs for cobalt and inorganic cobalt compounds that are at the same level or higher than the highest policy option of 20 / 4.2 µg/m^3. None of the competitor countries have OELs for both the inhalable and the respirable fraction. From the stakeholder consultation at least one international company has indicated that they may relocate the activities with the highest exposure concentrations to facilities outside the EU. The assessment has indicated that for SMEs under the lowest policy option, there is a risk of companies having to discontinue. It is in the order of 7% of all companies with exposed workers that might discontinue. For the higher policy options, the share is much lower. For the option of 10 / 2.5 µg Co/m^3, the estimated share is only 0.4% and for the highest policy option it is 0.1%. Under the option with the transitional period, only very few if any companies including SMEs might have to discontinue.

- **Time needed to achieve compliance.** The costs of adjustments will depend on the time provided for the adjustments. For some OELs, additional transition periods have been set for specific sectors or activities e.g. an additional transition period for copper smelters for the OEL on arsenic acid and its salts and an additional transition period for welding for the OEL on chromium VI.

Résumé Exécutif

La directive sur les agents cancérigènes, mutagènes et toxiques à la reproduction (directive 2004/37/CE), ci-après dénommée CMRD, protège les travailleurs contre l'exposition à des agents cancérigènes, mutagènes ou toxiques à la reproduction sur le lieu de travail. L'objectif de cette étude est d'étayer l'analyse d'impact de la Commission européenne concernant une éventuelle limite d'exposition professionnelle (LEP) pour le cobalt et les composés inorganiques du cobalt.

Le cobalt métal et les composés inorganiques du cobalt sont utilisés en aval dans de nombreux secteurs. Au total, 27 secteurs et 2 activités intersectorielles sont analysés. En outre, 32 secteurs ou activités transsectorielles, indiqués dans les bases de données nationales, les CSR (rapports sur la sécurité chimique) et la littérature, ont été examinés et exclus de l'évaluation détaillée. Les principaux facteurs pris en compte pour exclure des secteurs de l'analyse sont les suivants : les données disponibles indiquent que le percentile 95 (P95) des concentrations d'exposition est inférieur à la VLEP la plus basse et que l'évaluation n'aurait donc aucun impact, ou les données disponibles indiquent que l'application ne peut pas avoir lieu aujourd'hui. Pour les applications intersectorielles en aval, certains secteurs dont l'usage est limité sont exclus et le nombre estimé de travailleurs exposés ainsi que le nombre d'entreprises sont attribués aux principaux secteurs de l'application. Par exemple, l'affûtage d'outils en métal dur peut, dans une certaine mesure, avoir lieu dans de nombreux secteurs, mais cette activité est, dans l'analyse, attribuée au secteur C25.62 "Usinage", qui est considéré comme comprenant les entreprises spécialisées dans cette activité. En outre, pour certaines activités, il n'a pas été possible d'obtenir une répartition détaillée entre les secteurs où les alliages sont utilisés et la répartition des activités entre les secteurs est assez incertaine. Cette approche n'affecte pas les coûts et bénéfices globaux, mais génère certaines incertitudes concernant la répartition des impacts par secteurs. Au total, l'étude a estimé qu'environ 113 000 travailleurs sont exposés au cobalt et aux composés inorganiques du cobalt.

Les coûts et les bénéfices (par rapport à la situation de référence) estimés dans ce rapport et associés à chaque option politique sont résumés dans le tableau 0.1. Les bénéfices sont indiqués pour la méthode 1 et la méthode 2. Les coûts correspondent à la valeur actuelle (VA) sur 40 ans avec un taux d'actualisation statique de 3 %. Ils reposent sur l'hypothèse d'une rotation du personnel de 5 %. Les coûts estimés dépassent les bénéfices pour toutes les options politiques : pour la VLEP de 1 / 0,5 µg/m3 recommandée par le Comité d'évaluation des risques (CER), les coûts sont de 63 à 68 fois supérieurs aux bénéfices. Pour les autres options, les coûts dépassent les bénéfices bien moins significativement.

Tableau 0.1 Résumé des coûts et avantages monétisés (taux d'actualisation statique, en plus du niveau de référence)

Option politique	1 / 0,5 µg Co/m ³	5 / 1,25 µg Co/m ³	10 / 2,5 µg Co/m ³	Option période transitoire	20 / 4,2 µg Co/m ³
Total des bénéfices M1 en millions d'euros	€ 160	€ 140	€ 81	€ 70	€ 31
Gains totaux M² en millions €	€ 150	€ 130	€ 80	€ 70	€ 29
Coûts totaux en millions d'euros	€ 9 800	€ 1 900	€ 640	€ 590	€ 180
Rapport coût-bénéfice M1	63	14	8	8	6
Rapport coût-bénéfice M2	68	15	8	8	6

*Notes : *Les valeurs se rapportent à la méthode 1 (volonté de payer, valeurs correspondant à la volonté de payer pour la mortalité et la morbidité) et à la méthode 2 (année de vie ajustée en fonction de l'invalidité, DALY). ** Les options politiques représentent la VLEP pour les fractions inhalable et respirable, respectivement séparées par une barre oblique.*
Source : Consultant

L'analyse multicritère résumant à la fois les impacts monétisés et qualitatifs est présentée dans le tableau 0.2. Le tableau multicritère inclut l'option proposée par l'ACSH (Comité consultatif pour la sécurité et la santé sur le lieu du travail). L'option proposée par l'ACSH inclut une période transitoire, de sorte que, dans un premier temps, la VLE sera de 20 / 4,2 µg Co/m³ et après 6 ans, la VLE sera de 10 / 2,5 µg Co/m³.

Tableau 0-21 Analyse multicritères (tous les impacts sur 40 ans et en complément de la référence) par option VLEP, million d'euros

Impact	Parties prenantes concernées	1 / 0,5 µg Co/m ³	5 / 1,25 µg Co/m ³	10 / 2,5 µg Co/m ³	Option période transitoire	20 / 4,2 µg Co/m ³
Coûts directs - ajustement						
Mesures de gestion des risques - première année	Entreprises	€ 1 500	€ 710	€ 240	Ne peut pas être monétisé	€ 90
Mesures de gestion des risques - récurrentes	Entreprises	€ 2 200	€ 430	€ 110	Ne peut pas être monétisé	€ 20
Mesures de gestion des risques – arrêt	Entreprises	€ 6 000	€ 700	€ 230	Ne peut pas être monétisé	€ 20
Mesures de gestion des risques - total	Entreprises	€ 9 600	€ 1 800	€ 580	€ 530	€ 130
Mesures de gestion des risques - total par entreprise	Entreprises	€ 630	€ 120	€ 38	€ 35	€ 8
Mesures de gestion des risques hors coûts de cessation		€ 260	€ 80	€ 24	Ne peut pas être monétisé	€ 8

Impact	Parties prenantes concernées	1 / 0,5 µg Co/m ³	5 / 1,25 µg Co/m ³	10 / 2,5 µg Co/m ³	Option période transitoire	20 / 4,2 µg Co/m ³
d'activité - total par entreprise en activité ('000 €)						
Surveillance (échantillonnage et analyse)	Entreprises	€ 110	€ 90	€ 60	€ 50	€ 40
Coûts directs - administratifs						
Coût de la charge administrative de l'entreprise	Entreprises	13 €	9 €	7 €	6 €	4 €
Coûts directs de conformité – total						
Coûts d'ajustement, de suivi et d'administration	Entreprises	€ 9 800	€ 1 900	€ 640	€ 590	€ 180
Coûts d'ajustement, de suivi et de charge administrative par entreprise	Entreprises	€ 640	€ 130	€ 42	€ 38	€ 12
Coûts directs - coûts d'application						
Frais de transposition	Secteur public	€ 0,9	€ 0,9	€ 0,9	€ 0,9	€ 0,9
Coûts d'application	Secteur public	Des coûts de mise en application peuvent survenir en raison du respect des nouvelles VLEP, mais ces coûts ne sont pas estimés car ils sont spécifiques au régime d'inspection individuel des États membres.				
Coûts indirects - autres						
Entreprises abandonnant au moins une partie de leur activité - %	Entreprises	7,1%	0,9%	0,4%	Ne peut pas être quantifié	0,1%
Coûts totaux de mise en conformité en % du CA sur 40 ans (arrêts compris)	Entreprises	Jusqu'à 3% (petites entreprises)	Jusqu'à 1% (petites entreprises)	Jusqu'à 0,4% (petites entreprises)	Ne peut pas être quantifié	Jusqu'à 0,2% (petites entreprises)
Coûts de mise en conformité la première année en % du CA (hors arrêt)	Entreprises	Jusqu'à 29 % (petites entreprises), mais jusqu'à 4 % (moyennes entreprises)	Jusqu'à 10 % (petites entreprises), mais jusqu'à 1,5 % (moyennes entreprises)	Jusqu'à 5,8% (petites entreprises), mais jusqu'à 0,75% (moyennes entreprises)	Ne peut pas être quantifié	Jusqu'à 2,3% (petites entreprises), mais jusqu'à 0,3% (moyennes entreprises)
Emploi – Emplois perdus	Travailleurs et familles	25 850	2 760	1 120	Ne peut pas être quantifie	80

Impact	Parties prenantes concernées	1 / 0,5 µg Co/m ³	5 / 1,25 µg Co/m ³	10 / 2,5 µg Co/m ³	Option période transitoire	20 / 4,2 µg Co/m ³
Emploi – Coût social	Travailleurs et familles	€ 2 000	€ 220	€ 80	Ne peut pas être monétisé	€ 7
Compétitivité internationale	Entreprises	Impacts négatifs	Aucun impact significatif	Aucun impact significatif	Aucun impact significatif	Aucun impact significatif
Consommateurs	Consommateurs	Aucun impact	Aucun impact	Aucun impact	Aucun impact	Aucun impact
Marché interne	Entreprises	Des effets positifs, mais non significatifs				
Recherche et innovation	Entreprises	Impact négatif (réduction de la R&I, mais incitation à la R&I dans les alternatives sans cobalt)	Impact négatif limité (réduction de la R&I, mais incitation à la R&I dans les alternatives sans cobalt)	Aucun ou impact négatif limité (réduction de la R&I, mais incitation à la R&I dans les alternatives sans cobalt)		Aucun ou très limité impact négatif
EM/régions spécifiques – EM qui devraient modifier leurs VLEP	Secteur public	Tous	Tous	Tous	Tous	Tous
Régulation	Entreprises	0 €	0 €	0 €	0 €	0 €
Bénéfices directs – amélioration du bien-être – santé						
Réduction des cas de mauvaise santé – cancer du poumon	Travailleurs et familles	71	51	23	23	12
Réduction des cas de mauvaise santé – maladie pulmonaire restrictive	Travailleurs et familles	4 370	4 370	2 840	2 840	1 000
Réduction des cas de problèmes de santé – irritation des voies respiratoires supérieures	Travailleurs et familles	14 150	12 270	7 360	7 360	2 140
Mauvaise santé évitée, incl. coûts immatériels (M1 à M2)	Travailleurs et familles	150 - 140 millions d'euros	130 à 120 millions d'euros	75 à 74 millions d'euros	69 à 68 millions d'euros	29 à 27 millions d'euros
Bénéfices directs – bien-être amélioré – sécurité						
Coûts évités	Entreprises	€ 2	€ 2	€ 1	€ 1	€ 0

Impact	Parties prenantes concernées	1 / 0,5 µg Co/m ³	5 / 1,25 µg Co/m ³	10 / 2,5 µg Co/m ³	Option période transitoire	20 / 4,2 µg Co/m ³
Coûts évités	Secteur public	€ 8	€ 7	€ 4	€ 4	€ 1
Agenda politique de l'UE	Tous	Contribution au Green Deal de l'UE : stratégie sur les produits chimiques et vers un environnement sans produits toxiques				
Bénéfices directs – bien-être amélioré – environnemental						
Rejets dans l'environnement	Tous	Réduction limitée des rejets de cobalt dans l'environnement. Les changements vers des alternatives sans cobalt auront un impact positif tandis que l'augmentation des coûts de certains articles pourrait avoir un impact négatif. L'augmentation des coûts de recyclage peut avoir un impact négatif.				
Bénéfices directs – efficacité du marché						
Des règles du jeu équitables	Entreprises	Une VLEP harmonisée au niveau de l'UE contribuerait à garantir des conditions de concurrence équitables entre les entreprises opérant dans les différents États membres de l'UE.				
Bénéfices indirects						
Simplification administrative	Entreprises	Si tous les États membres disposaient d'une VLEP harmonisée, cela réduirait la charge administrative pour les entreprises exerçant leurs activités dans plusieurs États membres.				
Synergie	Entreprises	Impact mineur positif.				
Responsabilité sociale des entreprises	Entreprises	Impact mineur positif.				
Coûts évités liés à la définition de la VLEP	Secteur public	€ 0,5	€ 0,5	€ 0,5	€ 0,5	€ 0,5
Autres impacts						
Recyclage – perte d'activité	Entreprises de recyclage	Impacts négatifs dûs aux coûts de mise en conformité.	Impacts négatifs dûs aux coûts de mise en conformité.	Impacts négatifs mineurs.	Impacts négatifs mineurs.	Impacts négatifs mineurs.
Impacts sur les droits fondamentaux	Tous	La surveillance obligatoire des niveaux de cobalt contribuera à garantir que le droit fondamental des travailleurs à un environnement de travail respectueux de la santé humaine soit respecté de manière fiable.				
Impacts sur la numérisation	Entreprises	Aucun impact sur la numérisation n'est attendu.				
Contributions aux objectifs de développement durable des Nations Unies	Tous	En ce qui concerne le troisième objectif de développement durable – « *bonne santé et bien-être – amélioration de la santé des travailleurs et de leurs familles* » – le commentaire ci-dessus concernant les impacts sur les droits fondamentaux s'applique également.				

Source : Consultant

Notes : Les chiffres ayant été arrondis, il est possible que leur somme ne corresponde pas exactement au total indiqué.

Les principales incertitudes et questions à prendre en compte dans le processus de décision sont les suivantes :

- **Évaluation des effets non cancérigènes:** L'évaluation des effets non cancérigènes est sujette à des incertitudes. Une évaluation de sensibilité a été réalisée en utilisant les valeurs les plus élevées pour le poids de l'invalidité engendrée par les maladies concernées. L'évaluation de sensibilité indique que les bénéfices des paramètres non cancéreux pourraient être trois fois plus élevés. Le rapport avantages-coûts serait ainsi ramené à près d'un tiers des valeurs présentées dans le tableau 0-1.

- **Fraction inhalable ou respirable.** Les options stratégiques consistent en des paires de VLEP qui sont fixées indépendamment, sur la base des différents effets sur la santé de la fraction inhalable et de la fraction respirable, respectivement. En outre, pour la fraction inhalable, l'option politique la plus élevée est fixée sur la base du mode de VLEP national dans les États membres où une VLEP est établie. Le rapport entre la VLEP pour la fraction respirable et la fraction inhalable diffère selon les options politiques avec un rapport fraction respirable / fraction inhalable (R:1) de 1:2 pour l'option politique 1 / 0,5 µg/m3 et de 1:4,7 pour l'option politique 20 / 4,2 µg/m3. Sur la base des données relatives aux rapports entre les fractions respirables et inhalables pour les différents secteurs, on estime qu'avec l'option 1 / 0,5 µg/m3, le plus difficile pour tous les secteurs sera de se conformer à la fraction inhalable, à l'exception du soudage et d'autres activités similaires à haute température. Dans le cas de l'option 20 / 4,2 µg/m3, pour certains secteurs utilisant des composés de cobalt, la VLEP pour la fraction respirable sera la plus difficile à respecter, tandis que pour les secteurs utilisant du cobalt métal, c'est la fraction inhalable qui sera la plus difficile à respecter.

- **Niveau des coûts d'ajustement.** Les données de sortie du modèle de coût doivent être interprétées avec prudence car le calcul repose sur un certain nombre d'hypothèses et de simplifications décrites dans la section 6.3 et la note méthodologique. Les hypothèses ont été élaborées en consultation avec les parties prenantes de l'ACSH, y compris des représentants des travailleurs, des employeurs et des États membres. Néanmoins, les données donnent une indication de l'ampleur. Comparés au chiffre d'affaires des entreprises, les coûts d'ajustement sont faibles pour la majorité des secteurs et pour tous sauf les deux niveaux VLEP les plus bas. Les coûts d'ajustement pour les deux options politiques les plus élevées sont de l'ordre de moins de 0,5 % du chiffre d'affaires. Les niveaux de coûts d'ajustement estimés par les entreprises pour la consultation des parties prenantes sont sensiblement plus élevés que ceux calculés par le modèle de coût, sauf pour l'option politique 1 / 0,5 µg/m³. La principale différence est due aux différences dans la prise en compte de l'utilisation existante des équipements de protection respiratoire. Pour les estimations des coûts de la présente étude, il est supposé que les équipements de protection respiratoire peuvent être utilisés pour réduire l'exposition en dessous de VLEP pour certaines situations d'exposition où l'utilisation des équipements de protection respiratoire est généralement acceptée aujourd'hui et où le champ d'application des mesures techniques préventives pour limiter l'exposition des travailleurs est déjà épuisé (par exemple certaines opérations de nettoyage et de maintenance); voir la section 7.2.16 pour une discussion détaillée.

- **Recyclage**. L'introduction d'une VLEP pourrait, pour les deux options politiques les plus basses, diminuer le pourcentage de cobalt dans les déchets récupérés au sein de l'UE en raison des coûts d'ajustement supplémentaires. Une partie du cobalt contenu dans les déchets peut soit être éliminée sans récupération, soit être exportée pour récupération hors de l'UE. La récupération accrue du cobalt au sein de l'UE est en accord avec l'autonomie stratégique ouverte de l'UE et conforme aux intentions et aux critères de la loi européenne sur les matières premières critiques, même si la proposition de règlement ne fixe pas de critères spécifiques en termes de récupération du cobalt. Pour les batteries, des objectifs de récupération sont fixés dans le nouveau règlement sur les batteries et les déchets de batteries, mais pour d'autres catégories de déchets, il peut être pertinent d'étudier la manière de garantir que l'introduction d'une VLEP ne rend pas la récupération du cobalt non rentable au sein de l'UE.

- **Matière première critique et transition écologique.** Le cobalt est une matière première essentielle et est utilisé pour certaines des technologies clés de la transition écologique, telles que les batteries pour véhicules et le stockage et les aimants dans les éoliennes. Les coûts d'ajustement liés à la mise en œuvre des VLEP peuvent être répercutés sur les articles, ce qui peut entraîner une hausse des coûts des technologies clés de la transition écologique. D'un autre côté, l'introduction d'une VLEP pourrait, entre autres, pousser au développement d'alternatives sans cobalt, par exemple concernant certains outils et batteries pour lesquels des alternatives sont déjà sur le marché, et rendre l'UE moins dépendante des matières premières importées de pays extérieurs à l'UE. Ce n'est que pour les deux options politiques les plus basses qu'il pourrait y avoir un impact. Pour les deux options politiques les plus élevées, les coûts d'ajustement ne devraient entraîner qu'un changement petit et marginal du prix des articles, ce qui n'aurait pas d'impact sur la transition verte.

- **Impacts sur les PME**. Les coûts de conformité comprenant les mesures de gestion des risques, la surveillance et la charge administrative sont relativement élevés pour les petites et moyennes entreprises pour toutes les options politiques. L'impact varie selon l'option politique. Pour les deux options politiques les plus basses, les principaux impacts pourraient être attendus. Dans les secteurs où la charge de coût est élevée, la compétitivité des PME pourrait être négativement affectée sous les deux VLEP les plus bas. Pour les deux options politiques les plus élevées, la charge de coût supplémentaire n'affecterait pas significativement le fonctionnement des PME dans la majorité des secteurs. Notez que la période de transition des options politiques facilitera la planification et le financement de l'utilisation de mesures de gestion des risques supplémentaires par les entreprises. Cela sera important pour les PME. Il n'est donc pas attendu que les PME soient significativement affectées sous l'option politique avec période de transition.

- **Fermeture et dislocation**. Il est peu probable qu'une VLEP pour le cobalt et les composés inorganiques du cobalt soit la seule cause de fermeture des entreprises, ce qui en réalité, pour de nombreuses moyennes et grandes entreprises, peut se traduire par une délocalisation en dehors de l'UE, alors que pour les petites entreprises, cela peut être un arrêt des activités. Les pays concurrents de l'UE ont des VLEP pour le cobalt et les composés inorganiques du cobalt qui sont au même niveau ou supérieurs à l'option politique la plus élevée de 20/4,2 µg/m ^{3}. Aucun des pays concurrents n'a de VLEP pour la fraction inhalable et la fraction respirable. Lors de la consultation des parties prenantes, au moins une entreprise internationale a indiqué qu'elle pourrait délocaliser les activités présentant les concentrations d'exposition les plus élevées vers des installations en dehors de l'UE. L'évaluation a indiqué que pour les PME sous l'option politique la plus basse, il y a un risque que les entreprises doivent cesser leurs activités. Cela concerne environ 7 % de toutes les entreprises ayant des travailleurs exposés qui pourraient cesser leurs activités. Pour les options politiques les plus élevées, le pourcentage est beaucoup plus bas. Pour l'option de 10 / 2,5 µg Co/m³, le pourcentage estimé est de seulement 0,4 % et pour l'option politique la plus élevée, il est de 0,1 %. Sous l'option avec période de transition, très peu d'entreprises, y compris des PME, pourraient devoir cesser leurs activités.

- **Temps nécessaire pour parvenir à la conformité.** Les coûts des ajustements dépendront du temps prévu pour les ajustements. Pour certaines VLEP, des périodes de transition supplémentaires ont été fixées pour des secteurs ou activités spécifiques, par exemple une période de transition supplémentaire pour les fonderies de cuivre pour la VLEP sur l'acide arsenic et ses sels et une période de transition supplémentaire pour le soudage pour la VLEP sur le chrome VI.

KURZFASSUNG

Die Richtlinie über Karzinogene, Mutagene und Reproduktionstoxische Stoffe (Richtlinie 2004/37/EG), im Folgenden CMRD, schützt Arbeitnehmer vor der Exposition gegenüber Karzinogenen, Mutagenen oder reproduktionstoxischen Stoffen am Arbeitsplatz. Ziel dieser Studie ist es, die Folgenabschätzung (IA) der Europäischen Kommission für einen potenziellen Grenzwert für berufliche Exposition (OEL) für Kobalt und anorganische Kobaltverbindungen zu unterstützen.

Kobaltmetall und anorganische Kobaltverbindungen werden in nachgelagerten Anwendungen in zahlreichen Sektoren eingesetzt. Insgesamt werden 27 Sektoren und 2 branchenübergreifende Aktivitäten analysiert. Darüber hinaus wurden 32 Sektoren oder branchenübergreifende Aktivitäten, die in nationalen Datenbanken, CSRs (Chemical Safety Reports) und der Literatur angegeben sind, überprüft und von der detaillierten Bewertung ausgeschlossen. Die Hauptfaktoren, die bei dem Ausschluss von Sektoren aus der Analyse berücksichtigt wurden, sind, dass die verfügbaren Daten darauf hinweisen, dass das 95. Perzentil (P95) der Expositionskonzentrationen unter dem niedrigsten bewerteten OEL liegt und die Bewertung daher keinen Einfluss anzeigen würde, oder dass die verfügbaren Daten darauf hinweisen, dass die Anwendung heute möglicherweise nicht stattfindet. Für branchenübergreifende nachgelagerte Anwendungen werden einige Sektoren mit begrenztem Einsatz ausgeschlossen und die geschätzte Anzahl der exponierten Arbeitnehmer und Unternehmen den Hauptsektoren für die Anwendung zugeordnet. Als Beispiel kann das Schärfen von Hartmetallwerkzeugen in vielen Sektoren in gewissem Umfang stattfinden, diese Aktivität wird jedoch in der Analyse dem Sektor C25.62 ‵Mechanik‵ zugeordnet, der als Unternehmen gilt, die auf diese Aktivität spezialisiert sind. Darüber hinaus konnte für einige Aktivitäten keine detaillierte Aufteilung zwischen den Sektoren, in denen die Legierungen verwendet werden, ermittelt werden und die Verteilung der Aktivitäten zwischen den Sektoren ist recht unsicher. Dieser Ansatz hat keine Auswirkungen auf das Gesamtkosten und -nutzen Verhältnis, führt jedoch zu einigen Unsicherheiten bei der Verteilung der Auswirkungen zwischen den Sektoren. Insgesamt hat die Studie geschätzt, dass rund 113.000 Arbeitnehmer Kobalt und anorganischen Kobaltverbindungen ausgesetzt sind.

Die in diesem Bericht für die Optionen geschätzten Kosten und Nutzen (im Vergleich zur Basislinie) sind in Tabelle 0.1 zusammengefasst. Die Vorteile werden sowohl für Methode 1 als auch für Methode 2 angezeigt. Die Kosten sind der Barwert (PV) über 40 Jahre mit einem statischen Abzinsungssatz von 3%. Sie gehen von einem Personalwechsel von 5% aus. Die geschätzten Kosten übersteigen die Vorteile für alle Optionen: Bei dem vom Ausschuss für Risikobewertung (RAC) empfohlenen OEL von 1 / 0,5 µg/m^3 liegen die Kosten zwischen 63- und 68-mal höher als die Vorteile. Für die anderen Optionen übersteigen die Kosten die Vorteile mit einem viel niedrigeren Verhältnis.

Tabelle 0.1 Zusammenfassung der monetarisierten Kosten und des Nutzens (statischer Abzinsungssatz, relativ zum Basisszenario)

Option	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Option Übergangsfrist	20 / 4.2 µg Co/m³
Gesamtnutzen M1 in Mio. €	160	140	81	€ 70	31
Gesamtnutzen M2 in Mio. €	150	130	80	€ 70	29
Gesamtkosten in Mio. €	9.800	1.900	640	€ 590	170
Kosten-Nutzen-Verhältnis M1	63	14	8	8	6
Kosten-Nutzen-Verhältnis M2	68	15	8	8	6

*Anmerkungen: *Die Werte beziehen sich auf Methode 1 (Bereitschaft zur Zahlung, WtP-Werte für Mortalität und Morbidität) und Methode 2 (Disability Adjusted Life Year, DALY). ** Die politischen Optionen stellen den OEL für die einatembare und lungengängige Fraktion dar, jeweils getrennt durch einen Schrägstrich.*
Quelle: Studienteam

Die Multikriterien Analyse, die sowohl die monetären als auch die qualitativen Auswirkungen zusammenfast, ist in Tabelle 0.2 dargestellt. Die Multikriterien Analyse Tabelle enthält die von der ACSH (Beratenden Ausschusses für Sicherheit und Gesundheit am Arbeitsplatz) vorgeschlagene Option. Die von der ACSH vorgeschlagene Option beinhaltet eine Übergangsfrist, sodass der OEL anfangs bei 20 / 4,2 µg Co/m³ liegt und nach 6 Jahren auf 10 / 2,5 µg Co/m³ gesenkt wird.

Tabelle 0.2 Multikriterien-Analyse (alle Auswirkungen über 40 Jahre und relative zum Basisszenario pro Option, Million Euro

Auswirkungen	Betroffene Interessen gruppe	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Option Übergang sfrist	20 / 4.2 µg Co/m³
Direkte Kosten - Anpassung						
Risikomanagementmaßnahmen - erstes Jahr	Unternehmen	€ 1.500	€ 710	€ 240	Kann nicht monetarisiert werden	€ 90
Risikomanagementmaßnahmen - wiederkehrend	Unternehmen	€ 2.200	€ 430	€ 110	Kann nicht monetarisiert werden	€ 20
Risikomanagementmaßnahmen - Einstellungen	Unternehmen	€ 6.000	€ 700	€ 230	Kann nicht monetarisiert werden	€ 20
Risikomanagement maßnahmen - gesamt	Unternehmen	**€ 9.600**	**€ 1.800**	**€ 580**	**€ 530**	**€ 130**
Risikomanagementmaßnahmen - gesamt pro Unternehmen	Unternehmen	€ 630	€ 119	€ 38	€ 35	€ 8
Risikomanagementmaßnahmen exklusive Stilllegungskosten - gesamt je fortgeführtes Unternehmen (in Tsd. €)	Unternehmen	€ 260	€ 80	€ 24	Kann nicht monetarisiert werden	€ 8
Überwachung (Probenahme und Analyse)	Unternehmen	€ 110	€ 90	€ 60	€ 50	€ 40
Direkte Kosten - Verwaltung						

Auswirkungen	Betroffene Interessengruppe	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Option Übergangsfrist	20 / 4.2 µg Co/m³
Unternehmenskosten der Verwaltungslast	Unternehmen	€ 13	€ 9	€ 7	€ 6	€ 4
Direkte Compliance-Kosten - gesamt						
Anpassungs-, Überwachungs- und Verwaltungslastkosten	Unternehmen	**€ 9.800**	**€ 1.900**	**€ 640**	**€ 590**	**€ 180**
Anpassungs-, Überwachungs- und Verwaltungslastkosten pro Unternehmen	Unternehmen	€ 640	€ 130	€ 42	€ 38	€ 12
Direkte Kosten - Durchsetzungskosten						
Umsetzungskosten	Öffentlicher Sektor	€ 0,9	€ 0,9	€ 0,9	€ 0,9	€ 0,9
Durchsetzungskosten	Öffentlicher Sektor	Durchsetzungskosten können entstehen, um die Einhaltung neuer OELs zu gewährleisten. Diese Kosten werden jedoch nicht geschätzt, da sie spezifisch für das individuelle Inspektionsregime der Mitgliedstaaten sind.				
Indirekte Kosten - andere						
Unternehmen stellen mindestens einen Teil ihres Geschäfts ein - % Gesamte	Unternehmen	7,1%	0,9%	0,4%	Kann nicht quantifiziert werden	0,1%
Compliance-Kosten als % des Umsatzes über 40 Jahre (einschließlich Einstellungen)	Unternehmen	Bis zu 3% (kleine Unternehmen)	Bis zu 1% (kleine Unternehmen)	Bis zu 0,4% (kleine Unternehmen)	Kann nicht quantifiziert werden	Bis zu 0,2% (kleine Unternehmen)
Erstjahrs Compliance-Kosten als % des Jahresumsatzes (ohne Einstellungen)	Unternehmen	Bis zu 29% (kleine Unternehmen), aber bis zu 4% (mittlere Unternehmen)	Bis zu 10% (kleine Unternehmen), aber bis zu 1,5% (mittlere Unternehmen)	Bis zu 5,8% (kleine Unternehmen), aber bis zu 0,75% (mittlere Unternehmen)	Kann nicht quantifiziert werden	Bis zu 2,3% (kleine Unternehmen), aber bis zu 0,3% (mittlere Unternehmen)
Beschäftigung – Arbeitsplatzverluste	Arbeitnehmer & Familien	25.850	2.760	1.120	Kann nicht quantifiziert werden	80
Beschäftigung – Soziale Kosten	Arbeitnehmer & Familien	€ 2.000	€ 220	€ 80	Kann nicht quantifiziertw werden	€ 7
Internationale Wettbewerbsfähigkeit	Unternehmen	Negative Auswirkungen	Keine signifikanten Auswirkungen	Keine signifikanten Auswirkungen	Keine signifikanten Auswirkungen	Keine signifikanten Auswirkungen
Verbraucher	Verbraucher	Keine Auswirkungen	Keine Auswirkungen	Keine Auswirkungen	Keine Auswirkungen	Keine Auswirkungen
Binnenmarkt	Unternehmen	Positive Auswirkungen von kleinerer Bedeutung				
Forschung und Innovation	Unternehmen	Negative Auswirkungen (Reduzierung von	Begrenzter negativer Auswirkungen (Reduzieru	Keine oder begrenzte negative Auswirkungen (Reduzierung von F&I, aber Anreiz zu F&I in		Keine oder nur sehr begrenzte negative

Auswirkungen	Betroffene Interessengruppe	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Option Übergangsfrist	20 / 4.2 µg Co/m³
		F&I, aber Anreiz zu F&I in kobaltfreien Alternativen)	ng von F&I, aber Anreiz zu F&I in kobaltfreien Alternativen)	kobaltfreien Alternativen		Auswirkungen
Spezifische MS/Regionen - MS, die OELs ändern müssten	Öffentlicher Sektor	Alle	Alle	Alle	Alle	Alle
Regulierung	Unternehmen	€ 0	€ 0	€ 0	€ 0	€ 0
Direkter Nutzen – verbessertes Wohlbefinden - Gesundheit						
Reduzierte Fälle von Krankheiten – Lungenkrebs	Arbeitnehmer & Familien	71	51	23	23	12
Reduzierte Fälle von Krankheiten – restriktive Lungenerkrankung	Arbeitnehmer & Familien	4.370	4.370	2.840	2.840	1.000
Reduzierte Fälle von Krankheiten – Reizung der oberen Atemwege	Arbeitnehmer & Familien	14.150	12.270	7.360	7.360	2.140
Vermeidung von Krankheiten, einschließlich immaterieller Kosten (M1 bis M2)	Arbeitnehmer & Familien	€ 150 - 140 Millionen	€ 130 - 120 Millionen	€ 75 - 74 Millionen	€ 75 - 74 Millionen	€ 29 - 27 Millionen
Direkter Nutzen – verbessertes Wohlbefinden - Sicherheit						
Vermiedene Kosten	Unternehmen	€ 2	€ 2	€ 1	€ 1	€ 0
Vermiedene Kosten	Öffentlicher Sektor	€ 8	€ 7	€ 4	€ 4	€ 1
EU-Politikagenda	Alle	Beitrag zum EU-Grünen Deal: Chemiestrategie für eine giftfreie Umwelt				
Direkter Nutzen– verbessertes Wohlbefinden - Umwelt						
Umweltfreisetzungen	Alle	Begrenzte Reduzierung der Umweltfreisetzung von Kobalt. Änderungen zu kobaltfreien Alternativen werden positive Auswirkungen haben, während erhöhte Kosten für einige Artikel negative Auswirkungen haben könnten. Erhöhte Recyclingkosten könnten sich negativ auswirken.				
Direkter Nutzen– Markteffizienz						
Level Playing Field	Unternehmen	Ein harmonisierter OEL auf EU-Ebene würde dazu beitragen, gleiche Wettbewerbsbedingungen für Unternehmen zu gewährleisten, die in verschiedenen EU-Mitgliedstaaten tätig sind.				
Indirekter Nutzen						
Verwaltungsvereinfachung	Unternehmen	Sollten alle Mitgliedstaaten einen harmonisierten OEL haben, würde dies die Verwaltungslast für Unternehmen mit Aktivitäten in mehreren Mitgliedstaaten reduzieren.				
Synergie	Unternehmen		Einzelne positive Auswirkungen			
Corporate Social Responsibility	Unternehmen		Einzelne positive Auswirkungen			

Auswirkungen	Betroffene Interessengruppe	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Option Übergangsfrist	20 / 4.2 µg Co/m³
Vermiedene Kosten für die Festlegung von OELs	Öffentlicher Sektor	€ 0,5	€ 0,5	€ 0,5	€ 0,5	€ 0,5
Andere Auswirkungen						
Recycling – Geschäftsverlust	Recycling-unternehmen	Negative Auswirkungen durch Compliance-kosten.	Negative Auswirkungen durch Compliance-kosten.	Leicht negative Auswirkungen.	Leicht negative Auswirkungen.	Leicht negative Auswirkungen.
Auswirkungen auf Grundrechte	Alle	Die obligatorische Überwachung der Kobaltwerte wird dazu beitragen, dass das Grundrecht der Arbeitnehmer auf Arbeitsumgebungen, die die menschliche Gesundheit respektieren, zuverlässig durchgesetzt wird.				
Auswirkungen auf die Digitalisierung	Unternehmen	Es werden keine Auswirkungen auf die Digitalisierung erwartet.				
Beiträge zu den nachhaltigen Entwicklungszielen der UNO	Alle	In Bezug auf das dritte Ziel der nachhaltigen Entwicklung - *"gute Gesundheit und Wohlbefinden - verbesserte Gesundheit von Arbeitnehmern und Familien"* - gilt der oben genannte Kommentar zu Auswirkungen auf Grundrechte ebenfalls.				

Quelle: Studienteam

Anmerkungen: Die Summe kann sich aufgrund von Auf- bzw. Abrunden von der Gesamtsumme unterscheiden.

Die Hauptunsicherheiten und Fragen, die im Entscheidungsprozess berücksichtigt werden müssen, sind:

- **Bewertung der nicht krebsbedingten Endpunkte:** Die Bewertung der nicht krebsbedingten Endpunkte ist mit Unsicherheiten behaftet. Es wurde eine Sensitivitätsbewertung durchgeführt, bei der die hohen Werte für das Behinderungsgewicht der relevanten Krankheiten verwendet wurden. Die Sensitivitätsbewertung deutet darauf hin, dass die Vorteile der nicht krebsbedingten Endpunkte etwa dreimal höher sein könnten. Dies würde das Kosten-Nutzen-Verhältnis auf fast ein Drittel der in Tabelle 0-1 dargestellten Werte ändern.

- **Einatembare vs. lungengängige Fraktion:** Die Optionen bestehen aus Paaren von OELs, die unabhängig voneinander auf der Grundlage der unterschiedlichen gesundheitlichen Auswirkungen der einatembaren und der lungengängigen Fraktion festgelegt werden. Darüber hinaus wird für die einatembare Fraktion die höchste politische Option auf der Grundlage des Modus der nationalen OEL in den Mitgliedstaaten festgelegt, in denen ein OEL festgelegt ist. Das Verhältnis zwischen dem OEL für die lungengängige und die einatembare Fraktion unterscheidet sich zwischen der politischen Option mit einem Verhältnis von lungengängiger zu einatembarer Fraktion (R:1) von 1:2 für die 1 / 0,5 µg/m3-Option und 1:4,7 für die 20 / 4,2 µg/m3. Auf der Grundlage von Daten über die Verhältnisse von lungengängiger zu einatembarer Fraktion für die verschiedenen Sektoren wird beurteilt, dass bei der 1 / 0,5 µg/m3-Option die Einhaltung des einatembaren Bruchteils für alle Sektoren außer beim Schweißen und ähnlichen Hochtemperaturaktivitäten die größte Herausforderung darstellen wird. Bei der 20 / 4,2 µg/m3-Option wird für einige Sektoren, die Kobaltverbindungen verwenden, der OEL für die lungengängige Fraktion die größte Herausforderung darstellen, während für Sektoren, die Kobaltmetall verwenden, die einatembare Fraktion die größte Herausforderung darstellen wird.

- **Höhe der Anpassungskosten.** Die Angaben des Kostenmodells sollten mit Vorsicht interpretiert werden, da die Berechnung auf einer Reihe von Annahmen und Vereinfachungen basiert, wie sie in Abschnitt 6.3 und der methodischen Notiz dargelegt sind. Diese Annahmen wurden in Absprache mit den Interessenvertretern des ACSH Arbeitsgruppe für Chemikalien, einschließlich Vertretern der Arbeitnehmer, der Arbeitgeber und der Mitgliedstaaten, getroffen. Dennoch geben die Daten einen Hinweis auf die Größenordnung. Im Vergleich zum Umsatz der Unternehmen sind die Anpassungskosten für die Mehrheit der Sektoren und für alle bis auf die zwei niedrigsten OEL gering. Die von den Unternehmen für die Stakeholder-Konsultation geschätzten Anpassungskosten sind deutlich höher als die vom Kostenmodell berechneten, mit Ausnahme der Option 1 / 0,5 µg/m3. Der Hauptunterschied wird darauf zurückgeführt, dass die bestehende Nutzung von Atemschutzgeräten berücksichtigt wird. Für die Kostenschätzungen der vorliegenden Studie wird davon ausgegangen, dass Atemschutzgeräten eingesetzt werden kann, um die Exposition in bestimmten Expositionssituationen unter den OEL zu senken, in denen der Einsatz von Atemschutzgeräten heute allgemein akzeptiert ist und das Potenzial für weitere technische Präventivmaßnahmen zur Begrenzung der Exposition der Arbeitnehmer bereits erschöpft ist (z.B. einige Reinigungs- und Wartungsarbeiten); siehe Abschnitt 7.2.16 für eine detaillierte Diskussion.

- **Recycling.** Die Einführung eines OEL kann, bei den beiden niedrigsten Optionen, den Prozentsatz des in der EU wiedergewonnenen Kobalts im Abfall aufgrund der zusätzlichen Anpassungskosten verringern. Ein Teil des Kobalts im Abfall könnte entweder ohne Wiedergewinnung entsorgt oder zur Wiedergewinnung außerhalb der EU exportiert werden. Eine erhöhte Wiedergewinnung von Kobalt innerhalb der EU im Einklang mit der offenen strategischen Autonomie der EU und entspricht den Absichten und Benchmarks des europäischen Gesetzes über kritische Rohstoffe, auch wenn der Verordnungsvorschlag keine spezifischen Benchmarks für die Kobaltwiedergewinnung festlegt. Für Batterien werden in der neuen Verordnung über Batterien und Altbatterien Wiedergewinnungsziele festgelegt, aber für andere Abfallkategorien könnte es relevant sein zu untersuchen, wie sichergestellt wird, dass die Einführung eines OEL die Wiedergewinnung des Kobalts innerhalb der EU nicht unrentabel macht.

- **Kritischer Rohstoff und grüne Wirtschaft.** Kobalt ist ein kritischer Rohstoff und wird für einige der Schlüsseltechnologien im grünen Übergang wie Batterien für Fahrzeuge und Speicher sowie Magnete in Windturbinen verwendet. Die Anpassungskosten für die Umsetzung der OELs könnten auf die Artikel übertragen werden, was zu höheren Kosten für Schlüsseltechnologien in der grünen Wirtschaft führen könnte. Andererseits könnte die Einführung eines OEL unter anderem Anreize für die Entwicklung von kobaltfreien Alternativen schaffen, z.B. für einige Werkzeuge und Batterien, für die bereits Alternativen auf dem Markt sind, und die EU weniger abhängig von Rohstoffimporten aus wenigen Ländern außerhalb der EU machen. Nur bei den beiden niedrigsten politischen Optionen könnte es eine Auswirkung geben. Bei den beiden höchsten politischen Optionen würden die Anpassungskosten nur eine so geringe und marginale Änderung der Artikelpreise bewirken, dass dies keine Auswirkungen auf die grüne Wende hätte.

- **Auswirkungen auf KMU.** Die Kosten für die Einhaltung, bestehend aus Risikomanagementmaßnahmen, Überwachung und Verwaltungslast, sind für kleine und mittlere Unternehmen bei allen Optionen relativ hoch. Die Auswirkungen variieren je nach politischer Option. Bei den beiden niedrigsten Optionen könnten die Hauptauswirkungen erwartet werden. In Sektoren, in denen die Kostenbelastung hoch ist, könnte die Wettbewerbsfähigkeit von KMU bei den beiden niedrigsten OEL negativ beeinflusst werden. Bei den beiden höchsten Optionen wird die zusätzliche Kostenbelastung nicht als signifikant angesehen, um die Funktionsfähigkeit von KMU in der Mehrzahl der Sektoren zu beeinträchtigen. Beachten Sie, dass die Übergangsfrist der Optionen es den Unternehmen erleichtern wird, die Nutzung zusätzlicher Risikomanagementmaßnahmen zu planen und zu finanzieren. Dies wird für die KMU wichtig sein. Es wird daher nicht erwartet, dass KMU unter der politischen Option mit Übergangsfrist signifikant betroffen sein werden.

- **Einstellung und Verlagerung.** Ein OEL für Kobalt und anorganische Kobaltverbindungen wird wahrscheinlich nicht der einzige Grund für Unternehmen sein, ihre Tätigkeit einzustellen, was in der Realität für viele mittlere und große Unternehmen eine Verlagerung außerhalb der EU bedeuten kann, während es für kleine Unternehmen eine Einstellung der Aktivitäten bedeuten kann. Die Wettbewerberländer der EU haben OELs für Kobalt und anorganische Kobaltverbindungen, die auf dem gleichen Niveau oder höher liegen als die höchste Option von 20 / 4,2 µg/m3. Keines der Wettbewerberländer hat OELs für den einatembaren und den lungengängigen Anteil. Aus der Stakeholder-Konsultation hat mindestens ein internationales Unternehmen angegeben, dass es die Aktivitäten mit den höchsten Expositionskonzentrationen möglicherweise in Einrichtungen außerhalb der EU verlagern wird. Die Bewertung hat ergeben, dass bei den KMU unter der niedrigsten politischen Option das Risiko besteht, dass Unternehmen ihre Tätigkeiten einstellen müssen. Es wird davon ausgegangen, dass etwa 7% aller Unternehmen mit exponierten Arbeitnehmern ihre Tätigkeiten einstellen könnten. Bei den höheren politischen Optionen ist der Anteil viel geringer. Bei der Option von 10 / 2,5 µg Co/m^3 wird der geschätzte Anteil nur 0,4% und bei der höchsten politischen Option nur 0,1% betragen. Bei der Option mit Übergangsfrist müssen nur sehr wenige, wenn überhaupt, Unternehmen einschließlich KMU ihre Tätigkeiten einstellen.

- **Zeitbedarf für die Umsetzung.** Die Kosten für Anpassungen hängen von der für die Anpassungen zur Verfügung stehenden Zeit ab. Für einige OELs wurden zusätzliche Übergangsfristen für bestimmte Sektoren oder Aktivitäten festgelegt, z.B. eine zusätzliche Übergangsfrist für Kupferschmelzen für das OEL für Arsen(III)-säure und ihre Salze und eine zusätzliche Übergangsfrist für das Schweißen für das OEL für Chrom(VI).

1 INTRODUCTION

This chapter comprises the following sections:

- Section 1.1: Political and legal context
- Section 1.2: Background
- Section 1.3: The study

1.1 Political and legal context

1.1.1 The Carcinogens, Mutagens and Reprotoxic substances Directive

The Carcinogens, Mutagens and Reprotoxic substances Directive (Directive 2004/37/EC), hereinafter the CMRD, protects workers from exposure to carcinogens, mutagens or reprotoxic substances at work.

Substances within the scope of the Directive are substances that meet the following criteria:

- 'Carcinogen' means:
  - (i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (the CLP);
  - (ii) a substance, mixture or process referred to in Annex I to the CMRD as well as a substance or mixture released by a process referred to in that Annex;
- 'Mutagen' means:
  - a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;
- 'Reprotoxic substance' means:
  - a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008.

Cobalt and a number of inorganic cobalt compounds are today within the scope of the CMRD, although no OEL has been established, as they meet the criteria for classification as category 1A or 1B carcinogen, mutagen or reproductive toxicant.

As a consequence, employers' have today a number of obligations related to cobalt and inorganic cobalt compounds within the scope of the CMRD which include:

- The employer shall reduce the use of the substances at the place of work by replacing them, in so far as is technically possible, with substances, mixtures or process(es) which, under their conditions of use, are not dangerous or is less dangerous to workers' health or safety, as the case may be.

- Where it is not technically possible to replace the substance, the employer shall ensure that the substances are, in so far as is technically possible, manufactured and used in a closed system.
- Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers to the substances is reduced to as low a level as is technically possible.
- Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.

The requirements for minimisation of the exposure apply today to cobalt and inorganic cobalt compounds within the scope of the directive irrespective of establishing an OEL.

The minimum requirements for protecting workers that are exposed to carcinogens and mutagens are, for some substances, expressed by an Occupational Exposure Limit (OEL). For each OEL, Member States (MS) are required to establish a corresponding national limit value (OEL), from which they can only deviate to a lower but not to a higher value. Today, no limit value for cobalt and cobalt compounds are established at EU level.

An OEL expresses the concentration of the relevant substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to the CMRD. The limit values are defined as: ‘‘*limit value’ means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III*” (Article 2 (d). The CMRD furthermore specifies that the “*Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III.*” (Article 5,4)

Even the concentration in the workplace is measured as Co (cobalt), a limit value for inorganic cobalt compounds is considered to only apply to inorganic cobalt compounds under the scope of the CMRD. A similar approach was used for nickel compounds as part of the OELs 4 study and inorganic arsenic compounds as part of the OELs 3 study.

Of importance for the current assessment, in the case of any activity likely to involve a risk of exposure to cobalt and inorganic cobalt compounds within the scope of the Directive, 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 substances.

To determine the degree of exposure it would typically be necessary to measure the workplace concentrations. It should be noted that measurements of workplace concentrations are not specifically linked to the assessment of compliance with an OEL. The assessment shall be renewed regularly, but the CMRD does not require regular monitoring if changes in the conditions which may affect workers’ exposure to the substances does not occur. This is further discussed in the Methodological Note.

1.1.1.1 Example specifically for cobalt

The consequences of substances coming into the scope of the CMD can be illustrated by industry's comments to the proposal for classification of cobalt metal as carcinogenic 1B, Muta. 2 and Repr. 1B (ECHA, 2017). According to one organisation: *"The classification will lead to the imposition of very stringent health and safety measures to ensure safe working conditions. It will be very challenging, nearly impossible, to implement in all circumstances these conditions to ensure the very low SCL*[3] *for all exposure routes, Besides the production of cobalt, our indications are that this is also applicable to several other downstream applications such as the production, use and maintenance of hardmetal tools, the cobalt plating of products, etc… This will involve in certain cases a complete change of the production technology already installed* " (ECHA, 2017). And further, as described by one company in the hardmetal sector: "*In addition, the proposed carcinogenicity (Carc. 1B by all routes of exposure), reproductive (Repro. 1B), and mutagenicity (Muta. 2) classifications would trigger a major change in the manufacturing process of hardmetal. Production would have to change dramatically into an enclosed, highly automated system like the ones employed by the pharmaceutical industry, which will be extremely challenging if not impossible for article manufacturing"* (ECHA, 2017). The new classification went into force by 1 October 2021. Is has been in focus in the stakeholder consultation for this study to ensure that the assessment takes into account the measures taken in response to the new classification of the cobalt metal.

1.1.2 REACH

The substances within the scope of the study are subject to the requirements for registrations under REACH (Regulation (EC) No 1272/2008). For some intermediate uses, the use is further described in section 3.9.

Restrictions. None of the substances within the scope of this study are subject to restrictions under REACH. For five cobalt salts, a restriction proposal was prepared by ECHA (European Chemicals Agency) in 2018 (ECHA 2018a), but the proposal has been withdrawn by Commission Decision of 8th April 2022 on the termination of the restrictions process on cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) under REACH (C(2022) 2137 final).

A number of arsenic, cadmium, nickel, lead, and inorganic ammonium substances subject to restrictions contain cobalt, but none of the substances are registered and consequently out of the scope of this study. The relevant entries in REACH Annex XVII are as follows: Arsenic compounds (entry 19), cadmium and its compounds (entry 23), nickel and its compounds (entry 27), lead and its compounds (entry 63), and inorganic ammonium salts (entry 65).

Authorisation. None of the substances within the scope of this study are subject to authorisation under of REACH.

Chemical Safety Reports (CSRs). As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an exposure assessment and risk characterisation that address all the identified hazards of the substance. The CSRs include for all Worker Contributing Scenarios (WCS) a description of the operational conditions and the risk management measures. This CSRs provide key information for the risk assessments to be undertaken in accordance with the requirements of the CMRD.

[3] SCL: Specific Concentration Limit.

Classification and Labelling Inventory (C&L Inventory). This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process. Self-classifications of substances within the scope of the study are listed in Table 1-3.

Risk management option analysis. A risk management option analysis (RMOA) for five cobalt salts from 2017[4] concluded that follow-up regulatory action at EU level was needed and that a restriction would be the most appropriate for the five substances. The restriction process has later been terminated as described above and replaced by the policy option of establishing an OEL. For cobalt metal and other inorganic cobalt compounds no RMOA has been developed.

1.1.3 Other relevant legislation

CLP. A harmonised classification of cobalt and a number of inorganic cobalt compounds has been established under the CLP (Regulation (EC) No 1272/2008). The harmonised classification of the substances within the scope of the study is indicated in Table 1-2.

Authorisation as feed material. The use of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additive is authorised by Commission Implementing Regulation (EU) No 601/2013 of 24 June 2013[5]. The aim of the Regulation is to reduce the risk of occupational exposure. The Regulation concern the incorporation of the additive in the feed (in form a premixture), the form of the feed (pellet form), appropriate protective measures and declarations to be made on the labelling of the additive and premixture with a level indicating "*It is recommended to limit the supplementation with Cobalt to 0,3 mg/kg in complete feed.*"

Medical Devices Directive (MDR). Changes to EU MDR 2017/745 require devices containing more than 0.10% (w/w) cobalt to indicate the presence of cobalt as a potential carcinogenic, mutagenic, and reprotoxic substance. In the response to these requirements, several manufacturers provide low-cobalt grades of stainless steel for medical applications.

1.2 Background

1.2.1 Initiatives by European Commission

As stated in the Tender Specifications, in February 2021, the Commission presented its Europe's Beating Cancer Plan[6], with the aim of tackling the entire disease pathway, from prevention to

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[4] Accessed Dec. 2022 at https://www.echa.europa.eu/documents/10162/60163f64-8961-9f0a-c8b4-e2f3837d8398

[5] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:172:0014:0022:en:PDF

[6] Europe's Beating Cancer Plan. Communication from the commission to the European Parliament and the Council. https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf

quality of life of cancer patients and survivors. Actions to fight cancer at the workplace, in particular through the continuous revision of the CMRD, are key components of the Cancer Plan.

On 8 April 2022, the Commission adopted a Decision on the termination of the restrictions procedure with regard to five cobalt salts initiated by the Commission's request to the European Chemicals Agency (ECHA) dated 12 April 2017. According to the preamble to the Decision, the evaluation by RAC and SEAC (Committee for Socio-Economic Analysis) indicates that an OEL in the area of occupational safety and health (OSH) covering cobalt and its compounds is a more appropriate policy action for the workers' protection than a restriction on 5 cobalt salts under REACH.

The Commission has asked the advice of RAC to assess the scientific relevance of occupational exposure limits for some carcinogenic chemical substances. In support of the Commission's request, ECHA has prepared a scientific report concerning occupational limit values for cobalt and inorganic cobalt compounds at the workplace used as background documentation for the RAC opinion.

In the preparatory phase of making the scientific report, a call for evidence was started on 20 August 2021 to invite interested parties to submit comments and evidence on the subject. The Scientific Report and its later revision as Annex to the RAC opinion (ECHA, 2022) as well as the responses to the stakeholder consultation have been used as an offspring for the current study.

The 'EU Strategic Framework on Health and Safety at Work 2021-2027' [7] states that new scientific data indicates that limit values should be established for cobalt and that protective limit values will be proposed by the Commission.

1.2.2 Opinion of the Committee for Risk Assessment (RAC)

On the 1st December 2022, the Committee for Risk Assessment (RAC) published its opinion on the scientific evaluation of occupational exposure limits for cobalt and inorganic cobalt compounds, which is summarised in Table 1-1.

Table 1-1 The outcome of the RAC evaluation to derive limit values for cobalt and cobalt compounds and the evaluation for dermal exposure and suggested notations (RAC, 2022)

Derived limit values	**Concentration**
Occupational exposure limit value (OEL) - 8-hour time weighted average (TWA)	Inhalable fraction: 0.001 mg Co/m³ (1 µg Co/m³) Respirable fraction: 0.0005 mg Co/m³ (0.5 µg Co/m³)
Short term exposure limit (STEL)	Not relevant
Biological limit value (BLV)	Not established
Biological guidance value (BGV)	Females: 0.002 mg (2 µg) Co/L urine Males: 0.0007 mg (0.7 µg) Co/L urine
Notations	
Notations	'Skin sensitisation' and 'Respiratory sensitisation'

The key conclusions of the evaluation are used as starting points for the health assessment in the current study and further described in Chapter 2.

[7] https://osha.europa.eu/en/safety-and-health-legislation/eu-strategic-framework-health-and-safety-work-2021-2027

Selected key conclusions of the evaluation are (RAC, 2022):

- Workers are often exposed to a mixture of cobalt compounds. Because individual cobalt species cannot be separately monitored in mixed exposure scenarios, RAC recommends the limits should be applied to all cobalt inorganic compounds.

- The OEL for the inhalable fraction is derived from human data on non-cancer lung effects in humans derived from Nemery *et al.* (1992) from diamond polishing industry without hard-metal and tungsten co-exposure, showing symptoms and mild, but statistically significant, decreases in lung function at inhalation exposure levels.

- Thresholds for chronic inflammatory lung effects of the respirable fraction of 0.5 µg/m^3 and of the inhalable fraction of 1 µg/m^3 were derived in a weight-of-evidence approach based on data from subchronic and chronic animal studies on cobalt sulphate hexa/heptahydrate, supported by the data for cobalt metal, as well as based on human data on cobalt exposure in the hard-metal industry.

- Lung cancer observed in the animal studies and non-cancer respiratory effects observed in exposed workers are the main critical toxic endpoints of cobalt metal and its soluble inorganic compounds. Other toxic effects of cobalt and its soluble salts include respiratory and skin sensitizing properties and reproductive toxicity. The available evidence from humans does not clearly show an increased risk of cancer among hard-metal workers or workers in cobalt salt manufacturing. However, a definite conclusion cannot be drawn from the human data due to several important limitations.

- There is multiple evidence on the thresholded mechanisms of action of cobalt and chronic lung inflammation is likely to play a crucial role in the genotoxicity and carcinogenicity of cobalt. The threshold for lung inflammation is therefore the basis for the OEL, although genotoxic effects at levels below this threshold cannot be totally excluded.

A notation on 'Skin sensitisation' is proposed, but there are only limited data on systemic uptake via the skin and thus no 'skin' notation is proposed.

1.2.3 Scientific Committee on Occupational Exposure Limits (SCOEL)

No SCOEL recommendation for cobalt and inorganic cobalt compounds has been prepared.

1.2.4 Advisory Committee on Safety and Health at Work (ACSH)

The ACSH has in its opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation from 2021 listed cobalt and inorganic cobalt compounds as a priority carcinogen under the CMRD (immediate priorities) (ACHS, 2021). In the ACSH opinion, the scope of the OEL is narrowed from cobalt and its compounds to cobalt and inorganic cobalt compounds. As consequence, one of the cobalt salts within the scope of the restriction proposal, cobalt di(acetate), become out of scope of the OEL. The background for the change in scope is not reported.

The ACSH opinion on OEL value for cobalt and inorganic cobalt compounds was adopted on 22 September 2023. The opinion notes that cobalt and inorganic cobalt compounds to workers should be controlled by the intervention at the EU level. In the discussions, it was agreed that there should be an OEL for both the inhalable and the respirable fractions. The OEL should be set at the value of 20 µg Co/m^3 for the inhalable fraction and 4.2 µg Co/m^3 for the respirable fraction. After 6 years, the limit values should be set at of 10 µg Co/m³ for the inhalable fraction and 2.5 µg Co/m³ for the respirable fraction.

1.3 The study

This report is one of six reports elaborated within the framework of a study undertaken for the European Commission by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), COWI A/S (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), and EPRD Office for Economic Policy and Regional Development (Poland). The six reports are:

- Methodological Note;
- Report for 1,4-dioxane;
- Report for isoprene;
- Report for polycyclic aromatic hydrocarbons (PAH);
- Report for welding fumes;
- Report for cobalt and inorganic cobalt compounds.

One of the aims of the study is to provide the Commission with the most recent, updated and robust information on a number of substances with the view to support the European Commission in the preparation of an Impact Assessment report to accompany a potential proposal to amend Directive 2004/37/EC.

The specific objective of this report is to assess the impacts of introducing one or several OELs for cobalt and inorganic cobalt compounds under the scope of the CMRD.

Details on the methodology used across all substances are included in the Methodological Note. The note also includes an initial screening of potential impacts for all impact categories.

1.3.1 Study objectives

The general objectives with regard to these substances (except for welding fume) include a detailed assessment of the baseline scenario (past, current, and future), as well as the assessment of the impacts of introducing a new Occupational Exposure Limit (OEL) and, where appropriate, a Short-Term Exposure Limits (STEL) and a skin notation and a respiratory notation.

The specific objective of this report is to assess the impacts of introducing an OEL for cobalt and inorganic cobalt compounds accompanied by notations for 'Skin sensitisation' and 'Respiratory sensitisation'.

1.3.2 Pricing

Costs and benefits are calculated at 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.) Cost data are based upon 2018 data (OELs 5). 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. Because the ratio of costs to benefits is more important than their actual financial value, the study team decided that it was better to present 2019-2020 values, than attempt to adjust to 2023 prices.

1.3.3 Limit values assessed

Throughout this document the term 'Limit Values' is used to refer to the group of measures being proposed. This includes OELs, STELs, BLVs and notations. Furthermore, in some context derived risk factors as applied in e.g. Germany and France are also referred to as non-binding limit values.

OELs are 8-hour time weighted average (TWA) exposures and define a threshold beyond which workers must not be exposed. OELs are set by the European Commission. For each OEL, Member States are required to establish a corresponding national limit value, from which they can only deviate to a lower but not a higher value.

In addition to setting/reviewing OELs, the European Chemicals Agency (ECHA) has also been mandated to adopt, as appropriate, scientific opinions on the establishment of:

- biological limit values; and
- notations.

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'.

A 'notation' is a means of alerting employers that air sampling alone is insufficient to accurately quantitate exposure and that other measures may need to be taken. For example, a 'skin notation' would indicate that measures need to be taken to prevent significant absorption through the skin while a notation for 'skin sensitization' indicates that exposure of skin should be avoided as even low exposures may lead to sensitization.

1.3.4 Existing limit values at EU level

No OEL or other limit values at EU level have been established for cobalt and inorganic cobalt compounds.

1.3.5 Substances in the scope of the study

Inorganic cobalt substances[8] within the scope of this study are cobalt and inorganic cobalt compounds within the scope of the CMRD and registered under REACH.

1.3.5.1 Substances withing the scope of the CMRD

Substances within the scope of the directive are substances that meet the criteria for classification as category 1A or 1B carcinogen, mutagen or reproductive toxicant as set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (the CLP). Substances that meet the criteria may either have a harmonised classification and listed in Annex VI to the CLP or they may have been classified by the manufacturers' or importers' self-classification.

Harmonised classification

Harmonised classification under the CLP has been established for cobalt and 7 inorganic cobalt compounds. Cobalt and five of the compounds are classified carcinogenic (Carc. 1B or 1A); of these, cobalt and four cobalt compounds are further classified reprotoxic (Repr. 1B). Of the substances within the scope, the production/import of cobalt lithium nickel oxide (EC number 442-750-5) has ceased as described in section 3.2.1.

[8] In this study, the term 'substances' is used in accordance with the use of the term under REACH. Cobalt substances includes both cobalt metal, cobalt compounds and complex reaction masses, matte, residues, etc. containing cobalt. Cobalt compounds are a subset of cobalt substances.

Two of the substances with harmonised classification (cobalt oxide and cobalt sulphide) are not classified carcinogen, mutagen and/or reprotoxic substance according to the harmonised classification, but for cobalt oxide, the self-classifications in the C&L Inventory classify the substances as Carc. 1B and Repr. 1B (see Table 1-3).

According to the ECHA Scientific Report (now Annex 1 to the RAC opinion), Annex VI to the CLP lists eight entries for the classification of cobalt and its inorganic compounds for registered substances. Of these, six substances are classified carcinogenic.

Please note that the organic compound cobalt di(acetate) with a harmonised classification as carcinogenic and included in the restriction proposal for five cobalt salts (ECHA, 2018) is not within the scope of the current study.

Table 1-2 Harmonised classification of cobalt and inorganic cobalt compounds according to Annex VI to the CLP

EC No	Chemical name	CAS No	Hazard class and category	Hazard statement code
208-169-4	Cobalt carbonate	513-79-1	**Carc. 1B** Muta. 2 **Repr. 1B** Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F *** H334 H317 H400 H41
215-154-6	Cobalt oxide	1307-96-6	Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410
215-273-3	Cobalt sulphide	1317-42-6	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410
231-158-0	Cobalt	7440-48-4	**Carc. 1B** Muta. 2 **Repr. 1B** Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4	H350 H341 H360F H334 H317 H413
231-589-4	Cobalt dichloride	7646-79-9	**Carc. 1B** Muta. 2 **Repr. 1B** Acute Tox. 4 * Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F *** H302 H334 H317 H400 H410
233-334-2	Cobalt sulphate	10124-43-3	**Carc. 1B** Muta. 2 **Repr. 1B** Acute Tox. 4 * Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic	H350i H341 H360F *** H302 H334 H317 H400 H41
233-402-1	Cobalt dinitrate	10141-05-6	**Carc. 1B** Muta. 2 **Repr. 1B**	H350i H341 H360F ***

EC No	Chemical name	CAS No	Hazard class and category	Hazard statement code
			Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H334 H317 H400 H410
442-750-5	Cobalt lithium nickel oxide	-	**Carc. 1A** Acute Tox. 2 * STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H330 H372 ** H317 H400 H410

** The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard statement not specifying the route of exposure as the necessary information is not available. *** For fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under the Directive. These hazard statements are indicated by the reference in Table 3 of Annex VI to the CLP.

Self-classification

A substance or mixture which meets the criteria for classification as a carcinogen, mutagen and/or reprotoxic substance (category 1A or 1B) according to the criteria described in Annex 1 to CLP Regulation does not necessarily have a harmonised classification.

Self-classified substances that meet the criteria would also be within the scope of the CMRD. The table below lists six registered substances classified Carc. 1B, Repr. 1B or both as indicated in the manufacturers' or importers' self-classification in the C&L inventory at ECHA's website. In addition, the Cobalt REACH Consortium self-classify cobalt monoxide as Carc. 1B and Repr. 1B, but this self-classification does not appear from the C&L inventory as the substances have a harmonised classification (see the table above) and for substances with a harmonised classification only this classification is listed in the C&L inventory.

In total, cobalt and 15 inorganic cobalt compounds have a classification that makes the substances within the scope of the CMRD.

For one of the substances, cobalt titanite green spinel (269-047-4), the Inorganic Pigment (IP) Consortium notes in its response to the stakeholder consultation to the ECHA (2022) Scientific Report that for this substance, several classifications notified to the C&L inventory include a classification as Carcinogen 1A, affected by impurities. This classification is exclusively due to the presence, in certain compositions of this substance, of nickel titanium trioxide as impurity and is not related to the content of cobalt in this substance. For the current study it will be assumed that inorganic cobalt compound classified carcinogenic will be within the scope of the OEL irrespective of the reason for the classification as carcinogenic.

Table 1-3 Self-classification of cobalt and inorganic cobalt compounds according to the C&L inventory for Hazard class and category of relevance for the CMRD

EC No	Substance	CAS No	Hazard class and category of relevance for the CMRD
215-154-6	Cobalt oxide *	1307-96-6	Carc. 1B Repr. 1B
235-362-0	Cobalt lithium dioxide	12190-79-3	Repr. 1B

EC No	Substance	CAS No	Hazard class and category of relevance for the CMRD
237-358-4	Cobalt molybdate	13762-14-6	Carc. 1B Repr. 1B
244-166-4	Cobalt dihydroxide	21041-93-0	Carc. 1B Repr. 1B
269-047-4	Cobalt titanite green spinel	68186-85-6	Carc 1A **
269-093-5	Olivine, cobalt silicate blue	68187-40-6	Repr. 1B
480-390-0	Cobalt lithium manganese nickel oxide	NA	Carc. 1A Repr. 1B
700-042-6	Aluminium cobalt lithium nickel oxide	177997-13-6	Carc. 1A Repr. 1B
701-439-7	Reaction mass of cobalt olivine and crystalline silicon dioxide	68187-40-6	Repr. 1B

* As indicated by the Cobalt REACH Consortium's self-classification. The C&L inventory lists the harmonised classification only.
** Classification according to more than 50% of companies with joint entries in the C&L inventory. For all entries, about 10% classify the substance Carc 1A.

1.3.5.2 Substances outside the scope of the study

Because individual cobalt species cannot be separately monitored in mixed exposure scenarios, RAC recommends the limits should be applied to all inorganic cobalt compounds (RAC, 2022). To apply the OEL to all inorganic cobalt compounds would, however, not be in compliance with the definition of an OEL within the CMRD (see section 1.1.1). Consequently, inorganic cobalt compounds which are not within the scope of the CMRD as well as organic cobalt compounds will only be considered within the scope of the study when present in mixed exposure scenarios together with inorganic cobalt substances within the scope of the CMRD.

As mentioned in section 1.1.1, similar approach was used for nickel compounds as part of the OELs 4 study and inorganic arsenic compounds as part of the OELs 3 study.

For use of substances outside the scope of the CMRD, two considerations are necessary in order to determine if the use of the substances are outside the scope of this study:

- Are the substances used for processes where also substances within the scope of the CMRD are used, and is it for the monitoring of total Cobalt (Co) in the workplace air possible to distinguish between the contribution from the different substances?
- Are the substances used in processes (e.g. thermal processes) where substances within the scope of the CMRD is generated unintentionally by transformation of the substances?

This concern:

- Inorganic cobalt compounds (mainly various pigments) which are not a carcinogen, mutagen or reprotoxic substance as defined by the CMRD.
- The organic cobalt compounds (mainly carboxylates and resonates) which are outside the definition of the OELs assessed but may be within the scope of the CMRD.

The organic compounds cobalt carboxylates and resonates are used e.g. for rubber adhesion agents and driers for paints. For the latter applications, cobalt metal is also used and as part of the assessment it is discussed to what extent it is possible to distinguish between processes where cobalt metal is used and processes where the organic compounds are used.

The organic cobalt compounds are not used for thermal processes where decomposition of the substances can be expected.

A number of inorganic cobalt compounds are used as pigments. Most of the pigments are self-classified as 'Not Classified', but a few have a classification as carcinogen and/or mutagen.

The pigments are not used for thermal processes and formation of substances within the scope from the use of 'Not classified' pigments is assessed to be insignificant.

1.3.5.3 Brief description of the primary uses of the substances within the scope of the study

Cobalt is a hard lustrous bluish grey metal. It has a melting point of 1,495°C, a boiling point of 2,927°C and a density of 8.9 g/cm^3 (slightly more than iron). Pure metallic cobalt has few applications, but its use as an alloying element for heat- or wear-resistant applications and as a source of chemicals makes it a strategically important metal. A brief description of the primary uses of registered cobalt and inorganic cobalt compounds within the scope of the CMRD is provided in the table below.

Table 1-4 Brief description of the primary end uses of cobalt and inorganic cobalt compounds within the scope of the CMRD

EC No	Chemical name	Description
208-169-4	Cobalt carbonate	Catalysts Manufacture of chemicals Fermentation process/biogas production Fertilizers and feed grade materials Manufacture of pigments, frits, glass and ceramic ware Water treatment chemicals, oxygen scavenger and corrosion inhibitor Surface treatments
231-589-4	Cobalt dichloride	
233-334-2	Cobalt sulphate	
215-154-6	Cobalt oxide	Alloys (magnets) Batteries manufacture (alkaline rechargeable batteries) Catalyst and catalyst precursor Electronic (varistors, thermistors) Manufacture of pigments, frits, glass and ceramic ware
231-158-0	Cobalt	Cobalt alloys Manufacture of chemicals Hardmetal and diamond tools Magnets Electronic equipment
233-402-1	Cobalt dinitrate	Catalysts production Manufacture of chemicals Manufacture of other cobalt compounds during battery production Surface treatments Water treatment chemicals, oxygen scavenger and corrosion inhibitor
235-362-0	Cobalt lithium dioxide	Manufacture of pigments, frits, glass and ceramic ware
244-166-4	Cobalt dihydroxide	
237-358-4	Cobalt molybdate	Catalyst, intermediate

EC No	Chemical name	Description
269-047-4	Cobalt titanite green spinel	Pigment
269-093-5	Olivine, cobalt silicate blue	
701-439-7	Reaction mass of cobalt olivine and crystalline silicon dioxide	
442-750-5	Cobalt lithium nickel oxide	Batteries
480-390-0	Cobalt lithium manganese nickel oxide	
700-042-6	Aluminium cobalt lithium nickel oxide	

Source: REACH Cobalt consortium, REACH registration dossiers for the substances (ECHA ECHA (2023a), and Study on the EU's list of Critical Raw Materials. Critical Raw Materials Factsheets (Latunussa et al., 2002).

2 BACKGROUND FOR ANALYSING THE HEALTH IMPACTS

This chapter comprises the following sections:

- Section 2.1: Summary of epidemiological and experimental data.
- Section 2.2: Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects).
- Section 2.3: Groups at extra risk
- Section 2.4: Summary of background for analysing health impacts

2.1 Summary of epidemiological and experimental data

2.1.1 Identity and classification

Identity

The identification and physico-chemical properties of cobalt are described in the following Table 2-1. For a detailed list physico-chemical properties of inorganic cobalt compounds please see Annex 1 in the report from RAC (ECHA, 2022).

Table 2-1 Identity and physico-chemical properties of cobalt

Endpoint	Value
CAS No.	7440-48-4
EC No.	231-158-0
Description	Solid, compact or particulate, metallic, odourless element
Molecular formula	Co
Physical state (at 20 °C and 1013 hPa)	solid
Density (g/cm³ at 20 °C)	8.86
Melting point (°C)	1495
Water solubility (mg/L at 20°C)	2.94

Source: (ECHA, 2022)

Classification

A harmonised classification according to Annex VI of the CLP Regulation is available for cobalt and seven inorganic cobalt compounds. The harmonised classification is summarised in Table 1-2 in section 1.3.5.

The use of several cobalt compounds is restricted in the European Union due to their classifications as carcinogen category 1A or B and reproductive toxicant category 1B. "*The substances should not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than either the relevant specific or generic concentration limit in Part 3 of Annex VI to Regulation (EC) No 1272/2008" (ECHA, 2022).*

2.1.2 General toxicity profile, critical endpoints and mode of action

2.1.2.1 Toxicokinetics (ECHA, 2022)

Absorption

Relevant exposure routes are oral and inhalation. Inhalation absorption is highly dependent on the particle size of cobalt. Particles >2 µm are likely to deposit in the upper respiratory tract. where they are either adsorbed via dissolution or swallowed. Smaller particles reach the lower respiratory tract, where they are dissolved and phagocytosed.

In a physiologically based pharmacokinetic (PBPK) model for the human respiratory tract a fast and complete absorption for cobalt chloride and cobalt nitrate was calculated (100% absorption in 100 minutes), for cobalt oxides, cobalt metal and cobalt alloys values between 70% and 100% in 10 minutes were calculated.

In general, oral absorption is higher for cobalt substances which are more water soluble. In an oral rat study with cobalt chloride, oral absorption between 13 – 34% of the administered dose was observed while for the physiologically insoluble cobalt oxide the absorption was between 1% and 3%.

Distribution

As a constituent of vitamin B12, cobalt is an essential metal and therefore can be found throughout the body. In animal experiments with inhalation exposure increased concentrations of cobalt were detected in lung, liver and kidney. Animal experiments with oral exposure to cobalt dichloride also showed increased concentrations of cobalt in heart, gastrointestinal tract, testes, epididymides, blood and brain.

It could be demonstrated that cobalt sulphate can cross the placenta barrier in rats; increased cobalt concentrations were measured in foetal blood and amniotic fluid.

Metabolism

Cobalt as a metal is not metabolised in the body.

Excretion

Excretion after inhalation exposure is highly dependent on the solubility of the cobalt substance. The more soluble a substance is, the more rapidly it is eliminated via the lungs by transfer to the blood and excretion via urine and faeces. Faecal excretion appears to correlate with mechanical clearance from the lungs and is therefore more important for insoluble compounds than for those with higher solubility. Excretion after oral exposure is mainly via faeces. In an oral study with rats exposed via gavage to a single dose of cobalt dichloride or tricobalt tetraoxide excretion was more or less complete after 72 h. More than 80% were excreted via faeces, urinary excretion was >12% for cobalt dichloride and about 0.1% for tricobalt tetraoxide.

2.1.3 Cancer endpoints – toxicological and epidemiological key studies (existing assessments)

IARC (International Agency for Research of Cancer) classified cobalt metal with tungsten carbide as ‘probably carcinogenic to humans’ (Group 2A) (IARC, 2006). In the same report cobalt metal without tungsten carbide, cobalt sulphate and other soluble cobalt(II) salts were considered as ‘possibly carcinogenic to humans (Group 2B)’.

In 2022 IARC re-assessed the carcinogenicity of cobalt metal (without tungsten carbide or other metal alloys), soluble cobalt(II) salts, cobalt(II) oxide, cobalt(II,III) oxide, cobalt(II) sulphide, and other cobalt(II) compounds. The results are published in IARC monograph 131 (IARC, 2023) and a paper by Karagas *et al.* (2022). In these publications it is outlined that cobalt metal and soluble cobalt(II) salts were reclassified as 'probably carcinogenic to humans' (Group 2A), cobalt(II) oxide was classified as 'possibly carcinogenic to humans' (Group 2B) and cobalt(II,III) oxide, cobalt(II) sulphide and other cobalt(II) compounds, were 'not classifiable as to their carcinogenicity to humans' (Group 3).

Cobalt and several inorganic cobalt compounds have a harmonised classification for carcinogenicity according to Annex VI of the CLP Regulation (Canc. 1A or B).

Numerous studies on carcinogenic effects of cobalt have been published. The epidemiological evidence can be considered as inconsistent. This is mainly due to confounding factors (smoking and co-exposure to other carcinogenic substances). Older studies from the hard-metal-production provide indications of lung cancer. In addition to the limitations already mentioned, the risk estimates in these studies were not calculated by mean exposure intensity or cumulative exposure to cobalt (e.g. Lasfargues *et al.*, 1994).

According to RAC (2022a) newer studies from the hard-metal industry could not show a clear relationship between cobalt exposure and mortality from lung cancer (e.g. Marsh *et al.*, 2017a, Marsh *et al.*, 2017b). It is worth mentioning that none of the available studies with hard-metal exposure allows a distinction between effects caused by cobalt and effects caused by cobalt-tungsten carbide.

Epidemiological studies with workers from the production of cobalt and from the use of cobalt compounds (non-hardmetals) did not show a consistent evidence of an increased cancer risk (e.g. Moulin *et al.* (1993), Mur *et al.* (1987), Sauni *et al.* (2017), Tüchsen *et al.* (1996)). Information on exposure levels is not provided for all studies and if it is available the exposure of workers was quite high.

Experimental evidence of carcinogenicity in rodents was found in two chronic inhalation NTP () studies with cobalt sulphate heptahydrate (soluble, NTP, 1998) and cobalt metal (non-soluble, NTP, 2014). In both studies a statistically significant dose-dependent increase of alveolar/bronchiolar adenomas and carcinomas (combined) in the lung was observed in both species. Overall, the NTP studies provide clear evidence of carcinogenicity in F344/NTac rats and B6C3F1/N mice of both sexes.

No tumour formation in the upper respiratory tract was observed in epidemiological studies and in animal studies after exposure to cobalt sulphate hexa/heptahydrate and cobalt metal. Premalignant lesions (hyperplasia, metaplasia and atrophy) in epithelial cells of the nose, and larynx suggest a potential for carcinogenicity. However, according to RAC the upper respiratory tract seems to be more than an order of magnitude less sensitive for the carcinogenic effects compared to the lower respiratory tract (ECHA, 2022).

In animal studies with rats pheochromocytomas and pancreatic cancers were observed after exposure to cobalt metal. RAC discusses that these tumour types at high doses have been linked to lung damage associated hypoxia and are therefore not relevant at dose levels not causing lung damage (ECHA, 2022).

2.1.4 Genotoxicity

According to RAC there is strong evidence supporting the role of oxidative stress, stabilisation of HIF-1α (hypoxia-inducible factor-1 alpha) and inflammation on genotoxicity and carcinogenicity after cobalt exposure (RAC, 2022). RAC has also discussed genotoxicity of cobalt in detail in the restriction proposal from 2020. In the last two years new publications have become available which grouped cobalt compounds according to their solubility in biological fluids and their ability to cause lung inflammation, oxidative stress and stabilisation of HIF-1α (e.g. Danzeisen *et al.*, 2022, Viegas *et al.*, 2022). Danzeisen *et al.* postulated key events for carcinogenicity of biosoluble cobalt compounds involving accumulation of cobalt in tissue, formation of ROS (Reactive oxygen species), hypoxia and cytotoxicity, inflammation, epithelial damage, and hyperplasia. Danzeisen *et al.* did not consider a mutagenic mode of action since "available evidence was considered to show that cobalt is not directly mutagenic" (RAC, 2022).

Nevertheless, RAC outlines that "the available data is not sufficient to exclude the possible role *of other (threshold or non-threshold) mechanisms in the carcinogenicity of cobalt, including mutagenicity, epigenetic changes, alterations in DNA repair and immunosuppression."*

2.1.5 Non-cancer endpoints – toxicological and epidemiological key studies (existing assessments)

RAC considers three occupational exposure settings in the context of the OEL derivation. These are:

a) production and use of cobalt and cobalt compounds,
b) production and use of hard-metal and
c) polishing of diamonds.

According to RAC exposure to cobalt is associated with diseases like obstructive lung disease /asthma, whereas exposure to cobalt-containing hard-metal is an established cause of parenchymal lung disease. It is assumed that workers in the hard-metal industry are co-exposed to tungsten carbide which might potentiate the effects of cobalt and result in a synergism. Parenchymal lung disease is also reported in workers from the diamond-polishing industry (RAC, 2022).

In the following sections the main non-cancer effects of inhalation cobalt exposure at workplaces covering the three exposure settings outlined above will briefly be summarised.

2.1.5.1 Parenchymal lung disease

Parenchymal lung disease is an umbrella term for a group of respiratory diseases affecting the interstitium of the lungs. Hard-metal lung disease (also called 'cobalt lung disease' or interstitial lung disease) is one of these 200 different diseases. According to RAC no cases of hard-metal lung disease have been documented in exposure settings other than those somehow related to hard-metal or diamond polishing (ECHA, 2022). RAC further elaborates that the exact role of cobalt and the mechanism of parenchymal lung disease after exposure to cobalt in combination with other components, such as tungsten carbide or diamond dust is not understood. The involvement of immunological effects in the pathogenesis has been discussed but remains unclear.

Only a small percentage of exposed workers is affected from hard-metal disease and the disease does not exhibit a linear dose-response relationship (Nemery, 1990, Nemery *et al.*, 2001).

According to RAC there is only a limited number of specifically designed epidemiological studies assessing the prevalence or incidence of interstitial lung disease in hard-metal workers, in contrast to numerous case reports or clinical surveys. In addition, the comparison of the results from these studies is complicated by the use of different criteria for detecting the disease (radiological and/or functional), by previous exposure to other agents causing pulmonary fibrosis (silica or coal dust), and in some cases by the absence of an unexposed control group. Nemery *et al.* (2001) state that individual susceptibility factors play a significant role in its pathogenesis of the disease. RAC concludes that parenchymal lung disease and fibrosis are unlikely to occur in the concentration range below 100 µg/m³. Based on all these findings, no DRR (Dose Response Relationship) solely covering this endpoint will be derived in section 2.2.

2.1.5.2 Decrease in lung function

Human data

Numerous studies from different industrial sectors describe decreased lung function in association with cobalt exposure. RAC considers the study by Nemery *et al.* (1992) with diamond polishing workers the most relevant one which is also used for the derivation of the OEL for the inhalable fraction of cobalt. Therefore, this study is described in detail in the following paragraph.

Nemery *et al.* (1992) performed a cross-sectional study with 195 diamond polishing workers from 10 workshops in Belgium. The workers were exposed to cobalt while using polishing disks made of microdiamonds cemented with cobalt. The corresponding control group consisted of 59 workers from three other diamond polishing workshops without cobalt exposure (0.4 ± 0.6 µg Co/m³, personal samples). Stationary and personal air samples were collected, and urinary cobalt concentrations were measured. The exposed workers were divided in two groups, depending on the cobalt concentrations in the workshops: High exposure group (15.1 ± 11.7 µg Co/m³, personal samples) and low exposure group (5.3 ± 3.2 µg Co/m³, personal samples). In spirometry measurements FCV (forced vital capacity), FEV_1 (forced expiratory volume in 1 second) and FEF_{25-75} (forced expiratory flow during exhalation of 25-75% of FVC) were measured. According to Nemery *et al.* (1992) mean FVC, FEV_1, and FEF_{25-75} values were at or above the values predicted from population reference values in all groups (values not provided in the publication, only shown in a figure with bar diagram). However, for all three parameters mean values were statistically significantly lower in the high exposure group (personal samples). The effects were not due to differences in smoking habits. It must be noted that in the study no control for potential confounding by overall dust concentration was performed and past exposure (to cobalt or anything else) was not assessed.

RAC has used this study for the derivation of the OEL of 1 µg Co/m³ for the inhalable fraction by dividing the concentration from the low exposure group (5.1 µg/m³ used by RAC instead of 05.3 µg/m³ as provided in the publication) with a factor of 5 for intraspecies differences.

In an internal comparison within saw filers exposed to cobalt-containing hard-metal dust reduction of FEV_1 correlated with the estimated cobalt exposure level and reduction of FVC with the duration of tungsten carbide exposure (Kennedy *et al.*, 1995). The study did not consider confounding by other workplace dust exposure. In 105 of the 278 air samples collected chromium with a mean concentration of 4 µg/m³ was detected which might have confounded the results.

Alexandersson (1979, only available in Swedish) reported impairment of ventilatory lung function (FEV_1, FVC, FEV% and MMF (maximum mid-expiratory flow)) at 60 µg/m³ from a cross-sectional study in hard-metal production workers. In the exposure group with 12,0000 µg

Co/m³ a tendency (not further described by RAC what this means) for impairment of FVC was observed, while in the exposure group with 8 µg/m³ reduced FEV_1 and MMF were seen. However, effects on lung function may have been caused by higher past exposures.

In the only available longitudinal study from the cobalt industry among workers from a cobalt production plant it was observed that cobalturia contributed significantly to the decline of FEV_1 over time but only in association with smoking (Verougstraete *et al.*, 2004). According to the authors a slight decline was observed in the best fit model for TWA-values of 10, 20 or 40 µg Co/m³.

Animal data

Inhalation studies were performed by NTP with cobalt sulphate and cobalt metal particles (NTP, 1991, 1998, 2014). In the chronic study with cobalt metal rats and mice were exposed to 0, 1.25, 2.5 and 5 µg Co/m³. In the chronic NTP study with cobalt sulphate hexahydrate 0, 300, 1,0000 and 3,000 µg/m³ were applied to rats and mice, corresponding to 0, 67, 2,230 and 6,700 µg Co/m³. No NOAECs (No observed adverse effect concentration) for respiratory tract effects could be identified in the chronic studies. The LOAEC (Lowest observed adverse effect concentration) for chronic pulmonary inflammation in rodents is 67 µg/m³. RAC used this LOAEC as the basis for the derivation of the OEL for the respirable cobalt fraction. After correction for the worker exposure situation (*6/8 h *6.7/10 m³) assessment factors of 5 for severity (LOAEC versus NOAEC), 2.5 for interspecies differences, and 5 for intraspecies differences were applied. The resulting OEL for the respirable cobalt fraction is 0.5 µg/m³.

2.1.5.3 Irritation of the respiratory tract

Several epidemiological studies have assessed the prevalence of respiratory tract symptoms.

In the epidemiological study by Nemery *et al.* (1992) which is described in more detail in section 2.1.5.2 above, statistically significant differences in the prevalence of respiratory symptoms were observed in the high exposure group (15.1 ± 11.7 µg Co/m³, personal samples) compared to the control group, for upper respiratory tract symptoms in general (nose, throat, eye, not further described), work-related upper respiratory tract symptoms, cough in general and work-related cough. This was not observed in the low exposure group (5.3 ± 3.2 µg Co/m³, personal samples). No significant differences to the control group were observed in both exposure groups for phlegm, dyspnea, and wheezing.

Kennedy *et al.* (1995) conducted a cross-sectional study with 118 saw filers in lumber mills in British Columbia. Exposure was via cobalt-containing hard-metal dust during maintenance tasks. Average cobalt concentration is reported with 5 µg/m³, co-exposure to chromium (the exact chromium type was not analysed) was observed in 108 of 278 air samples and was not corrected for in the analysis. Compared to the non-exposed control group the saw filers showed statistically significant ($p< 0.001$) more respiratory symptoms like phlegm, cough and wheezing. No significant difference was found for breathlessness or nasal symptoms.

In cross-sectional studies by (Alexandersson, 1979, publications only available in Swedish) from four Swedish hard-metal production plants, increased prevalence of respiratory tract irritation was observed starting at exposure concentrations of 2 and 3 µg/m³. Irritation of eyes, nose or throat were reported, but also cough and phlegm. In higher exposure groups (5-10, 8, 12 and 60 g/m³) irritation effects were also present, but no dose response could be observed.

2.1.5.4 Respiratory Sensitisation

Cobalt, cobalt dichloride, cobalt sulphate and other cobalt compounds are known to cause occupational asthma and have a harmonised classification for respiratory sensitisation.

There are indications that the mechanism is mostly non-immunological, however, in some cases type I allergic reactions were suspected (ECHA, 2022).

Overall, RAC concluded that based on the currently available data no NOAEC or dose-response relation for asthma can be set and that cobalt-induced asthma is uncommon in workers nowadays (ECHA, 2022). In the context of the RAC opinion on the restriction proposal of soluble cobalt salts, stakeholders provided information that under the current exposure conditions cobalt-induced occupational asthma is rare (0 to 1 asthma cases per year based on information from three Member States) (RAC/SEAC, 2020, 2022a).

Swennen *et al.* (1993) performed a cross-sectional study in 82 exposed workers and matched controls of a cobalt production plant in Belgium. The geometric mean of the current 8 h TWA was about 125 µg/m³ with 25% of the values being above 500 µg/m³ (personal samples). Swennen *et al.* reported respiratory effects linked to asthma (wheezing, dyspnoea), asthma prevalence per se was not analysed.

In a cross-sectional study by Linna *et al.* (2003) based on a Finnish cohort of workers in cobalt salt manufacturing an increased incidence of occupational asthma was observed. The average exposure concentration for cobalt was 45 µg/m³. Co-exposure to nickel, H2S, SO2, NH3 and total dust was also given in the factory but did not influence the increasing risk of asthma as shown with multivariate analyses.

The most detailed and extensive study investigating occupational asthma after cobalt exposure is from Sauni *et al.* (2010) and investigated workers from the same plant in Finland as the study from Linna *et al.* In this study, asthma was described at an average exposure of 30 µg/m³ (P50) (5 of 55 workers in leaching and solution purification, range between 1967 and 1987). Workers were co-exposed to irritant gases (NH3, H2S, exposure well below the respective OELs). Higher exposure to cobalt resulted in increased incidences of asthma. Based on 22 asthma cases in the plant, Sauni *et al.*, concluded that exposure to cobalt sulphates resulted in an asthma incidence density of 0.005 new asthma cases per person-years.

According to RAC 'a more extensive literature search indicates that large epidemiological studies on cobalt asthma are lacking, and the knowledge is largely based on case reports or small series often with limited analysis of risk by level of exposure' (ECHA, 2022).

Based on the available literature the lowest LOAEC overserved for asthma was around 30 µg/m³ (Sauni *et al.*, 2010) and a derivation of a DRR is not possible for this endpoint.

2.1.5.5 Reproductive toxicity

Fertility effects

Cobalt metal and several cobalt compounds have a harmonised classification as Repr. 1B (H360F) or are notified by the registrants as Repr. 1B (H360) or Repr. 1A (H360) as significant effects on the male reproductive system can be observed.

No epidemiological studies investigating this endpoint are available. In a subchronic (90-day) study by NTP, animals were exposed to 0, 300, 1,000, 3,000, 10,000, and 30,000 µg/m³ cobalt sulphate heptahydrate (0, 67, 223, 670, 2,230, 6,700 µg Co/m³) for 6 h/d. Sperm morphology and vaginal cytology evaluations were performed only for animals exposed to 0, 3,000, 10,000, or 30,000 µg/m³ (0, 670, 2,230, 6,700 µg Co/m³). Significant effects in male animals were seen on right epididymal weight, sperm motility and on number of abnormal sperm. In females cycle length was increased (detailed results for both sexes are reported in Table 2-8 below).

Several other animal studies showed effects on male fertility in rodents. However, the LOAEC of 670 µg Co/m³ for reduced sperm motility identified in the 90-day inhalation study from NTP is the lowest LOAEC identified. Therefore, RAC based the calculation of a DNEL (Derived no-effect level) for fertility on this study.

Developmental toxicity

No relevant epidemiological studies on developmental toxicity after cobalt exposure are available. Several animal studies in rats, mice and rabbits investigating the endpoint developmental toxicity were identified by RAC. The studies have different designs and exposure durations (e.g. exposure only during organogenesis or until the end of lactation), but animals were always exposed orally. In the Annex to the RAC opinion a summary of all studies that were considered is provided (see table 30 in ECHA, 2022). RAC points out that all studies have deficiencies and limitations. At high exposure reduced foetal weight, growth and skeletal retardation, resorptions, and pup mortality were observed. LOAELs of 5,400 µg Co/kg bw/d and NOAELs (No observed adverse effect levels) as high as 24,800 µg/kg bw/d are reported (RAC, 2022).

RAC concluded that the DNELs for developmental toxicity would be higher than the DNEL for fertility. Details on this are described in section 2.2.3.

2.1.5.6 Cardiovascular effects, thyroid effects, nervous/sensory effects and haematological effects

RAC outlines that "*after oral exposure, cobalt salts have caused cardiac effects. However, evidence on such effects in workers is limited*". The Nordic Expert Group agrees with this conclusion and states in their assessment on occupational chemical exposures and cardiovascular disease: "*There is insufficient evidence for an association between exposure to cobalt and CVD* [cardiovascular disease]" (Midtgard *et al.*, 1994). Therefore, this endpoint is not further investigated in the current report.

Thyroid-related, haematological and nervous/sensory effects after cobalt exposure are mainly observed in the non-occupational setting after oral exposure or exposure from hip implants (ECHA, 2022). A few studies investigated effects in occupational settings. However, the data are very limited, and effects were in most cases observed at very high exposure. These endpoints are not further evaluated in this report.

2.1.6 Biological monitoring – toxicological and epidemiological key studies (existing assessments)

The determination of cobalt in blood or urine can be used as indicator for internal exposure. Normally determination in urine is preferred since it is non-invasive and the concentration in urine corresponds better to external cobalt exposure. In addition, cobalt concentrations in urine are about 10-times higher than those in blood (ECHA, 2022).

Several analytical methods for the determination of cobalt in urine are available. With these methods LOQs (Limit of Quantification) of 0.06 µg Co/L blood (inductively coupled plasma / mass spectroscopy) can be reached (ECHA, 2022).

RAC did not propose a BLV for cobalt and inorganic cobalt compounds in the recent opinion (RAC, 2022).

2.1.7 Group approach for cobalt compounds

Cobalt is a metal and can be found in organic and inorganic forms. The current document as well as the RAC opinion and corresponding Annex (ECHA, 2022, b) deal with inorganic cobalt forms for which data are available and for which use at higher tonnages is known.

Since the toxic moiety of cobalt and inorganic cobalt compounds is the Co^{2+} ion, the group approach followed by RAC is justified and also followed in the current document.

2.2 Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)

2.2.1 Starting point

The starting point of the following quantitative considerations is the recent evaluation performed by RAC (ECHA, 2022, b).

RAC proposed an 8 h-TWA OEL of 0.5 µg/m³ for the respirable cobalt fraction and a value of 1 µg/m³ for the inhalable fraction. Further, RAC proposed BGVs of 2 µg Co/L urine (females) and 0.7 µg Co/L urine (males) "*unless there is specific national data supporting the use of other values*" (RAC, 2022). RAC does not propose a BLV since exposure via air at levels corresponding to the proposed OELs might result in urinary levels which are very close to the 95th percentiles of the general population. The Committee did not establish a STEL value since the critical effects caused by cobalt exposure are related to long-term exposure.

A notation for skin sensitisation and respiratory sensitisation is recommended. RAC recommends the OEL should be applied to all inorganic cobalt compounds and also for the hard-metal exposure scenario.

RAC justifies the selection of the study by Nemery *et al.* (1992) as the basis for the OEL for the inhalable fraction with the following arguments (quoting from RAC (RAC, 2022)):

- 'The study provides a dose-effect relationship between ventilatory function indices *and cobalt exposure.*
- Cobalt exposure was reliably measured by personal, static, and biomonitoring *measurements, correlating very well with each other.*
- Based on measurements very close to the discs (1 cm), only traces and no other *relevant exposures were apparent.*
- Workers were not exposed to hard-metal and tungsten carbide.
- A dust-related decrease in lung function can be excluded as well for two reasons. First of all, dust exposure was very low and not higher than in control workshops as reported by the authors. In addition, workers were very young (20-30 years of age) and general dust-related decreases in lung function appear usually only after longer term (tens of years) exposure. The workplaces (with exception) were described as rather clean, and the authors acknowledge a type of 'healthy workshop' effect. The workshops of this survey therefore

were characterised by apparently good hygiene practice, and this allowed the detection and attribution of lung function effects to low cobalt exposure as the plausible cause.

- RAC further stresses that according to the authors no clinically manifest cases of hard-metal disease/cobalt-lung were discovered in this survey. According to the author, the selection of the workshops *was not based on previous lung disease cases in these workplaces.'*

RAC also mentions that the LOAEC from the Nemery study (15,100 µg/m³, based on lung function parameters) is rather close to the LOAEC from the study by Sauni *et al.* (2010). In this study a LOAEC of 30,000 µg/m³ for clinically relevant asthma was established.

RAC considers carcinogenicity in animal studies and non-cancer related respiratory effects in exposed workers as the critical toxicological endpoints after cobalt exposure. For carcinogenicity they did not identify a threshold. However, RAC believes that a 'break point' for the carcinogenic effects can be established at 0.5 µg/m³.

RAC also believes that below the break point of 0.5 µg/m³ chronic lung inflammation is unlikely to occur and the risk of secondary genotoxicity and oxidative stress are significantly reduced. The Committee further outlines "*…although RAC agrees that there is data to support the plausibility of a ROS* [reactive oxygen species]*, hypoxia and inflammation-based MoA, the available data is not sufficient to exclude the possible role of other (threshold or non-threshold) mechanisms in the carcinogenicity of cobalt, including mutagenicity, epigenetic changes, alterations in DNA repair and immunosuppression.*"

In a pragmatic approach the threshold for lung inflammation (observed in chronic animal studies) is the basis for the proposed OEL (0.5 µg/m³, for the respirable cobalt fraction). "*RAC considers that when the OEL is derived from inflammatory lung effects, the risk of cancer is substantially reduced at exposure levels below the level of the recommended OEL.*" (RAC, 2022).

For the inhalable cobalt fraction an OEL of 1 µg/m³ was derived based on evidence of reduced lung parameters and respiratory symptoms in chronically exposed workers (RAC, 2022).

2.2.2 ERR (Exposure Risk Relationship) for carcinogenic effects

2.2.2.1 Approach

In the more recent past the German AGS (Ausschuss für Gefahrstoffe) and RAC (in the context of the restriction proposal) have derived exposure-risk relationships for workers exposure to cobalt by the inhalation route. For both evaluation the animal the in vivo inhalation carcinogenicity study data on cobalt sulphate in rats was used (NTP, 1998) for the ERR derivation and both ERRs are 'kink-functions' with a break point.

Some details on both ERRs are presented in the following:

Ausschuss für Gefahrstoffe, Germany (AGS, 2023)
The chronic NTP data on inhalation exposure of rats to cobalt sulphate was used as the basis. AGS identified a break point (inflammation and hyperplasia/metaplasia in the lung) in the dose-response at a (worker´s) concentration of 2.2 µg Co/m³.

Based on the animal data a $hBMD_{10}$ (workers) of 51 µg Co/m³ was calculated and used as PoD (Point of departure) for the ERR derivation. Overall, the following risks were calculated:

- 4 µg Co/m³ corresponding to an excess cancer risk of 4 per 1000 (tolerance risk level)
- 2 µg Co/m³ corresponding to an excess cancer risk of 4 per 10 000 (acceptable risk level I)
- 0.2 µg/m³ corresponding to an excess cancer risk of 4 per 100 000 (acceptable risk level II).

RAC/SEAC Opinion on Restriction Proposal for five cobalt salts (RAC/SEAC, 2020)
Again, the chronic inhalation study by NTP with rats and mice exposed to cobalt sulphate was the basis for the ERR derivation. The (worker´s) concentration identified by RAC as the break point is 0.5 µg Co/m³ (difference to AGS assessment is based on different assessment factors, the LOAECs are identical). The ERR derived by RAC is applicable for the respirable fraction. Under the assumption that the respirable fraction is expected to represent ≤50% of inhalable dust, a limit value of 1 µg/m³ was calculated for the inhalable fraction. The PoD for the ERR is a $hBMDL_{10}$ (workers) of 95 µg/m³.

In order to use the same formulae as RAC, in the following the concentration is indicated in the unit mg Co/m³ (1 mg Co/m³ = 1000 µg/m³).

According to RAC (2020) the risk above the break point can be calculated using the formula:

1.0576 x exposure concentration (as mg Co/m³, respirable fraction) - 0.0004763

The risk below the break point follows the formula:

0.105 x exposure concentration (as mg Co/m³).

RAC opinion on scientific evaluation of occupational exposure limits (ECHA, 2022, b)
For RAC´s current assessment which is considered in the present document (ECHA, 2022, b), RAC generally follows their assessment from the 2020 restriction proposal (RAC/SEAC, 2020) and confirms that the identification of a break point for lung cancer as an estimated threshold level for chronic lung inflammation is still a relevant and appropriate approach for the cancer risk assessment.

The following Equation 2-1 and Equation 2-2 are provided in the RAC opinion for the calculation of lung cancer risks in workers above and below the break point (assuming continuous exposure over a work life, i.e. 40 years, 8 h/d, 5 d/week), in Figure 2-1 the ERR is shown graphically:

Equation 2-1 ERR for cobalt (lung cancer, derived for respirable fraction) above break point of 0.5 µg/m³

$$Excess\ \mathrm{Cancer}\ Risk\ (fraction) = 1.06 * c_{Cobalt(respirable\ fraction)}$$

ERR above the break point, with c > 0.5 µg/m³ (respirable fraction), C_{cobalt} in the equation in mg/m³.

Equation 2-2 ERR for cobalt (lung cancer, derived for respirable fraction) below break point of 0.5 µg/m³

$$Excess\ \mathrm{Cancer}\ Risk\ (fraction) = 0.105 * c_{Cobalt(respirable\ fraction)}$$

ERR below the break point, with c ≤ 0.5 µg/m³ (respirable fraction), c_{cobalt} in the equation in mg/m³.

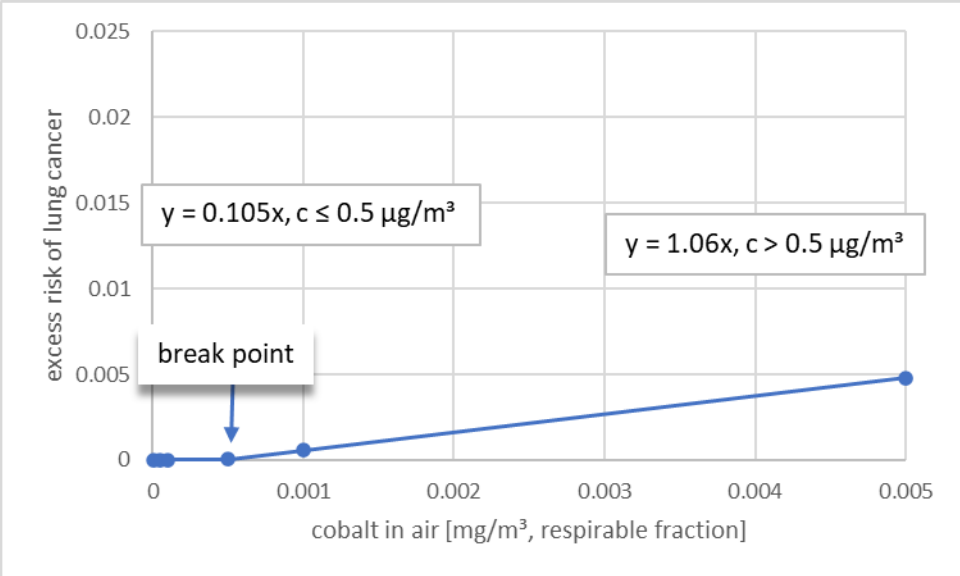

Figure 2-1 *ERR for the lung cancer after cobalt exposure (applicable for the respirable cobalt fraction)*

2.2.2.2 Discussion

The ERR is derived based on effects observed in chronic animal studies. Epidemiological data did either not clearly show an increased cancer risk in workers or the studies have limitations (i.e. no adjustment for confounding factors, exposure to other carcinogens, no quantitative exposure analysis). RAC states (based on the Marsh study (2017a, b)) that in a rough comparison of absolute life-time lung cancer risks in the general population and the absolute lifetime predicted risks based on animal data (assuming 40 years workplace exposure and cohort follow-up for a lifetime) on overestimate of the animal ERR can be suggested. However, RAC also outlines that this comparison cannot easily be done due to several reasons (for example 'the animal dose response assumes 40 years of exposure, while in the hard-metal follow-up cohort much shorter exposures (overall one third 1-4 years, one third 5-19 years, one third at least 20 years) were reported' For more details please see ECHA 2022b).

Overall, RAC concludes that "*the human data are considered overall to be too limited to draw conclusions regarding the carcinogenicity of cobalt and inorganic compounds. Furthermore, there is no indication that humans are more sensitive compared to animals and overall, the animal and human data are not in contradiction.*" RAC also stresses that "*these human epidemiological data do not allow either identifying a carcinogenicity threshold to be identified for cobalt exposure, or quantitative modification of the dose-response derived from the animal data at levels of exposure experienced by the hard-metal workers followed.*" (ECHA 2022b)

Tumours at other locations than the lung are discussed, the evidence however is limited. Regarding the upper respiratory tract neither epidemiological nor animal studies have shown any evidence of carcinogenicity. Nevertheless, animal data show that pre-malignant lesions in the nose or larynx can be found that might suggest a potential for carcinogenicity. RAC states that the upper respiratory tract is at least one order of magnitude less sensitive for carcinogenic effects compared to the lung.

2.2.3 DRR for non-carcinogenic effects

Cobalt exposure causes adverse effects on several systems. DRRs were derived for the following endpoints:

- Lower respiratory tract toxicity: Decrease in lung function
- Upper airway irritation
- Male fertiliy (DRR not applicable in the concentration range considered in the policy options)

The DRRs for each of these endpoints will be discussed in the following subsections.

As outlined in section 2.1.5.4 on respiratory sensitisation numerous cobalt compounds are known to cause occupational asthma (which is reflected in the harmoinised classification for respiratory sensitisation). RAC could not set a NOAEC for asthma and the available data do not allow the derivation of a DRR for this endpoint.

Under the current exposure situation at workplaces, asthma seems to be rare. However, the DRRs established in the following section of the report are used to calculate costs at different policy option, meaning at different exposure concentrations above the OEL proposed by RAC. These options might include scenarios that are above the current workplace situation.

RAC has outlined that the available studies on developmental toxicity after cobalt exposure all have deficiencies and limitations. Nevertheless, several effects e.g. reduced fetal weight or pup mortality were observed in animal studies. RAC concludes that 'DNELs for developmental toxicity would be higher than the DNEL calculated for fertility' (RAC, 2022). For the current assessment all studies listed in table 30 in the Annex to the RAC opinion (ECHA, 2022) were evaluated and DNELs for developmental toxicity were calculated (by applying route to route extraplation, correction for human exposure and assessment factors as described in the ECHA guidance R.8 (ECHA, 2012)). All calculated DNELs (development) were way above the highest policy option (calculated DNELs not reported here). Therefore, no DRR for this endpoint was derived.

2.2.3.1 Decrease in lung function

Approach

Decrease in lung function is described in numerous epidemiological studies. RAC used the epidemiological study by Nemery *et al.* (1992) with diamond polishing workers as basis for the derivation of the OEL for the inhalable cobalt fraction.

This study can also be used for the derivation of a DRR for the endpoint 'decrease in lung function'. In the following Table 2-2 the results from the spirometrical analysis are summarised.

Cobalt concentrations are given as inhalable cobalt in air.

Table 2-2 Lung function indices reported in the study by Nemery et al. (1992)

	Control group N = 59, 0.4 µg Co/m³	**Low exposure group N = 102 5.3 µg Co/m³**	**High exposure group N = 92 15.1 µg Co/m³**
Men/women	46/13	93/9	73/19

	Control group N = 59, 0.4 µg Co/m³	Low exposure group N = 102 5.3 µg Co/m³	High exposure group N = 92 15.1 µg Co/m³
FVC# (mL), men	5,648 ± 936	5,445 ± 754	5,184 ± 799*
FVC# (mL), women	4,033 ± 688	4,018 ± 627	3,733 ± 592*
FEV_1# (mL), men	4,644 ± 803	4,451 ± 679	4,191 ± 712$
FEV_1# (mL), women	3,416 ± 634	3,468 ± 684	3,123 ± 599$
FEV_1/FVC (%), men	82.3 ± 5.7	81.9 ± 6.5	80.9 ± 6.5
FEV_1/FVC (%), women	84.7 ± 5.3	86.0 ± 7.3	83.6 ± 8.6
FEF_{25-75}# (mL/s), men	4,721 ± 1,394	4,565 ± 1,296	4,086 ± 1,242*
FEF_{25-75}# (mL/s), women	3,818 ± 962	3,902 ± 1,269	3,449 ± 1,942*
Mean PEF# (L/min), men	-	611 ± 65	582 ± 76$
Mean PEF# (L/min), women	-	475 ± 56	445 ± 65$

Source: Nemery et al. (1992)
*#FVC: forced vital capacity, FEV_1: forced expiratory volume in 1 second, FEF_{25-75}: forced expiratory flow during exhalation of 25-75% of FVC, PEF: peak expiratory flow. * $p<0.05$ for difference between low and high exposure group by two-way analysis of variance, adjusting for sex. $ $p<0.01$ for difference between low and high exposure group by two-way analysis of variance, adjusting for sex*

Parameters measured in spirometric examinations are highly variable and depend on gender, age, sex, height and ethnicity. Therefore, a comparison of the values measured is only possible if the lung function parameters are expressed as 'percent of the predicted'. This means that the values have to be compared to values of a reference population matching in the relevant parameters (male/female etc.). The Global Lung Function Initiative (GLI) has collected numerous respiratory function data from around the world and created a calculator which enables a comparison of measured lung function values (like FVC) with values from the matching reference population. The result is provided as 'percent of the predicted' value[9].

Using information provided in the publication by Nemery *et al.* (1992) on sex, mean height and age and assuming a Caucasian ethnicity (study performed in Belgium) the calculator provided the data presented in Table 2-3. In the Nemery study only 41 women (divided in three exposure groups consisting of 13, 9 and 19 women respectively) but 212 men (46 + 93 + 73) were included. Therefore, the derivation of a DRR was based on the data obtained from men. As can be seen in Table 2-3 the percent predicted for FEV_1 are varying around 100%. However, compared to the control group, FEV_1 (and also FVC, data not shown here) are reduced in the high exposure group.

RAC outlines that the effects on lung function at the LOAEC of 15 µg Co/m³ were mild and "*with an unknown clinical relevance*".

For the current report the effects observed in the Nemery study were assigned to chronic conditions that can be summarised as 'restrictive lung diseases'. These diseases are characterised by reduced expansion of the lungs followed by reduced lung volumes. According to the literature, restrictive lung diseases are characterised by a reduction of both, forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) while the ratio of these two parameters (FEV_1/FVC) remains constant above 80%. In obstructive lung diseases FEV_1 is significantly reduced while FVC is also reduced, but not by the same ratio as FEV_1, the FEV_1/FVC ratio is less

[9] http://gli-calculator.ersnet.org/index.html

than 70% (Lee *et al.*, 2015). Based on this description, mild restrictive lung diseases are used as the clinical outcome of the observed effects in the Nemery study.

For the parameters 'reduction in FEV_1 and FVC', DRRs for excess risk of restrictive lung disease were derived but only the more conservative one (DRR based on reduced FEV_1) was selected (DRR based on reduction of FVC not shown here).

Restrictive lung diseases encompass an entire category of extrapulmonary, pleural, or parenchymal respiratory diseases. These diseases are characterized by restriction of lung expansion, resulting in decreased lung volume, increased work of breathing, and inadequate ventilation and/or oxygenation (Caronia *et al.*, 2020). Restrictive lung diseases can be divided into two groups depending on the place of action: intrinsic lung diseases (diseases of the lung parenchyma like interstitial lung diseases and pneumonitis) and extrinsic diseases (extrapulmonary diseases involving for example the respiratory muscles). Cobalt exposure causes intrinsic lung diseases (Caronia *et al.*, 2020).

Table 2-3 Values for FEV_1 based on the study of Nemery et al. (1992), given in percent predicted and calculated with the global Lung Function Initiative calculator (detailed information in text above)

	Control group 0.4 µg Co/m³	**Low exposure group 5.3 µg Co/m³**	**High exposure group 15.1 µg Co/m³**
FEV_1 (% predicted)	102.713	102.779	99.283
LLN for FEV_1 (mL) (Lower limit of normal, corresponding to the 5th percentile based on reference population)	3,624	3,447	3,358

Source: Nemery et al. (1992)

According to a document published by several German societies 'Leitlinien zur Spirometrie' (Criée *et al.*, 2015), the 5th percentile of the normally distributed values in a reference population (lower limit of normal, LLN) are considered as a pathological threshold. The LLN is dependent on sex, age, height and ethnicity. For the exposure groups in the Nemery study LLNs were calculated in the Lung Function Initiative calculator (shown in Table 2-3 above).

From the data reported in Table 2-2 and Table 2-3 no direct information on the fraction of affected human individuals can be derived. Therefore, a transformation has to be performed, which allows to estimate the affected fraction (percent of individuals of total exposed).

The criterion '5th percentile of a corresponding reference population' can be applied to the data reported by Nemery *et al.* (1992). The parameter FEV_1 is normally distributed in the population. By using the equation for a normal distribution in Excel and mean and standard deviation as given for each exposure group, the percentage of affected individuals (FEV_1 below 5th percentile) was calculated. In the following Table 2-4 the data as given in the Nemery study (first three columns) and affected individuals with FEV_1 below the 5th percentile of their corresponding reference population are provided as calculated in Excel.

Table 2-4 Mean values for FEV_1 (in mL) in Nemery et al. (1992) and calculation of affected individuals above the control. Assuming a normal distribution, the cut-off criteria is set as the 5th percentile of a corresponding population.

Concentration Co (µg/m³)	FEV_1 (mL)	Standard deviation (mL)	Affected individuals (%)	Affected individuals above control (%)
0.4	4,644	803	10.20	0
5.3	4,451	679	6.96	0
15.1	4,191	712	12.10	5.14

Source: Study team based on Nemery et al. (1992)

Normally, RAC´s OEL for the inhalable cobalt fraction (1 µg/m³) would be used as the starting point for the DRR with zero risk at this concentration. However, as can be seen in Table 2-4, the number of affected individuals above the control is zero in the low exposure group (considering the 5th percentile of the individuals in this exposure group). In this case the starting point of the DRR is not the OEL but the concentration 5.3 µg/m³.

Please note that the DRRs are expressed in µg Co/m³, whereas the ERR indicated above, in order to use same equation as RAC, is expressed in mg Co/m³.

OELThe DRR for decrease in lung function is created from the points in the following table.

Table 2-5 DRR for endpoint decrease in lung function, derived from Nemery et al. (1992)

	Co Concentration (inhalable fraction) (µg/m³)	Affected individuals above control group (%)
Starting point	5.3	0.00
High exposure group in Nemery study	15.1	5.14

Source: Study team based on Nemery et al. (1992)

The ‘affected individuals above control group’ (considered as individuals who suffer from restrictive lung diseases) were plotted against the cobalt concentration in air and the result is presented in Figure 2-2.

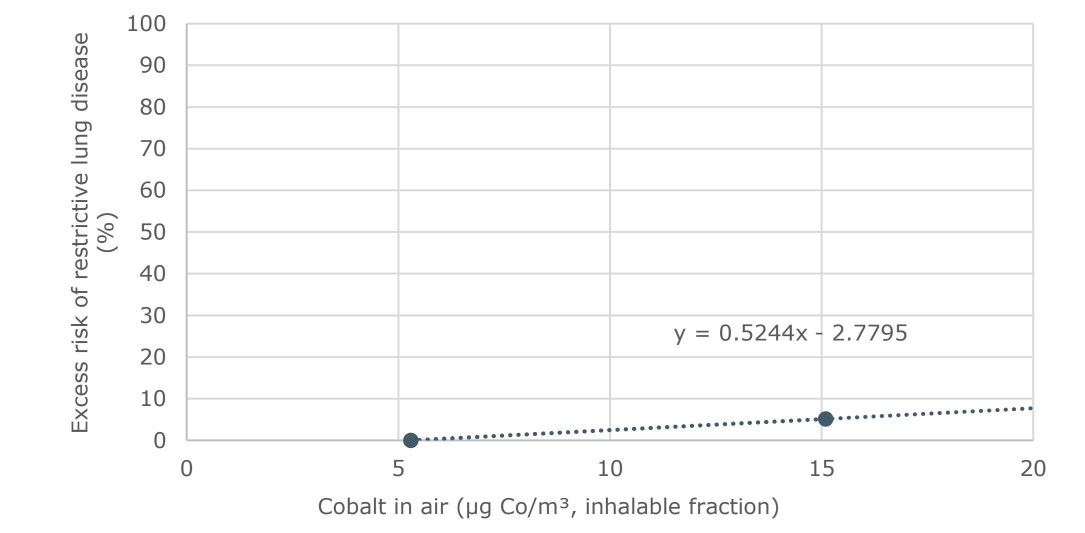

Figure 2-2 *DRR for the endpoint decrease in lung function after cobalt exposure (inhalable cobalt fraction).*

The dose response relation for the excess risk of restrictive lung disease can therefore be described with the following equation:

Equation 2-3 *DRR for cobalt (endpoint decrease in lung function, derived for inhalable fraction)*

$$Excess\ Risk(restrictive\ lung\ disease)(\text{percentage}) = 0.5244 * \left(c_{Cobalt(inhalable\ fraction)}\right) - 2.7795$$

With c valid from ≥ 5.3 µg/m³ to 20 µg/m³ (inhalable fraction). For concentrations above 20 µg/m³ the data does not allow to estimate if the DRR should be higher or lower. In the absence of better data, the DRR is also applied for concentrations above 20 µg/m³ which primarily is relevant for calculations of current burden of disease from past exposure at higher concentrations.

At the highest policy option (20 µg Co/m³, inhalable fraction) an excess risk of 7.71% for restrictive lung diseases can be calculated.

In the study by Nemery no information on the exposure duration of the workers is provided, however chronic exposure (> 1 year can be expected). In the absence of information a MaxEx (Maximum Exposure Time) of 1 year is assumed.

Discussion

General limitations of the study by Nemery *et al.* (1992) are reported in section 2.1.5.2. The DRR for restrictive lung diseases is based on reduction of FEV_1 in the high exposure group. A reduction of FVC was also observed in the study. Since both parameters can be seen as an indicator for restrictive lung diseases, DRRs were calculated based on both parameters. The DRR based on FVC reduction is not shown here since it resulted in a slightly less conservative DRR compared to the DRR based on FEV_1 reduction. For an inhalable cobalt fraction of 20 µg/m³ (highest policy option) the DRR as described above based on FEV_1 results in an excess risk for restrictive lung disease of 7.71%. When using the DRR based on FVC, the excess risk would be 5.71%. Both values are in the same range and do not contradict each other.

A major limitation of the Nemery study and also of the current evaluation is the low number of female workers that were included. This may just be an effect of the real workplace situation, but limits the validity of the derived DRR, since it is based only on data for male workers as lung parameters cannot be averaged over the sexes.

2.2.3.2 Upper airway irritation

Approach

Based on the study by Nemery *et al.* (1992) describing respiratory tract symptoms in diamond polishing workers exposed to cobalt, DRRs for the endpoint 'upper airway irritation' and 'cough' could be derived.

Nemery *et al.* (1992) observed statistically significant differences in the prevalence of respiratory symptoms (upper airway irritation in nose, throat, eye and cough, not further described, no severity given) in the high exposure group (15.1 ± 11.7 µg Co/m³, personal samples) compared to the control group. No significant differences to the control group were observed in the low exposure group (5.3 ± 3.2 µg Co/m³, personal samples). The data on symptom prevalence are summarised in the following Table 2-6. Cobalt concentrations are given as inhalable cobalt in air.

Table 2-6 Prevalence of (work-related) self-reported symptoms as documented in the study by Nemery et al. (1992). Values in parentheses are percentages.

	Control group N = 23, 0.4 µg Co/m³	Low exposure group N = 102 5.3 µg Co/m³	High exposure group N = 91 15.1 µg Co/m³
Upper airway irritation (nose, throat, eye)	14 (61)	52 (51)	68 (74)[#]
Work-related upper airway irritation (nose, throat, eye)	7 (30)	27 (26)	40 (43)[#]
Cough	2 (9)	15 (15)	31 (34)[#]
Work-related cough	0 (0)	4 (4)	11 (12)[#]
Phlegm	3 (13)	23 (23)	25 (27)
Work-related phlegm	0 (0)	7 (7)	8 (9)
Dyspnea	0 (0)	6 (6)	10 (11)
Work-related dyspnea	0 (0)	1 (1)	5 (5)
Wheezing	3 (13)	12 (12)	11 (12)
Work-related wheezing	3 (13)	5 (5)	4 (4)

Source: Nemery et al. (1992)

[#] *Prevalence significantly different (p<0.05) by chi-square analysis*

A dry cough is a common symptom of intrinsic lung diseases (see section 2.2.3.1, Caronia *et al.*, 2020). Besides, cough can be a secondary symptom to irritation in the respiratory tract (called 'upper airway cough syndrome[10]'). Therefore, only a DRR for work-related upper airway irritation was derived.

Based on the reported percentages of affected workers excess risks above the background as reported in Table 2-7 were calculated.

[10] https://bestpractice.bmj.com/topics/en-us/1209

Table 2-7 Excess risks above the background for work-related upper-airway irritation based on the study by Nemery et al. (1992). In the last row RAC´s proposed OEL for inhalable cobalt is added

Effect	Cobalt exposure concentration (inhalable fraction in µg/m³)	workers affected (%)	Excess risk above background (%)
Work-related upper airway irritation	0.4	30	0
	5.3	26	0
	15.1	43	13
*RACs proposed OEL for inhalable cobalt fraction**	1	-	0

Source: Study team based on Nemery et al. (1992)
**Value for the RAC´s proposed OEL not taken from the study by Nemery et al. (1992), but included in this table*

In the following Figure 2-3, the DRRs for work-related upper airway irritation is presented. An intraspecies factor of 2.5 was applied to the low exposure concentration (5.3 µg/m³) and the resulting value (2.12 µg/m³) was used as the exposure concentration associated with an excess risk of zero (starting point of the DRR, 2.12 µg/m³ can be considered a DNEL-analogue value for upper airway irritation). The factor was applied to depict the potential intraspecies differences between workers[11].

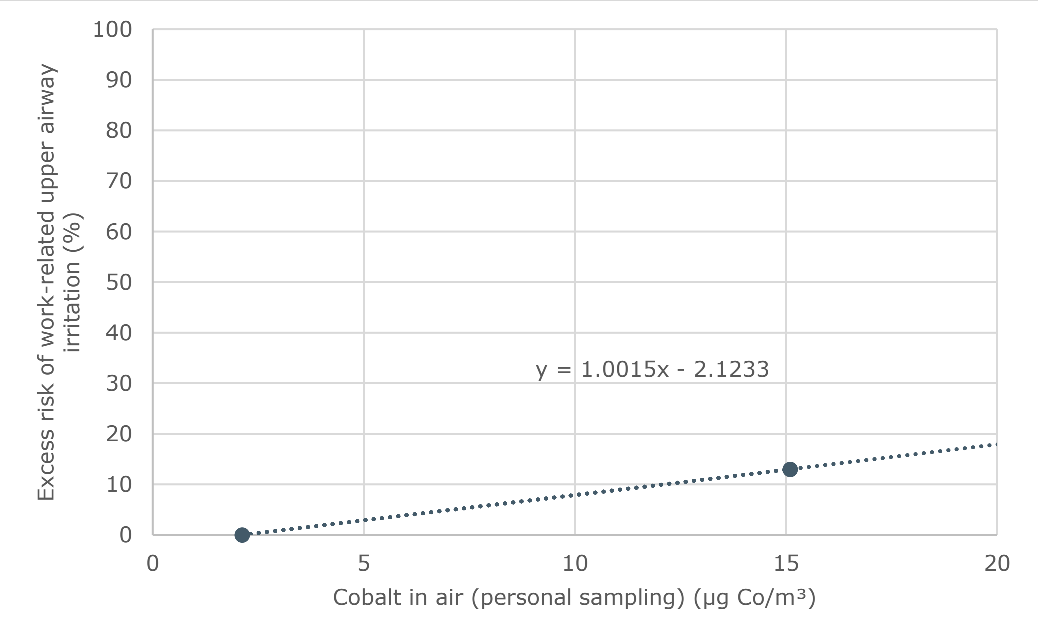

Figure 2-3: DRR for the endpoint work-related upper airway irritation after cobalt exposure (inhalable cobalt fraction). The dotted line is the trendline as calculated in Excel.

With the DRR equation for upper airway irritation an excess risk of 17.9% is calculated at 20 µg/m³.

[11] This is necessary as sensitive individuals cannot be considered by calculating lower percentiles of the distribution – due to the way the data are presented; a factor of 2.5 is considered sufficient as the cohort comprised 102 individuals.

The dose response relation for airway irritation can therefore be described with the following two equation:

Equation 2-4 DRR for cobalt (endpoint upper airway irritation, derived for inhalable fraction)

$$Excess\ Risk(upper\ airway\ irritation)(\text{percentage}) = 1.0015 * \left(c_{Cobalt(Inhalable\ fraction)}\right) - 2.1233$$

With c valid from 2.12 µg/m³ to 20 µg/m³ (inhalable fraction). For concentrations above 20 µg/m³ the data does not allow to estimate if the DRR should be higher or lower. In the absence of better data, the DRR is also applied for concentrations above 20 µg/m³ which primarily is relevant for calculations of current burden of disease from past exposure at higher concentrations.

Nemery *et al.* (1992) do not mention the exposure duration of the examined workers. Therefore, MaxEx is set at the standard value of 1 year.

Discussion

In the study by Nemery *et al.* (1992) workers replied to a questionnaire that was administered by the investigating physician. According to the description in the publication, the questionnaire was designed for the study and consisted of open and closed questions.

With questions regarding time course and intensity over the working week and during the year, the study team tried to establish a possible work-relation of the reported respiratory symptoms. The questionnaire is not attached to the publication and the only information provided are the results reported in Table 2-6. The workers could report several symptoms. As symptoms are self-reported, they are associated with uncertainty due to the individual judgement of the workers.

Based on the data reported by Nemery *et al.* (1992), a NOAEL of 5.3 µg Co/m³ for respiratory symptoms can be established. However, Kennedy *et al.* (1995) reported 'respiratory symptoms' (phlegm, cough wheezing) at 5 µg Co/m³ (results also obtained with a questionnaire). In this study co-exposure to chromium was observed and not corrected for. According to the authors the 'nasal effects' might also be related to chromium exposure. Alexandersson (1979) reported respiratory tract irritation at 2 – 3 µg Co/m³. However, these exposure concentrations were associated with explicit tasks, workers exposed to 2 µg Co/m³ for example were working on screening machines. Since the work of Alexandersson is only available in Swedish it is difficult to assess the relevance of these findings. Both studies could not be used for the derivation of DRRs.

2.2.3.3 Male fertility

Approach

RAC calculated a DNEL for fertility effects in males based on a 90-day inhalation toxicity study in mice (NTP, 1991, ECHA, 2022). Reduced sperm motility was identified as the most critical endpoint in this study. A dose dependant effect could be seen, and the effect was already significant in the lowest exposure group (LOAEC: 670 µg Co/m³). The LOAEC was corrected for worker exposure duration (*6/8 hours * 6.7/10 m³) and assessment factors of 2 (subchronic to chronic exposure), 2.5 (interspecies differences), 5 (intraspecies differences) and 3 (dose-response, LOAEC-NAEC[12] extrapolation) were applied. The calculated DNEL(fertility) is 4 µg Co/m³.

In the absence of human data this subchronic NTP study in mice was also used as the basis for the derivation of a DRR for the endpoint fertility.

In the NTP study B6C3F1 mice (10 animals of each sex and dose group) were exposed on 5 days per week to air containing cobalt sulphate heptahydrate at concentrations of 0, 300, 1,000, 3,000, 10,000, and 30,000 µg/m³ (0, 67, 223, 670, 2,230, and 6,700 µg Co/m³) for 6 h/d (plus T90) for 13 weeks. Sperm morphology and vaginal cytology evaluations were performed only for animals exposed to 0, 3,000, 10,000, or 30,000 mg/m³ (0, 670, 2,230, 6,700 µg Co/m³). Significant results from this evaluation are reported in Table 2-8.

Table 2-8 Relevant parameters regarding reproductive toxicity with significant changes compared to control groups in NTP 90-day toxicity study with male and female mice exposed to cobalt sulphate heptahydrate

	0 µg/m³ (0 µg Co/m³)	**3,000 µg/m³ (670 µg Co/m³)**	**10,000 µg/m³ (2,230 µg Co/m³)**	**30,000 µg/m³ (6,700 µg Co/m³)**
Male mice				
Right epididymal weight (mg)	0.042 ± 0.002	0.043 ± 0.001	0.045 ± 0.001	0.034 ± 0.001
Sperm motility (percent)	87.0 ± 0.76	78.6 ± 2.44	75.6 ± 2.25	46.6 ± 7.76
Abnormal sperm (percent)	1.29 ± 0.164	1.38 ± 0.113	0.98 ± 0.105	3.80 ± 0.626
Female mice				
Cycle length (days)	4.20 ± 0.20	4.11± 0.11	4.20 ± 0.13	5.00 ± 0.24

Source: (NTP, 1991)

As outlined in section 2.1.5 many studies in rats and mice showed effects on male fertility. Decreased sperm motility was also observed in a 14-week and 90-day inhalation toxicity study with cobalt metal in rodents starting at a concentration of 1,2500 µg Co/m³ (in rats) and of 2,500 µg Co/m³ (in mice) (NTP, 2014).

The effect on female fertility seen in the NTP study with cobalt sulphate heptahydrate (increased cycle length) was not observed in rats. The 90-day NTP study with cobalt metal showed a significantly longer oestrous cycle length in female mice in the highest exposure group (10,000 µg/m³) (NTP, 2014), but again, the effect was not observed in rats.

From the data reported in Table 2-8 no direct information on the fraction of affected human individuals can be derived. Therefore, a link to human data has to be drawn and a transformation has to be performed, which allows to estimate the affected fraction (% individuals of total exposed).

The endpoint 'reduced total sperm motility' is an endpoint which can be linked to respective observations in humans. WHO (2021) provides information on the distribution of this parameter in the human male population (parameter 'total sperm motility' includes progressive and non-progressive sperm, 3,488 healthy individuals, see Table 2-9). In the past, the 5th percentile was

[12] NAEC: No adverse effect concentration

considered as a limit to judge on abnormal low cases of sperm motility (WHO, 2010). Although this strict criterion was not maintained by WHO (2021) for the sake of a case-by-case evaluation of infertility cases, it is applied here to assess the relevance of the observed decrease in total sperm motility as observed the 90-day inhalation NTP study with mice (NTP, 1991). Following WHO (2021) the criterion for a relevant effect on total sperm motility is 22% reduction of total motile sperm.

Table 2-9 Distribution in human males for the parameter total sperm motility (in%, normally distributed)

5th percentile (P5)	50th percentile (P50)	95th percentile (P95)
42%	64%	90%

Source: WHO (2021)

This criterion can be applied to the subacute study of NTP (1991). In the NTP study the criterion of total sperm motility reduced by 22% would result in a critical effect size of 61.7% sperm motility (control minus 22%). The parameter 'sperm motility' is normally distributed in the population. By using the equation for a normal distribution in Excel and mean and standard deviation as given for each exposure group, the percentage of affected individuals (sperm motility below 5th percentile) was calculated. In the following Table 2-10 the data as given in the NTP study (first three rows) and affected individuals with total sperm count below the 5th percentile are provided as calculated in Excel.

Table 2-10 Mean values for sperm motility (in%) in NTP (1991) and calculation of affected individuals above the control. Assuming a normal distribution, the cut-off criteria is set as the 5th percentile of a healthy male population.

Concentration Co (µg /m³)	Sperm motility (%)	Standard deviation (%)	Affected individuals (%)	Affected individuals above control (%)
0	87.0	0.76	0.00	0.00
670	78.6	2.44	0.00	0.00
2,230	75.6	2.25	0.00	0.00
6,700	46.6	7.76	99.57	99.57

Source: NTP (1991) and study team.

Normally, RAC´s DNEL(fertility) of 4 µg Co/m³ derived for the same endpoint would be used as the starting point for the DRR with zero risk at this concentration. However, as can be seen in Table 2-10 the number of affected individuals above the control is zero at 2,230 µg Co/m³ (not yet transformed to human exposure conditions). In this case the starting point of the DRR is not the OEL or the RAC DNEL but this concentration.

Therefore, the DRR for male infertility is created from the points in the following table.

Table 2-11 DRR for male reproductive toxicity, derived from NTP (1991)

	Co concentration (respirable fraction) (µg/m³)	Affected individuals above control group (%)
Starting point: 2,230 µg Co/m³ exposure group in NTP study, transformed to human exposure (*6/8 * 6.7/10)	1,121	0.00
6,700 µg Co/m³ exposure group in NTP study, transformed to human exposure (*6/8 * 6.7/10)	3,367	99.57

Source: Study team based on NTP (1991)

The 'affected individuals above control group' (considered as individuals who suffer from infertility) were plotted against the cobalt concentration in air and the result is presented in Figure 2-4.

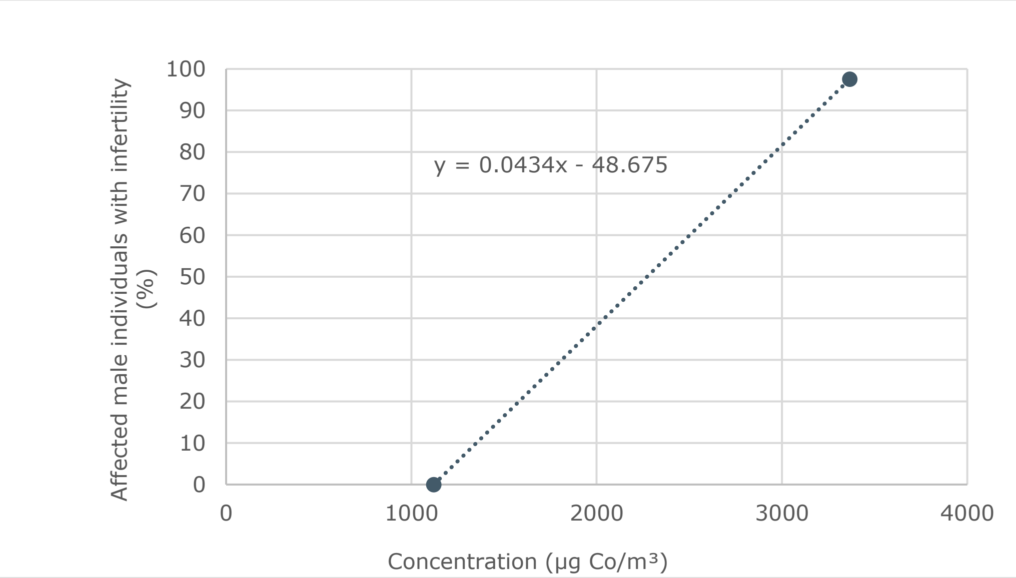

Figure 2-4 DRR for the endpoint reduced sperm motility after cobalt exposure (respirable cobalt fraction).

The dose response relation for infertility in males can therefore be described with the following equation:

Equation 2-5 DRR for cobalt (endpoint male fertility, derived for respirable fraction)

$$Excess\ Risk(infertility\ in\ males)(\text{percentage}) = 0.0434 * \left(c_{Cobalt(respirable\ fraction)}\right) - 48.675$$

With c starting at ≥ 1,120 µg/m³.

In the range of the policy options (highest option for respirable cobalt fraction is 4.2 µg/m³) no excess risk for male infertility is expected. The infertility effects only become relevant at very high exposure concentrations starting at about 1,120 µg/m³ (respirable cobalt fraction).

MaxEx is set at the duration of 3 m (0.25 years) to include a full sperm life cycle.

Discussion

Reproductive toxicity is a relevant toxicological endpoint when considering effects after exposure to cobalt metal and inorganic cobalt compounds. Cobalt and several cobalt compounds have a harmonised classification as Repr. 1B (H360 F), for example cobalt dichloride, cobalt sulphate or cobalt carbonate. No human data investigated this endpoint are available.

Effects on male testis and testicular function were observed in several inhalation studies with rats and mice (NTP, 1991, 2014) with the parameter 'reduced sperm motility' being the most sensitive one.

As can be seen in Figure 2-4 the DRR for the endpoint male fertility (based on the parameter 'reduced sperm motility') is not applicable in the concentration range considered in the policy options. Uncertainties that should be considered are the absence of human data. However, the

DRR starts at about of 1120 µg/m³ (which is more than two orders of magnitude above the highest policy option).

Fertility effects in females were also considered. As can be seen in Table 2-8 cell cycle length was significantly increased in the highest exposure group (6,700 µg Co/m³) with a NOAEC of 2,230 µg Co/m³ for this effect. After correction of this exposure concentration for duration and respiratory volume of workers (*6/8 *6.7/10) and assessment factors of 2 (subchronic to chronic exposure), 2.5 (interspecies differences), and 5 (intraspecies differences) the calculated DNEL(fertility female) would be 44.8 µg Co/m³ (respirable cobalt fraction), much outside the policy options. Therefore, no DRR for the endpoint female fertility was derived.

2.3 Groups at extra risk

No specific groups at extra risk were identified by RAC (RAC, 2022).

2.4 Summary of background for analysing health impacts

2.4.1 Summary of exposure, uptake and health effects

Routes of exposure and toxicokinetics

Relevant exposure routes are oral and inhalation. Inhalation absorption is highly dependent on the particle size of cobalt. As a metal cobalt is not metabolised in the body. Excretion after inhalation exposure is highly dependent on the solubility of the cobalt substance, the more soluble thesubstance is, the more rapidly it is eliminated via the lungs by transfer to the blood and excretion via urine and faeces.

Adverse health effects

Cobalt and several inorganic cobalt compounds have a harmonised classification for carcinogenicity according to Annex VI of the CLP Regulation (Canc. 1A or B). Numerous studies on carcinogenic effects of cobalt have been published. However, the epidemiological evidence can be considered as inconsistent mainly due to the presence of confounding factors or limitations of the studies. Experimental evidence of alveolar/bronchiolar adenomas and carcinomas (combined) in the lung of rodents was found in two chronic inhalation NTP studies with soluble cobalt sulphate heptahydrate and non-soluble cobalt metal. RAC considers carcinogenicity in animal studies and non-cancer related respiratory effects in exposed workers as the critical toxicological endpoints after cobalt exposure. For carcinogenicity they did not identify a threshold. However, RAC believes that a ‘break point’ for the carcinogenic effects can be established at 0.5 µg/m³ and derived an ERR for lung cancer (RAC, 2022). This ERR is also applied in the present report.

The main critical non-cancer endpoints after inhalation exposure are respiratory effects observed in exposed workers.

RAC considers three occupational exposure settings in the context of the OEL derivation. These are a) production and use of cobalt and cobalt compounds, b) production and use of hard-metal and c) polishing of diamonds. According to RAC exposure to cobalt is associated with diseases like asthma, whereas exposure to cobalt-containing hard-metal is an established cause of parenchymal lung disease. Parenchymal lung disease is also reported in workers from the diamond-polishing industry. Numerous studies from different industrial sectors describe decreased lung function and respiratory tract irritation in association with cobalt exposure.

Cobalt metal and several cobalt compounds also have a harmonised classification as Repr. 1B (H360F) or are notified by the registrants as Repr. 1B (H360) or Repr. 1A (H360) as significant effects on the male reproductive system can be observed. These classifications are based on animal data (e.g. reduced sperm motility) as no relevant epidemiological data are available investigation fertility or developmental toxicity effects.

Effects mainly observed after oral cobalt exposure or in non-occupational settings (cardiovascular diseases, thyroid-related, haematological and nervous/sensory effects) are not considered for the current assessment. In the following table the carcinogenic and non-carcinogenic endpoints are listed.

Table 2-12 Relevant carcinogenic and non-carcinogenic endpoints and their use for deriving ERRs and DRRs

Endpoint	Assessment
Lung cancer	Considered quantitatively for ERR
Other cancer sites (upper respiratory tract, pheochromocytomas and pancreatic cancer)	Not considered (not relevant or secondary to lung cancer)
Decrease in lung function	Considered quantitatively for DRR
Parenchymal lung disease	Not considered (unlikely to occur in concentration range below 100 µg/m³)
Irritation of the respiratory tract	Considered quantitatively for DRR
Respiratory sensitisation (asthma)	Not considered (no dose response data available for DRR derivation)
Reproductive toxicity – male fertility	Not considered quantitatively for DRR (only relevant above highest policy option)
Reproductive toxicity – female fertility	Not considered quantitatively for DRR (only relevant above highest policy option)
Reproductive toxicity - developmental toxicity	Not considered quantitatively for DRR (only relevant above highest policy option)
Cardiovascular effects, thyroid effects, nervous/sensory effects and haematological effects	Not considered (effects only considered relevant in a non-occupational setting)

2.4.2 Summary of ERR and DRR

The ERR and DRR equations use the concentration in mg Co/m³. The ERR and DRRs are further used in the calculation of current and future disease burden.

Please note the differences between the ERR and DRRs: The ERR concern the respirable fraction in mg Co/m³ whereas the DRRs concern the inhalable fraction in µg/m³. The ERR is indicated as ratio; the DRRs as percentage.

The ERR for cobalt and inorganic cobalt compounds derived by RAC (RAC, 2022) is also considered for the current report (excess risk of lung cancer), it is a kink function with a break point at 0.5 µg/m³ and follows the two equations (depending on the concentration):

$$Excess\ \text{Cancer}\ Risk\ (fraction) = 1.06 * c_{Cobalt(respirable\ fraction)}$$

ERR above the break point, with c > 0.5 µg/m³ (respirable fraction), c_{Co} in the equation in mg/m³ and

$$Excess\ \text{Cancer}\ Risk\ (fraction) = 0.105 * c_{Cobalt(respirable\ fraction)}$$

ERR below the break point, with c ≤ 0.5 µg/m³ (respirable fraction), c_{Co} in the equation in mg/m³.

DRRs for cobalt and inorganic cobalt compounds were derived for the following endpoints (please note that the concentration here is expressed in µg/m³):

- Lower respiratory tract toxicity: Decrease in lung function (considered as restricitive lung diseases)

  $$Excess\ Risk(restrictive\ lung\ disease)(\text{percentage}) = 0.5244 * \left(c_{Cobalt(inhalable\ fraction)}\right) - 2.7795$$

  - With c valid from ≥ 5.3 µg/m³ to 20 µg/m³ (inhalable fraction).

- Upper airway irritation (nose, eye, throat)

  $$Excess\ Risk(upper\ airway\ irritation)(\text{percentage}) = 1.0015 * \left(c_{Cobalt(Inhalable\ fraction)}\right) - 2.1233$$

  - With c valid from 2.12 µg/m³ to 20 µg/m³ (inhalable fraction).

- Male fertiliy (DRR not applicable in the concentration range considered in the policy options)

For concentrations above 20 µg/m³ the data does not allow to estimate if the DRRs should be higher or lower. In the absence of better data, the DRRs are also applied for concentrations above 20 µg/m³ which primarily is relevant for calculations of current burden of disease from past exposure at higher concentrations.

3 CURRENT SITUATION

This chapter comprises the following sections:

- Section 3.1: Existing national limits
- Section 3.2: Relevant uses, processes and sectors
- Section 3.3: Exposure concentration
- Section 3.4: Exposed workforce
- Section 3.5: Current risk management measures (RMMs)
- Section 3.6: Voluntary industry initiatives
- Section 3.7: Examples of good/best practice
- Section 3.8: Standard monitoring methods/tools
- Section 3.9: Intermediate uses not covered by certain REACH procedures
- Section 3.10: Market analysis
- Section 3.11: Alternatives
- Section 3.12: Current disease burden (CDB)
- Section 3.13: Summary of the current situation

3.1 Existing national limits

3.1.1 OELs and STELs in Member States

Current OEL and STEL values for cobalt and its inorganic compounds are shown in the table below.

As part of the stakeholder consultation, Member States' authorities have been asked a question regarding the binding/indicative status of the national OELs and similar limit values. Information regarding the binding vs. indicative status of the OEL has been provided by 13 Member States (Belgium, Bulgaria, Cyprus, Denmark, Finland, Germany, Latvia, Lithuania, Netherlands, Poland, Slovakia, Spain, and Sweden). For the remaining Member States, this information has been collected from the OELs 3 report on OEL and STEL deriving systems from 2018 (Kalberlah and BierWisch, 2018) and the GESTIS database[13]. It has not been investigated whether the OELs have changed status in some Member States in recent years.

Table 3-1 Current OELs and STELs in EU Member States and selected non-EU countries for cobalt and inorganic cobalt compounds

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
EU Member States				

[13] https://www.dguv.de/ifa/gestis/index-2.jsp

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
Austria [1,2,3]	100 (I) *	Cobalt and cobalt alloys, cobalt oxide, cobalt sulphate and cobalt sulphide - TRK value#, Carc, Srd, Sk A value of 0.5 for certain processes	400 (I) *	- TRK value#, Carc, Srd, Sk
Belgium [1,2,4]	20 (I, V) **	Cobalt metal (dust and fume) - Carc	-	
Belgium [4]	5 (R) **	Hardmetal of cobalt and tungsten carbide, as Co	-	
Bulgaria [5]	100 **	Cobalt and inorganic compounds	-	
Croatia [6]	100 **	Cobalt and its compounds - Srd	-	
Cyprus [7]	100 **	Metal dust and fumes, total dust	-	
Czechia [8]	50 (R) *	Cobalt and its compounds - Carc, Repro, S	0.1 (R) *	- Carc, Repro, S
Denmark [1,2,9]	10 **	Cobalt, powder, dust, smoke, and inorganic compounds Carc	20 **	- powder, dust, and smoke, Carc
Estonia [10]	50 *	Cobalt and its inorganics compounds - S	-	
Finland [1,2,11]	20 (I) ^^	Cobalt and its inorganics compounds	-	
France [2,12]	2.5 ^	Cobalt compounds, excluding hardmetals Recommendation derived by ANSES	12.5 ^	- recommendation derived by ANSES
Germany [1,2,13]	4 (R) § * 0.2 (R) $ 20 (I) !	Cobalt and cobalt compounds classified as Carc 1A and 1B	40 (R) § *	- Cobalt compounds classified as Carc 1A and 1B, 15 min average value
Greece [14]	100 *	Cobalt and its compounds	-	
Hungary [1,2,15]	20 15 *	Cobalt and its inorganic compounds, S [15] A value of 0.1 mg/m³ applies for cobalt and its compounds [1,2]	400 *	- Cobalt and its compounds [1,2]
Ireland [1,2,16]	20 ^	Cobalt and its compounds, S	-	
Italy [17]	-		-	
Latvia [1,2,18]	500 **	- Cobalt, cobalt (II) and (III) oxide	-	
Lithuania [19]	50 **	Cobalt and its inorganic compounds	-	

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
		- Carc, S		
Luxembourg [20]	-		-	
Malta [21]	-		-	
Netherlands [1,2,22]	20 (D, F) **	Cobalt (dust and smoke)	-	
Poland [1,2,23]	20 **	Cobalt and its inorganic compounds	-	
Portugal [24]	-		-	
Romania [1,2,25]	50 *	Cobalt, cobalt oxide,	100 *	- Cobalt, 15 min average value
Slovakia [26]	50 **	Cobalt and its com-pounds, total dust - S	-	
Slovenia [27]	-		-	
Spain [1,2,28]	20 (I) ^^	Cobalt and inorganic co-balt compounds - S, Carc (cobalt and specific compounds)	-	
Sweden [1,2,29]	20 (I) **	Cobalt and its inorganic compounds - Carc, S, Sk	-	
European Union	-		-	
RAC [2]	1 (I) 0.5 (R)	Cobalt and its inorganic compounds - Srd	-	
Candidate countries				
Albania [45]	-		-	
Bosnia and Herze-govina [46]	-		-	
Georgia [47]	-	- S	-	
Moldova [48] [49]	50 *	Cobalt (oxide of cobalt) - Carc, S (Cobalt in urine 15 µg/l Sampling time: at the end of the work shift or work week)	100*	- S
Montenegro [50]	-		-	
North Macedonia [51]	500 (I) 100 (I)	Cobalt (metal, cobalt ox-ide and cobalt sulfide) - obtaining powder from coal catalysts, carbide substrates and and powder, compaction and mechanical treat-ment of magnets (prep unsintered pieces) - Others	-	
Serbia [52]	-		-	
Turkey [40]	-		-	
Ukraine [53]	-		-	
EU candidate countries				
Albania				
Bosnia and Herze-govina				

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
Georgia				
Moldova,				
Montenegro				
North Macedonia,				
Serbia,				
Turkey [40]	-		-	
Ukraine				
Non-EU countries				
Australia [1,30]	50 (D, F) ***	- S	-	
Brazil [31]	-		-	
Canada, Ontario [32]	-		-	
Canada, Québec[1,33]	20 ***	- Carc, S	-	
China [1]	50%		100%	- 15 min average value
India [34]	-		-	
Japan, MHLW [1,35]	20 ***		-	
Japan, JOSH [1,36]	50 ^^^	- Carc, Srd	-	
Norway [1,2, 37]	20 (T)& ^^	- Cobalt and its inorganic compounds, except Co(II)	-	
Russia [38]	4% 1%	- Cobalt, acceptable risk under daily exposure (at least 24), Sk - Cobalt, acceptable risk under chronic exposure (at least 1 year), Sk	-	
South Korea [1]	20%		-	
Switzerland [1,2, 39]	50 (I) *	- Cobalt and its com-pounds, Carc, Repro, S, Sk	-	
United Kingdom [1,2,41]	100 *	- Cobalt and its com-pounds, Carc (only for cobalt dichloride and sul-phate), S	-	
USA, ACGIH [42]	20 (I) ^	- Carc, Srd	-	
USA, NIOSH [1,43,$$]	50 (D, F) ^	- Cobalt	-	
USA, OSHA [1,2,44]	100 (D, F) *	- Cobalt	-	

Notes:
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific) source unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire
! The adoption of this value is currently being discussed.

(T) Total dust

ANSES = French Agency for Food, Environmental and Occupational Health & Safety
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
TRK value= Technical Guidance Concentrations ('Technische Richtkonzentrationen') in Austria
(I) = inhalable fraction/aerosol
(R) = respirable fraction/aerosol
(V) = vapour
(D) = dust
(F) = fume
Carc = notation for carcinogenicity. Where a more detailed notation for carcinogenicity was given, the following notations were reported:
Repro = notation for reproductive toxicity assigned
S = notation for sensitisation assigned. Where a more detailed notation for sensitisation was given, the following notation was reported:
Srd = respiratory and skin/dermal sensitisation
Sk = skin notation assigned or danger of skin absorption
- no value available
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk
$$ For NIOSH recommended exposure limits (RELs), 'TWA' indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.'; Online: https://www.cdc.gov/niosh/npg/pgintrod.html , assessed December 2022
 # TRK value ('Technische Richtkonzentration', Technical Guidance Concentration), based on technical feasibility

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3.1.2 Minimum, maximum, average and scope of national OELs

A summary of OELs for cobalt and inorganic cobalt compounds in EU Member States and the levels proposed by RAC (RAC, 2022) is provided in the table below.

Table 3-2 Summary of OELs for cobalt and inorganic cobalt compounds in EU Member States and levels proposed by RAC in its opinion to the Restriction proposal

OEL, µg Co/m³, 8-h TWA		Comment
Inhalable fraction	**Respirable fraction**	
	0.2	Workplace exposure concentration corresponding to the proposed acceptable cancer risk (Germany, respirable only)
1	0.5	OELs at the level proposed by the RAC opinion (RAC, 2022)
	4	Workplace exposure concentration corresponding to the proposed tolerable cancer risk (Germany, respirable only, binding)
10		Minimum binding OEL as observed among those Member States where an OEL exists (Denmark); concern total dust
20		Mode of OELs observed among those Member States where a binding OEL exists – is used in more than half of Member States where an OEL exists
500		Maximum binding OEL as observed among those Member States where an OEL exists (Latvia, binding)

Source: Study team based on Table 5-1.

The scope of the national OELs with regard to substances covered can be summarised as shown in the table below.

*Table 3-3 Scope of current limit values with regard to substances covered in Member States***. An * indicates that the limit value has a binding character.*

Scope compared to reference OELs	Scope	Member States	Number
Similar scope **	Cobalt and inorganic cobalt compounds	Bulgaria *, Denmark *, Estonia *, Finland, Hungary *, Lithuania*, Poland *, Spain, Sweden *	9
Wider scope - organic cobalt compounds included	Cobalt and its compounds	Croatia, Czechia *, Greece *, Ireland, Slovakia *	5
More narrow scope - some inorganic cobalt compounds excluded	Cobalt and cobalt alloys, cobalt oxide, cobalt sulphate and cobalt sulphide	Austria *	6
	Cobalt metal (dust and fume) and hardmetal of cobalt and tungsten carbide	Belgium *	
	Cobalt, metal dust and fumes	Cyprus *	
	Cobalt, cobalt (II) and (III) oxide	Latvia *	
	Cobalt (dust and smoke)	the Netherlands *	
	Cobalt, cobalt oxide	Romania *	
Wider for some substances, narrower for others	Cobalt and cobalt compounds classified as Carc 1A and 1B	Germany (stipulated risk levels) *	2
	Cobalt compounds, excluding hardmetals	France (recommended risk levels)	
No OEL		Italy, Luxembourg, Malta, Portugal, Slovenia	5

** Indicates the limit value is binding.*
*** Uncertain to what extent inorganic cobalt compounds outside the scope of the CMRD would be included.*
****Include both OELs and other occupational limit values such as risk values.*
Source: Study team based on Table 5-1.

The occupational limit values in three Member States concern the respirable fractions, whereas in the rest of Member States, where an OEL or other occupational limit value is established, the OEL concern the inhalable fraction, or no fraction is specified. None of the Member States have currently binding limit values for both respirable and inhalable fraction.

*Table 3-4 Respirable vs. inhalable fraction covered by the occupational limit values**. An * indicates that the limit value has a binding character.*

Scope compared to reference OELs	Member States	Number
Respirable fraction	Belgium *, Germany *, Czechia *	3
Inhalable or nothing specified	Austria *, Bulgaria *, Croatia, Denmark *, Estonia *, Finland, France, Greece *, Hungary *, Ireland, Latvia *, Lithuania *, the Netherlands *, Poland *, Romania*, Slovakia *, Spain, Sweden *	18
No OEL	Italy, Luxembourg, Malta, Portugal, Slovenia	5

** Indicates the limit value is binding.*
*** Include both OELs and other occupational limit values such as risk values.*
Source: Study team based on Table 5-1.

3.2 Relevant uses, processes and sectors

The following section describes the uses, processes and sectors.

The section is organised as follows:

- It sets out with a summary of REACH registration data in section 3.2.1 indicating the registered volumes for cobalt and all inorganic cobalt substance to indicate which substances are used in the largest quantities and the volumes of inorganic cobalt compounds outside the scope of the study. This is followed with an indication of the process categories involved which show that the use of cobalt and inorganic cobalt compounds involves nearly all process categories under REACH.

- Section 3.2.2 summarises the information on manufacture of cobalt and inorganic cobalt compounds.

- Section 3.2.3 sets out with an overview of the volumes used for different applications by group of substances. The objective of this overview is to illustrate which uses of cobalt are main in terms of volumes and the information is used later in the impact assessment. The overview is followed by subsections on the main uses of the substances. In many of the data sources the description is based on use areas and not sectors and the aim of this section is the describe the overall use areas which often involved many sectors in the entire product chains.

- This is followed by three subsections on processes that may also potentially lead to occupational exposure: Processes unintentionally leading to the generation of the substances (3.2.4), recycling activities (section 3.2.5) and processes involving cobalt and inorganic cobalt compounds present as impurities (section 3.2.6).

- The information form input for the overview of sectors in section 3.2.7. The section sets out with a description of sources of information on sectors and an overview of identified sectors. As many of the data sources does not indicate sectors but use areas, the previous description of uses and supply chains is used to identify the relevant sectors. Based on the criteria for selection of sectors to be included in the study, section 3.2.7.4 lists sectors excluded and section 3.2.7.5 lists sectors taken forward for the study.

3.2.1 Summary of REACH registration data

According to the Annex 1 to the RAC opinion on cobalt and inorganic cobalt compounds(ECHA, 2022), there are 42 substances registered under REACH for cobalt and inorganic cobalt compounds (ECHA, 2022). For 34 of these sub-stances, tonnage information is available as part of a REACH registration. These include 29 substances with full registration, and five substances only registered as an intermediate. Chemical Safety Reports are available for those with a full registration.

The type of REACH registrations and the total tonnage band for REACH registrations are shown in Table 3-5. The table also indicate the name of the consortia responsible for registration. Data from REACH consortia have been collected from two consortia: Cobalt REACH consortium (CoRC) administrated by the Cobalt Institute, and the Inorganic Pigment (IP) which is administrating the registration of certain inorganic pigments. Substances not covered by these consortia are (registered applications):

- Cobalt molybdate (EC No 237-358-4): Catalyst, intermediate
- Tripotassium hexacyanocobaltate (EC No 237-742-1): Intermediate in the manufacture of another substance
- Cobalt lithium manganese nickel oxide (EC No 480-390-0): Batteries
- Lithium nickel cobalt aluminium oxide (EC No 700-042-6): Batteries

These substances are used for the same sectors as other inorganic cobalt compounds and exposure due to the application of the substances have been collected by the sector-specific data collection.

Inorganic cobalt compounds outside the scope of the study registered in the largest quantities are tricobalt tetraoxide, cobalt hydroxide oxide, and iron cobalt chromite black spinel which are all registered in the 1,000-10,000 tonnes range.

*Table 3-5 REACH registrations for registered cobalt and inorganic cobalt compounds. Registered tonnage and number of registrants (reg). The table shows names of consortia for the registration of the substances. Substances within the scope of the study are marked with an *. The tonnage is t/y of the cobalt compounds.*

Substance (REACH registration name)	EC Number	Registered tonnage, t/year intermediate	Registered tonnage, t/year full registration	Consortium
Cobalt carbonate *	208-169-4	<10 (<5 reg)	1,000-10,000 (8 reg)	CoRC
Cobalt trihydroxide	215-153-0		'Cease manufacture'	
Cobalt oxide *	215-154-6	<10 (<5 reg)	1,000-10,000 (26 reg)	CoRC
Tricobalt tetraoxide	215-157-2	10-1,000 (<5 reg)	1,000-10,000 (29 reg)	CoRC
Cobalt sulphide *	215-273-3	10-1,000 (12 reg)	1,000-10,000 (31 reg)	CoRC
Cobalt *	231-158-0		10,000-100,000 (96 reg)	CoRC
Cobalt dichloride *	231-589-4	<10 (<5 reg)	1,000-10,000 (6 reg)	CoRC
Cobalt sulphate *	233-334-2	1,000-10,000 (<5 reg)	>100,000 (15 reg)	CoRC
Cobalt dinitrate *	233-402-1		1,000-10,000 (10 reg)	CoRC
Octacarbonyldicobalt	233-514-0	<10 (<5 reg)		
Cobalt hydroxide oxide	234-614-7	10-1,000 (<5 reg)	1,000-10,000 (<5 reg)	CoRC
Cobalt lithium dioxide *	235-362-0		10-1000 (7 reg)	CoRC
Aluminium cobalt oxide	235-762-5	<10 (<5 reg)		
Cobalt molybdate *	237-358-4	<10 (<5 reg)	10-1000 (<5 reg)	
Tripotassium hexacyano-cobaltate	237-742-1		10-1000 (<5 reg)	
Cobalt dihydroxide *	244-166-4	(<5 reg)	>100,000 (19 reg)	CoRC
Cobalt titanite green spinel *	269-047-4		10-1000 (7 reg)	IP
Cobalt zinc aluminate blue spinel	269-049-5		1,000-10,000 (14 reg)	IP

Substance (REACH registration name)	EC Number	Registered tonnage, t/year intermediate	Registered tonnage, t/year full registration	Consortium
Iron cobalt chromite black spinel	269-060-5		1,000-10,000 (21 reg)	IP
Cobalt magnesium tin spinel	269-066-8			IP
Cobalt chromite blue green spinel	269-072-0		10-1000 (19 reg)	IP
Olivine, cobalt silicate blue *	269-093-5		1,000-10,000 (15 reg)	IP
Cobalt chromite green spinel	269-101-7		10-1000 (12 reg)	IP
Iron cobalt black spinel	269-102-2		<10 (<5 reg)	IP
Cobalt zinc silicate blue phenacite	270-208-6		<10 (<5 reg)	IP
Leach residues, zinc ore-calcine, zinc cobalt	273-769-5	1,000-10,000 (6 reg)		
Cobalt aluminate blue spinel	310-193-6		1,000-10,000 (27 reg)	IP
Cobalt lithium nickel oxide *	442-750-5		'Cease manufacture'	
Cobalt lithium manganese nickel oxide *	480-390-0		10,000-100,000 (16 reg)	?
N/A	485-210-4		'Tonnage data confidential'	
Dipotassium hexacyanocobalt(II)-ferrate(II	603-073-2		<10 (<5 reg)	
Cobaltate(1-), tetracarbonyl-, sodium (1:1), (T-4)-	696-062-7		'Intermediate use only'	
Lithium nickel cobalt aluminium oxide *	700-042-6		1,000-10,000 (7 reg)	
Reaction mass of cobalt olivine and crystalline silicon dioxide *, **	701-439-7		100 - 1,000 tonnes (7 reg)	IP
Cobalt manganese nickel dihydroxide	839-353-8		<10 (<5 reg)	
Reaction mass of cobalt sulphide and nickel sulphide and trinickel disulphide	910-663-6	1,000-10,000 (<5 reg)		CoRC
Reaction mass of cobalt and copper and iron	912-664-7	<10 (<5 reg)		CoRC
Reaction product of soluble nickel salt, cobalt salt, manganese salt with alkalines	931-895-4			
N/A	939-184-0		<10 (<5 reg	?
Trizinc bis[hexacyanidocobaltate] dodecahydrate	942-358-9		<10 (<5 reg	?
(Nickel cobalt manganese)	951-904-5		<10 (<5 reg)	?

Substance (REACH registration name)	EC Number	Registered tonnage, t/year intermediate	Registered tonnage, t/year full registration	Consortium
monoxide and tri(nickel cobalt manganese) tetraoxide				

Source: Based on ECHA (2022) supplemented with information from the registration database and the study teams research regarding consortia.
** Within the scope of the study, ** Not included in ECHA (2022)*

Besides the cobalt compounds listed above, the ECHA scientific report lists a number of other sub-stances containing a significant amount of cobalt or its inorganic compounds such as matte and slags and waste solids from manufacture of precious metal, copper and cadmium. These substances are residues from various non-ferrous production and indicate the potential for occupational exposure from the processes generating these residues and the processes for recovery of metals from the residues. The substances are listed in the table below.

Table 3-6 Registered substances containing a significant amount of cobalt or its inorganic compounds, tonnes/y

Substance name	EC No	Intermediate registration	Full registration
Cement copper	266-964-1	10,000-100,000 (12 reg)	10,000-100,000 (6 reg)
Leach residues, cadmium cake	293-309-7	10,000-100,000 (8 reg)	
Matte, precious metal	308-506-6		1,000-10,000 (<5 reg)
Slags, precious metal refining	308-515-5	1,000-10,000 (<5 reg)	1,000-10,000 (6 reg)
Slimes and sludges, precious metal refining	308-516-0	1,000-10,000 (<5 reg	10,000-100,000 (5 reg)
Waste solids, precious metal refining	308-526-5		1,000-10,000 (5 reg)

Source: ECHA (2022)

Manufacturing process categories (PROCs) relating to cobalt and inorganic cobalt compounds in REACH registration dossiers are shown in the table below. The table illustrates that nearly all Process Categories are represented both for cobalt and the inorganic cobalt compounds within the scope.

Table 3-7 Manufacturing Process Categories (PROCs) for cobalt and inorganic cobalt compounds according to REACH registration dossiers

Process Category (PROC)		Cobalt	Inorganic cobalt compounds within the scope
PROC 1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	X	X
PROC 2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	X	X
PROC 3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	X	X
PROC 4	Chemical production where opportunity for exposure arises	X	X

Process Category (PROC)		Cobalt	Inorganic cobalt compounds within the scope
PROC 5	Mixing or blending in batch processes	X	X
PROC 6	Calendering operations	X	X
PROC 7	Industrial spraying	X	X
PROC 8a	Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	X	X
PROC 8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities	X	X
PROC 9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	X	X
PROC 10	Roller application or brushing	X	X
PROC 11	Non-industrial spraying		X
PROC 12	Use of blowing agents in manufacture of foam	X	
PROC 13	Treatment of articles by dipping and pouring	X	X
PROC 14	Tabletting, compression, extrusion, pelletisation, granulation	X	X
PROC 15	Use as laboratory reagent		X
PROC 19	Hand-mixing with intimate contact and only PPE[14] available		X
PROC 21	Low energy manipulation of substances bound in materials and/or articles	X	X
PROC 22	Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	X	X
PROC 23	Open processing and transfer operations with minerals/metals at elevated temperature	X	X
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	X	X
PROC 25	Other hot work operations with metals	X	X
PROC 26	Handling of solid inorganic substances at ambient temperature	X	X
PROC 27a	Production of metal powders (hot processes)	X	X
PROC 27b	Production of metal powders (wet processes)	X	
PROC 28	Manual maintenance (cleaning and repair) of machinery	X	X

3.2.2 *Manufacture of cobalt and inorganic cobalt compounds*

An initial literature search has been undertaken to identify applications of the substances and relevant sectors.

The following is based on information on applications and sectors in the scientific reports prepared by ECHA (ECHA 2018a, 2022a), national exposure databases: SIREP (Scarcelli *et al.*, 2020), ASA (2014), and COLCHIC (Emili *et al.*, 2019), registration dossiers and generic[15] CSRs

[14] PPE: Personal protective equipment

[15] 'Generic CSR' is in this context used for the CSRs developed by the Cobalt REACH Consortium or other consortia for each registered substance. These generic CSRs are used as background for the confidential

for cobalt and a number of cobalt substances, assessments undertaken for the Cobalt Institute and Cobalt REACH Consortium (RPA, 2020; eftec, 2019; Mistry *et al.*, 2020; eftec, 2023), CAREX (Carcinogen Exposure Inventory) Canada (2022) and information from the organisation's websites, IARC Monograph on cobalt in hardmetals and cobalt sulphate (IARC, 2006), USGS minerals Yearbook (USGS, 2022). Furthermore, specific information has been collected from other sources as specifically indicated below.

3.2.2.1 Mining and refinery of cobalt

Cobalt is mainly mined as a by-product from copper and nickel mines. Both underground and surface mining technologies are used.

In the EU, cobalt is mined in Finland as a by-product to copper and nickel production. Refined cobalt is produced by several companies in Finland. Besides mined cobalt, the feed for refinery is imported as crude cobalt hydroxide and nickel matte as well as cobalt-bearing scrap from the cemented carbide, battery, and catalyst industries. The cobalt mining production in Finland in 2018 is reported at 1,277 tonnes, while the refinery capacity in Finland is reported at 16,500 tonnes (USGS, 2022). The output is both cobalt metal and intermediate nickel-cobalt sulphide and other cobalt compounds. In Europa, cobalt is furthermore refined in Norway with a refinery capacity of 3,500 tonnes (metal), in Belgium with a refinery capacity of 1,600 (metal powder, oxide, hydroxide) and, in France with a refinery capacity of 277 tonnes (chloride) in 2018, (USGS, 2022).

The domestic production of cobalt in EU-27 were during the period 1960 to 1990 stable at a level of about 2,000 tonnes/year. From 1990 to 2020 the domestic production has increased steadily to a level of 14,000 tonnes/year (Godoy León *et al.*, 2021). The study was done for current Member States of the EU (EU27).

3.2.3 Overview of key intentional production processes and uses

3.2.3.1 Volumes used

The main uses for cobalt and its inorganic compounds, according to the Cobalt Institute, are on a global scale battery production for electric vehicles, tablets and smartphones (57%), nickel-based alloy production (13%), manufacturing tools (8%), pigments (6%), catalysts (5%), magnets (4%), soap and drying agents (2%) while other applications account for 5%.

The table includes a group of 'Bespoke/Niche Applications'. According to ECHA (2028) the bespoke uses cover manufacture of humidity indicator cards, water treatment chemicals sector, and laboratory reference standards. These applications are further described in section 3.2.3.19.

The consultant company eftec has in 2019 and 2023 undertaken surveys for the Cobalt Institute on the use of cobalt in the EU (eftec, 2019;2023). The 2023 survey is part of an impact assessment undertaken by eftec for the Cobalt Institute. The main results of the impact assessment are presented in section 7.2.10.5 and Annex D.

Data has been collected by a survey by members of the different consortia for cobalt and cobalt compounds and summarised by eftec (2023). The table below present the data collected from

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CRSs developed by each registrant. The part used for this study is the CSR's section 9 & 10 concerning exposure.

respondents to the survey. For cobalt metal, 38% of the volume manufactured or imported into the EU is exported whereas for cobalt compounds less than 3% is exported.

These data have been used by eftec in combination with the tonnage bands of registrations and other data sources for estimation of the volumes used.

According to eftec (2023), the organic compounds (the Green Consortium) substances are all outside the scope defined by the present study, however, the questionnaire data revealed that a significant share (75%) is manufactured or internally used alongside substances in scope. It is therefore believed that majority of the Green Consortium volumes will be impacted by a OEL and is thus indirectly in scope. The background is likely that the majority of the organic compounds are manufactured on the basis of inorganic compounds and thus the manufacture of the substances would be within the scope.

Table 3-8 Volumes of cobalt and cobalt compounds manufactured and imported in the EU. Data estimated from responses to eftec (2023) survey. All volumes in tonnes/year of the substances (i.e. not calculated into tonnes of cobalt).

	Total manufactured in the EU27 (M)	Total imported into the EU-27 (I)	Total volume within the EU27 (M+I)	% sold and/or internally used in the EU27	% sold and/or internally used outside the EU27	% of volume directly or indirectly in scope **
Cobalt metal	13,500	14,600	28,100	62%	38%	100%
Inorganic cobalt compounds under CoRC	171,600	33,700	205,300	97%	3%	100%
Organic cobalt compounds under CoRC	9,400	4,600	14,000	97%	3%	75%
Inorganic pigments under IP consortium	25,500	6,800	32,300	100%	0%	84%
Other *	136,900	58,600	195,500	99%	1%	100%

*Source: eftec, 2023. * Include among other cobalt lithium nickel oxide and lithium nickel cobalt used in the production of batteries. **Based on respondent data.*

Some cobalt substances are used as intermediates in the production of other cobalt substances and are not used in downstream uses.

Based on from data from respondents to the eftec 2023 survey and data from stakeholder webinars, eftec (2023) has estimated that 39% of the volumes sold and/or internally used in the EU-27 was actually used in downstream uses. Eftec (2023) notes that eftec (2019) on the other hand, found that 67% of the volumes sold and/or internally used was eventually used in downstream uses. According to eftec (2023), this may be partly due to the differing substances in scope but is also an indication of potential underreporting of downstream use volumes in the 2023 survey (insufficient responses from downstream users) compared to manufacture and import in the respondent data.

The data as reported by eftec (2023) are shown in Table 3-9. The indicated tonnage is tonnage of the substances and not tonnage of cobalt. The data are, together with other data shown further down in this subsection, used to point at uses that might lead to occupational exposure to cobalt but not directly used to derive number of exposed workers or exposure concentrations. No attempt has consequently been taken for calculating the volumes in terms of tonnage of cobalt.

The total tonnage is estimated at 176,810 tonnes/year of the substances of which manufacture of precursor chemicals for batteries account for 77%. The use as metal account for 7% of the total, mainly in the form of metallurgical alloys and hardmetal and diamond tools.

The table also shows the results of the respondents' view on percent of the use directly or indirectly in scope of the OEL for cobalt and inorganic cobalt substances. It is not described how 'indirectly' in scope is defined or how the percentages were derived for the two uses where only, or mainly, organic compounds were used: Adhesion and manufacture of driers/paints. Whereas at the manufacturing step the organic cobalt compounds are produced from inorganic compounds and thus within the scope, it has for the current study not been confirmed that the organic substances, when used downstream e.g. for production of tyres or other rubber products, are used together with substances within the scope. This has e.g. specifically been asked in a video conference with a number of manufacturers of tyres which could not confirm any general use of substances within the scope.

Table 3-9 Annual volumes of cobalt and cobalt compounds used in the EU27 in 2023 by broad use area (eftec, 2023). Volumes are in tonnes of the substances per year.

Broad uses	Annual volumes used in the EU27 (tonnes/y) *						
	Metal	In-organic	Organic	In-organic pig-ments	Other **	Total	% in scope***
Manufacture of other chemicals	0	1,500	1,500	1,000	0	4,000	75%
Metallurgical alloys	3,800	0	0	0	0	3,800	100%
Cemented carbide/diamond tools	4,800	700	0	0	0	5,500	100%
Magnetic alloys	1,300	0	0	0	0	1,300	100%
Manufacture of precursor chemicals for batteries	5	82,200	0	0	53,800	136,000	100%
Manufacture of catalysts	900	3,200	0	0	0	4,100	100%
Use as catalysts - used as catalyst precursor	0	2,300	0	0	0	2,300	100%
Use as catalysts - used as oxidation catalyst/for PTA and IPA	300	1,700	100	0	0	2,100	100%
Manufacture of pigments and dyes	0	1,500	0	2,000	0	3,500	97%
Use in surface treatment - Formulation of surface treatment	300	100	0	0	0	400	100%
Use in surface treatment - Passivation or anti-corrosion treatment processes	400	0.4	0	0	0	400	100%
Use in surface treatment - Metal or metal alloy plating	10	300	0	0	0	300	103%
Manufacture of driers / paints	700	0	2,300	0	0	3,000	100%
Adhesion (incl. rubber adhesion agent)	0	0	8,700	0	0	8,700	77%
Formulation and use in animal feed grade materials	0	700	100	0	0	800	100%

Broad uses	Annual volumes used in the EU27 (tonnes/y) *						
	Metal	In-or-ganic	Organic	In-or-ganic pig-ments	Other **	Total	% in scope***
Formulation and industrial use of mixtures in biogas production	0	100	0	0	0	100	100%
Professional use in biogas production	0	100	0	0	0	100	100%
Use in fermentation, fertiliz-ers, biotech, scientific re-search and standard analy-sis	0	10	0	0	0	10	100%
Use in electronics	0	100	0	0	0	100	100%
Use in humidity indicators cards, plugs and/or bags with printed spots	0	100	0	0	0	100	100%
Formulation of water treat-ment chemicals, oxygen scavengers, corrosion inhib-itors	0	100	0	0	0	100	100%
Total	**12,515**	**94,810**	**12,700**	**3,000**	**53,800**	**176,810**	**98%**

** In the report, the groups are indicated by consortia names: Blue consortium (metal), Red Consortium (inorganic cobalt compounds), Green consortium (organic cobalt compounds), IP Consortium (inorganic pigments). The specific compounds covered by the specific consortia are listed in eftec (2023). **% directly or indirectly in scope (based on respondent data). *** 'Other' consortia not specified.*
PTA: Purified terephthalic acid; IPA: Isophthalic acid.

Similar about ten years old data are presented in a previous report on the cobalt value chain of cobalt prepared by Eftec for the Cobalt Institute (eftec, 2019). The assessment includes 23 cobalt compounds covered by three REACH consortia administrated by the Cobalt Institute and do not include the pigments administrated by other consortia. Table 3-10 breaks down the aggregated volume of cobalt and 23 cobalt compounds used within the EU28 by broad use category, around 2011 - 2014 which has been estimated at approx. 47,500 tonnes per year. The cobalt compounds are here split into cobalt salts (the compounds addressed by the restriction proposal), cobalt oxides and the organic cobalt carboxylates. This makes a direct comparison with the 2023 data complicated. Furthermore, no data are available to deduct the share of the UK and, as the data mainly is used to indicate where exposure to cobalt takes place, no attempt has been done to estimate the volume used in the EU27.

The consumption of cobalt carboxylates is shown for reference only in order to illustrate the significance of the volume used for these substances compared to substances within the scope of the current study. The data are compared with the updated volume to indicate the trends in consumption within the last ten years in section 3.10.8.

The substances are organised into the following groups which are also used for other overviews in subsequent sections:

- Metal: cobalt metal and cobalt alloys;
- Salts: Cobalt carbonate, cobalt dichloride, cobalt dinitrate, cobalt sulphate, cobalt di(acetate) (the five cobalt salts included in the restriction proposal (ECHA, 2018a);

- Oxides: Cobalt oxide, tricobalt tetraoxide, cobalt dihydroxide, cobalt hydroxide oxide, cobalt sulphide;

- Carboxylates: Cobalt (II) 4-oxopent-2-en-2-olate, cobalt oxalate, cobalt, borate neodecanoate complexes, cobalt, borate 2-ethylhexanoate complexes, cobalt, borate propionate complexes, resin acids and resin acids, cobalt salts, naphthenic acids, cobalt salts, cobalt bis(2-ethylhexanoate), neodecanoic acid, cobalt salt, stearic acid, cobalt salt, cobalt(2+) propionate, cobalt(2+) isononanoate, fatty acids, tall-oil, cobalt salts.

Please note that the majority of cobalt pigments are not included in the table, the category 'Pigments (incl. decolourising (glass)' includes only the use of the above listed substances as pigments. Data on pigments within the scope are to be collected by the further project implementation and added to the data collected by the Cobalt Consortium.

The table sum up the total volumes by use areas across the four broad cobalt substance groups. The exceptions are the use of cobalt compounds when: (i) used as catalyst precursor, and (ii) used in the chemical broad use categories. Typically for these two broad use categories the cobalt compound is used as an intermediate for the manufacture of other compounds. Therefore, for these applications the data has in eftec (2019) been corrected for double account (indicated in red).

Table 3-10 Annual volumes of cobalt and cobalt compounds used in the EU28 (eftec, 2019). The volumes used for pigments includes only pigments with REACH registrations administrated by the Cobalt Institute.

Broad uses	**Annual volumes used in the EU28 (tonnes/y)**					
	Metal (2011-13)	Salts (2011-13)	Oxides (2011-13)	Carboxylates (2012-14)	TOTAL	%
Cobalt-containing alloys	1,300				1,300	2.7
Hardmetal and diamond tools **	1,900				1,900	4.0
Magnetic alloys	900		<50		900	1.9
Chemicals*	7,800	26,700	11,500	2,100	(26,700)	56.2
Batteries*	1,600		100		1,600	3.4
Catalysts - used as catalyst precursor	1,100	1,200	1,600	100	(1,600)	3.4
Catalysts - used as oxidation catalyst/for PTA and IPA	200	1,200		100	1500	3.2
Pigments (incl. decolourising (glass))	200		2,200		2,400	5.0
Surface treatment	200	500	100		800	1.7
Driers / paints	500			1,600	2,100	4.4
Adhesion agent *			100	5,900	6,000	12.6
Biotech - animal feed and fertilizer	200	300	<<50		500	1.0
Biotech - biogas production		100			100	0.2
Biotech - fermentation, biotech processes, health and medicine		<<50		-	<<50	0.1

Broad uses	Annual volumes used in the EU28 (tonnes/y)					
	Metal (2011-13)	Salts (2011-13)	Oxides (2011-13)	Carbox-ylates (2012-14)	TOTAL	%
Electronics			<50		<50	0.01
Bespoke/Niche Applications		<50			<50	0.1
Other				100	100	0.2
Total	**15,700**	**30,000**	**15,700**	**10,000**	**approx. 47,500**	**100%**

*Table notes from original: Figures have been rounded (volumes to nearest 100 tonnes). The numbers reported for the animal feed sector could potentially be overestimated due to changes made to comply with Regulation (EC) no 1831/2003 on additives for use in animal nutrition. * Due to the data collection and confidentiality, volumes used for 'Batteries' and 'Adhesion (inc. rubber adhesion agent)' is underreported in this table, as these uses are included within the chemicals sector. For example, estimates reported in the market overview note (eftec, 2018b) and JRC (Joint Research Centre) report (Alves et al., 2018) indicate a higher proportion of cobalt compounds being used in the batteries sector. ** Note from authors of this report: The original indicates this as 'Carbide Diamond Tools'.*

The finished products are used in a wide range of industries with portable electronics and automotive accounting for more than 70% of total use (mainly use of batteries), while other end-use sectors are power and motive (4% of total), energy (4%), aerospace (4%), fabrication (3%), machinery (1%), plastics (1%), agriculture (1%), construction (1%), chemical (1%) and others (2%) (Cobalt Institute, 2022).

A quite different distribution by application areas is provided in a report from the Joint Research Centre on Material System Analysis of five battery-related raw materials; among these cobalt (Matos *et al.*, 2020). The figure below illustrates the share of finished products produced and used in the EU in 2016. The study is a substance flow analysis mainly based on Eurostat commodity statistics, geological surveys and information from the Cobalt Institute. Compared with the results presented by eftec (2019), the share of the metallic uses, first of all the cobalt alloys (indicated as super alloys) account for a larger share and also significant higher volumes whereas batteries account for significantly less. It has not been possible to find an explanation for the major differences between the two overviews, but it is by the authors of this report assessed to be more uncertain to establish an overview of cobalt uses on commodity statistics and the data from eftec (2019) and the Cobalt Institute is assessed better to represent the actual distribution.

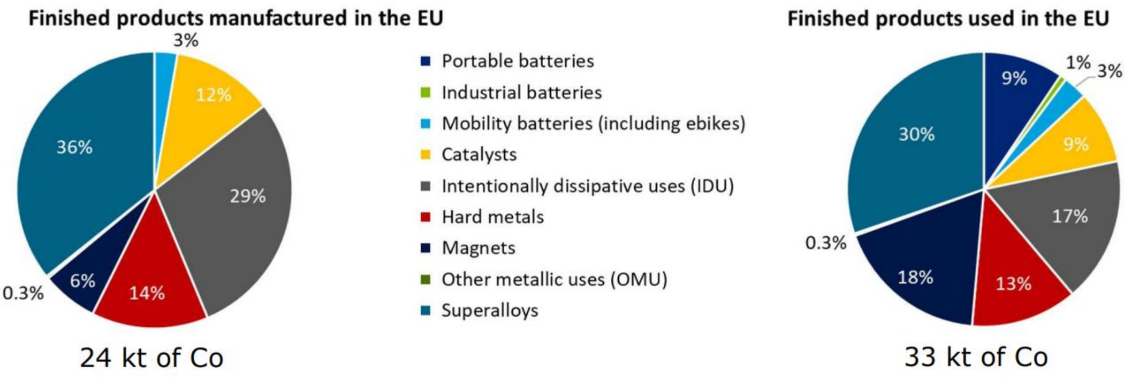

Figure 3-1 *Shares of finished products containing cobalt manufactured in the EU (left) and shares of finished products containing cobalt used in the EU (right) in 2016, by application. Source: Matos et al., 2020.*

The following brief description of applications of cobalt and inorganic cobalt compounds is based on Annex I to the RAC opinion (ECHA, 2022), the ECHA 2018 Annex XV Restriction Report, documents at the website of the Cobalt Institute, eftec (2023), and various information collected as part of the stakeholder consultation. If no references are provided the presented information is common knowledge as described in the ECHA reports.

3.2.3.2 Production and downstream use of cobalt-containing alloys

Alloys represent today about 13% of the total global cobalt consumption (Cobalt Institute, 2022). Cobalt is rarely used as a structural material in the pure form but almost always as an alloy in combination with, nickel, chromium, and/or tungsten. Cobalt-nickel (Co-Ni) alloys are used in jet engines, jet turbines, gas turbines, chemical processing, petroleum refining, marine, electronics and other industrial applications where high-temperature strength and wear resistance is important and common stainless steels may not provide adequate performance. In the energy sector, cobalt alloys are used in steam turbines, power plant protective coatings and on wind turbine blades for renewable energy. The machining of the alloys may take place by specialised companies providing components to the sectors or within companies in the sectors. Exposure via inhalation would mainly take place by casting, machining, and welding of the alloys. Exposure may take place in multiple sectors.

In the dental and medical sectors, cobalt and cobalt alloys are used in dental alloys and implants (e.g. crowns and fillings), medical implants (e.g. stents, pacemakers), medical devices, and prosthetics (e.g. knee and hip replacements). Cobalt-chrome (Co-Cr) alloys are used in orthopaedic and dental implants due to their biocompatibility, high resistance to corrosion and wear resistance. For dental restorations, the supply chain has more steps: 1) Manufacturing of pre-sintered so-called CAD/CAM[16] blanks, which take place in relatively few companies in an industrial process, and 2) fabrication and finalization of dental restoration on the basis of the CAD/CAM blanks which take place in dental laboratories.

The final use of the implants in the dental and medical clinics is not considered to result in air exposure to cobalt.

[16] CAD/CAM refers to the computer software used for computer aided design (CAD) and computer aided manufacturing.

According to IARC (2006), production and use of cobalt alloys gives rise to occupational exposure to cobalt during the welding, grinding and sharpening processes, but the generic CSRs list a number of other Worker Contributing Scenarios.

3.2.3.3 Production of hardmetal tools and diamond tools

Tool materials represent today about 8% of the total global cobalt consumption (Cobalt Institute, 2022). Two overall types of cobalt-containing tools are produced: Hardmetal tools and diamond tools. They are used for different purposes.

Hardmetals (also known as cemented carbides) are materials made by 'cementing' hard tungsten monocarbide grains in a binder matrix of a tough cobalt or nickel alloy by liquid phase sintering. The production of hardmetal tools consists of several steps, the first being the formation of tungsten carbide from tungsten oxide and elementary carbon through carburization to form tungsten carbide powder. Secondly, mixing of tungsten carbide and cobalt powders is performed, followed by granulation. After granulation the material is pressed, pre-sintered (heated) and then machined into desired shapes. The pieces are finally sintered at 1400–1500°C. The products may afterwards be sand blasted and covered with a protective layer (Klasson *et al.* 2016). The sintered hardmetal parts are manufactured by relatively few manufactures and sold to downstream tool manufactures as so-called 'blanks'.

The addition of cobalt to the tungsten carbide increases resistance to wear, hardness and mechanical strength, required for cutting tools, machine tools, engine components and other industrial applications.

The hardmetal blanks are used by tool manufacturers to produce many types of machine tools. The hardmetal tools are used in almost all manufacturing industries and are used to sharpen, drill, cut or mill various components. The automotive, aerospace, energy and general engineering sectors all use hardmetals to facilitate the processing of steels, other metals, wood and composite materials. Also, mining, construction, oil and gas industries use high-performance hardmetal tools and applications for rock processing.

Hardmetal is recycled both as production scrap and post-consumer scrap.

Diamond tools are used to cut stone, marble, glass, concrete and other materials and to grind or polish various materials, including diamonds. The bonding material for cobalt-containing diamond tools differs from the hard-metal tools and are typically cupper-iron-cobalt (Cu–Fe–Co) alloys. The diamond tools are produced by powder metallurgy, whereby microdiamonds are imbedded in a matrix of compacted, extra-fine cobalt powder. The proportion of cobalt in bonded diamond tools is higher (up to 90%) than in hardmetal.

Exposure may take place through several steps of the production processes with the highest exposure levels in the manufacture of the hardmetal blanks.

3.2.3.4 Production of other hardmetal parts

Apart from the use in tools hardmetals are used for wear parts for many applications. The International Tungsten Industry Association lists on their web site the following applications: 'Cemented carbide wear parts are used in wire and section drawing, cold and hot rolling, stone-working, working of wood and plastics, in the textile, magnetic tape and paper industries, in the food and medical industries, the glass industry, for stamping and punch drawing (e.g. can making) and a large number of structural components, including plungers, boring bars, compacting dies and punches, high pressure dies and punches, seal rings, pulverizing hammers, needles, carbide feed rolls, chuck jaws, and others'. [17] The hardmetal is also used for other applications such as studs for winter tyres and pole tips.

The manufacture of the hardmetal blanks typically takes place by the same companies producing the hardmetal blanks for tools with similar exposure situations.

3.2.3.5 Service life of hardmetal tools and diamond tools

According to IARC (2006), during the use of hard-metal tools (e.g. in drilling, cutting, sawing), the levels of exposure to cobalt or hard-metal dust are much lower than those found during their manufacture. However, the grinding of stone and wood with hard-metal tools and the maintenance and sharpening of these tools may release cobalt into the air at significant concentrations.

The hardmetal tools are used in multiple sectors and no split by end-use sector has been obtained.

The usage of diamond tools can according to a leading manufacturer and a key supplier for the industry be divided into three major categories:

- Processing of natural stone, starting with the block extraction in the quarries and ending with polishing operations for the finished product and all production steps in between. Accounts for approximately 40% of the consumption.

- Construction industry where diamond tools are used for drilling and cutting of concrete, asphalt and other construction materials. Accounts for approximately 40% of the consumption.

- Industrial usage where metal bonded diamond tools are used for cutting and grinding of glass, ceramics and other hard abrasive materials. Accounts for approximately 20% of the consumption.

Exposure may take place by the application of the diamond tools as dust of the bonding material is generated by the use.

3.2.3.6 Production and use of magnetic alloys

Cobalt is used in the production of permanent magnets for a range of 'high tech' applications in the automotive and other sectors. Cobalt is ferromagnetic and is commonly alloyed with aluminium and nickel to produce magnets. Cobalt is used in soft metal magnets, hardmetal magnets (AlNiCo), samarium magnets (SMCo; rare earth magnets), and neodymium-iron-boron (Nd-Fe-B) magnets. The magnets are used for multiple applications e.g. in electric motors, guitar pickups, microphones, sensors, loudspeakers, medical instruments, generators, and actuators. The substances used are cobalt metal, tricobalt tetraoxide, and cobalt monoxide.

Exposure may take place by the manufacture of the magnets and handling of magnets.

3.2.3.7 Specialty steels

Cobalt is an alloying element of high-speed steels (HSS) for the manufacture of cutting tools when high strength at elevated temperature is required. Cobalt is used in both traditional tool

[17] https://www.itia.info/wear-parts.html

grades as well as in powder metallurgy grades at typical compositions ranging from 8% to 13% cobalt (Latunussa *et al.*, 2020). High speed steel is a type of steel that is designed to withstand the temperatures and stresses of high-speed applications such as saw blades and drill bits. High speed steel with cobalt tends to have superior hardness and heat resistance compared to other HSS.[18]

According to Eurofer (2021) over 80% of stainless steel contains more than 0.1% of cobalt. At low concentrations the content is mainly unintentional content e.g. originating from recycling of scrap.

High-strength steels are manufactured by intentionally adding cobalt to stainless-steel grades, with a typical concentration range between 0.1 and 0.6%. High-strength steels have niche applications, such as landing gear for aircraft, and make up a small percentage of the stainless-steel market. According to RPA (2020), Eurofer estimates that stainless steel grades with intentionally added cobalt make up around 1% of the stainless steel market.

Exposure may potentially take place by production of the steels or by processing the steels.

3.2.3.8 Welding, brazing, and thermal spraying

Cobalt alloys is used in welding, brazing and plasma and thermal spraying processes in industrial and professional settings. Various welding methods are used such as gas-shielded arc (MAG) and oxy-acetylene welding processes (Ferri *et al.*, 1994).

In these instances, exposure to fumes may be significant for workers via inhalation.

The hazard potential associated with welding processes is driven by the diversity of exposures to different contaminants which may either be contained in the welding objects or in the welding consumables. According to the German Technical Rules for welding work (TRGS, 528), monitoring of cobalt from welding work is prescribed only for welding of cobalt alloys.

3.2.3.9 Additive manufacturing (3D printing) in powder-bed processes

Cobalt chrome materials are used for additive manufacturing of medical implants with high wear and corrosion resistance and high temperature components in aerospace.

Exposure by inhalation may take place by manufacture and handling of the powders and by the printing process.

3.2.3.10 Manufacture of cobalt compounds

In the chemicals sector, cobalt substances are used as intermediates for producing cobalt or other cobalt-containing substances. This use contributes to the final cobalt-containing products, such as other inorganic cobalt compounds and organic cobalt carboxylates.

Exposure takes place by a number of activities such as raw material handling and final powder handling, wet and hot processes, etc.

A number of the cobalt substances are used for this application.

[18] Griggs Steel at: https://www.griggssteel.com/high-speed-cobalt/

3.2.3.11 Production and use of batteries

Batteries represent today about 57% of the total global cobalt consumption (Cobalt Institute, 2022). Cobalt dinitrate and cobalt sulphate are used as intermediates in the manufacture of re-chargeable batteries for the automotive market and for storage applications.

Three types of high-density batteries use cobalt (CoRC, 2022):

- Nickel-cadmium (Ni-Cd) batteries in standby and other industrial applications (e.g. railways, aviation, telecom, etc.);
- Nickel metal hydride (Ni-MH) batteries in hybrid electric vehicles and portable applications; and
- Lithium ion (Li-ion) batteries in telephones and computers, and the developing electric mobility market.

Different cobalt substances are used as chemical precursors for manufacture of battery cathode materials. Cobalt dinitrate and cobalt sulphate are transformed into cobalt hydroxide or tricobalt tetraoxide which are further used in the manufacture of cathodes for nickel-based batteries (and for lithium-ion batteries). The most popular lithium-ion technology to power portable electronic devices like phones, laptops and tablets is the lithium-cobalt oxide (LCO) battery which has a cathode composed of $LiCoO_2$. The majority of modern electric vehicles use these battery chemistries in lithium-nickel-manganese-cobalt-oxide (NMC) batteries which have a cathode containing 10-20% cobalt. Cobalt compounds are also used in the electrodes for nickel-based batteries (Ni-Cd and Ni-MH) in the form of chemical precursors for production of cobalt dihydroxide.

Cobalt substances used for the production of batteries are cobalt metal, cobalt monoxide, cobalt dihydroxide, tricobalt tetraoxide, lithium cobalt dioxide, cobalt sulphate, and cobalt dinitrate.

Inhalation exposure may take place during several activities in the production of battery cathode materials, production of batteries and recycling of batteries.

3.2.3.12 Production and use of catalysts

Catalysts represent today about 5% of the total global cobalt consumption (Cobalt Institute, 2022). Catalysts are added to chemical processes to increase the rate of chemical reaction. They are not used in the reaction and may continue to act repeatedly, which means that small amounts of catalyst can affect the speed of the reaction. Cobalt metal and cobalt compounds are used both as a catalyst and as an intermediate in the production of catalysts and catalyst precursors. Cobalt substances within the scope of this study are used in two main catalytic areas in the refinery and petrochemical sector:

- Hydro-treating and desulphurisation in refineries;
- Fischer Tropsch technique to convert carbon monoxide and hydrogen into liquid hydrocarbon fuels (GTL (gas to liquid) process).

Beside these uses of catalysts, some organic cobalt compounds are used as catalysts in the plastics and detergents sectors. As the organic compounds are outside the scope of the OEL, these applications are considered outside the scope of study. These concern:

- Cobalt di(acetate) (EC No 200-755-8) and possibly other organic cobalt compounds are used directly as oxidation catalyst for polyester precursors; isophthalic acid (IPA) and purified terephthalic acid (PTA) in the plastics sector (ECHA, 2018b).

- Cobalt carbonyl-based catalysts are used in the production of aldehydes from alkenes in the OXO reaction in plastics and detergents sectors (ECHA, 2018b).

- One company were using cobalt di(acetate) as an oxidation catalyst to produce bio-based intermediate chemicals from high oleic-content vegetable oils (ECHA, 2018b).

Cobalt-containing catalysts are also used in smaller applications such as steam reforming, benzoic acid production, fluorination of hydrocarbons, polymerisation of butadiene and oxidation of xylenes. For the GTL process, a number of emerging applications e.g. in Power-to-X and biogas to liquid fuels are under development but it is unclear to what extent these use cobalt.

Catalysts are porous materials that come in various shape and sizes. The catalysis typically takes place in a closed reactor packed with a series of catalyst layers.

Cobalt substances used for catalysts are (some used as intermediates): Cobalt metal, cobalt monoxide, cobalt dihydroxide, tricobalt tetraoxide, naphthenic acids cobalt salts, cobalt bis(2-ethylhexanoate), neodecanoic acid cobalt salt, cobalt(2+) propionate, cobalt di(acetate), cobalt sulphide, cobalt sulphate, and cobalt dinitrate.

Exposure may take place by the production of catalyst, loading and unloading the catalyst from the reactor, recycling and recovery of the catalysts.

3.2.3.13 Manufacture and use of pigments, frits and dyes

Cobalt and cobalt compounds are used to produce pigments and dyes. Cobalt-containing minerals have the ability to impart colour and are therefore used in pigments and dyes. The cobalt substances are used as a raw material in order to introduce the cobalt in the inorganic pigment or frit as a chemical use. The cobalt substances (and substances derived from these cobalt substances) are used to manufacture inorganic pigments/frits/ceramics/glass and may also be used in dyes or as a (de)colorant in textiles/ceramics/plastics.

According to the Frit Consortium (2023) the starting material for the manufacture of frits is tricobalt tetraoxide (EC No 215-157-2) which is outside the scope of the CMRD. The registration dossier for tricobalt tetraoxide indicates that some grades may have impurities of cobalt oxide, but according to the Frit Consortium only grades without impurities above 0.1% is today used for the manufacture of frits. According to the Frit Consortium, no cobalt substances within the scope of the CMRD are formed by the manufacture or use of the frits. However, one company have for the stakeholder consultation reported the use of cobalt oxide for frits.

A wide range of inorganic cobalt compounds are used for manufacture of pigments and as the final pigments. Pigments, within the scope of the CMRD, registered for various uses are olivine, cobalt silicate blue, cobalt titanite green spinel and reaction mass of cobalt olivine and crystalline silicon dioxide.

The main applications of the inorganic cobalt compounds in the scope of the CMRD for pigments, frits and dyes seems to be for glass and ceramics production. The final use in paints (see section 3.2.3.15) and textiles and are indicated as well in the registrations but such use has not been confirmed by the stakeholder consultation.

In the glass production, cobalt is added to give the glass a distinctive blue colour, but cobalt compounds are also used for decolouring of some specialty glasses (decolourising slightly coloured glass by adding a complementary colour) (Glass Alliance Europe, undated). The cobalt content of various glass types is: Clear glass (decolouriser use) (1-2 ppm CoO), light blue glass container glass (20 ppm CoO), dark blue glass container glass (160 ppm CoO), bronze tinted flat glass (25 ppm CoO), and dark grey tinted flat glass (80).

Exposure may take place by manufacturing the pigments, application of the pigments or colourants in glass and finally by application of mixtures containing the pigments.

3.2.3.14 Surface treatment

The surface treatment applications involve the conversion of the cobalt substances into other cobalt substances on the surface of a treated article. Cobalt sulphate and cobalt dinitrate are the most commonly used cobalt salts in the surface treatment sector, with some limited use of cobalt di(acetate). It is noted that cobalt carbonate and cobalt dichloride are not widely used due to difficulties with handing and issues of corrosion, respectively.

The two primary uses of cobalt substances within the surface treatment sector are:

- passivation or anti-corrosion treatments (e.g. conversion layers/coatings on automotive parts), and
- metal or metal-alloy plating, such as electroplating, electroforming, or electroless (autocatalytic) plating (e.g. technical/decorative cobalt-alloy plating).

Passivation. Cobalt salts are used in the generation of ‘conversion layers’ (also called passivation), typically on zinc- or zinc alloy-coated metallic products for corrosion protection. Conversion layers delay the initial attacks on the metallic protective layer made of zinc or zinc alloy. For this reason, they are used mainly for improving the corrosion resistance of zinc plated metal, leading to longer service life and operating time of metal components, particularly in the automotive industry. Cobalt(II) salts are added to the application solutions of Cr(III)-based conversion coatings, which are alternative surface treatments for the use of Cr(VI). In this process, the galvanized components are dipped in a treatment solution containing trivalent chromium compounds and a proportion of cobalt salts. The cobalt ions are integrated into the surface as oxides or as spinels. The addition of cobalt salts is necessary if corrosion protection is required in warm or hot environments (e.g. engine spaces, brakes, gearboxes and in electrical parts in housings, etc.).

Cobalt salts have important applications in the automotive, aerospace and defence sectors as well as in window construction.

Plating. Cobalt salts are used in metal or metal alloy plating (mainly gold-cobalt and tin-cobalt plating) to enhance hardness and wear resistance and/or for metal colouring (RAC/SEAC, 2020). Plating is a similar process to passivation but in this case electrical current is used to form the surface. Cobalt salts are added to solutions of other metals (e.g. nickel, tungsten, iron, molybdenum, chromium, zinc, and precious metals) to form alloys in electroplating. During the plating process, the cobalt substances are transformed into cobalt metal. For example, in gold-cobalt electroplating, gold and cobalt are formed and deposited concurrently, building a surface coating of gold alloy. These alloys have improved properties (e.g. hardness, wear resistance) compared to gold on its own.

Exposure may take place by the surface treatment and by contact with surface treated surfaces. Exposure may take place in multiple sectors.

3.2.3.15 Driers and pigments in paints

Organic cobalt compounds have been the most widely used primary drier metal for alkyd paints. Cobalt, in the form of organic compounds, is used in concentrations of approx. 0.06% and maximum 0.2% (based on the binder solid content) (Hansen *et al.*, 2015).

Inorganic cobalt substances registered for this use are cobalt, cobalt dihydroxide and cobalt monoxide. The use of other inorganic cobalt compounds is according to the available information negligible.

As shown in Table 3-10, it is estimated that in 2011-2013 500 tonnes/y of cobalt metal was used for this application while at the same time 1,600 tonnes/y of the organic cobalt carboxylates were used.

As part of the stakeholder consultation, information has been searched for confirm the use of the inorganic substances as driers in paint. No information has been obtained that confirm the use of inorganic cobalt compounds as driers, but according to the available information some manufacturers of paints may use inorganic cobalt compounds to in-house convert to organic compounds added as driers to the paint. This should explain the indicated use of inorganic cobalt compounds for this application.

Pigments, within the scope of the CMRD, registered for use in paints are olivine, cobalt silicate blue, cobalt titanite green spinel and reaction mass of cobalt olivine and crystalline silicon dioxide.

Exposure by inhalation may take place by the use of the compounds within the scope to produce organic compounds, whereas by the application of these paints, and later by dust-generating processing of the coatings (e.g. sanding), only exposure to organic cobalt compounds takes place.

3.2.3.16 Adhesion agent in rubber

Cobalt substances are used for production and industrial use as a rubber adhesion agent and in the handling of rubber products (tyres, conveyors, etc.) in industrial settings, as well as reuse of rubber tyres at End-of-Life in other settings. Cobalt carboxylates are used to promote adhesion between the rubber compound and the brass-plated steel cord in the manufacture of steel-cord-reinforced radial tyres.

Of the substances registered as used for this purpose, cobalt dihydroxide is the only inorganic cobalt compound used. As shown in Table 3-10, it is estimated that in 2011-2013 100 tonnes/y cobalt oxides was used for this application while at the same time 5,900 tonnes/y of the organic cobalt carboxylates were used. The available information indicates that cobalt dihydroxide is not used as rubber adhesion agent, but may be used by some companies to produce these agents.

3.2.3.17 Feed materials

Cobalt is an essential element for animals because a cobalt atom is present in each molecule of vitamin B12 (cobalamin).

According to ECHA (2018a), in 2016 in the EU around 200 tonnes/y was used for animal feed and 130 tonnes/y for biogas production.

According to an overview submitted by European Feed Manufacturers' Federation (FEFAC, 2017) the use of cobalt salts in the animal feed sector involves a number of processes which can be divided into five stages (in branched supply chains):

- 1) Manufacture of the cobalt salts; < 5 companies; Included under manufacture of cobalt compounds.
- 2) Manufacture of cobalt-containing preparations with a concentration of 2.5 to 10% of cobalt salts (i.e., 1-5% cobalt). The cobalt salts are mixed up with carriers, which can be either sorbitol or glycerol. The purpose is to reduce worker's exposure further down the supply chain. This operation is performed by specialised companies (no more than five in the EU). At this stage the starting material is cobalt salts in a powder form and the final diluted product is also in a powder form with concentrations of the cobalt salts at 2.5 to 10%, i.e. 1-5% cobalt. In the case of cobalt carbonate (which represents 90% of the use of cobalt salts in this sector), the formulation is followed by a coating step aimed at reducing workers' exposure at the following stages of the supply chain. The starting material is cobalt carbonate in powder form and the final product is a preparation of coated granulated cobalt carbonate at concentrations of 1-5% of cobalt. This operation is performed by three companies in the EU.
- 3) Manufacture of premixtures, 'dietetic feed' and 'mineral feed'. The cobalt-containing preparations are mixed up and diluted with other feed additives and carriers and incorporated into a premixture. The starting materials are the preparations of cobalt salts, either in powder form or as coated granulated cobalt carbonate, whereas the final product (i.e. the premixture), is usually in a powder form, sometimes in a liquid form, at concentrations between 0.005 and 0.75%, and more and more below 0.01%. These operations are performed by approximately 300 companies.
- 4) Manufacture of compound feed, i.e. either complete feed with concentrations of cobalt at 1 ppm (0.0001%) or complementary feed at levels not exceeding 100 ppm (0.01%). Certain dietetic feed may contain cobalt salts at levels above 100 ppm. Since the introduction of the authorisation requirements in 2014, cobalt-containing compound feed can only be placed on the market in non-powdered forms unless it contains coated granulated cobalt carbonate. These operations are performed by approximately 4,000 companies.
- 5) Professional use (farmers) of the final feed with a cobalt concentration 0.1 to 1 ppm in 'complete feed' and 1-10 ppm in 'complementary feed'. No data on numbers of companies.

The exposure levels for the different stages are reflecting the concentrations of cobalt in the input materials as further described in section 3.2.8.

Substances used are cobalt carbonate (major use), cobalt sulphate, and cobalt di(acetate).

Exposure may take place by all stages, but available data indicates that due to the low concentrations of cobalt in 'complete feed' and 'complementary feed', the exposure concentrations by the two latter stages are below the levels relevant for the assessed OELs (further discussed in section 3.3).

3.2.3.18 Use as essential element in biogas production, fermentation and others

Besides the presence of cobalt in vitamin B12 (cobalamin), cobalt has also been identified in many other enzymes that are essential for vital biochemical processes in plant and animal species, as well as micro-organisms. Therefore, cobalt substances have several applications in the biotechnology and health sectors, including:

- Fermentation and biotechnological processes;
- Health and medicines;
- Biogas production; and
- Fertilizer production

According to ECHA (2018a), in 2016 in the EU around 130 tonnes/y cobalt salts were used for biogas production while the consumption for fermentation, biotech processes, health and medicine sectors combined was estimated to be significantly less than 10 tonnes/year.

The biogas production takes place within several sectors. As an example, in Denmark 181 biogas facilities were distributed as follows[19]:

- 54% based on agricultural biproducts (Assumed sectors: 'C35.2 Manufacture of gas' for the large facilities; 'A01.4 Animal production' for the smaller reactors on farms);
- 27% based on waste water sludge ('37.00 Sewerage');
- 15% based on non-hazardous waste and landfill gas ('C38.21 Treatment and disposal of nonhazardous waste';
- 4% in industry (various sectors e.g. within the food industry).

Biogas production will therefore be assessed as a cross-sectoral activity in the same way as welding.

Cobalt salts are used in small amounts as a nutrient additive necessary for bacterial cell growth and reproduction in biogas production from energy crops. The cobalt salts in this sector are used either in pre-weighted bags (that are used without opening, i.e. thrown in large biomass reactors) or in small amounts.

Exposure may take place by all steps from manufacture of cobalt-containing preparations to the final use of the preparations, however the available data indicate that exposure at levels above the lowest of the assessed OELs mainly take place by the formulation of the mixtures used.

According to ECHA (2018b), Fertilisers Europe provided information to suggest that cobalt carbonate can be added to fertilisers as a micro-nutrient in the form of a chelate or a water-soluble complex involving ligands. The use for cobalt compounds for manufacture of fertiliser, however, is indicated in the CSR for cobalt dihydroxide and not indicated in the CSR for cobalt carbonate. According to ECHA (2018b), based on discussion with the Cobalt Institute, which had been in contact with the fertilisers industry and could not find any record of current use of any of the five cobalt salts in fertilisers in Europe. To the best of their knowledge there was no use of the five cobalt salts in either formulation or use of fertilisers at present. No use of the cobalt

[19] https://ens.dk/sites/ens.dk/files/Bioenergi/liste_over_biogasanlaeg_i_dk.pdf

compounds within the scope of this study has been identified through requests to Fertilizer Europe or the Cobalt Institute.

Substances reported to be used are cobalt dihydroxide, cobalt dichloride, cobalt di(acetate), cobalt sulphate, and cobalt dinitrate (CoRC, 2022).

3.2.3.19 Other applications

A number of niche applications of cobalt and inorganic cobalt compounds have been reported.

Processing aid in the production of polyamide powders

Cobalt metal is used as a processing aid in the production of polyamide powders for the cosmetic industry. According to the registration dossiers, formulation is the only step that takes place for this use. No information on volumes used has been available.

Manufacture of pharmaceuticals

Cobalt is used for production of pharmaceuticals for veterinary use where the addition of cobalt is used as nutrient in combination with the pharmaceutical active agents.

Oxygen scavengers

Cobalt sulphate, cobalt dichloride, cobalt dinitrate and cobalt carbonate are used as oxygen scavengers in water treatment applications, helping to prevent corrosion which might lead to failures of boiler systems. The volumes of cobalt used in these applications is reported to be in the range of 1-10 tonnes/y (ECHA, 2018a). According to eftec (2023), oxygen scavengers and corrosion inhibitors are used across various industries including food and beverage, pharmaceutical, oil and gas, electronics, and water treatment industries. Cobalt-catalysed oxygen scavengers are added to multi-layered PET bottles to maintain freshness and extend shelf life. Cobalt sulphate, cobalt carboxylates, cobalt dichloride, cobalt dinitrate and cobalt carbonate are used as oxygen scavengers in water treatment applications to remove dissolved oxygen from the water, which can cause rust and corrosion in pipes and other equipment. Additionally, the food and beverage, electronics, and pharmaceutical industry use oxygen scavengers to prolong shelf life by preventing oxidation. Similarly, the oil and gas industry use oxygen scavengers to protect pipelines, storage tanks, and other equipment from corrosion caused by oxygen exposure (eftec, 2023)

Humidity indicator cards

Cobalt dichloride is used as an indicator of humidity and moisture in the electronics industry, and in industrial and military applications. Humidity indicators can be supplied to the market in a number of formats (e.g. including plugs, cards and indicating silica gel sachets and canisters). ECHA (2018) report that <200 kg of cobalt dichloride is used globally in this sector. No other cobalt salt is in use for manufacturing the humidity indicator cards.

Laboratory reference standard and laboratory reagents

Cobalt compounds are used as laboratory reference standards e.g. in the nuclear energy sector. Furthermore, various cobalt compounds are used as laboratory reagents.

Niche applications in the electronics industry

Small amounts of cobalt are used in the electronics industry in the production of varistors, magnetic recording material, matched expansion alloys for use in optical and laser instruments and leads/connectors in semi-conductor applications. Most integrated circuits are likely to contain small amounts of cobalt which provides wear resistance and electrical resistivity. Even though the volume of cobalt used may be small, these electronic applications are used in a number of sectors such as automotive, computing, communications, and medical sector. Electronics are produced in multiple industries covering telecommunications, defence, consumer electronics, computing, industrial equipment and semi-conductors. Total consumption for electronic components has been estimated at <50 tonnes/y in 2011-13 (Table 3-10).

The substances used are cobalt monoxide, tricobalt tetraoxide, cobalt dihydroxide, and cobalt metal.

Fuel cells

Fuel cells is an emerging use of cobalt mentioned in many scientific reports. The information collected from the stakeholder consultation indicates that the use of cobalt for fuels cells is still at the R&D (Research & Development) stage.

3.2.4 Processes unintentionally generating cobalt and inorganic cobalt compounds

No application where substances outside the scope of the CMRD may lead to exposure to substances within the scope have been identified.

3.2.5 Recycling

According to a survey of the consultant eftec for the Cobalt Institute (eftec 2023): *"Recycling is a rapidly growing industry, being driven alongside the increase demand in cobalt-containing batteries and production in Europe (Council of the EU, 2022). As of 2021, about 22% of cobalt substances used in Europe are recycled (CIC energy GUNE, 2021), including from batteries, catalysts, superalloys, and hard metals."*

"Recycling of materials containing cobalt is carried out by utilising three processes: direct, pyrometallurgical and hydrometallurgical recycling:

- *Direct recycling starts by extracting cobalt substances without breaking down or changing their chemical structure.*
- *Pyrometallurgical recycling first involves smelting End-of-Life (EoL) materials (see Table 3.3 for list of materials recovered) before the cobalt can be leached. Metal recovery with an impurity management process is then performed and cobalt sulphates are removed.*
- *Hydrometallurgical recycling uses a different leaching process that does not require smelting. Cobalt sulphates are then removed and recovered. In some cases, materials containing cobalt that go through the pyrometallurgical smelting process can then be passed through the hydrometallurgical leaching process, depending on desired recovered materials".* (eftec 2023).

According to a report by Matos *et al.* (2020) from the Joint Research Centre (JRC), batteries for electric vehicles and superalloys are recycled in significant proportion at their end of life. However, batteries for consumer electronics, hard metals for metal tooling, and catalysts are collected and recycled in lower proportion at their end-of-life, because collection is less efficient. Pigments and other dissipative applications (e.g. chemicals for pharmaceuticals) are not recyclable. Magnets and metallic applications such as semi-conductors and printed circuit boards are not-functionally recycled (downcycled). As a result, a total amount of around 6,400 tonnes Co (considering also the amount exported) was functionally recycled in 2016 in the EU. Non-functional recycling, considered as losses, accounted for around 4,000 tonnes Co, mainly in the production of steel. The remainder of the cobalt-bearing scrap (about 11,000 tonnes Co) was disposed of and considered as addition to landfill. Nearly 60% of Co was collected. According to Matos *et al.* (2020) cobalt losses in waste, downcycling and net-export of recycled cobalt prevent the existence of more close-loop material flows in the EU, despite significant end-of-life recycling rates in some of the applications (e.g. superalloys).

According to eftec (2023) data were not available for estimating the volumes recycled in the EU27 in 2023. Annual volumes recovered by respondents to the eftec (2023) survey was 5,400 tonnes in 31,550 tonnes material recycled. The recycled materials were magnets, hardmetal scraps, lithium-ion batteries, catalysts and 'black mass' (crushed and shredded end-of-life battery cells).

3.2.6 Presence of cobalt and inorganic cobalt compounds as impurity

In addition to the intentional uses of cobalt and cobalt compounds, cobalt as an element will be pre-sent at trace levels in most media. For other substances (e.g. arsenic and asbestos) some identified relevant processes have been mining (of ores for which the substances are not specifically extracted), tunnel excavation, stone grinding or sand blasting. A screening of the literature has not identified any significant exposure to cobalt present as impurity apart from those mining processes where cobalt-containing ores are extracted which are included under primary production of cobalt.

Stainless steel alloys have traditionally contained 0.05-0.40% cobalt. Since cobalt (Co) is an unintentional impurity when mining nickel, nickel-rich stainless steel grades have contained small amounts of cobalt (Wang *et al.*, 2022). According to Eurofer (2021) over 80% of stainless steel contains more than 0.1% of cobalt. In response to the requirements of the Medical Devices Regulation to indicate the presence of cobalt as a potential carcinogenic, mutagenic, reproductive toxin substance if present in the steel at more than 0.1%, many manufacturers have introduced low-cobalt steel to the medical devices market (e.g. [20]). The presence of cobalt as impurity in stainless steel may result in exposure to cobalt at low concentrations by welding and similar processes.

It is considered that the total occupational exposure to cobalt as trace element in other applications will be insignificant and this exposure is not further assessed.

3.2.7 Overview of sectors

3.2.7.1 Sources of information about sectors using cobalt and inorganic cobalt compounds

The information on sectors with exposure to cobalt and cobalt has been taken from the following sources:

- The background report to the RAC opinion (ECHA, 2022) and the ECHA (2018a) restriction proposal for five cobalt salts;
- Consultation survey responses;

[20] https://www.carpentertechnology.com/blog/low-cobalt-stainless-steel-alloys-for-compliant-medical-devices

- Surveys submitted by the Cobalt Institute (eftec, 2019; 2023);
- CSRs submitted by the Cobalt Institute;
- Finnish ASA database (ASA, 2014);
- Italian SIREP database (Scarselli *et al.* 2020);
- CAREX Canada for the occupation and number of workers (CAREX, 2021);
- The French SUMER/COLCHIC databases.

3.2.7.2 Summary of sector data sources

A gross list of identified sectors with potential risk of exposure to cobalt and inorganic cobalt compounds is shown in Table 3-11. For most of the data sources, sectors are not specifically indicated by use of NACE codes but application areas are described. The most relevant sectors have been derived as part of the current study. It is in the table indicated if data on exposed workforce (W) or exposure concentrations (E) are available. In many of the data sources (e.g. ECHA, 2018a, ECHA, 2022 and eftec, 2023) the data on workforce or exposure levels are not provided by sector, but by aggregated use areas e.g. 'use in metallurgical alloys' or 'Use in fermentation, fertilizers, biotech, scientific research, and standard analysis'. The interpretation of data on exposure concentrations and exposed workforce in terms of sectors are provided in section 3.3. and 3.4. and the table below provides only a first rough overview.

Table 3-11 Gross list of identified sectors with potential risk of exposure to cobalt and inorganic cobalt compounds

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
A01.20	Animal production	M				E					X
B07.29	Mining of other non-ferrous metal ores								W		X
C10.91	Manufacture of pre-pared feeds for farm animals	W, E	M		W, E	E				E	X
C13.30	Finishing of textiles		M								
C15.11	Tanning and dressing of leather; dressing and dyeing of fur		M								
C16	Manufacture of wood and of products of wood and cork						W		W		
C17.12	Manufacture of paper and paperboard		M								
C19.20	Manufacture of refined petroleum products [catalysts]	W, E	E	W, E	W, E	E					X
C20.12	Manufacture of dyes and pigments	W, E	E	W, E	W, E	E					X
C20.13	Manufacture of other inorganic basic chemi-cals	W, E	E	W, E	W, E	E	W	W, E			X
C20.14	Manufacture of other organic basic chemicals	W, E	E	W, E	W, E	E		W, E			X

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
C20.15	Manufacture of fertilis-ers and nitrogen com-pounds	M		M		E					
C20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics [incl. frits]		M	W, E	W, E	E					X
C20.59	Manufacture of other chemical products n.e.c. [incl. catalysts]	M	E	W, E	W, E	E		W, E			X
C21.10	Manufacture of phar-maceutical products			W, E	W, E	E	W	W, E			X
C21.20	Manufacture of phar-maceutical prepara-tions	M						W, E			
C22.11	Manufacture of rubber tyres and tubes; re-treading and rebuilding of rubber tyres		E		W, E	E					X
C22.19	Manufacture of other rubber products		E		W, E	E					
C22.2	Manufacture of plastics products	W, E	M								
C23.1	Manufacture of glass and glass products		E		W, E	E					X
C23.4	Manufacture of other porcelain and ceramic products		E			E					X

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
C23.7	Cutting, shaping and finishing of stone										X
C24.10	Manufacture of basic iron and steel and of ferro-alloys		E	W, E	W, E	E	W				X
C24.45	Other non-ferrous metal production		E	W, E	W, E	E					X
C25.5	Forging, pressing, stamping and roll-forming of metal; pow-der metallurgy					E			W		X
C25.61	Treatment and coating of metals	W, E	E	W, E	W, E	E		W, E		E	X
C25.62	Machining [incl. service life of hardmetal tools]					E				E	X
C25.73	Manufacture of tools		E	W, E	W, E	E		W, E			X
C25.99	Manufacture of other fabricated metal prod-ucts [incl. additive manufacturing]				W, E	E		W, E			X
C26.1	Manufacture of elec-tronic components and boards		E	W, E	W, E						X
C26.51	Manufacture of instru-ments and appliances for measuring, testing and navigation [incl.	W, E	E		W, E	E					X

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
	humidity indicator cards]										
C26.80	Manufacture of mag-netic and optical media			W							X
C27	Manufacture of electri-cal equipment			W		E				W	X
C27.20	Manufacture of batter-ies and accumulators	W, E	E	W, E		E					X
C28	Manufacture of ma-chinery and equipment n.e.c.						W		W	W	X
C28.11	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines		M		W, E						X
C29	Manufacture of motor vehicles, trailers and semi-trailers			W, E					W		X
C30	Manufacture of other transport equipment								W		X
C30.30	Manufacture of air and spacecraft and related machinery		M		W, E						X
32.12	Manufacture of jewel-lery and related arti-cles		M		W						X
C32.50	Manufacture of medical and dental instruments and supplies		E	W, E		E		W, E	W	E	X

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
E36	Water collection, treat-ment and supply						W			W	
E38.12	Collection of hazardous waste						W				X
E38.21	Treatment and disposal of non-hazardous waste									W	X
E38.22	Treatment and disposal of hazardous waste										X
E38.32	Recovery of sorted ma-terials				W, E	E					X
F41	Construction of build-ings					E					X
F42	Civil engineering										X
F43.34	Painting and glazing					E	W				
F45.2	Maintenance and repair of motor vehicles								W		
M71.20	Technical testing and analysis	W	E		W, E	E	W	W, E			
M72	Scientific research and development	W	E		W, E	E	W	W, E		W	X
N	Administrative and support service activi-ties						W				
O84	Public administration and national defence						W				
P	Education						W				

Sector (NACE Code)	NACE description	ECHA, 2018a	ECHA, 2022	Stake-holder survey	Cobalt Institute surveys and web-site	CSR reports	ASA	SIREP	Carex Canada	SUMER/ COLCHIC	Derived from sup-ply chain infor-mation
Q86.23	Dental practice activi-ties								W		
	Biogas	W, E	E		W, E	E					X
	Welding, brazing					E				E	X

Consultation responses include response received by the questionnaire survey. W = number of workers, E = exposure concentrations, M = mentioned. M is only indicated for sectors where number of workers or exposure concentrations are not indicated. X = not mentioned but derived as part of this study from supply chain information i.e. infor-mation on downstream application and waste disposal. Information in hard brackets [] are comments from the authors on relevant products.

3.2.7.3 Criteria for selection of sectors for further analysis

Cobalt is used for numerous applications in a wide range of sectors. In order to allocate the used resources on sectors, where demonstrated exposure to cobalt in concentrations relevant for the reference OELs takes place, a number of applications/sectors have been excluded from the further analysis. The criteria for exclusion are as follows:

- The available data indicates that the P95 of the exposure concentrations is below the lowest assessed OEL as the assessment would indicate no impact.
- The available data indicates that the application may not take place today or the application area is small as compared to other areas.
- For cross-sectoral applications, some sectors with limited use may be excluded and the estimated number of workers exposed are allocated to the main sectors for the application.

It should be noted that dermal and hand-to-mouth exposure may take place in more down-stream sectors which may for example result in contact dermatitis.

3.2.7.4 Uses or sectors excluded from analysis

The following applications/sectors have been excluded from the detailed assessment for the reasons listed in the table below.

Table 3-12 Uses and sectors excluded from detailed analysis

Use or sector	Source of information on use or sector	Reasons for exclusion
A01.20 Use of animal feeds	Contact dermatitis has been reported for the use of animal feeds with cobalt (Ratcliffe and English, 1997)	According to ECHA (2018b) '*Under the conditions of use described, the Dossier Submitter understands that exposure levels arising from the industrial and/or professional use of feed grade formulations may be significantly low (well below 0.01 µg Co/m^3)*.' None of the national databases indicates exposure to workers in agriculture.
B08.11 Quarrying of ornamental and building stone, limestone, gypsum, chalk and slate	May use diamond tools for cutting stone	No data on exposure levels for use of diamond tools in quarrying of natural stone have been identified, but as the activities primarily take place outdoors, the exposure levels are expected to be low compared to exposure by use of the diamond tools for cutting natural stone in industrial or professional setting. All use of diamond tools for cutting natural stone has been allocated to C23.7 'cutting shaping and finishing of stone' where the main exposure is expected to take place.
C13.30; C15.11; C17.12 Use of pigments/dyes in textiles, fur articles, leather, wood and cork	Listed together with other uses of pigments in generic CSR for cobalt and some cobalt compounds	The available information indicates that the use of compounds within the scope for pigments/dyes in textiles, fur articles, leather, wood and cork is very limited (if any). The study focuses on the possible use of pigments and dyes for paint and varnishes, plastics, glass and ceramics.
C16 Manufacture of wood and of products of wood and cork	ASA (2014) and CAREX (2021)	Concern likely the sharpening of tools in the wood industry. Sharpening activities are all included under 'Machining' but may in fact take place within multiple sectors.

Use or sector	Source of information on use or sector	Reasons for exclusion
C20.16 Use as catalyst in manufacture of plastics in primary forms	Restriction report five cobalt salts (ECHA, 2018b)	Available information indicates that only cobalt di(carbonate) and other organic cobalt substances are used for the application.
C20.15 Manufacture of fertilisers	Restriction report five cobalt salts (ECHA, 2018b); information from industry	According to ECHA (2018b) based on discussion with the Cobalt Institute, the Institute have been in contact with the fertilisers industry and could not find any record of current use of any of the five cobalt salts in fertilisers in Europe. To the best of their knowledge there was no use of the five cobalt salts in either formulation or use of fertilisers at present. Fertilizer Europe has not responded to requests on data on the use of cobalt compounds in the production of fertiliser. For the current study no use in fertilisers has been identified by CoRC. Use of catalysts for production of fertilisers has been described in the literature but no confirmation on this use has been obtained. It cannot be excluded that some use of cobalt compounds for fertilisers take place, but the potential impact of establishing an OEL is considered very small compared to other sectors.
C22.19 Manufacture of other rubber products	Generic CSRs for cobalt compounds	Organic cobalt compounds are used for manufacture of tyres (in C22.11) and reinforced conveyer belts (in this sector). Available data suggest that inorganic compounds in some companies producing tyres in-house is converted to organic compounds. No information indicating this should be the case for manufacture of other rubber products has been available.
C24.45 Other non-ferrous metal production Subsector: copper production	Stakeholder survey	One company in the copper sector with two sites has reported exposure concentrations below those relevant for the assessed policy options. It cannot be excluded that some companies in the copper sector could be impacted by implementation of the lowest of the policy options.
C28; C29; C30 Service life of cobalt-containing magnets and varistors	Generic CSR for cobalt	The Worker Contributing Scenarios concern various activities considered to be included under production of magnets and production of electronic components. The exposure by application of the magnets and varistors for manufacturing of electrical and electronic devises is considered negligible.
C32.12 Jewellery	Input to ECHA stakeholder consultation (Francéclat *et al.*, 2022)	According to an input to the ECHA OEL stakeholder consultation from four organisations in the French jewellery sector (Francéclat *et al.*, 2022), cobalt salts are used in the watchmaking and jewellery sectors in surface treatment processes for the deposition of metal alloys. The processes are either subcontracted to companies specialising in electroplating or, in the case of the largest companies, performed by the jewellery and watch-part manufacturers themselves in-house. In a measurements campaign covering three companies in 2018, the exposure concentration of all samples was below 0.23 µg Co/m^3 for the inhalable fraction. The impact of establishing an OEL at the level of the assessed policy options is for those companies undertaking the activities in-house therefore considered insignificant.

Use or sector	Source of information on use or sector	Reasons for exclusion
		Hardmetal are used in some watches but the sintering of the hardmetals is done within the sector of manufacturing of tools. The European Federation of Jewellery has been contacted as part of the stakeholder consultation for this study, but no data has been provided from the federation or companies within the sector. Subcontracted activities are covered by the sector 'C25.61 Surface treatment of metals'.
E38.22 Treatment and disposal of hazardous waste	Not listed in any of the data sources but derived from the knowledge on the supply chain.	No data indicating exposure at relevant exposure levels have been identified.
F41,42 Construction	Not listed in any of the data sources but derived on the knowledge on the supply chain.	Main exposure to cobalt compounds within the scope in the construction industry is assumed to take place by cutting and drilling of concrete, asphalt and other construction materials with diamond tools. Available data indicates that the exposure levels would be below the assessed policy options. Data on possible exposure to naturally occurring cobalt e.g. by tunnelling work has been searched but no data has been identified.
F43 Specialised construction activities	Listed in the dataset from the Finnish ASA register (ASA 2014).	The Finnish ASA national databases include information on exposure to cobalt sulphate and cobalt dichloride by specialised construction activities but just indicate that the concentration is below the Finnish OEL of 20 µg/m^3. Not clear what is covers, could be demolition, not indicated elsewhere.
F43.34 Painting and glazing	CSRs for cobalt oxide	According to available information, only organic cobalt compounds are used in paints. Cobalt oxide may be used in-house by paint manufacturers to convert to the organic compounds used in the paint.
F45.2 Maintenance and repair of motor vehicles	CAREX Canada	Not indicated by other sources and no evidence for exposure by inhalation has been identified.
M72 Scientific Research & Development.	Small quantities of cobalt and inorganic cobalt compounds may be used in Scientific Research & Development and this sector is listed in the dataset from the Finnish ASA register (ASA, 2014).	Besides the small quantities used, it is considered that inhalation exposure is adequately controlled and that the contribution to total cobalt exposure from these activities are insignificant. Stakeholder input from R&D in the automotive industry confirm low concentrations below the lowest policy option.
M71.20 Laboratories	Italian SIREP database (Scarcelli *et al.*, 2020)	Mentioned under companies with exposed workers by Scarletti *et al.* (2020), but no data on exposure levels are provided. Exposure may take place when sampling or by use of analytical standards with cobalt. No data on exposure have been available. The exposure levels are expected to be low and exposure within this sector has been excluded from previous OEL studies except for asbestos (which is a special situation with sampling in air with high concentrations).

Use or sector	Source of information on use or sector	Reasons for exclusion
		Laboratory staff in the companies which e.g. take samples for monitoring material quality is included under the relevant sectors. Dental laboratories are included under C32.50 Medical and dental devices.
N Administrative and support services for business	Listed in the dataset from the Finnish ASA register (ASA 2014).	Not clear what it covers but could be some inspection and enforcement activities. Considered that exposure levels would be lower than the assessed policy options.
O84 Public administration and defence	Listed in the dataset from the Finnish ASA register (ASA 2014)	Assumed to be activities within defence similar to the activities included in other sectors such as in the aviation and aerospace sector.
Q86.23 Dental practice activities	Not specifically indicated, but dental technicians are indicated in various sources	Dental implants could in principle be produced in some dental practices, but the available information indicates that production of medical and dental implants would predominantly take place within sector C32.50 - Manufacture of medical and dental instruments and supplies.
Multiple sectors Fuel cells	Various research projects described on websites of research institutions	Use of cobalt in fuel cells seems to take place at R&D level and is not mentioned in the registrations or generic CSRs.
Multiple sectors Use of water treatment chemicals	ECHA (2018b). Generic CRS for cobalt carbonate	The generic CSR for cobalt carbonate indicates for the exposure scenario for use of water treatment chemicals, oxygen scavengers, and corrosion inhibitors a measured P90 concentration of 0.3 µg/m³ i.e. no impact of introduction of the assessed policy options are expected. The formulation of water treatment chemicals is included in sector on manufacture of other inorganic basic chemicals.
Multiple sectors Service life of cobalt-containing batteries	Generic CSR for cobalt	The generic CSRs estimate the P90 concentrations in both industrial and professional settings to be 0.001 µg/m³.
Multiple sectors Handling of tyres in industrial settings (activity within sector).	Generic CSR for cobalt	The generic CSRs for cobalt and cobalt dihydroxide estimate the P90 exposure concentrations at 0.001 µg/m³.
Multiple sectors Manufacture, service life and repair of electronic devices	Generic CSR for cobalt	Cobalt is used in certain electronic components. In the final components, the cobalt is sealed and occupational exposure by e.g. assembly of electronic devices and replacement of components is considered insignificant as long as the components are intact. The manufacture of cobalt-containing electronic components and recycling of electronic devices are included in the analysis.
Multiple sectors Service life of articles with cobalt alloys	Generic CSR for cobalt	Occupation exposure to cobalt in cobalt alloys is expected to take place by manufacturing processes (casting, cutting, welding, grinding, etc.) whereas inhalation exposure by use of the final articles is likely insignificant. The generic CSR for cobalt includes an Exposure Scenario for 'Service life of cobalt-containing alloys, steels and tools in industrial settings' but the Worker Contributing Scenarios concern various industrial processes and not handling of

Use or sector	Source of information on use or sector	Reasons for exclusion
		the final articles. Some exposure may take place by repair of articles (e.g. by welding) but this is assumed to be included in the analysis of welding and other processes.
Multiple sectors Service life of surface treated articles	Generic CSR for cobalt carbonate	Dermal exposure may take place when handling surface treated articles, but inhalation exposure by the use of surface treated articles is here assumed to be negligible except for extensive handling of surface treated articles in companies producing such articles. The CSR for cobalt carbonate includes an exposure scenario for industrial handling of surface treated articles (passivated/plated) but indicate the market sector as 'Use in surface treatment'.
Multiple sectors Use of humidity indicator cards	Generic CSR for cobalt dichloride	The measured P90 exposure concentration of cobalt dichloride by use of humidity indicator cards is indicated to be 0.002 µg/m³. The manufacture of humidity indicator cards is included in sector C26.51.

3.2.7.5 Sectors taken forward for analysis

The sectors taken forward for analysis are outlined in Table 3-13.

The list consists of 27 sectors or groups of sectors and two cross-sectoral activities. For comparison, the socioeconomic assessment undertaken for the Cobalt Institute has divided the analysis on 25 application areas of which a number are cross-sectoral (include organic cobalt compounds as well).

Table 3-13 Analysed sectors with risk of exposure to cobalt and inorganic cobalt compounds

NACE code	Short name for sector	NACE description	Uses / processes
C10.91	Manufacture, feeds	Manufacture of prepared feeds for farm animals	Manufacture of prepared feeds for farm animals
C19.20	Petrochemical, catalyst	Manufacture of refined petroleum products	Service life of catalysts in oil refining
C20.12	Manufacture of dyes and pigments	Manufacture of dyes and pigments	Manufacture of dyes and pigments
C20.13-20.14	Manufacture of basic chemicals	Manufacture of other inorganic basic chemicals; Manufacture of other organic basic chemicals	Manufacture of other inorganic cobalt compounds Production of polyamide powder for cosmetics Manufacture of driers/paints Manufacture of formulations for surface treatment Manufacture of cobalt carboxylates and resinates (intermediate use)
C20.30	Manufacture of paints and inks	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	In-house manufacture of organic cobalt driers
C20.59	Catalysts	Manufacture of other chemical products n.e.c.	Production of catalysts; use of cobalt as an intermediate in the manufacture of catalysts

NACE code	Short name for sector	NACE description	Uses / processes
C20.59	Formulation	Manufacture of other chemical products n.e.c.	Manufacture and use of aqueous mixtures for local metallization of cobalt and cobalt alloys Formulation of water treatment chemicals Formulation of products for biogas production Formulation of products for biotechnology
C21.20	Pharmaceuticals	Manufacture of pharmaceutical preparations	Manufacture of veterinary preparations with cobalt
C22.11	Production of tyres	Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	In-house manufacture of organic cobalt adhesion agents
C23.1	Glass	Manufacture of glass and glass products	Use of pigments and decolouriser in glass
C23.4	Ceramics	Manufacture of other porcelain and ceramic products	Use of pigments in ceramics industry
C23.7	Cutting stone	Cutting, shaping and finishing of stone	Service life of diamond tools
C24.10	Steel	Manufacture of basic iron and steel and of ferro-alloys	Production of cobalt alloyed steels
C24.45	Manufacture of cobalt and cobalt alloys	Other non-ferrous metal production	Production of primary cobalt metal Recovery of slags, matte, slimes and sludges from non-ferrous metal production Production of cobalt alloys powder
C25.5	Powder metallurgy	Forging, pressing, stamping and roll-forming of metal; powder metallurgy	Production of sintered articles not covered elsewhere
C25.61	Surface treatment of metals	Treatment and coating of metals	Plating and passivation (surface treatment) Thermal spraying Painting metal (non-metallic surface treatment)
C25.62	Machining	Machining	Service life of hardmetal tools and diamond tools
C25.73	Manufacture of tools	Manufacture of tools	Production of hardmetal tools and diamond tools
C25.99	Manufacture of other fabricated metal products n.e.c.	Manufacture of other fabricated metal products n.e.c.	Use of cobalt metal in additive manufacturing (3D-printing) Production of magnets Use of cobalt-containing alloys for sandblasting in industrial setting Industrial use of cobalt-containing mixtures in brazing technique
C26.1	Production of electronic components and boards	Manufacture of electronic components and boards	Production of varistors and other electronic components Production of printed circuit boards
C26.51	Humidity indicator cards	Manufacture of instruments and appliances for measuring, testing and navigation	Production of humidity indicators

NACE code	Short name for sector	NACE description	Uses / processes
C27.2	Batteries	Manufacture of batteries and accumulators	Production of batteries
C28.11	Engines and turbines	Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	Use of cobalt alloys (thermal spraying, welding, machining, etc.)
C29.10-30	Automotive	Manufacture of motor vehicles, trailers and semi-trailers; Manufacture of other transport equipment	Plating and passivation (surface treatment) Service life of hardmetal tools
C30.30	Air and spacecraft	Manufacture of air and spacecraft and related machinery	Use of cobalt alloys (thermal spraying, welding, machining, etc.)
C32.50	Medical and dental devices	Manufacture of medical and dental instruments and supplies	Production of medical and dental implants and restorations
E38.32	Metal recovery	Recovery of sorted materials	Manufacture of secondary cobalt metal Recycling of hardmetal scrap Recycling of batteries Recycling of catalysts Recycling of electrical and electronic waste (WEEE)
	Cross-sectoral activities	Biogas	Nutrient in biogas production
	Cross-sectoral activities	Welding	Welding of cobalt alloys (various sectors)

3.2.8 Summary

Cobalt has a number of applications as metal and inorganic compounds.

The main applications of cobalt metal are in hard metal and diamond tools, cobalt alloys, magnets, electronic components and surface treatment such as thermal spraying. Exposure may take place in upstream production processes by production of the cobalt metal, cobalt alloys and steel alloys, and in downstream production processes which include production of hardmetal and diamond tools, production of magnets and electronic components, production of medical and dental devices, production of turbines and engines, production of aircraft and spacecraft, and welding of cobalt alloys. Occupational exposure by inhalation in the use phase is insignificant for most applications with the exception of sharpening of hardmetal tools and the service life of diamond tools. For tools and cobalt alloys, cobalt metal is used in many sectors, and data have not been available for an exact split of the uses on sectors. For cross-sectoral downstream applications, some subsectors with limited use are consequently excluded and the estimated number of workers exposed and the number of companies are allocated to the main sectors for the application area. As an example, sharpening of hardmetal tools may to some extent take place in many subsectors within the metal sectors C25-C28, but this activity is in the analysis allocated to the sector C25.62 ‘Machining’ which is considered to include those companies specialised in this activity.

The main applications of inorganic cobalt compounds are batteries, catalysts, surface treatment, pigments, production of organic cobalt compounds, and as essential elements in feed materials, veterinary agents, biogas production and fermentation. Occupational exposure takes place by upstream processes such as production of cobalt chemicals, battery precursors, catalyst, pigments, preparations for surface treatment, oxygen scavengers and biogas production, and by downstream processes in the production of batteries, ceramics, glass, petrochemicals, electronic components, humidity indicator cards, feed material and biogas production. The occupational exposure by the service life of e.g. batteries, ceramics and glass articles is insignificant.

Some occupational exposure take place by recovery of cobalt from waste. Cobalt is recovered first of all from scrap of hardmetals and cobalt alloys and from batteries.

In total, 27 sectors and 2 cross-sectoral activities are analysed. Furthermore, 32 sectors or cross-sectoral activities, indicated in national databases, CSRs and the literature have been screened and excluded from the detailed assessment. The main factors considered in the exclusion of sectors from the analysis was that the available data indicates that the 95 percentile (P95) of the exposure concentrations is below the lowest assessed OEL as the assessment would indicate no impact, or that the available data indicates that the application may not take place today. In addition, for some cross-sectoral downstream applications, some sectors with limited use are excluded and the estimated number of workers exposed, and number of companies are allocated to the main sectors for the application. This approach does not affect the overall costs and benefits but introduces some uncertainties in the distribution of the impacts between sectors.

3.3 Exposure concentration

3.3.1 Data sources

Data about workers exposed to cobalt and its inorganic compounds and the associated exposure levels are usually available as a total cobalt (Co) concentration, which does not indicate whether the cobalt originated from substances within the scope of this study or organic cobalt substances. However, most processes where more than one cobalt compound is used would apply either inorganic compounds or organic compounds, respectively. In all processes where cobalt metal or inorganic cobalt compounds within the scope of the study are used, the entire concentration of cobalt is considered to be within the scope of the study.

The following data sources has been used:

- Exposure data from national databases (section 3.3.3)
- Exposure data from the Chemical Safety Reports of REACH registrations (further described in section 3.3.1.1)
- Exposure data collected by the Cobalt REACH Consortium for update of registration data (further described in section 3.3.1.2)
- Exposure data from the stakeholder survey (further described in section 3.3.1.3)
- Exposure data from the literature

The section starts out with a description of the ratios of inhalable to respirable fraction which is later used for estimating exposure concentrations for the respirable fraction.

3.3.1.1 Use of data from Chemical Safety Reports

Data on exposure concentrations and risk management measures have been extracted from publicly available CSRs, Sections 9 & 10, on environmental and occupational exposure. The data are from generic CSRs prepared by the Cobalt REACH Consortium. The CRSs have been updated in 2021. Such generic CSRs have been developed to provide information on uses and use conditions to registrants and to communicate to downstream users in sector-specific terminology. The data in the generic CSRs are considered to represent typical use conditions for the various exposure scenarios. In this section, selected information of the main Risk Management Measures (RMMs) of importance for the occupational exposure by inhalation is presented whereas more information on current RMMs is extracted for the costs assessment in section 7.2. The numbering of the Worker Contributing Scenarios (WCS) is the numbering used in the CSRs. The first numbers are in the CSRs used for Environmental Contribution Scenarios.

For each WCS, the following information is presented:

- Process categories (PROCs) involved. For many of the WCS, data are aggregated for more than one PROC.
- Technical RMMs which include information on containment and ventilation which is of importance for understanding the conditions as regards exposure by inhalation. For ventilation, the efficiency provided represent the effectiveness with regard to reducing exposure by inhalation. A '-' indicates that no containment or ventilation is indicated. The CSRs may include other information on the technical and organisational conditions e.g. that the work takes place outdoors, but these conditions are not summarised here.
- Respiratory protective equipment (RPE). The CSRs indicate the use of RPE at two levels
    - Respiratory protective equipment (RPE) is required: e.g. RPE with minimum APF = 10.
    - RPE may be used. In this case the CSRs use the following description: '*Respiratory protective equipment (RPE) as precautionary measure: RPE protecting from local effects via inhalation. Due to potential adverse effects of the substance to the respiratory tract, RPE (minimum assigned protection factor of 10) is prescribed on a precautionary basis for all workplaces unless inhalation exposure to the substance can be excluded*.' In these cases, an * is indicated after the indicated minimum assigned protection factor (APF)[21].
    - Max duration and shifts per year. A '-' indicates that no information about max duration or shifts per year is provided. If a column with shifts per year is missing, no data are provided in the CSR.
- Exposure concentration expressed as the P90 8h-TWA in µg Co/m³ for the inhalable fraction. The duration of the exposure has been taking into account when deriving the 8h-TWA. The data may either be based on measurements (typically based on monitoring data from several companies) or estimated using an occupational exposure assessment tool for metals, MEASE 1.02.01. The provided P90 values are adjusted for the use of RPE, but it is not specifically indicated which protection factors has been applied. If newer exposure data, considered to be representative for the sector, are available they are in general preferably used for developing the exposure concentration distributions used for the further analysis.

3.3.1.2 Use of data collected by the Cobalt REACH Consortium

EBRC Consulting has in 2023 for the Cobalt REACH Consortium (CoRC) collected and processed exposure data from member companies for use in an update of the CSRs for the substances covered by the consortium (EBRC, 2023). The whole dataset of quality screened exposure values consists

[21] The Assigned Protection Factor (APF) of a respirator reflects the level of protection that a properly functioning respirator would be expected to provide to a population of trained users. The APF is in general lower than the Nominal Protection Factor determined in a laboratory situation.

of 3,342 measurements of the inhalable fraction from 1995-2022 and 471 measurements of respirable fraction from 2015-2022.

The dataset obtained include inhalable data only. EBRC Consulting consider the respirable data to be less representative and more uncertain and has not submitted these.

The dataset is an extended and updated version of the dataset presented in appendix 3 to Annex 1 to the RAC opinion (ECHA, 2022).

EBRC Consulting applies statistical methods to derive estimates of statistics parameters under the assumption that exposure data are lognormal distributed and consider the exposure distribution, sample size and confidence levels in the estimates. All data are from personal sampling. The collected data are considered as representing the companies in the sectors covered across Europe.

The data are organised into sectors on the basis of similar exposure groups (SEG) where data from similar expose situations have been aggregated across sectors where it is considered that exposures could be similar. The data indicated for each sector may thus not have been measured within the specific sectors but are aggregated across sectors and similar data may be reported for more than one sector.

The dataset aggregates data over a period of time and do not represent the newest data collected by the CoRC and do not reflect the decreases in exposure concentrations in recent years. As there might be a tendency of more data reported from larger companies and from companies in Western and Northern Europe it is considered that including the older data may compensate for a possible bias in the dataset toward the better performing companies.

The dataset without adjustment for the use of RPE and duration is presented in Annex C. In the tables within this section, the concentrations are adjusted for the use of RPE and duration in the same way as used for the CSRs under REACH and in accordance with the methodology used by ECHA (2018a) for the restriction proposal. The applied RPE is established by EBRC Consulting for the registration dossiers and considered to be representative for the RPE typically used for the processes. Some companies may use RPE with a higher APF for some processes while other may use less. Typically, companies answering the stakeholder consultation and companies visited by the site visits have used RPE with a higher APF.

3.3.1.3 Data from stakeholder survey

Exposure data has been provided by 31 companies for the stakeholder survey. Some companies provided very limited data e.g. min and max values only. For sectors where comprehensive datasets are available from other sources, only datasets which includes more than a few samples, and which are reported by statistical parameters used for this study (e.g. AM (Arithmetic Mean) or percentiles) are reported in the following subsections. Companies with apparent mistakes in the reporting (e.g. reporting same concentrations for more processes) have been contacted in order to clarify the questions if they have indicated in the questionnaire that they were open for further contact. The main change introduced to the questionnaire replies after the contact has been changing of the indicated sectors; otherwise, the contact has been used for improving the consultants understanding of the exposure situations.

The overall statistics of the survey are provided in the Methodological Note. Apart from information on concentrations and reported in the current section and risk management measures reported in Annex B, the results of the stakeholder survey as regards feasibility and costs of compliance with the different policy options are summarised in section 7.2.10. Furthermore, some information on number of workers per company is included in section 5.4 on exposed workforce and information on which fraction is most challenging to comply with is added to section 3.3.2.

3.3.2 Inhalable vs. respirable fraction

As most monitoring data from industry represent the inhalable fraction and the ERR for calculating the number of cases of cancer is derived on basis of the respirable fraction, it has for many of the sectors been necessary to convert the concentrations from inhalable to respirable fraction.

Various ratios of respirable to inhalable (R:I) fraction have been reported in the literature.

According to ECHA (2022), Okamoto *et al.* (1998), demonstrated based on more than 1,600 data points from different type of works, that the highest R:I particulates weight ratio was in welding (1:2) and the lowest in foundries (1:5) while powder handling resulted in a ratio of (1:2.5). The data are not specifically for cobalt. A R:I weight ratio of 1:2 means that the concentration in the workplace air measured as the respirable fraction will be 50% the concentration measured as the inhalable fraction. Based on Okamoto's findings and previous regulatory assessments, ECHA (2018) estimated that a ratio of 1:2 (50% of respirable particles) could be used as a worst-case estimate to extrapolate the respiratory fraction from the inhalable fraction to take into account the different scenarios where exposure to the cobalt salts may occur.

RAC concluded in its opinion to the restriction proposal that a R:I ratio of 1:2 (50% respirable dust) is a reasonable worst case for the ratio of the respirable to the inhalable dust fraction. RAC furthermore agreed to take forward different values 1:2 and 1:1 (50% and 100% respirable dust) for risk assessment in order to simplify comparisons.

Newer data, specifically for cobalt, indicates that the fraction for welding and maybe other high-temperature processing, stands out and the fractions for other work processes are considerably lower.

Wippich *et al.* (2022) extracted 639 parallel measurements of cobalt concentrations in inhalable and respirable dust fractions from the non-public exposure database MEGA maintained at the Institute for Occupational Safety and Health of the German Social Accident Insurance and investigated the data by regression analysis. The measurements were from 2011-2020, and the data pairs could be assigned to different activity groups. All measurements are representative for a whole 8-h shift. As shown in Table 3-14, the arithmetic mean (AM) for cobalt for all samples were 26 μg/m^3 in inhalable dust, and 3 μg/m^3 cobalt in respirable dust corresponding to a mean R:I ratio of 1:9. The R:I ratio for the arithmetic means varied from 1:2.3 for welding to 1:12 for 'Filling/transport/storage'. For the P50 the differences were slightly smaller varying from 1:3 for welding to 1:11 for 'Filling/transport/storage'. The 'heuristic groups' established, welding and grinding, are subsets of 'High temperature processing' and 'Machining/abrasive techniques'. The 'welding' group aggregates data for a number of welding techniques and various cobalt content of the welding material which might influence the cobalt concentration in both dust fractions and thereby influence the conversion function.

It was found that there was no linear relationship between respirable and inhalable values across the 5 analysed groups and that a fixed R:I conversion factor could not be established. Instead, conversion functions were developed on the basis of data from personal sampling. The resulting conversion functions of all groups are power functions with exponents between 0.704 and 0.794. As an example, the conversion function for conversion from inhalable ($C_{I(Co)}$) to respirable concentration ($C_{R(Co)}$) in mg/m³ for high temperature processing is expressed as: $C_{R(Co)} = C_{I(Co)}^{0.734} * e^{-3.083}$. The conversion functions were calculated considering the measurement systems and sampling rates applied in Germany and the authors note that if these functions are applied on data associated with other sampling systems, other measurement uncertainties must be considered, and the parameters may differ.

Table 3-14 Descriptive statistics of respirable (Res) and inhalable (Inh) cobalt samples used in the study, with the amount of paired cobalt concentrations (n) arithmetic mean (AM), P50 and maximum measured concentration (Max). Concentration in µg/m³. The measurements were from 2011 - 2020. P95 not reported in the paper.

Group	n	AM			P50			Max		
		Res	Inh	R:I	Res	Inh	R:I	Res	Inh	R:I
Entire dataset	639	3	26	1:8	0.3	2	1:7	110	950	1:8
Entire dataset only personal meas.	515	3	30	1:10	0.42	2.5	1:6	110	950	1:8
Working activities										
High temperature processing	145	2	7	1:3	0.23	0.7	1:3	65	240	1:4
Filling/transport/storage	49	8	97	1:13	1.1	12	1:11	98	950	1:10
Machining/abrasive techniques	234	3	26	1:8	0.52	3.6	1:7	110	570	1:5
Heuristic groups										
Welding	96	1.2	2.7	1:2	0.19	0.56	1:3	65	70	1:1
Grinding	161	3	27	1:9	0.27	2.9	1:11	110	570	1:5

** The paper also provide data on standard deviation and minimum measured concentration.*
Source: Wippich et al., 2022.

For the current study, data on inhalable and respirable concentrations have been reported from two sectors. The data are further described in section 3.3.4. The ratios for manufacture of tools are well in accordance with the ratios reported in the literature. For the maintenance of catalysts in the petrochemical industry, the ratios are closer to the ratios reported for welding.

Table 3-15 Descriptive statistics of respirable (Res) and inhalable (Inh) cobalt samples reported for the stakeholder survey. It is not reported to what extent measurements of respirable and inhalable fraction are paired, but as the number of samples and period of measurements are the same it is assumed that they would be.

Sector	n		AM			P50			P95		
	Res	Inh	Res	Inh	R:I	Res	Inh	R:I	Res	Inh	R:I
C25.73 Manufacture of tools (all processes)	47	47	9	71	1:8	5.4	50	1:9	21	190	1:9
C19.20 Petrochemical, catalyst	15	15	1.3	3.6	1:3	0.13	0.61	1:5	15.9	40.3	1:3

Source: Stakeholder survey.

For the stakeholder survey, companies were asked which OEL of the sets of OEL in the policy options would be most costly to comply with. The question was answered by 31 respondents. Most of the respondents answered that they expected the OEL for respirable fraction to be the most costly to comply with and many companies answered that for some processes the OEL for the inhalable fractions would be the most challenging whereas for other processes the OEL for the respirable fraction could be most challenging. However, only for the use of catalyst in the petrochemical sector actual data showing this was provided, and it cannot be excluded that the companies considered the OEL for the respirable fraction most challenging because they did not have any data on the respirable fraction.

Table 3-16 Respondents indication of which OEL would be most costly to comply with

Sector (n)	OEL most costly to comply with	
	OEL for inhalable fraction	OEL for respirable fraction
C19.20 Petrochemical, catalyst		1
C20.12 Manufacture of dyes and pigments	1 (some processes)	1, 1 (some processes)
C20.13 Manufacture of other inorganic basic chemicals	1	1
C20.14 Manufacture of other organic basic chemicals	1 (some processes)	1 (some processes)
C20.30 Manufacture of paints and inks		2
C20.59 Catalysts	1 (some processes)	1 (some processes), 1
C23.19 Glasses	1 (some processes)	1 (some processes)
C23.40 Ceramics	3 (some processes)	3, 3 (some processes)
C24.10 Steel		1
C24.45 Manufacture of cobalt and cobalt alloys	2	4
C25.61 Surface treatment of metals		1
C25.73 Manufacture of tools	3	2
F42 Construction	1	

Wippich *et al.* (2021) have undertaken a similar analysis for nickel which cover more processes. For welding and high temperature cutting the materials would often contain both nickel and cobalt and for these processes the data for nickel may also be relevant for cobalt. The assessment for nickel includes a closer assessment of the data for welding. At the workplace, there is often no spatial separation of welding and grinding. In many cases a mixture of dusts, produced by the same worker, who is grinding for a certain time-share of the shift, cannot be excluded. In order to take into account that the R:I ratio is different for grinding and welding, the analysis distinguish between welding with less than 5% grinding time fraction (GTF) og more that 5% grinding time fraction (GTF). For welding (GTF < 5%) the R:I ratio for the AM was 1:2.2 while it for welding (GTF > 5%) was 1:4.5. For high temperature cutting, the R:I ratio was 1:2.2 whereas it for grinding was 1:12. The data could indicate that also for cobalt the R:I ratio for high temperature cutting could be close the ratio for welding.

Stefaniak *et al.* (2009) measured airborne cobalt concentrations among cemented tungsten carbide workers. The study reports inhalable and respirable concentrations for 22 work areas each represented by 1 to 14 samples (in total 104 samples). For all work areas, the R:I ratio of the GM (Geometric Mean) varied from 1:5 to 1:22. For 10 work areas within 'Forming/machining' the R:I ratio varied from 1:5 for 'maintenance' to 1:17 for 'pressing'; for 5 work areas within 'Metal separation' the R:I ratio varied from 1:12 for 'metal separation' to 1:22 for 'Reclamation B'; and for 7 work areas within 'Powder handling' the R:I ratio varied from 1:6 for 'Inventory control' to 1:15 for milling.

Andersson *et al.* (2021) measured workplace concentrations in two Swedish hardmetal industries. For the total dataset of 34 stationary measurements the R:I ratio was 1:10 for the AM and 1:12 for the P50 concentration. For the personal measurements, only the concentration of inhalable fraction is reported.

Kim *et al.* (2015) measured airborne cobalt concentrations in manufacturing industries in Korea. In 16 personal measurements covering four processes (plating, mix & weighing, moulding and finishing) the R:I ratio was 1:27 for the overall GM and 1:19 for the overall AM.

Summary. In summary, the R:I ratio of 1:2 used by RAC in its opinion to the Restriction Proposal reflects the ratio for welding, high temperature cutting and similar processes. This ratio will here be applied for these processes.

For other processes an average R:I ratio between 1:4 and 1:10 seems to more adequately reflect the actual measuring data. The ratio will depend on the particle size distributions of the particles in the workplace air.

For sectors where actual data are available to demonstrate that the ratio is likely in the range of 1:≥8, such as hardmetal tool production and other processes in the metal sector, a ratio of 1:8 will be applied whereas a ratio of 1:4 will be applied for chemicals and all other sectors. The approach with three different ratios has been discussed with the Cobalt Institute which agrees this is a useful approach.

The applied ratios are shown in the table below.

Table 3-17 Applied R:I ratios by sector

NACE code	Short name for sector	R:I ratio
C10.91	Manufacture, feeds	1:4
C19.20	Petrochemical, catalyst	1:4
C20.12	Manufacture of dyes and pigments	1:4
C20.13-20.14	Manufacture of basic chemicals	1:4
C20.30	Manufacture of paints and inks	1:4
C20.59	Catalysts	1:4
C20.59	Formulation	1:4
C21.20	Pharmaceuticals	1:4
C22.11	Production of tyres	1:4
C23.1	Glass	1:4
C23.4	Ceramics	1:4
C23.7	Cutting stone	1:4
C24.10	Steel	1:8
C24.45	Manufacture of cobalt and cobalt alloys	1:8
C25.5	Powder metallurgy	1:8
C25.61	Surface treatment of metals	1:4
C25.62	Machining	1:8
C25.73	Manufacture of tools	1:8
C25.99	Manufacture of other fabricated metal products n.e.c.	1:8
C26.1	Production of electronic components and boards	1:8
C26.51	Humidity indicator cards	1:4
C27.2	Batteries	1:4

NACE code	Short name for sector	R:I ratio
C28.11	Engines and turbines	1:8
C29.10-30	Automotive	1:4
C30.30	Air and spacecraft	1:8
C32.50	Medical and dental devices	1:8
E38.32	Metal recovery	1:8
	Biogas	1:4
	Welding	1:2

3.3.3 Exposure data from national databases

Published data from national databases have been reviewed as part of identifying sectors and occupations with exposure to cobalt and inorganic cobalt substances.

The data from national databases are useful in identifying the most relevant sectors and identify where the highest exposure levels may be expected, but the reports often aggregate data over a long period (e.g. aggregated data from Italy for the period 1996-2016). For sectors where new data are available, e.g. from the Cobalt REACH Consortium and the stakeholder survey, those data are considered to better represent the current exposure levels than older data from national databases.

Italy. Scarselli *et al.* (2020) present data centrally collected and stored in the Italian Information System on Occupational Exposure to Carcinogens (SIREP) database. Employers are required to report the carcinogens used or produced by industrial process, data on number of exposed employees and the exposure levels. Nearly 75% of the measurements are from 5 subsectors on manufacture and use of metals, while about 10% concern manufacture of chemicals. The highest concentrations are reported for '25.7 Manufacture of cutlery, tools and general hardware' whereas the lowest level is reported for '28.3 Manufacture of agricultural and forestry machinery', which most likely represent the service life of the manufactured tools. The average exposure concentrations for women are slightly higher than for men.

Table 3-18 Distribution of mean levels of cobalt exposure with variability metrics by gender and activity sector, and overall (SIREP 1996-2016). Only sectors with more than 50 exposure measurements included. Data not adjusted for the use of RPE.

Gender	Sector of economic activity (NACE Rev. 2 code) **	n	AM	SD	GM	P25	P75
Women	25.6 Treatment and coating of metals; general mechanical engineering	71	3.56	15.47	0.48	0.20	5.00
	Other sectors	138	-	-	-	-	-
	Overall	209	3.79	10.92	0.44	0.09	4.50
Men	20.5 Manufacture of other chemical products	156	3.55	6.97	0.10	0.002	1.80
	24.1 Manufacture of basic iron and steel and of ferro-alloys	193	0.37	0.31	0.22	0.08	0.70
	25.6 Treatment and coating of metals; general mechanical engineering	642	5.29	32.59	0.31	0.08	1.00
	25.7 Manufacture of cutlery, tools and general hardware	93	7.32	8.46	3.69	5.00	7.00
	25.9 Manufacture of other fabricated metal products	126	0.75	1.66	0.16	0.06	0.84

Gender	Sector of economic activity (NACE Rev. 2 code) **	n	AM	SD	GM	P25	P75
	28.3 Manufacture of agricultural and forestry machinery	53	0.27	0.23	0.13	0.04	0.50
	Other sectors	229	-	-	-	-	-
	Overall	1,492	3.73	21.90	0.32	0.08	2.00
All		1,701	3.73	20.86	0.33	0.08	2.00

** AM: Arithmetic mean. SD: Standard deviation. GM. Geometric mean, P25 and P75: 25th and 75th percentiles.*
*** The report used NACE Rev 1 codes - they are here converted to the NACE Rev 2 codes that matches best.*
Source: Scarcelli et al., 2020.

France. Exposure data from the French COLCHIC database from 2007 to 2017 have been summarised by Emili *et al.* (2019).

The data collected in the COLCHIC database come from measurement campaigns performed in companies under the national social security scheme. The choice of targets leading to the measurements in this database stems from general prevention programs defined by a period of 4 years by the national health insurance system, as well as from national sampling surveys (Mater *et al.*, 2016). COLCHIC data are measured in companies within industries targeted as potentially problematic and in general, the concentrations reported in the COLCHIC database are higher than the concentrations reported in the other French database, SCOLA, which is related to regulatory compliance assessment (Mater *et al.*, 2016). The exposure concentrations represent workplace concentrations, and it is not indicated to what extent RPE has been used.

Actual concentrations are not reported, but the highest proportion of measurements above the French OEL was reported for production of animal feed, metal machining and manufactures of machine tools, production of dental components, surface treatment and sharpener (likely of hard-metal tools).

Table 3-19 Levels of exposure to cobalt by occupation as reported to the French COLCHIC database for the period 2007-2017. The data include exposure to both organic and inorganic cobalt compounds. Data not adjusted for the use of RPE.

Occupation	n	IE < 10 µg/m³	10 ≤ IE < 100 µg/m³	IE ≥ 100 µg/m³
Animal Feed Technician	15	20%	60%	20%
Metal machining operator	82	48%	41%	11%
Operator-setter on machine tool	87	66%	26%	8%
Hand finishing, control and packaging operator	15	80%	13%	7%
Other trades	112	83%	12%	5%
Dental technician	104	84%	12%	4%
Surface treatment operator	116	70%	27%	3%
Sharpener	41	66%	32%	2%
Sheet metal worker	68	84%	16%	-
Metal cutting operator	20	90%	10%	-
Operator on physical or chemical transformation devices	21	95%	5%	-
Welder	328	97%	3%	-
Operator on manufacturing machines, food industries	44	98%	2%	-
Operator on finishing, control and packaging machines	12	100%	-	-
Metal Production Operator	17	100%	-	-
Printing machine operator	11	100%	-	-

Occupation	n	IE < 10 µg/m³	10 ≤ IE < 100 µg/m³	IE ≥ 100 µg/m³
Manufacturing technician, mechanical engineering and metalworking	21	100%	-	-

There is no binding OEL for inorganic cobalt substances in France; the limit value referred to in the paper and used for indication of levels in this table is the binding OEL of 100 µg/m³ which is applicable to the organic cobalt compounds cobalt carbonyl et cobalt hydrocarbonyl (personal communication with the main author).
Source: Emili et al., 2019.

For the ECHA Scientific report, the most comprehensive database was submitted by France where cobalt exposure data from 2007 to 2017 were compiled (ECHA, 2022). The range of cobalt concentration from personal samples was 0.0015-1,500 µg/m³, the P90 for the entire dataset was 24.3 µg/m³ and the P50 value was 1.2 µg/m³. The exposure was highest in sectors of dental practice (P50: 10.7 µg/m³; P90: 255 µg/m³), powder metallurgies (P50: 30.2 µg/m³; P90: 243 µg/m³), aeronautical and space construction (P50: 7.5 µg/m³; P90: 107 µg/m³), metal processing and coating (P50: 2.0 µg/m3; P90: 75.5 µg/m³) and manufacture of other tools (P50: 5.0 µg/m³; P90: 70.3 µg/m³). For feed grade material use, the P50 exposure level reported, based on personal sampling, was 1.0 µg/m³, while the P90 percentile value was 32.1 µg/m³. The study team has asked for access to these data, but the original data have not been available for this study.

Finland. The Finnish Institute of Occupational Health (FIOH) gathered exposure concentrations of air pollutants in Finnish workplaces measured by FIOH. Samples were mainly taken from industrial environments, as well as sites of production, transportation and waste disposal. The report from the years 2008-2019 show that the P50 values for cobalt have increased slightly during the years, being 0.35 µg/m³ for the period 2016-2019 (n=231). The 95th percentile was 155 µg/m³ and 12% of the measurements exceeded the Finnish OEL for cobalt of 20 µg/m³. (FIOH, 2021 as cited by ECHA, 2022).

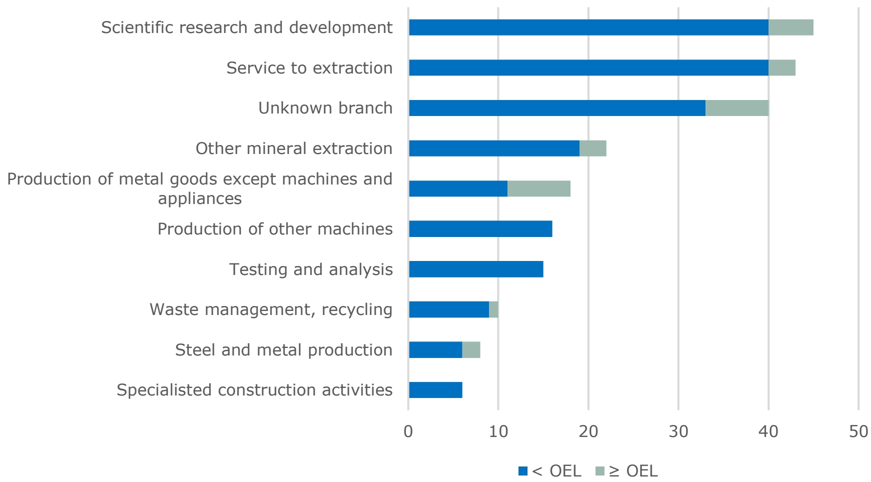

Figure 3-2 *Number of measurements 2016-2019 under and above the Finish OEL of 20 µg/m³, respectively (based on FIOH, 2022)*

Germany. A report from the Institute for Occupational Safety and Health of the German Social Accident Insurance (BGIA) provides workplace measurements for cobalt in certain sectors in Germany between 1992 and 2002 (Blome, 2006). It is not reported to what extent RPE is used for the various exposure situations. The measurement are personal measurements and cobalt in the respirable factors determined in accordance with the standard BGI-505-15. Data are provided for production of hardmetal (various processes), hardmetal processing, change of catalyst, manufacture of cobalt compounds, and manufacture of cobalt pigments. The data are included in the summary of data from the literature in Annex C.

3.3.4 Exposure data by sector

This section combines for each sector exposure data from Chemical Safety Reports (CSRs), the Cobalt Institute, the literature, national databases as describe above, and data obtained from the stakeholder survey.

A wealth of older data on exposure concentrations are available from the literature especially on exposure in hardmetal production. Regarding data from the literature, focus is on newer data from the last 10 years or data for activities where other, newer data are not available.

3.3.4.1 C10.91 Manufacture, feeds

As described in section 3.2.3.17, the supply chain for cobalt compounds used in feed materials has several stages.

The CSRs for cobalt and cobalt sulphate include exposure scenarios for the use in feed. The CSRs include five Worker Contributing Scenarios (WCS) for use of the substances. In the CSR for cobalt carbonate (main substance used), the processes are covered by 'Exposure scenario 14: Formulation or re-packing - Formulation of feed grade materials'. The concentration of cobalt carbonate in the input materials is reported at 1-5% i.e., the scenario represents the stage 'Manufacture of premixtures, 'dietetic feed' and 'mineral feed'. The input materials are not reported to be coated.

Table 3-20 Worker contributing scenarios for use of cobalt carbonate in Exposure scenario 14: 'Formulation or re-packing - Formulation of feed grade materials'. The scenario represents the stage of Manufacture of premixtures, 'dietetic feed' and 'mineral feed' with input materials with concentrations of 2.5 to 10% of cobalt salts; the reported concentration in the CSR is 1-5%. The input materials are not reported to be coated.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
4 Raw material handling	PROC 26, PROC 8b, PROC 9	LEV 90%	10	<= 20 min	<= 8	1.3
5 Formulation	PROC 3, PROC 1, PROC 2	Closed process LEV 78%	10 *	<= 21 min	<= 8	1.9
6 Filling	PROC 9, PROC 8b	-	10 *	<= 200	<= 12	0.8
7 Packaging	PROC 8b	-	10 *	<= 200	<= 12	4.2
8 Cleaning & Maintenance	PROC 28	-	10	<= 45 min	<= 12	2.1

** See explanation in section 3.3.1.1; **Inhalable fraction. All values have been estimated using MEASE 1.02.01 adjusted for the use of RPE. Source: Cobalt carbonate. Chemical Safety Report, Sections 9 & 10, 1 July 2021. LEV: local exhaust ventilation.*

According to FEFAC (2023) about 90% of the preparation of cobalt carbonate used at the stage described above is coated in order to minimise workers exposure. According to the sectors association, the bulk of cobalt salts used currently in the feed chain are coated cobalt carbonate which reduces substantially the exposure to cobalt.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-21 Measured exposure concentrations in the manufacture of feeds. The concentrations are adjusted for the use of RPE and the duration of the activities. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	0.5	0.1	0.4	0.9	1.8	2010-2022	10
Handling of low and/or medium dusty materials	I	162	0.3	0.1	0.2	0.7	1.0	2007-2022	10
Raw material handling	I	16	0.2	0.0	0.1	0.5	0.9	2003-2022	20
Raw material handling	I	27	0.4	0.3	0.5	0.7	1.0	2012-2019	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

No further exposure data have been obtained as part of the stakeholder consultation.

The CSRs for cobalt carbonate and other cobalt compounds, and the ECHA (2018 a,b) restriction report do not include exposure scenarios for the next step in the supply chain: Manufacture of 'complete feed' and 'complementary feed'. No exposure data for this stage have been identified. Considering that the highest P90 concentration when RPE is taken into account for the previous stage is 0.4 µg/m³ and that the concentration of the input materials for the Manufacture of 'complete feed' and 'complementary feed' is 10-100 times lower, it is estimated that the P90 exposure concentration for all WCS when RPE is taken into account will be well below 0.1 µg/m³, and no impact of introduction of an OEL is expected.

For the next stage in the supply chain, professional use (farmers) of the final feed, ECHA (2018b) states that under the conditions of use described, the exposure levels arising from the industrial and/or professional use of feed grade formulations may be well below 0.01 µg/m³.

The data provided by CoRC will be used for deriving exposure concentrations for the sector.

3.3.4.2 C19.20 Petrochemical, catalyst

CRSs for several inorganic cobalt compounds include WCS for use of the catalysts in industrial sites. Exposure takes place when the reactor is loaded and by replacement of the catalyst, whereas under the normal operation the reactor is closed, and no exposure of the refinery staff takes place. The operations are in most refineries undertaken by specialised contractors.

For some of the WCS, RPE with high assigned protection factors are applied; in particular manual work within reactor where RPE with a protection factor of 400 is typically used. Whereas the concentrations without adjustment for the use of RPE are very high, due to the various levels of protection factors, the P90 concentrations when RPE is taken into account are below 29 µg Co/m³ for all WCS.

Table 3-22 Example of Worker Contributing Scenarios for use of inorganic cobalt compounds in the manufacture of catalyst. Cobalt oxide. Exposure scenario 4: 'Use at industrial sites - Industrial use of cobalt oxide containing catalysts'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
2 Raw material handling of shaped catalysts	PROC 8b, PROC 9	Semi-closed process Semi-automated process	10 *	<= 120 min	-	0.9

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
3 Catalyst loading and unloading operations	PROC 4	Semi-closed process Semi-automated process	20	> 240 min	-	21
4 Manual work within reactor	PROC 26	Manual process	400	60 - 240 min	-	15
5 Closed use in chemical reactors	PROC 1	Closed process Refinery or chemical processes in sealed reactors	10 *	> 240 min	-	10
6 Vacuum unloading	PROC 8b, PROC 9	Fully automated process Highly efficient extraction hose to be used LEV 90%	10 *	60 - 240	-	6
7 Screening of spent catalyst	PROC 4	Low level containment with 90% exposure reduction during supervision Canopy hood with 50% exposure reduction during supervision and occasional opening of the system	20	> 240 min	-	29
8 Cleaning and maintenance	PROC 28		20	<= 120 min	<= 48	1.6

** See explanation in section 3.3.1.1; **Inhalable fraction, adjusted for the use of RPE.*
Source: Cobalt oxide. Chemical Safety Report, Sections 9 & 10, 30 June 2021

For the stakeholder survey, one company has provided exposure data for replacement of catalyst in a refinery aggregated for all processes except the manual work within reactor. For the manual work within the reactor, RPE with external air supply and a protection factor of more than 400 is worn and the cobalt concentration within the reactor is not measured.

The P95 of the dataset from the stakeholder survey is 10.2 µg Co/m³ for the inhalable fraction (excl. manual work within the reactor) without adjustment for the use of RPE which would result in a level 10 times lower i.e. a P95 value of about 1 µg Co/m³. The simple average of the P90 values from the CSR is 11.9 µg Co/m³. The dataset from the stakeholder consultation represents actual measurements and the RMMs used for the manual work within the reactor is considered not to be impacted by the OEL (as the APF is rather 2,000 or more), the dataset will be used for the assessment. No data have been provided by CoRC.

Table 3-23 Exposure data from stakeholder survey. The dataset does not include the manual work within the reactor where exposure levels are very high and equipment with external air supply is used as it is common to work in a nitrogen atmosphere.

Site	Activity	I,R	n W*	n	AM	P50	P95	Max	Year	APF
1	Replacement of catalyst in refinery, all processes	I	20	15	3.6	0.61	10.2	40.3	2016-2022	10
		R	20	15	1.3	0.13	2.3	15.9		10

*Source: Stakeholder survey. * Number of workers exposed.*

3.3.4.3 C20.12 Manufacture of dyes and pigments

CSRs for both cobalt and a number of the cobalt salts include WCS with quite similar data. CSRs for some of the pigments administrated by the IP Consortium (e.g. cobalt titanite green spinel and Olivine, cobalt silicate blue) has not been available.

An example of a WCS is shown in the table below.

Table 3-24 Example of WCS for use of cobalt and inorganic cobalt compounds in the manufacture of dyes and pigments. Cobalt metal. 'Exposure scenario 28: Use at industrial sites - Industrial use of cobalt in the manufacture of inorganic pigments, frits, ceramic ware, glass '.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
5 Raw material handling	PROC 26, PROC 21, PROC 8b	-	10	> 240 min	17.2
6 Preparation of raw material	PROC 5, PROC 1, PROC 2, PROC 3, PROC 4	Closed reaction vessel LEV: 90%	10 *	> 240 min	12
7 Wet process	PROC 4, PROC 1	Closed process Closed pipe system, closed reaction vessels, Semi-automated process LEV: 90%	10	> 240 mi	2.1
8 Hot process	PROC 23, PROC 1, PROC 22	Closed furnace or well-extracted open induction furnace LEV: 90%	10	> 240 min	18.1
9 Formulation and filling	PROC 9, PROC 3, PROC 8b	-	10 *	> 240 min	10
10 Packaging of massive objects	PROC 21	-	10 *	> 240 min	10
11 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data or calculated using MEASE 1.02.01 adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-25 Measured exposure concentrations by manufacture of pigments, frits and dyes. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Raw material) Handling of solutions	I	10	3.6	2.4	3.2	8.7	9.8	2013 - 2017	1
Cleaning and maintenance	I	229	3.8	1.0	3.0	7.6	14.2	2010 - 2022	10
Handling of massive objects/articles	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1
Hot (metallurgical) process	I	64	13.7	6.3	13.7	30.7	63.4	2007 - 2022	10

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Preparation of raw material	I	171	19.2	7.0	13.5	32.0	52.5	2007 - 2022	1
Raw material handling	I	100	5.6	1.3	4.5	15.0	28.2	2007 - 2022	10
Raw material handling	I	13	6.2	5.0	9.0	11.4	15.2	2013 - 2017	1
Raw material handling	I	16	3.7	0.9	1.4	11.6	22.1	2003 - 2022	20
Wet process	I	159	1.4	0.5	1.1	3.6	7.0	2007 - 2022	10
Reaction	I	133	5.7	3.0	6.0	9.8	24.0	2006 - 2018	1

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

For the stakeholder survey two companies have provided exposure data for manufacture of inks and pigments.

Table 3-26 Exposure concentrations reported for the stakeholder survey

Site	Activity	I,R	n W*	n	AM	P50	P95	Max	Year	RPE
1	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	I	30	19	6.2	4	18.2	20	2011-2022	Yes
	PROC 5 Mixing or blending in batch processes **	I	30	16	5.9	5	14.8	19		Yes
	PROC 8b Transfer of substance or mixture **	I	30	16	5.9	5	14.8	19		Yes
2 ***	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	I	12	15	6	6	15	15	2022	Yes
	PROC 9 Transfer of substance or mixture into small containers **	I	3	3	3	3.5	5	5		Yes

*Source: Stakeholder survey. * Number of workers exposed.**Same data are reported for two processes. ***Stationary sampling, same concentrations are reported for inhalable and respirable fraction.*

The data from the stakeholder survey is quite well in accordance with the data reported by the CoRC but are lower than those reported in the CSR considering that the data from the CSR for three of the WCS have not been adjusted for the use of RPE. As best estimate, the exposure data reported in the stakeholder consultation for the process with the highest concentration is used for deriving the exposure distribution.

3.3.4.4 C20.13-20.14 Manufacture of basic chemicals

The CSRs for a number of the inorganic cobalt compounds include exposure scenarios for manufacture of the substance. The table below shows the WCS for the manufacture of cobalt sulphate and the use of cobalt sulphate for manufacture of other cobalt compounds.

Table 3-27 Exposure scenarios for manufacture and use of cobalt sulphate

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
Exposure scenario 1: 'Manufacture - Manufacture of cobalt sulphate'						
4 Raw material handling	PROC 26, PROC 21, PROC 8b	-	10	<= 93 min	<= 121	8.8
5 Preparation of raw material	PROC 3, PROC 1	Closed reaction vessel LEV: 90%	10 *	<= 148 min	<= 178	9.7
6 Wet process	PROC 4, PROC 1	Semi-automated process Closed pipe system, closed reaction vessels	10	<= 120 min	<= 122	1.4
7 Hot process	PROC 22, PROC 1, PROC 27a	Closed furnace	10	<= 53 min	<= 51	5.2
8 Further processing	PROC 5, PROC 1	Closed transfer system, closed mill Integrated LEV: 10%	20	<= 295 min	<= 124	19.3
9 Filling of solutions	PROC 8b	-	10 *	<= 30 min	<= 80	0.6
10 Filling of liquids in closed system	PROC 2	Closed process	10	<= 15 min	<= 240	0.03
11 Handling of powders with moderate dustiness potential	PROC 26	-	10	<= 139 min	<= 94	11.3
12 Handling of powders with high dustiness potential	PROC 26	LEV: 90%	40	<= 139 min	<= 94	15.8
13 Cleaning & Maintenance	PROC 28	-	10	<= 94	<= 122	5.6
Exposure scenario 2: 'Use at industrial sites - Use of cobalt sulphate in the manufacture of other chemicals (intermediate use)'						
4 Raw material handling	PROC 26, PROC 8b, PROC 9	Integrated LEV: 90%	10	<= 150 min	<= 82 Shifts/year	12.3
5 Mixing/Reaction in vessel/bath	PROC 3, PROC 1, PROC 2, PROC 4, PROC 5	Closed process	10	<= 15 min	<= 80 Shifts/year	0.3
CS 6 Hot process	PROC 22, PROC 1	Closed furnace	10	<= 10 min	<= 240	1.0
7 Cleaning & Maintenance	PROC 28	-	10	<= 18 min	<= 78	1.0

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt sulphate. Chemical Safety Report, Sections 9 & 10.

Exposure data provided by CoRC (2023) are shown in the table below. The data are aggregated across the various manufactured cobalt compounds.

Table 3-28 Measured exposure concentrations by manufacture of cobalt compounds. The concentrations are adjusted for the use of RPE and duration. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Raw material) Handling of solutions	I	10	0.1	0.1	0.1	0.4	0.4	2013 - 2017	1
Cleaning and maintenance	I	229	0.6	0.2	0.5	1.3	2.3	2010 - 2022	10
Drying	I	16	3.7	0.9	1.4	11.6	22.1	2003 - 2022	20
Further processing in the manufacture of another substance	I	83	5.0	2.3	4.9	13.2	17.0	2007 - 2022	10
Handling of low and/or medium dusty materials	I	162	6.0	1.7	5.8	16.2	23.2	2007 - 2022	10
Handling of powders with high dustiness potential	I	99	2.2	0.5	2.5	7.1	8.7	2009 - 2022	40
Hot (metallurgical) process	I	64	1.5	0.7	1.5	3.4	6.9	2007 - 2022	10
Packaging of high dusty materials	I	16	0.5	0.1	0.2	1.5	2.8	2003 - 2022	20
Packaging of low and/or medium dusty materials	I	27	3.2	2.4	4.5	6.4	8.4	2012 - 2019	10
Packaging of very low dusty materials	I	38	0.1	0.0	0.0	0.1	0.4	2018	1
Preparation of raw material	I	171	5.9	2.2	4.1	9.8	16.1	2007 - 2022	1
Raw material handling	I	32	2.2	1.0	3.0	4.5	11.2	2004 - 2022	10
Raw material handling	I	100	1.1	0.2	0.9	2.9	5.5	2007 - 2022	10
Reaction	I	133	2.6	1.4	2.8	4.5	11.0	2006 - 2018	1
Wet process	I	159	0.3	0.1	0.3	0.9	1.8	2007 - 2022	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Several companies within the sector provided input for the stakeholder survey, but only one company within the EU provided a full dataset which is shown in the table below. The dataset demonstrates in accordance with the data provided by the CoRC very high exposure concentrations for some processes. RPE is used for all processes.

Table 3-29 Exposure concentrations reported for the stakeholder survey

Site	Activity	n W*	I,R	n	AM	P50	P95	Max	Year	RPE
1	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	30	I	8	828	60	3,174	3,861	2022	Yes
	PROC 8b Transfer of substance or mixture	10	I	4	19.3	19	38.9	39	2022	Yes
	PROC 27a Production of metal powders (hot processes)	10	I	20	619	350	1,820	2,200	2022	Yes

Site	Activity	n W*	I,R	n	AM	P50	P95	Max	Year	RPE
	PROC 2 Chemical production or refinery in closed continuous process	25	I	8	27.6	8.5	111	150	2022	Yes

*Source: Stakeholder survey. * Number of workers exposed in the process.*

As shown in the response to the stakeholder consultation, the number of workers exposed to the different processes varies but with no tendency toward more workers at lower concentrations. Consequently, the best aggregated estimate for the sector is derived by simple averages of the concentrations provided by the CoRC.

3.3.4.5 C20.30 Manufacture of paints and inks

The main cobalt compounds used in the manufacture of paints and inks are organic cobalt compounds used as driers. Cobalt oxide and cobalt dihydroxide are reported to be used by some companies and in-house converted to organic compounds. The WCS for the formulation of coatings, paints and inks using the substance as drier or pigment is shown below on the basis of the CSR for cobalt oxide.

Table 3-30 Example of Worker Contributing Scenarios for use of cobalt and inorganic cobalt compounds in the manufacture of other chemicals. Cobalt oxide. 'Exposure scenario 13: Formulation or re-packing - Formulation of coatings, paints and inks using cobalt oxide as drier or pigment)'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Raw material handling	PROC 26, PROC 8b, PROC 9	LEV: 90%	10	> 240 min	19
5 Formulation/Pre-formulation	PROC 5, PROC 1, PROC 2, PROC 3, PROC 4	Closed pipe system, closed reaction vessels LEV: 90% Vapour extraction units in the tank	10	> 240 min	2.7
6 Filling	PROC 9, PROC 8b	-	10 *	> 240 min	10
7 Cleaning & Maintenance	PROC 28		10	> 240 min	13.9

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data or calculated using MEASE 1.02.01 adjusted for the use of RPE.*
Source: Cobalt oxide. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

For the stakeholder survey three companies in the sector have responded; of these, one company has provided exposure data but the data concerned frits and the data therefore are presented under dyes and pigment, where frits are included.

The data provided by CoRC are used for deriving exposure concentrations for the sector.

3.3.4.6 C20.59 Catalysts

Use or manufacture of cobalt and inorganic cobalt compounds for catalysts is included in a number of exposure scenarios for cobalt, cobalt monoxide, cobalt dihydroxide, cobalt sulphate, and cobalt dinitrate (as well as for a number of cobalt compounds outside the scope of this study). One example for manufacture of cobalt oxide within manufacture of catalyst or catalyst precursors is shown in Table 3-31.

Table 3-31 Example of Worker Contributing Scenarios for use of inorganic cobalt compounds in the manufacture of catalyst. Cobalt oxide. 'Exposure scenario 2: Manufacture - Manufacture of cobalt oxide within catalyst or catalyst precursors (including regeneration)'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
4: Stabilisation of reduced cobalt metal catalysts	PROC 1	Closed process Fully automated process LEV: 90% *	20	> 240 min	-	1.4
5: Calcination of cobalt compounds within catalyst	PROC 2, PROC 1	Closed process	10 *	> 240 min	-	4.8
6: Forming (pelleting, extrusion)	PROC 14	Semi-closed process LEV: 90%	20	> 240 min	-	0.7
7: Closed screening of cobalt oxide containing catalysts	PROC 3	Closed process LEV: 90% *	20	> 240 min	-	1.4
8: Closed filling and storage of final cobalt oxide containing catalysts	PROC 8b, PROC 9	Closed process or open process with generic local exhaust ventilation.	10 *	> 240 min	-	3.7
9: Cleaning and maintenance	PROC 28	-	20	<= 120 min	<= 48	1.6

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt oxide. Chemical Safety Report, Sections 9 & 10, 30 June 2021

Apart from manufacture of catalyst, cobalt compounds are used for formulation of mixtures e.g. used for biogas production or water treatment chemicals. Whereas the exposure concentrations by formulation of mixtures for biogas production are relatively low compared with the concentrations by the manufacture of catalysts, the exposure concentration by the formulation of water treatment chemicals is significantly higher.

Data on personal monitoring of occupational exposure to cobalt compounds during the production and regeneration of catalysts were collected from Catalysts Europe companies in April 2022 (Catalysts Europe, 2022). Data were provided by 6 companies for 7 sites. For companies unable to provide exposure data during this most recent exercise occupational exposure measurements previously collected from 2015 onwards were included in order to prepare a sufficiently large database of exposure monitoring that is representative of the whole sector.

These data cover measurement of exposure to respirable and inhalable fractions of cobalt across a range of activities undertaken during catalyst processing. The measurements all relate to airborne concentrations of 'cobalt metal equivalent' but a variety of inorganic cobalt compounds (including cobalt nitrate, cobalt carbonate, cobalt hydroxide, cobalt (II) oxide, tricobalt tetraoxide and cobalt sulphide) are typically processed in catalyst production and the measurements cover all of these compounds in addition to cobalt metal.

All measurements were performed outside of any respiratory protection and the values are not adjusted with the applied protection factors.

Catalysts Europe consider the dataset as confidential and it cannot be provided in this report. The dataset is here considered the most comprehensive and up-to-date and has together with the total for all processes provided by the CoRC been used as background for deriving the exposure concentration distributions for the sector.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-32 Measured exposure concentrations by manufacture of catalysts. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Calcination and/or drying of catalysts	I	2	2.4	2.4	3.1	3.5	3.7	2013 - 2014	1
Cleaning and maintenance	I	33	0.7	0.3	0.6	2.7	13.2	2003 - 2019*	10
Closed catalysts manufacture	I	141	0.3	0.1	0.4	0.8	1.1	2005 - 2019	20
Closed screening of catalysts	I	8	12.1	11.7	17.0	20.9	21.3	2006 - 2009	1
Delivery and storage of raw material	I	27	0.5	0.3	0.6	0.9	4.5	2008 - 2015	1
Dissolution	I	6	0.2	0.1	0.2	0.4	5.7	2005 - 2008	1
Filtration and drying	I	4	2.6	3.1	3.4	3.4	10.4	2008 - 2009	1
Impregnation and drying of catalysts	I	4	0.4	0.5	0.5	0.5	10.4	2008 - 2009	1
Reduction of precipitate	I	8	1.5	1.5	2.1	2.6	21.3	2006 - 2009	1

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Several companies in the sector have answered the questionnaire but not provided exposure as they have made reference to the summary of exposure data submitted by Catalyst Europe as described above.

One company has provided data on manufacture of catalysts and process chemicals for petrochemicals industry as shown in the table below.

Table 3-33 Exposure data reported for the stakeholder survey

Site	Activity	I,R	n	AM	P50	P95	Max	Year	RPE
1	Manufacture of process chemicals for petrochemicals industry	I	6	12.6	8.3	41.3	38.3	2022 and before	10
		R	2	0.7	0.7	-	1.3	2022	10

Source: Stakeholder survey.

3.3.4.7 C20.59 formulation of other chemical products

Examples of exposure scenarios for formulation of mixtures for use in biogas production, fermentation and other biotechnological processes and water treatment from the CSR for Cobalt dichloride are shown in the table below.

Table 3-34 Examples of exposure scenarios for formulation of mixtures for use in biogas production, fermentation and other biotechnological processes and water treatment

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
Cobalt dichloride: Exposure scenario 15: Formulation or re-packing - Formulation of mixtures for use in biogas production [Market sector: Use in fermentation processes and biogas production]						
CS 4 Raw material handling	PROC 26	Integrated LEV: 90%	10 *	<= 480 min	<= 24	1.1
CS 5 Formulation of solutions	PROC 3	Closed pipe system, closed reaction vessels Semi-automated process Integrated LEV: 90%	10 *	<= 480 min	<= 24	6
CS 6 Production of solid formulations	PROC 3	Closed pipe system, closed reaction vessels Integrated LEV: 90%	10 *	<= 480 min	<= 24	1.1
CS 7 Filling of solutions containing <1% of cobalt dichloride	PROC 8b	-	10 *	<= 480 min	<= 24	1.1
CS 8 Packaging of solid formulations containing <1% of cobalt dichloride	PROC 26	Integrated LEV: 90%	10 *	<= 480 min	<= 24	1.1
CS 9 Cleaning & Maintenance	PROC 28	-	10 *	<= 480 min	<= 24	24.1
Cobalt dichloride: Exposure scenario 10: Formulation or re-packing - Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors						
CS 4 Formulation	PROC 26, PROC 15, PROC 2, PROC 4, PROC 5, PROC 8b, PROC 9	Integrated LEV: 90%	10	<= 480 min	<= 24	32.9
CS 5 Cleaning & Maintenance	PROC 28	-	10	<= 480 min	<= 24	24.1

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data (incl. analogous data) or calculated using MEASE 1.02.01 adjusted for the use of RPE.*
Source: Chemical Safety Report for cobalt dichloride, Sections 9 & 10.

Measured exposure concentrations by formulation of other chemicals as received from the CoRC are shown in the table below.

Table 3-35 Measured exposure concentrations by formulation of other chemicals. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Raw material) Handling of solutions	I	10	0.4	0.3	0.3	0.9	1.1	2013 - 2017	1
Cleaning and maintenance	I	229	0.3	0.1	0.2	0.5	0.9	2010 - 2022	10
Cleaning and maintenance	I	9	0.3	0.2	0.3	0.7	0.8	2004 - 2019	1

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	99	7.7	1.6	8.6	24.4	30.3	2009 - 2022	40
Formulation of solid materials	I	16	3.7	0.9	1.4	11.6	22.1	2003 - 2022	20
Formulation of solutions	I	159	1.4	0.5	1.1	3.6	7.0	2007 - 2022	10
Formulation of solutions	I	133	5.7	3.0	6.0	9.8	24.0	2006 - 2018	1
Handling and re-packaging of the solid substance	I	16	3.7	0.9	1.4	11.6	22.1	2003 - 2022	20
Handling of low and/or medium dusty materials	I	162	6.0	1.7	5.8	16.2	23.2	2007 - 2022	10
Handling of solutions	I	6	0.4	0.4	0.4	0.4	0.4	2017	1
Raw material handling (low dusty input materials)	I	1	0.0	0.0	0.0	0.0	0.0	2013	1
Raw material handling (solid input materials)	I	4	0.1	0.1	0.1	0.3	0.3	2013 - 2019	1

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

The data provided by CoRC are used for deriving exposure concentrations for the sector.

3.3.4.8 C21.20 Pharmaceuticals

In the pharmaceutical sector, cobalt compounds are reported to be used as nutrient in fermentation processes and as raw materials for the manufacture of some cobalt-containing pharmaceuticals for human and animal use.

According to the CSRs for cobalt carbonate and cobalt dichloride, the exposure scenarios for the use in fermentation processes, in biotech and scientific research and standard analysis, indicate that the P90 for all the worker contribution scenarios is below 0.6 µg/m^3 for the inhalable fraction without adjustment for the use of RPE.

In accordance with this, ECHA (2018b) states "*When exposure duration is taken into account, the RWC 8h TWA exposure estimates vary from 0.05 to 0.3 µg Co/m^3, depending on the process)".* RWC = Reasonable Worst Case estimate based on the P90 of the exposure data.

For the fermentation processes, impact of establishing an OEL at the level of the assessed policy options is therefore considered insignificant.

Table 3-36 Example of Worker Contributing Scenarios for use of inorganic cobalt compounds in fermentation processes. Cobalt carbonate. 'Exposure scenario 18: Use at industrial sites - Use in fermentation processes, in biotech and scientific research and standard analysis'.

Worker CS	PROC	Technical RMMs	RPE, minimum AFP	Max duration	Shifts per year	P90 **, µg/m³
4 Raw material handling	PROC 9, PROC 26, PROC 8b	LEV: 78%	10 *	<= 48 min	<= 31	0.1

Worker CS	PROC	Technical RMMs	RPE, minimum AFP	Max duration	Shifts per year	P90 **, µg/m³
5 Operations in closed systems	PROC 3	LEV: 78%	10 *	<= 251 min	<= 78	0.5
6 Handling at laboratory scale	PROC 15	LEV: 78%	10 *	<= 113 min	<= 34	0.2
7 Handling of liquid stock solution	PROC 5, PROC 3, PROC 8b, PROC 9	-	10 *	<= 199 min	<= 81	0.4

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt carbonate. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

Cobalt is used in various pharmaceuticals e.g. for treatment of animals. Available information indicates that the agents include organic cobalt compounds (e.g. EDTA[22] cobalt disodium).

For the stakeholder consultation, one company in the sector has reported on the use of cobalt chloride and cobalt sulphate as raw material for manufacture of pharmaceutical products. No exposure data or more detailed description of the application are provided.

For the stakeholder consultation for the restriction report for the fire cobalt salts (ECHA, 218b) one company reported to use cobalt salts (almost exclusively cobalt dichloride) in the manufacturing of pharmaceuticals (such as co-factor for enzymes used in kits for in-vitro diagnostics), diagnostic, and research-only products in the European Union and in indirect uses, including purchased cell culture media also containing cobalt salts. The total annual amount used was significantly below 1kg.

In the absence of actual data, it is as worst case assumed that exposure levels by use of the cobalt compounds as raw materials for pharmaceutical preparations is at the same level as reported for manufacture of catalysts.

3.3.4.9 C22.11 Production of tyres

The CSR for cobalt dihydroxide includes an exposure scenario for use of the substance in production of rubber adhesion agent. According to the available information, only organic cobalt compounds are used as rubber adhesion agents, but it is reported that some (or at least one) producer of tyres use inorganic cobalt compounds for in-house production of organic cobalt compounds.

Table 3-37 Example of Worker Contributing Scenarios for use of inorganic cobalt compounds in production of rubber. Cobalt dihydroxide. 'Exposure scenario 26: Use at industrial sites - Production and industrial use as rubber adhesion agent'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Raw material handling	PROC 9, PROC 5, PROC 8b	LEV: 90%	10 *	> 240 min	3.2
5 Kneading (mixing)	PROC 5, PROC 2, PROC 3	Closed process LEV: 90%	10 *	> 240 min	3.7
6 Shaping	PROC 21, PROC 14, PROC 6	LEV: 78%	10 *	> 240 min	0.1

[22] EDTA: Ethylenediaminetetraacetic acid

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
7 Finishing and shipping	PROC 21	-	-	-	0.1
8 Cleaning & Maintenance	PROC 28	-	10	> 240 min	17.2

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured data adjusted for the use of RPE.*
Source: Cobalt dihydroxide. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

No specific exposure data by application of the substances within the scope of this study for production of rubber products has been provided by CoRC (2023). The dataset from CoRC include only data on exposure to organic compounds but is shown here in the absence of data on exposure to the inorganic cobalt compounds in the sector.

Table 3-38 Measured exposure concentrations by use of organic cobalt carboxylates for production of rubber. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10
Finishing and shipping	I	4	0.1	0.1	0.1	0.1	0.1	2018	1
Kneading (mixing) in a closed process	I	36	0.6	0.1	0.2	2.3	4.2	2016 - 2018	1
Kneading (mixing) of very low dusty materials	I	38	0.1	0.0	0.0	0.1	0.4	2018	1
Raw material handling	I	33	0.9	0.1	1.0	2.0	5.0	2016 - 2018	1
Raw material handling (very low dusty input materials)	I	38	0.1	0.0	0.0	0.1	0.4	2018	1

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

In the absence of data on exposure by the specific applications of inorganic cobalt compounds, the exposure distribution is derived from the data provided by CoRC.

3.3.4.10C23.1 Glass

The main cobalt compounds used in the manufacture of glass is tricobalt tetraoxide which is outside the scope of this this study but some cobalt salts within the scope is reported to be used as well.

Use of cobalt substances in glass is also included in the CSRs for cobalt, cobalt sulphate, cobalt oxide, cobalt dihydroxide and cobalt carbonate in identical exposure scenarios covering industrial use of the substances in the manufacture of inorganic pigments, frits, ceramic ware, and glass. An example is shown under manufacture of pigments in section 3.3.4.3.

Exposure data specifically for production of glass reported by CoRC is shown in the table below.

Table 3-39 Measured exposure concentrations by the use of cobalt in glass production. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10
Further processing (under closed conditions)	I	36	0.6	0.1	0.2	2.3	4.2	2016 - 2018	1
Handling of massive objects/articles	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

For the stakeholder survey one company has reported on the use of cobalt oxide for glass but no exposure data are provided.

The European Container Glass Federation (FEVE, 2023) has for the stakeholder consultation reported that the organisation does not have a lot of exposure data, but the available data (only for the inhalable fraction) shows the following levels:

- Between <LOQ and 2.5 µg Co/m³ for activities linked to Co used as frits in the forehearths[23].
- Between < 0.1 µg Co/m³ to 5 µg Co/m³ for mould maintenance activities.

The organisation cannot assess whether these results are representative or not of the average situation in the container glass industry.

Considering the data on raw material handling reported by CoRC and the exposure scenario shown in Table 3-24, the levels reported above are considered to be in the low end, and similar exposure distribution as derived for manufacture of pigments and dyes will be applied here.

3.3.4.11 C23.4 Ceramics

Use of cobalt substances in ceramics is included in the CSRs for cobalt, cobalt sulphate, cobalt oxide, cobalt dihydroxide and cobalt carbonate in identical exposure scenarios covering industrial use of the substances in the manufacture of inorganic pigments, frits, ceramic ware, and glass. An example is shown under manufacture of pigments in section 3.3.4.3.

For the stakeholder consultation five companies representing seven sites within this sector has answered the questionnaire, but none of the companies have provided data on exposure concentrations.

In the absence of specific data for this sector, the exposure distribution derived for manufacture of dyes and pigments will be applied here.

3.3.4.12 C23.7 Cutting stone

Diamond tools are among other used for cutting of stone. The CSRs does not include WSC for use of diamond tools. A consumer exposure scenario for consumer use of diamond tools indicates an exposure concentration of 0 µg/m³ based on a qualitative assessment. No exposure data have been obtained from the Cobalt REACH Consortium or the stakeholder survey.

[23] Forehearth: A chamber at the end of a tank furnace from which glass is withdrawn for working.

Diamond tools differ in use from the hardmetal tools as these tools are used on hard materials and during normal use dust of the tool material is generated as the tool wear out during use.

In the assessment of the potential exposure, it is relevant to distinguish between outdoor use and indoor use and between dry use of the tools and wet use.

Some older studies on exposure by use of diamond tools have been identified.

In an Italian factory using diamond wheels to cut wood and stone, mean cobalt concentrations in air were found to be 690 µg/m^3 and dropped to 115 µg/m^3 after proper ventilation systems were installed (Ferdenzi *et al.*, 1994 as cited by IARC 2006). Elevated concentrations of cobalt were also reported in the urine of these workers (Van den Oever *et al.*, 1990; Suardi *et al.*, 1994 as cited by IARC, 2006). This is the only available study demonstrating exposure by using the diamond tools for cutting stone other than diamonds.

Oever *et al.* (1990) measured cobalt in the dust from the use of diamond disks for indoor diamond polishing works in Belgium. The cobalt content of the dust in personal air samples in rooms where cobalt disks were used ranged from 6.2 to 45 µg/m^3 with an AM of 20.4 µg/m^3. The cobalt content of the generated exhaust ventilation dust ranged from 2.4 - 3.3% in those situation where only cobalt-based disks were used. The use of RPE is not reported.

Nemery *et al.* (1992) conducted a cross-sectional study among 194 diamond polishing workers, from 10 workshops, exposed to cobalt when using polishing disks made of microdiamonds cemented with cobalt and 59 control subjects from three other diamond industry workshops without cobalt exposure (diamond sawing or cleaving or jewellery drawing). The AM airborne cobalt concentrations in stationary samples were 0.4 (Range: 0.02-0.3), 1.6 (0.5-4.3) and 10.2 (3.8-19.8) µg/m^3 in control, low and high exposure groups, respectively and while AM personal sample concentrations were 0.4 (Range: 0.08-1.5), 5.3 (0.2-11.2), and 15.1 (0.7-42.8) µg/m^3 for the three groups, respectively. The use of RPE is not reported.

As diamonds are harder than the diamond tool, the exposure to dust from the use of the tools on diamonds may be higher than the exposure levels when the tools are used on other stones.

A Japanese study has measured dust concentrations by use of diamond tools in an engine cutter under dry conditions and by a road cutter and a core drill under wet conditions (Murate at al., 2014). The cobalt concentration in the air around the workplace (indicated as 'environment') was only measured at the engine cutter where it was 3.3 µg Co/m^3. The total dust concentration in the air was about 100 times higher around the engine cutter than around the road cutter and core drill and the worker exposure to total dust was around 25 times higher by the engine cutter than by the road cutter.

Assuming a RPE with a APF of 10 is used, the exposure concentrations by indoor use are estimated at 2.5 µg Co/m^3 for the AM and 10 µg Co/m^3 for the P95.

3.3.4.13C24.10 Steel

Exposure by production of steel is included in the CSR for cobalt in the exposure scenario for production and industrial use of cobalt-containing alloys, steels and tools shown in Table 3-41 in section 3.3.4.14. It is not reported to what extent the data are actually representative for cobalt-containing steel production.

For production of highspeed and high strength steel with a cobalt content well above 1% it is in the absence actual data assumed that the exposure concentrations are similar to the concentrations when producing cobalt alloys.

3.3.4.14C24.45 Manufacture of cobalt and cobalt alloys

The manufacture of cobalt and cobalt alloys is represented by two of the exposure scenarios in the CSR for cobalt as shown in the table below.

Table 3-40 Cobalt. 'Exposure scenario 1: Manufacture - Manufacture of cobalt'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Raw material handling	PROC 26, PROC 21, PROC 8b	Segregated ball mill Low-pressure (partly encapsulated) when bags are opened, and material is dropped LEV: 90%	10	> 240 min	9.6
5 Leaching unit	PROC 3, PROC 1	Closed transfer systems, closed reactor and vacuum scrubbing system	10 *	> 240 min	6
6 Solvent extraction unit	PROC 3, PROC 1	Closed process	10	> 240 min	0.5
7 Tankhouse (electrowinning)	PROC 24, PROC 1, PROC 21, PROC 25	Closed process Closed pipe system and tanks	10	> 240 min	5.2
8 Shearhouse (cutting)	PROC 24, PROC 21	-	10 *	> 240 min	23.6
9 Powder production and milling	PROC 27a	LEV: 86% Extraction device in the surrounding calcination area	10	> 240 min	18
10 Screening and packaging	PROC 26	LEV: 90%	20	> 240 min	23.5
11 Packaging of metal chips	PROC 21	-	10 *	> 240 min	8.6
12 Supervision	PROC 4	-	10 *	> 240 min	10
13 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured data adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

In the table below, only some of the WCS actually represent manufacture of cobalt alloys whereas others represent the industrial uses for powder production and further processing covered by sector C25.5 Powder metallurgy in the next section.

Table 3-41 Cobalt. 'Exposure scenario 7: Use at industrial sites - Production and industrial use of cobalt-containing alloys, steels and tools'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Handling of massive materials	PROC 21	-	10 *	> 240 min	8.6
5 Sintering, melting and casting	PROC 23, PROC 22	Closed furnace LEV: 78%	10 *	-	1.4
6 Finishing of massive objects	PROC 25, PROC 13, PROC 14, PROC 21, PROC 24	-	10 *	> 240 min	23.6
7 Handling of powders	PROC 26	LEV: 78%	40	> 240 min	27.3
8 Powder production	PROC 27a, PROC 1, PROC 27b	Closed process	10 *	> 240 min	10
9 Further processing	PROC 24, PROC 1	Closed process	10 *	> 240 min	10
10 Thermal spraying – fully automated	PROC 1, PROC 7	Closed process, Segregated enclosed space, Fully automated process	10 *	> 240 min	10
11 Thermal spraying – NOT fully automated	PROC 7	LEV: 78%	20	> 240 min	19.5
12 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured or calculated data using MEASE 1.02.01 adjusted for the use of RPE. Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.*

Exposure data for manufacture of cobalt and cobalt alloys provided by CoRC (2023) are shown in the table below.

Table 3-42 Measured exposure concentrations by manufacture of cobalt and cobalt alloys. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10
Leaching unit	I	133	5.7	3.0	6.0	9.8	24.0	2006 - 2018	1
Packaging of metal chips	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1
Powder production and milling	I	184	7.8	2.8	7.5	18.0	38.8	2007 - 2021	10
Raw material handling (high dusty input materials)	I	74	4.5	0.8	2.6	10.3	17.9	2005 - 2021	10
Screening and packaging	I	232	10.4	4.6	12.4	26.5	34.7	2007 - 2022	20
Shearhouse (cutting)	I	32	5.2	1.0	7.2	17.3	20.4	2005 - 2022	1

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Solvent extraction unit	I	27	0.3	0.1	0.2	0.5	0.7	2006 - 2018	10
Supervision	I	61	9.2	7.6	11.2	17.0	24.0	2010 - 2022	1
Tankhouse (electrowinning)	I	41	2.7	1.9	3.2	5.2	6.5	2007 - 2009	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Seven companies within this sector have responded to the questionnaire; of these, two companies have provided a full dataset.

Table 3-43 Exposure data from stakeholder survey

Site	Activity	I,R	n W*	n	AM	P50	P95	Max	Year	RPE
1	PROC 23 Open processing and transfer operations	I	10	2	40.5	-	-	59	2022	Yes
	PROC 27b Production of metal powders (wet processes)	I	30	10	9.3	-	-	27	2022	Yes
	PROC 27a Production of metal powders (hot processes)	I	40	19	5.6	-	-	32	2022	Yes
	PROC 28 Manual maintenance (cleaning and repair) of machinery	I	10	20	19	-	-	230	2022	Yes
2	PROC 2 Chemical production or refinery in closed continuous process	I	4	2	9.4	9.4	10.6	10.7	2023	Yes
		I	6	20	1.6	1.6	2.8	3.1	2022	Yes
		I	20	8	0.5	0.0	1.7	1.7	2023	No

*Source: Stakeholder survey. * Same concentrations were reported for inhalable and respirable. **Number of workers exposed.*

Two papers on exposure to cobalt by production of cobalt in a Belgian and Finnish cobalt plant, respectively, has been reviewed (Sauni *et al.*, 2017, Lantin *et al.*, 2013) and the data are considered in section 3.3.9 on trends in exposure concentrations.

Compared to the data reported by the CoRC, the exposure data from the stakeholder survey are lower. As the dataset from the CoRC is more extensive, the exposure in this dataset is assumed to be more representative for the EU average and exposure distributions are derived from this dataset.

3.3.4.15C25.5 Powder metallurgy

Selected worker WCS for powder production is shown in the table below while the exposure scenario for sintering of hardmetal is described in section 3.3.4.18 on manufacture of tools.

Table 3-44 Cobalt. 'Exposure scenario 7: Use at industrial sites - Production and industrial use of cobalt containing alloys, steels and tools'. Selected WCS for powder production

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
7 Handling of powders	PROC 26	LEV: 78%	40	> 240 min	27.3

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
8 Powder production	PROC 27a, PROC 1, PROC 27b	Closed process	10 *	> 240 min	10
12 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured or calculated data using MEASE 1.02.01 adjusted for the use of RPE. Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.*

Exposure data provided by CoRC (2023) for sintered hardmetal articles are provided in section 3.3.4.18 on manufacture of tools. It is here assessed that the exposure data for production of hardmetal tools will also be applicable for other hardmetal articles.

One company provided for the stakeholder survey results of 2 measurements of respirable fraction of 1.1 and 2.3 µg/m³, respectively (without adjustment for PRE). All workers were wearing RPE.

The exposure distribution is assumed to be similar to the distribution by production of hardmetal tools.

3.3.4.16C25.61 Surface treatment of metals

Surface treatment of metals, passivation and plating, is represented by several exposure scenarios in the CSRs for cobalt and cobalt salts.

Table 3-45 Exposure scenarios for the use of cobalt for surface treatment of metals

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
Cobalt. Exposure scenario 17: 'Use at industrial sites - Industrial use of cobalt in passivation processes in surface treatment'					
CS 4 Raw material handling	PROC 21	-	10 *	> 240 min	8.6
CS 5 Wet processes	PROC 2, PROC 1	Closed pipe system, closed reaction vessels Semi-automated process LEV: 90%	10	> 240 min	2.1
CS 6 Passivation	PROC 13	-	10 *	> 240 min	2
CS 7 Packaging and handling of passivated articles	PROC 21	-	10 *	> 240 min	8.6
CS 8 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9
Cobalt. Exposure scenario 18: 'Use at industrial sites - Passivation processes in surface treatment at large industrial sites with continuous processes'					
CS 4 Raw material handling (exclusively very low dusty forms as input materials)	PROC 21	Fully automated process	10 *	> 240 min	8.6
CS 5 Passivation	PROC 2, PROC 13	Closed process Fully automated process Integrated LEV: 90%	10 *	> 240 min	1

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
CS 6 Packaging and handling of passivated articles	PROC 21	Fully automated process	10 *	> 240 min	8.6
Cobalt. Exposure scenario 19: 'Use at industrial sites - Industrial use of cobalt in plating processes in surface treatment'					
CS 4 Raw material handling	PROC 21	-	10 *	> 240 min	8.6
CS 5 Wet processes	PROC 2, PROC 1	Closed pipe system, closed reaction vessels Semi-automated process Integrated LEV: 90%	10	> 240 min	2.1
CS 6 Plating	PROC 13	Closed pipe system, closed reaction vessels Semi-automated process Integrated LEV: 90%	10	> 240 min	2.1
CS 7 Handling of coated/plated articles	PROC 21	-	10 *	> 240 min	8.6
CS 8 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9
Cobalt carbonate. Exposure scenario 9: 'Service life (worker at industrial site) - Industrial handling of surface treated articles (passivated/plated)' [in the market sector: Use in surface treatment]					
CS 2 Handling of articles	PROC 21	-	10 *	<= 480	2.8

** See explanation in section 3.3.1.1; **Inhalable fraction, measured or calculated using MEASE 1.02.01. For measured data, analogous data is used to some extent. Adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

Table 3-46 Cobalt sulphate. ' Exposure scenario 4: Formulation or re-packing - Formulation of metal surface treatment pre-formulations

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
CS 4 Raw material handling	PROC 26, PROC 8b	Integrated LEV: 90%	10 *	<= 15 min	<= 57	0.9
CS 5 Formulation of solutions	PROC 3, PROC 2	Closed pipe system, closed reaction vessels Semi-automated process LEV: 90%	10 *	<= 52 min	<= 59	1.2
CS 6 Filling of solutions containing <25% of cobalt sulphate	PROC 8b	-	10 *	<= 74 min	<= 57	0.8
CS 7 Cleaning & Maintenance	PROC 28	-	10 *	<= 24 min	<= 53	2.2

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data: Analogous data. Adjusted for the use of RPE.*
Source: Cobalt sulphate. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-47 Measured exposure concentrations by surface treatment. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Mechanical) Finishing/Processing of massive objects	I	32	5.2	1.0	7.2	17.3	20.4	2005 - 2022	1
(Raw material) Handling of solutions	I	10	0.2	0.1	0.2	0.5	0.6	2013 - 2017	1
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10
Cleaning and maintenance	I	9	3.0	2.0	3.1	6.8	8.4	2004 - 2019	1
Handling of dusty materials	I	232	10.4	4.6	12.4	26.5	34.7	2007 - 2022	20
Handling of low and/or medium dusty materials	I	162	6.0	1.7	5.8	16.2	23.2	2007 - 2022	10
Handling of massive objects/articles	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1
Handling/Finishing of (surface-treated) articles	I	6	1.9	1.9	2.1	2.8	3.2	2007 - 2013	1
Plating	I	60	2.6	1.4	2.8	6.1	7.1	2004 - 2017	1
Raw material handling (low dusty input materials)	I	1	0.0	0.0	0.0	0.0	0.0	2013	1
Raw material handling (solid input materials)	I	4	0.1	0.0	0.1	0.2	0.2	2013 - 2019	1
Wet process	I	159	1.4	0.5	1.1	3.6	7.0	2007 - 2022	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

For the stakeholder survey one company reports on surface treatment of metals for the aerospace sector but no exposure concentrations are reported.

BG ETEM (2009b) reports a value for stationary sampling in a blue passivation process in an automatic galvanising plant in Germany at <1 µg/m³.

The dataset from CoRC is considered to be representative for the situation across the EU and exposure distributions are derived on the basis of this dataset.

3.3.4.17C25.62 Machining

The use of hardmetal tools (service life of the tools) may take place in a number of sectors. The sector C25.62 Machining includes companies undertaking all kind of machining: Boring, turning, milling, eroding, planing, lapping, broaching, levelling, etc. A part of the hardmetal tools will be used in this sector whereas others are used in a number of sectors where similar processes are undertaken in specific departments. The exposure concentrations will be described for this sector, but similar concentration could be expected in other sectors.

Table 3-48 Cobalt. Exposure scenario 10 and 13: 'Service life (worker at industrial site) - Service life of cobalt containing alloys, steels and tools in industrial settings' and ' Service life (professional worker) - Service life of cobalt-containing tools in professional settings'

Worker CS	**PROC**	**Technical RMMs**	**RPE, minimum APF**	**Max duration**	**P90 **, µg/m³**
Exposure scenario 10: Service life (worker at industrial site) - Service life of cobalt containing alloys, steels and tools in industrial settings					
2 Handling and mechanical treatment of metal or hard coated tools, metals and/or alloys – low kinetic energy (Machining, dressing, polishing, stripping, boring, assembly, disassembly)	PROC 21	-	10 *	> 240 min	10
3 Use and mechanical treatment of metal or hard coated tools, metals and/or alloys – high kinetic energy (Sectioning, grinding, cutting, abrasive cutting, drilling)	PROC 24	-	10	> 240 min	11
Exposure scenario 13: Service life (professional worker) - Service life of cobalt-containing tools in professional settings					
2 Automated uses of cobalt-containing tools with confined and/or extracted machines (Milling/shaping, sawing, grinding)	PROC 21	Fully automated process LEV: 78%	10	> 240 min	17
3 Manual tasks using cobalt-containing tools (Abrasive cutting, sawing, grinding, drilling)	PROC 24	-	10	> 240 min	11
Exposure scenario 35: Service life (worker at industrial site) - Service life of hardmetal articles in industrial setting (similar EC for professional settings)					
2 Handling and use of hardmetal articles	PROC 24	-	10 *	-	0.1

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

Exposure data provided by CoRC (2023) are shown in the table below. The dataset distinguishes between low and high kinetic energy.

Table 3-49 Measured exposure concentrations by service life of hardmetal tools. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	**R, I**	**n**	**AM**	**P50**	**P75**	**P90**	**P95**	**Year**	**APF**
Handling and mechanical treatment (low kinetic energy) of tools, metals and/or alloys	I	26	10.0	10.0	10.0	20.0	20.0	1998 - 2021	1
Manual tasks using cobalt-containing tools	I	30	2.4	0.6	2.0	3.1	11.7	1995 - 2022	10
Handling and use of hardmetal articles	I	1	17.0	0.0	17.0	17.0	17.0	2003 - 2019	20

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

The German guidance on hardmetal working places (BGI/GUV-I 790-024, DGUV, 2010) includes exposure data (P50 and P95) by machining of hardmetal tools in grinding shops. The values are shown in the table below. The P95 values are 10 times higher by dry grinding as compared with wet grinding. The datasets represent measurements in 18 and 23 companies, respectively. The personal measurements are in general higher than the stationary and for the dry grinding they are six times higher for the P95.

Table 3-50 Measured exposure concentrations grinding of hardmetal tools in grinding shops. Personal samples. The concentrations are not adjusted for the use of RPE. All concentrations in µg Co/m³. Use of RPE is not reported.

Activity	R, I *	n	n, companies	P50	P95	Year
Personal:						
Dry grinding	NA	22	20	2.1	330	2007-2009
Wet grinding	NA	40	22	<LOQ (LOQ:1.7)	33	2007-2009
Stationary:						
Dry grinding	NA	21	18	<LOQ (LOQ:1.7)	52	2007-2009
Wet grinding	NA	42	23	<LOQ (LOQ:1.7)	18	2007-2009

*Source: DGUV, 2010. NA: not available. *The fraction is not indicated.*

The French COLCHIC database includes data for an occupation indicated as 'sharpeners' (Emili *et al.*, 2019). Of the 41 reported measurements, 2% were above 100 µg/m³, 32% between 10 and 100 µg/m³ and 66% below 10 µg/m³. The database also includes other occupations that may involve work with hard metals, but from the description it is not possible to determine the exact activities.

According to IARC (2016) "*During the use of hard-metal tools (e.g. in drilling, cutting, sawing), the levels of exposure to cobalt or hardmetal dust are much lower than those found during their manufacture. However, the grinding of stone and wood with hard-metal tools and the maintenance and sharpening of these tools may release cobalt into the air at concentrations of several hundred micrograms per cubic metre (Mosconi et al., 1994; Sala et al., 1994; Sesana et al., 1994)".*

One new study on exposure by the use of tools has been identified. As limited new data are available on down-stream uses of hard-metal tools, also some older data from the literature is summarised below. The older data may illustrate exposure levels in companies which have not taken further measures to reduce exposure (e.g. in Member States without a national OEL for cobalt) and be considered worst case situation.

Paganelli *et al.* (2020) studied occupational exposure of 132 hardmetal tool sharpeners from 17 companies in the province of Brescia, Italy (on average 8 exposed workers per company). 94 of the workers were working with cutting fluids (wet process) and 38 without (dry process). According to the authors, hardmetal tool sharpening plants are often small factories employing less than 10 workers each. Airborne cobalt concentrations were measured by stationary dust sampling over 6 to 7 hours in four companies, representative of the sector. The GM of all 19 samples were 0.30 µg/m³, the P50 0.27 µg/m³ and the maximum 4.5 µg/m³. LEV (aspiration hoods) were applied in 9 of 17 companies while RPE was used in 11 of 17 companies. In 8 of the 17 companies both LEV and RPE was used. Exposure concentrations in companies with or without LEV are not reported.

Imbrogno and Alborghetti (1994) measured exposure concentrations in 12 factories in Italy in which operations such as sharpening with diamond grinding stones were normally carried out. They included both small workshops that mainly perform sharpening operations for 6-8 h/day and large metallurgical and mechanical industries where operations with risk were carried out in the related tool or machine shop for different periods (from 30 min to 3-4 h/day). It is indicated that sharpening can be dry and/or wet, using diamond grinding wheels for sharpening tools of hard-metals and cobalt steels. The companies in total had 750 workers of which 60 were exposed to co-balt (corresponding to on average 5 exposed workers per company). Results of personal sampling are not presented. Comparison between mean concentration of stationary samples in the work-places with and without localised dust ventilation showed a mean concentration of 21 µg/m^3 when ventilation was applied (12 samples in 6 factories) while it was 138 µg/m^3 when no ventilation was installed (11 samples from 4 factories).

Sala *et al.* (1994) measured exposure concentrations in 11 small grinding plants for hardmetal tools in Italy. The GM for the personal samples was 91 µg/m^3 (5-1,338 µg/m^3; n=51) when no lo-cal ventilation was installed and 9 µg/m^3 (1-38 µg/m^3; n=55) when local ventilation was installed (fraction indicated as 'airborne dust'. For the stationary samples, the GM was 40 µg/m^3 (5-110 µg/m^3; n=52) when no local ventilation was installed and 12 µg/m^3 (4-58 µg/m^3; n=47) when lo-cal ventilation was installed. The use of RPE is not reported.

Quite similar results were obtained by Sasana *et al.* (1994) which examined exposure to cobalt during the wet grinding of hardmetal tools used in the wood industry. The grinding usually took place in small, specialized workshops. Without local ventilation, GM of the measurements at two sampling days was 376 and 91 µg/m^3, respectively, while the concentrations were about 10-20 times lower when local ventilation was installed. The use of RPE is not reported.

The newest dataset of Paganelli *et al.* (2020) indicates significantly lower exposure levels than re-ported from older studies and reported in the CSR and dataset from the CoRC and data from Ger-many and France but the dataset included only stationary samples and it is not specified where the stationary samplers have been placed. Therefore, the exposure distribution has been derived from the dataset from CoRC which is quite well in accordance with other data.

3.3.4.18C25.73 Manufacture of tools

Exposure by manufacture of hardmetal and diamond tools is extensively described both in the CSRs and the literature. Exposure scenarios for production of hardmetal powder, production of sin-tered hardmetal articles and production of diamond tools are presented in the table below.

Table 3-51 Cobalt. 'Exposure scenario 32: Use at industrial sites - Production of hardmetal powder'; ' Ex-posure scenario 33: Use at industrial sites - Production of sintered hardmetal articles ' and; 'Exposure scenario 8: Use at industrial sites - Industrial use of cobalt in the production of dia-mond tools'.

Worker CS	PROC	Technical RMMs	RPE, mini-mum APF	Max dura-tion	P90 **, µg/m³
Exposure scenario 32: Use at industrial sites - Production of hardmetal powder					
3 Weighing Pow-ders & Filling the Mill	PROC 26	Generic LEV: 78%	20	> 240 min	27
4 Milling	PROC 3	Generic LEV: 78%	10	> 240 min	10
5 Emptying the mill	PROC 8b	Generic LEV: 78%	10 *	> 240 min	12
6 Drying	PROC 9, PROC 3	Closed process Generic LEV: 78%	10 *	> 240 min	16
7 Cleaning & Maintenance	PROC 28	Generic LEV: 78%	20	> 240 min	18.6
Exposure scenario 33: Use at industrial sites - Production of sintered hardmetal articles					
3 Transfer to mixer	PROC 8b	LEV: 84%	10 *	15 - 60 min	0.5

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Mixing	PROC 3	Closed process	10	> 240 min	4
5 Press charging	PROC 8b	LEV: 78%	10	> 240 min	17.6
6 Pressing	PROC 14	Generic LEV: 78%	10	> 240 min	17.6
7 Shaping	PROC 21	Generic LEV: 78%	10 *	> 240 min	15
8 Sintering	PROC 22	Closed process Integrated LEV: 84%	10 *	> 240 min	6
9 Grinding and/or turning	PROC 24	Generic LEV: 78%	10 *	> 240 min	18
10 Edge rounding	PROC 24	Closed process Generic LEV: 78%	10 *	> 240 min	3
11 Coating	PROC 1	Closed process Integrated LEV: 84%	10	> 240 min	7.4
12 Brazing or welding	PROC 25	Generic LEV: 78%	10 *	> 240 min	24
13 Marking	PROC 21	Integrated LEV: 84%	10 *	> 240 min	24
14 Packaging	PROC 21	Integrated LEV: 84%	10 *	> 240 min	4.5
15 Cleaning & Maintenance	PROC 28	Generic LEV: 78%	10 *	> 240 min	11
Exposure scenario 8: Use at industrial sites - Industrial use of cobalt in the production of diamond tools					
4 Raw material handling	PROC 26, PROC 8b, PROC 9	Semi-automated process	20	> 240 min	23.5
5 Wet process	PROC 5, PROC 4	LEV: 78%	10 *	> 240 min	11
6 Hot (metallurgical) processes	PROC 25, PROC 14, PROC 22	LEV: 90% Exhaust ventilation in calcination area	10	> 240 min	18.1
7 Mechanical finishing processes	PROC 24, PROC 21	-	10 *	> 240 min	23.6
8 Packaging	PROC 21	-	10 *	> 240 min	8.6
9 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured data adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

Exposure data for provided by CoRC (2023) are shown in the table below.

Table 3-52 Measured exposure concentrations by production of hardmetal tools. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Mechanical) Finishing/Processing of massive objects	I	32	5.2	1.0	7.2	17.3	20.4	2005 - 2022	1
Brazing or welding	I	1	0.6	0.0	0.6	0.6	0.6	2022	1
Classifying of powder	I	9	6.5	8.0	9.0	9.4	10.2	2019 - 2021	10

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10
Cleaning and maintenance	I	54	1.2	0.8	1.4	2.7	4.5	2019 - 2022	20
Cleaning and maintenance	I	16	3.4	1.8	4.4	8.4	9.2	2019 - 2022	1
Drying	I	9	6.5	8.0	9.0	9.4	10.2	2019 - 2021	10
Grinding and/or turning	I	12	6.7	0.6	15.1	17.7	19.4	2018 - 2022	1
Handling of massive objects/articles	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1
Hot (metallurgical) process	I	64	13.7	6.3	13.7	30.7	63.4	2007 - 2022	10
Marking	I	1	0.6	0.0	0.6	0.6	0.6	2022	1
Milling	I	5	1.2	1.0	1.9	2.0	2.0	2019 - 2022	10
Mixing	I	3	1.6	0.1	2.4	3.8	4.3	2016 - 2021	200
Press charging and pressing	I	82	0.6	0.2	0.4	1.2	2.0	2013 - 2022	10
Raw material handling	I	232	10.4	4.6	12.4	26.5	34.7	2007 - 2022	20
Shaping	I	24	10.5	1.1	4.0	38.5	40.0	2014 - 2022	1
Sieving	I	9	6.5	8.0	9.0	9.4	10.2	2019 - 2021	10
Sintering	I	9	4.1	2.0	8.6	11.0	11.0	2014 - 2022	10
Transfer operation	I	2	5.9	5.9	8.8	10.6	11.2	2016 - 2021	40
Weighing Powders & Filling the Mill	I	41	3.3	2.0	4.2	9.5	9.5	2019 - 2022	20

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

In total 18 sites for manufacture of tool or production of metal powders for tools production were represented in the stakeholder survey. Some of the datasets are aggregating data from more exposure situations and more sites. The dataset demonstrates large differences between the responding companies.

Table 3-53 Exposure data from stakeholder survey

Site	Activity	I,R	N W*	n	AM	P50	P95	Max	Year	RPE
1	Production of hardmetal powder, aggregated	I		33	12	7.5	39	64	2022	Yes
2	Production of sintered hardmetal articles, aggregated	I		85	2	1.0	4.4	5.8	2022	No
3	Production of powder for hardmetal tools, aggregated, PROC 5, 9, and 17	I	24	47	71	50	190	193	2019-2022	40
	PROC 24 High mechanical energy work, manufacture of tools	I	84	57	38	17	136	180	2019-2022	40
4		I		8	91			260	2021	Yes

Site	Activity	I,R	N W*	n	AM	P50	P95	Max	Year	RPE
	Mixing and Preparation of Ready to press powder (tungsten carbide+Cobalt)	R		8	3			6	2021	Yes
	PROC 28 Manual maintenance (cleaning and repair) of machinery	I		8	535			3,100	2022	Yes
		R		8	25			130	2022	Yes
	Pressing, Filling of Press forms	I		2	120			130	2021	Yes
		R		2	6			6.3	2021	Yes
	Machining of green bodies	I		7	21			47	2022	No
		R		7	10			62	2022	No
5	Production of powder for hardmetal tools, aggregated, PROC 5, 9, and 17	I	30	24	96	47	297	320	2006-2021	40
	Production of hard-metal tools, PROC 8b	I	193	118	30	8	14	40		No
6	Production of hard-metal tools, aggregated	I		4	46	42	59	62	2019	Yes

*Source: Stakeholder survey. *Number of workers exposed.*

A number of studies report on exposure concentrations in the hardmetal industry.

Wahlqvist *et al.* (2020) performed measurements during 2017 and 2018 in two hard-metal production facilities in Sweden employing 130 and 1,400 workers, respectively. The highest exposure levels occurred in the powder department (AM at 7.1 µg/m^3) and by pressing of the items (AM at 2.7). Exposure was presented as 8-hour TWA of the inhalable fraction. RPE (P3-filtering face masks) were used by workers presumed to be exposed to higher levels of dust and cobalt, especially those in the powder department and in the pressing department when changing powder. The total average exposure concentration levels of inhalable cobalt decreased when adjusting for the use of respirators, from 3.3 µg/m^3 to 1.7 µg/m^3. The highest decrease was in the powder department, from 7.1 µg/m^3 to 2.2 µg/m^3 (indicating an average protection factor of RPE of approximately 3). Levels of airborne cobalt in the workplace have decreased considerably over the past years, which has been associated with improved hygiene and protective measures (Wahlqvist *et al.*, 2020).

Klasson *et al.* (2016) report on measurements during 2007 and 2009 in the larger of the hard-metal production facilities in Sweden. For cobalt, 6% of the samples (n = 72) exceeded the Swedish OEL 20 µg/m^3. These samples represented spray drying at the powder production department, set work in the laboratory and operating the Physical Vapor Deposition (PVD) furnace. For the powder department, the AM was 11 µg/m^3 whereas for pressing it was 1.4 µg/m^3 i.e. higher and lower, respectively, compared with the measurements 10 years later reported by Wahlqvist *et al.* (2020). For most departments, the number of measurements were quite low and the data are not shown in the summary table below.

Kettelarij *et al.* (2018), investigated in 2013 cobalt exposure among 76 workers (58 working in the production area and 18 in offices) by monitoring cobalt exposure in the air, on skin and in urine in a hard-metal company in Sweden. The P50 values and the range of cobalt concentration in the inhalable fraction were 5.6 (0.82-24) µg Co/m^3 for workers handling raw materials (similar to powder department in above-mentioned studies), 0.13 (0.012-0.55) µg Co/m^3 for those working with sintered material and 0.14 (0.026-0.45) µg Co/m³ for those handling final products. Other statistical parameters are not reported, and the data are not included in the summary table below.

Hutter *et al.* (2016), estimated the cobalt levels in the Austrian tungsten industry at the workplace collected from 1985 to 2012, and human biomonitoring data collected from 2008 to 2014. For cobalt 147 measurements were available; 45 personal and 102 stationary samples. The P50 value for cobalt exposure for the inhalable fraction for all years (personal and stationary measurements) was 20 µg/m³ (range 1-8,000 µg/m³). Both air and urine measurements exhibited an overall decreasing trend over time as further described in section 3.3.9. Notably, the P50 concentration was significantly higher than reported from the Swedish hardmetal industry where Wahlquist *et al.* (2022) reports a P50 level for all work processes at 2.2 µg/m³ in 2017-2018, but close to the P50 of 21 µg/m³ reported for Germany by Blome (2006) for the period 1996-2002.

The dataset from CoRC is considered to be representative for the exposure situation across the EU and is used for deriving the exposure distribution.

3.3.4.19C25.99 Manufacture of other fabricated metal products n.e.c.

The sector C25.99 on manufacture of other fabricated metal products includes various processes that may involve cobalt of which some are described elsewhere e.g. under sector C26.62 machining. Below is another process, additive manufacturing (3D-printing) described. Additive manufacturing may also be used in various other sectors such as the sector on medical and dental devices, powder metallurgy and air and spacecraft where the exposure concentrations by additive manufacturing are expected to be similar to those presented here.

The NACE code according to Eurostat also include the manufacture of metallic magnets.

Table 3-54 Cobalt. 'Exposure scenario 9: Use at industrial sites - Industrial use of cobalt metal in additive manufacturing (3D-printing)'

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
2 Handling of dusty raw materials	PROC 26	Semi-closed process LEV: 'Standard efficiency'	10	> 240 min	12
3 3D-printing in closed process	PROC 2	Highly automated process Closed process with occasional opening LEV: 'Standard efficiency'	10	> 240 min	15
4 Handling and sieving of powder for reuse	PROC 26	Semi-closed process LEV: 'Standard efficiency'	10	> 240 min	12
5 Maintenance work	PROC 28	-	10	> 240 min	5
6 Cleaning & Maintenance	PROC 28		40	> 240 min	16.9

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, June 2021.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-55 Measured exposure concentrations by additive manufacturing. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Cleaning and maintenance	I	229	5.1	1.3	4.0	10.0	18.8	2010 - 2022	10

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Handling of massive objects/articles	I	11	3.3	1.0	5.5	8.0	8.5	2005 - 2021	1
Hot (metallurgical) process	I	64	13.7	6.3	13.7	30.7	63.4	2007 - 2022	10
Preparation of pre-sintered materials	I	11	5.0	6.2	6.6	9.6	11.0	2003 - 2019	10
Preparation of raw material	I	171	19.2	7.0	13.5	32.0	52.5	2007 - 2022	1
Raw material handling	I	100	5.6	1.3	4.5	15.0	28.2	2007 - 2022	10
Wet process	I	159	1.4	0.5	1.1	3.6	7.0	2007 - 2022	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Ljunggren *et al.* (2019) report on personal measurements of the inhalable fraction by additive manufacturing (3-D printing) in an additive manufacturing facility in Sweden. The measurements were performed during two consecutive years, while in between, the company implemented several restrictions and guidelines to the workforce to reduce powder spreading in the additive manufacturing facility. The GM value was the first year 3.6 µg/m^3 (range: 0.6-15.9, n=6) while it the second year had decreased to 1.5 µg/m^3 (range 0.1-28.3 µg/m^3, n=8) (other statistical parameters are not provided, GM values usually close to P50).

Hebisch *et al.* (2021) summarise from various sources airborne cobalt exposure during 3D printing, where cobalt is used in additive manufacturing in powder-bed processes. The number of personal air samples for one of the datasets was 14. The exposure concentrations for cobalt and inorganic cobalt compounds measured in the respirable fraction by personal samples varied from ≤0.08 to 1.1 µg/m^3 by removal, cleaning, screening, and setting up. By post-processing measured levels were 0.12 to 1.2 µg/m^3 while it by sieving it was ≤0.10 µg/m^3. Mean values are not reported.

Graff *et al.* (2016) measured cobalt concentration in the air near the 3D printer and at the operator. The concentration near two printers was measured at 13 and 42 µg/m^3, respectively while the concentration of samples from the particle analysers placed on the operator was 38 µg/m^3 (one sample).

The dataset from CoRC is considered to be representative for the exposure situation across the EU and is used for deriving the exposure distribution.

3.3.4.20C26.1 Production of electronic components and boards

Cobalt is used for manufacture of various electronic components. The production of varistors is in the CSR for cobalt reported together with production of magnets which here is assumed to be included under powder metallurgy.

Table 3-56 Cobalt. 'Exposure scenario 27: Use at industrial sites - Industrial use of cobalt in the production of varistors and magnets (calcination/sintering processes)'

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
4 Raw material handling	PROC 26, PROC 21, PROC 8b		10	> 240 min		17.2

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
5 Preparation of raw material	PROC 5, PROC 1, PROC 2, PROC 3, PROC 4	Closed reaction vessel LEV: 90%	10 *	> 240 min		12
6 Wet process	PROC 4, PROC 1	Closed pipe system, closed reaction vessels Semi-automated process LEV: 90%	10	> 240 min		2.1
7 Preparation of pre-sintered materials	PROC 26, PROC 14, PROC 3, PROC 5, PROC 8b	LEV: 78% Local exhaust ventilation in powder handling areas	10	> 240 min		11
8 Hot process/sintering	PROC 22, PROC 1	Separation of workers: 71% Control room during furnace operations	10	> 240 min		18.1
9 Formulation and filling	PROC 9, PROC 3, PROC 8b	-	10 *	> 240 min		10
10 Packaging of varistors	PROC 21	-	10 *	> 240 min		10
11 Packaging of magnets	PROC 21	-	10 *	> 240 min		8.6
12 Cleaning & Maintenance	PROC 28		10	> 240 min		10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, measured or calculated data using MEASE 1.02.01 adjusted for the use of RPE. Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.*

The data reported by CoRC are the same as for manufacture of other fabricated metal products n.e.c. and the exposure distribution derived for manufacture of other fabricated metal products will also be applied here. This is considered to be representative for the manufacture of varistors.

However, cobalt is used for a number of other applications related to production of electronic components and boards but no data on exposure by these uses have been identified.

3.3.4.21C26.51 Humidity indicator cards

Manufacture of humidity indicator cards is a niche production. The measured concentration by the manufacture and the use of the cards is very close to the lowest levels of policy options whereas the exposure by use of the cards is well below the levels relevant.

Table 3-57 Exposure scenarios for the use of cobalt dichloride in the manufacture and use of humidity indicator cards.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
Exposure scenario 19: Use at industrial sites - Use in humidity indicator cards, plugs and/or bags with printed spots						

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
CS 4 Handling of liquid raw material	PROC 5, PROC 8b, PROC 9	-	10 *	<= 18 min	<= 160	0.1
CS 5 Further processing	PROC 4, PROC 13, PROC 8b, PROC 9	-	10 *	<= 185	<= 160	1
CS 6 Handling of humidity indicator cards or spotted bags	PROC 21	-	10 *	<= 480	<= 240	0.1
Exposure scenario 20: Service life (professional worker) - Handling of humidity indicator cards and/or bags with printed spots in professional settings						
CS 2 Handling of humidity indicator cards or spotted bags	PROC 21	-	10 *	<= 14 min	<= 218	0.002

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE. Values in brackets are concentrations indicated in similar exposure scenarios in the CSRs for cobalt oxide and cobalt metal.*
Source: Cobalt dichloride. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

In the absence of other data, the data from the CSR is used for deriving the exposure distributions using the reported P90 and the geometric mean (not shown here).

3.3.4.22C27.2 Batteries

The use of cobalt in the manufacture of batteries basically consists of two steps which may be undertaken in different companies: Manufacture of the cathodes and assembly of the batteries. The CSR for lithium cobalt dioxide include an exposure scenario for battery production shown in the table below. The table includes data in brackets for similar expose scenarios in the CSRs for other inorganic cobalt compounds.

When the battery is sealed in a closed container, the exposure to cobalt is insignificant.

Table 3-58 Lithium cobalt dioxide. 'Exposure scenario 2: Use at industrial sites - Battery production'

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
3 Raw material handling	PROC 26, PROC 3, PROC 4, PROC 8b	-	10	> 240 min	28.5 (21.8) (17.2)
4 Mix preparation	PROC 5, PROC 3	Closed reaction vessel Semi-automated process Integrated LEV: 90%	10	> 240 min	3.5 (2.7) (2.1)
5 Further processing	PROC 3, PROC 4, PROC 5, PROC 6, PROC 9, PROC 13	-	10	> 240 min	2.4 (2.4) (2.4)

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
6 Final processing and handling	PROC 14, PROC 21	Included in closed container Cobalt is in a sealed container (battery)	-	> 240 min	0.001 (0.001) (0.001)
7 Cleaning & Maintenance	PROC 28	-	10	> 240 min	19.4 (13.9) (10.9)

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE. Values in brackets are concentrations indicated in similar exposure scenarios in the CSRs for cobalt oxide and cobalt metal.*
Source: Lithium cobalt dioxide. Chemical Safety Report, Sections 9 & 10, 1 July 2021.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-59 Measured exposure concentrations by manufacture of precursors for batteries. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
(Mechanical) Finishing/Processing of massive objects	I	32	5.2	1.0	7.2	17.3	20.4	2005 - 2022	1
Cleaning and maintenance	I	99	0.5	0.1	0.5	1.5	1.9	2009 - 2022	40
Cleaning and maintenance	I	229	0.3	0.1	0.3	0.6	1.2	2010 - 2022	10
Mix preparation	I	159	0.2	0.1	0.2	0.6	1.2	2007 - 2022	10
Raw material handling	I	100	0.2	0.0	0.2	0.6	1.1	2007 - 2022	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Two datasets have been provided for the stakeholder consultation.

Table 3-60 Exposure data from stakeholder survey

Site	Activity	I,R	N W*	n	AM	P50	P95	Max	Year	RPE
*1 ***	Preparation of nickel hydroxide	I	NA	3	-	0.03	-	0.1	2022	No
	Manufacture of active of positive active material	I	NA	3	-	1.1	-	1.5		No
	Manufacture of Plates	I	NA	164	-	0.4	-	5.3		No
	Maintenance	I	NA	4	-	0.7	-	1.1		Yes
2	PROC 5 Mixing or blending in batch processes	I	27	9	2	2	-	4	2022	Yes
	PROC 9 Transfer of substance or mixture into small containers	I	20	6	1.2	1	-	4		No
	Slitting, calendering, coated electrode spiraling	I	40	15	0.5	0.1	-	2		Yes

*Source: Stakeholder survey. *Number of workers exposed. **Stationary sampling.*

The dataset from CoRC shows similar levels as reported for the stakeholder consultation and is used for deriving the exposure concentration.

3.3.4.23C28.11 Engines and turbines and C30.30 Air and spacecraft

Cobalt alloys are in particular used in the manufacture of engines and turbines and the manufacture of air and spacecraft. The processes may include welding, thermal spraying and other surface layer processes described elsewhere and mechanical treatment as described in the table below divided on low kinetic energy (machining, dressing, polishing, stripping, boring, assembly, disassembly) and high kinetic energy (sectioning, grinding, cutting, abrasive cutting, drilling).

Table 3-61 Cobalt. 'Exposure scenario 10: Service life of cobalt containing alloys, steels and tools in industrial settings'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
2 Handling and mechanical treatment of metal or hard coated tools, metals and/or alloys – low kinetic energy	PROC 21	-	10*	> 240 mi	10
3 Use and mechanical treatment of metal or hard coated tools, metals and/or alloys – high kinetic energy	PROC 24	-	10	> 240 min	11
4 Use of cobalt alloy in laser surface treatment	PROC 25	Closed process	10	-	1

** See explanation in section 3.3.1.1; **Inhalable fraction, Measured data adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

No data specifically for use of cobalt alloys are provided by CoRC.

Cobalt is used for various applications in the sectors. As an example, Julander *et al.* (2010) describe a facility for development and manufacturing of components for gas turbines and space propulsion where exposure to cobalt took place by job tasks in three departments: (i) Sharpening of hardmetal drills, cutting tips and blades (tungsten carbides containing cobalt); (ii) production of nozzles and other combustion structures (metal alloys containing nickel, cobalt, and chromium); and (iii) thermal application of different surface layers on solid metal items (powders containing nickel, cobalt, and chromium). The paper does not provide data on air concentrations.

The exposure distributions have been derived from the above-described processes for handling and mechanical treatment of metal which are estimated to be most representative for the most common exposure situations in the sector.

3.3.4.24C29.10-30 Automotive

The main process involving cobalt in the automotive sector is surface treatment and the same distribution as applied for C25.61 surface treatment of metals will be applied for this sector.

3.3.4.25C32.50 Medical and dental devices

According to a stakeholder input from the Association of German Dental Manufacturer (VDDI, 2021), cobalt alloys are processed in dental laboratories by dental technicians using casting, sintering, additive (SLM: Selective laser melting) or subtractive procedures (milling) to produce custom-made products as customised dental restorations according to a dentist's prescription. Crown or bridge frameworks are often veneered with ceramics or composites. Cobalt-based solders and laser welding rods (fillers, materials for laser welding) are also used. Hard soldering or laser welding is used in dental technology to overcome problems with the fit, or to repair or extend existing prosthetic restorations. The processes involved in medical implants are assumed to be similar to those of producing dental implants.

Data from the CSR for cobalt for service life of dental alloys containing cobalt in professional settings are shown in the table below.

Table 3-62 Cobalt. 'Exposure scenario 14: Service life (professional worker) - Service life of dental alloys containing cobalt in professional settings.'

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
2 Handling of ingots	PROC 21	-	10 *	> 240 min	-	25
3 Melting and casting	PROC 23, PROC 22	Closed furnace and or extracted furnace	10 *	> 240 min	-	25
4 Hand fettling	PROC 24	LEV: 80% Integrated tool / machine extraction	10 *	> 240 min	-	25

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data not adjusted for the use of RPE. The data apparently is based on an aggregated dataset with 79 samples.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

The dataset from CoRC does not include data on production of dental or medical implants.

For the stakeholder survey one company involved in the process of producing CAD/CAM blanks has answered the questionnaire.

Table 3-63 Exposure data from stakeholder survey, personal sampling

Site	Activity	I,R	N W*	n	Min	AM	P50	P95	Max	Year	RPE/APF
1	PROC 5 Mixing or blending in batch processes	I	7-10	3	21	-	-	-	381	2021	10
	PROC 24 High (mechanical) energy work-up	I	4	4	33	-	-	-	613		10
	Milling and handling to CoCr restoration in dentistry	I	7	1	-	-	14	-	-		10
	PROC 28 Manual maintenance (cleaning and repair) of machinery	I	7	1	-	-	6**	-	-		10

*Source: Stakeholder survey. *Number of workers exposed. **Stationary sampling.*

BG ETEM (2020) reports on exposure concentrations in 8 dental laboratories in Germany measured from 2012-2018. The measurements of the respirable fraction were done in accordance with TRGS 402. In 10 of 16 measurements, the concentration was below the LOQ of 0.093 µg Co/m³. The highest measured concentration was 0.47 µg Co/m³. All workstations were equipped with LEV.

Kettelarij *et al.* (2016) measured cobalt exposure of 13 dental technicians working in a dental laboratory i Stockholm by personal air sampling. Work benches for 8 participants were placed in one room and supplied with local process ventilation. RPE was not used. Metal analysis of all samples was performed with ICP-MS (Inductively Coupled Plasma Mass Spectrometry). For 8 measurements, where the technicians worked with CoCr alloys, an AM of 41 µg/m^3 and a maximum value of 155 µg/m^3 (8-h TWA) can be estimated from the data reported in an annex to the paper. For 3 measurements where the technicians were not working with CoCr alloys, the AM was 1.4 µg/m^3 and the maximum value 3.0 µg/m^3. The authors note that for cobalt, 2 participants were exposed to levels above the Swedish OEL (20 µg/m^3) whereas the OEL for nickel was not exceeded; Cr VI was not measured.

Beaucham *et al.* (2015) measured exposure to cobalt and other metals at an orthopaedic implant manufacturer in the USA in 2013. The employees in the building of concern machined and finished cobalt-chromium femoral implants used for prosthetic knee joints. Respirator use was optional and varied by department. For cobalt, 10 personal samples were collected with a sample duration of about 7.5 h. The AM can be calculated at 4.4 µg/m^3 with a maximum level of 26 µg/m^3. Statistical parameters calculated on the basis of the data provided in the paper are shown in Table 16-5.

The concentrations reported in the literature varies considerable between the studies from the different countries. The exposure data from the CSR is used as basis for the exposure distributions as these data are in between the levels reported from different Member States.

3.3.4.26E38.32 Metal recovery

Metal recovery of cobalt from waste include mainly recycling of hardmetal-containing scrap, recycling of cobalt alloys and recovery of cobalt from batteries.

Exposure data from the exposure scenario 'Recycling of hardmetal-containing scrap materials' is included in the table below.

Table 3-64 Cobalt. 'Exposure scenario 3: Manufacture - Recycling of hardmetal-containing scrap materials'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
3 Scrap handling	PROC 8b	LEV: 78%	10	> 240 min	3.3
4 Processing operation	PROC 5, PROC 21	Closed process LEV: 84%	10 *	> 240 min	15
5 Transfer to recycling unit	PROC 8b	LEV: 78%	10 *	> 240 min	12
6 Chemical recycling	PROC 1	Closed process LEV: 84%	10	> 240 min	20
7 Mechanical recycling (zinc or cold stream)	PROC 1	Closed process LEV: 84%	10	> 240 min	4.9
8 Transfer to milling after mechanical recycling	PROC 8b	LEV: 78%	10	> 240 min	4.9
9 Milling	PROC 3	Closed process LEV: 78%	10	> 240 min	4.9
10 Filling	PROC 9	LEV: 84%	10	> 240 min	4.9
11 Cleaning & Maintenance	PROC 28	LEV: 84%	10	15 - 60 min	1.5

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Chemical Safety Report, Sections 9 & 10.

Exposure data provided by CoRC (2023) are shown in the table below.

Table 3-65 Measured exposure concentrations by recycling of cobalt-containing scrap. The concentrations are adjusted for the use of RPE. All concentrations in µg Co/m³.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Chemical recycling	I	6	0.2	0.1	0.1	0.3	0.3	2020 - 2022	10

Source: Cobalt REACH Consortium 2023. Unadjusted data and more parameters are provided in the summary table in Annex C.

Exposure to cobalt may occur by various waste handling operations for hazardous waste. Data are available for handling of electronic waste.

For metal recovery, the data from the CSR will be applied as the number of measurements in the dataset from CoRC consist of 6 measurements only.

Processes involving dismantling of products and handling of metals e.g. by scrap dealers and handling of e-waste are also included under E38.32 Metal recovery. No data on exposure by scrap dealers are available, but the exposure situation is expected to be similar to the exposure by use of articles of cobalt alloys and hardmetals, and it is assumed that the air exposure levels would be below the lowest of the policy options.

Some data are available on exposure by handling of e-waste.

Occupational exposure to cobalt among recycling workers handling e-waste has been evaluated in two studies, one from Sweden and one from Germany.

Gerding *et al.* (2021) monitored metal exposure of 51 recycling workers (and 20 in a control group) during recycling of electronic waste in five sheltered workshops in Germany during 2017-2018. Exposure to metals, including cobalt, was monitored with combined air monitoring and biomonitoring. Both inhalable and respirable dust fractions were sampled by personal and stationary sampling. The LOQ for cobalt was 0.083 µg/m³. The most common work activity was electrical equipment disassembly. For the personal sampling, the P50 value and range for cobalt in the respirable fraction were 0.022 (0.018-0.024) µg/m³. For the inhalable fraction the P50 and range for cobalt were 0.035 (0.018-0.31) µg/m³. The concentration for stationary samples were quite similar. Notably the R:I ratio was less than 1:2 (Gerding *et al.*, 2021). The workers did not wear RPE during work. The maximum levels measured for nickel was below the new OEL.

Julander *et al.* (2014), evaluated the exposure of recycling workers in Sweden to toxic metals including cobalt, using both personal air monitoring and biomonitoring. In total, 55 recycling workers and 10 office workers from three e-waste companies in Sweden were monitored between 2007 and 2009. The GM and range for cobalt in the inhalable fraction were 0.066 (0.0017-3.3) µg/m³ for recycling workers and 0.0035 (0.0021-0.0046) µg/m³ for office workers, respectively. Even the number of measurements for office workers were low the results indicate some exposure of the recycling workers to cobalt would take place. The maximum levels measured for lead and nickel were below the new OELs for the two substances (Cr VI not reported).

Both datasets indicates that exposure concentrations would be below those relevant for the assessed policy options.

3.3.4.27 Cross-sectoral: Biogas

Data from the CSR for cobalt sulphate for industrial and professional use cobalt for biogas production are shown in the table below. Formulation of mixtures used for biogas production is included under sector C20.59 Formulation.

The max duration of the operation is <= 15 min. When this is taken into account, an 8-h TWA of 0.04 µg Co/m^3 is estimated for both professional and industrial sites and for dosing of solid and liquid material. The data are apparently the same as reported below from CoRC but adjusted for the duration.

In accordance with this, ECHA (2018b) states "*The industrial and professional use of the cobalt-containing mixtures result in air concentration levels (RWC) of 0.5 µg Co/m^3 and exposure estimates of 0.02 µg Co/m3 (RWC 8h TWA). It is to be noted that the use of biogas mixtures by professional workers takes place exclusively in biodegradable bags, i.e. as a solid massive form*."

Table 3-66 Cobalt sulphate. Exposure scenario 19 ' Use at industrial sites - Use in biogas production' and

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	Shifts per year	P90 **, µg/m³
Cobalt sulphate: Exposure scenario 19: 'Use at industrial sites - Use in biogas production'						
4 Dosing of solid material	Proc 26	-	10*	<= 15 min	<= 240	0.04
5 Dosing of liquid material	PROC 8b, PROC 9	-	10*	<= 15 min	<= 240	0.04
Cobalt sulphate: Exposure scenario 20: 'Professional use in biogas production'						
2 Handling of sealed bags	PROC 8b	-	10*	<= 15 min	<= 240	0.04

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data adjusted for the use of RPE.*
Source: Cobalt sulphate. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

Exposure data provided by CoRC (2023) are shown in the table below. Apparently the 0.5 µg Co/m^3 has been the Limit of Quantification of the analytical method.

Table 3-67 Measured exposure concentrations by use of cobalt compounds for biogas production. All concentrations in µg Co/m^3. Data not adjusted for duration.

Activity	R, I	n	AM	P50	P75	P90	P95	Year	APF
Industrial use in biogas production	I	6	0.5	0.5	0.5	0.5	0.5	2017	1
Professional use in biogas production	I	6	0.5	0.5	0.5	0.5	0.5	2017	1

Source: Cobalt REACH Consortium 2023. More parameters are provided in the summary table in Annex C.

No other data on exposure concentrations by use of cobalt substances in biogas production have been identified.

The P90 of 0.04 µg/m³ the CSR will be used as background for estimating the exposure distributions.

3.3.4.28 Cross-sectoral: Welding and thermal spraying

Welding

Based on the available data, it is assumed that only welding of cobalt alloys or steel alloys with high cobalt content causes workers to be exposed to cobalt compounds at levels relevant for the assessed policy options. Stainless steel and other high-alloy steels may include cobalt at levels up to 0.1% as unintentional content typically added together with the nickel.

Table 3-68 Exposure scenarios welding in industrial and professional settings

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
Exposure Scenario 11: 'Service life (worker at industrial site) - Welding in industrial settings'					
CS 2 Welding in industrial settings (Covers welding and manual brazing)	PROC 25	-	40	> 240 min	30
Exposure Scenario 12: 'Service life (professional worker) - Welding in professional settings.'					
CS 2 Welding in professional settings	PROC 25	-	40	60 - 240 min	36

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data or calculated using MEASE 1.02.01 adjusted for the use of RPE. Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.*

Paired measurements of respirable and inhalable fraction by welding from the German MEGA database are shown in the table below. It is not reported which type of alloys are welded and the data may be a combination of exposure levels by welding cobalt alloys and welding in stainless steel.

Table 3-69 Paired air measurements of cobalt in the respirable and inhalable fraction by welding as reported to the German MEGA database.

Activity	R, I	n	Min	AM	P50	Max	Year	APF
Welding	I	96	0.058	2.7	0.56	70	1989-2020	NA
	R	96	0.026	1.2	0.17	65	1989-2020	NA

Source: Wippich *et al.*, 2022

Ferri *et al.* (1994) measured exposure to cobalt by welding in a small workshop in Italy. The alloy welded was Stellite with a content of 59% cobalt, 28% chromium and small quantities of carbon, tungsten and vanadium. The material was used for producing moulds for ceramic tiles. Cobalt content was measured on the collected particle samples using atomic absorption spectrometry (AAS). The exposure concentrations were highly dependent on the welding technique. The GM values for oxy-acetylene braze-welding (n=5) was 3.7 µg/m³, by MAG welding (n=7) it was 161.2 µg/m³ and by mould lapping (n=) 37.1 µg/m³. The lower concentrations reached by the oxy-acetylene braze-welding is according to the authors probably owing to the lower temperature reached in the first process, below the evaporation temperature of cobalt. The possible use of LEV or RPE is not reported.

A study by U.S. National Institute for Occupational Safety of metal and noise exposures at an aircraft parts manufacturer measured exposure to cobalt of welders and welder supervisors (Feldmann and Jackson, 2019). The metal aircraft parts were cast off-site and received initial processing at this facility. Metal content of the parts varied based on metallurgical requirements and the cobalt content varied from 2% to 15%. Full-shift exposures to cobalt in the personal breathing zone was measured in accordance with NIOSH Method 7300. Three of four welders and one of three welding supervisors evaluated had detectable levels of cobalt in their breathing zones on at least one of the days of monitoring. The measured concentrations ranged from 0.085 to 7m.1 µg/[3] for 4 welders and from 0.03 to 0.32 µg/m^3 for three welding supervisors. Statistical parameters are not provided.

In small fabrication shops in the USA, the geometric mean for cobalt exposure for welders (N=8) was measured at 0.05 µg/m^3, for non-welding metal workers (n=8) it was 0.07 µg/m^3 and for by-standers (N=16) 0.04 µg/m^3 (Insley *et al.*, 2019). The base metal being welded consisted of various grades of carbon steel and neither the base metal nor the consumable wire contained cobalt. The measurements were conducted in 2018.

Exposure distributions are based on the data from the CSR which are well in accordance with reported data on welding in Stellite (when RPE is taken into account) and higher than the concentration reported by Wippich *et al.* (2022).

Thermal spraying

Exposure by use of cobalt for thermal spraying from the CSR for cobalt is shown in the table below.

Table 3-70 Cobalt. 'Exposure scenario 20: Use at industrial sites - Industrial use of cobalt in thermal spraying in surface treatment'.

Worker CS	PROC	Technical RMMs	RPE, minimum APF	Max duration	P90 **, µg/m³
4 Preparation of massive spraying materials (e.g. wires)	PROC 21	-	10 *	> 240 min	8.6
5 Preparation of dusty spraying materials	PROC 26	LEV: 90%	20	> 240 min	23.5
6 Thermal spraying – fully automated	PROC 1, PROC 7	Closed process Fully automated process Segregated enclosed space	10 *	> 240 min	10
7 Finishing of massive objects	PROC 24	-	10 *	> 240 min	23.6
8 Handling and packaging of finished massive objects	PROC 21	-	10 *	> 240 min	8.6
9 Cleaning & Maintenance	PROC 28	-	10	> 240 min	10.9

** See explanation in section 3.3.1.1; **Inhalable fraction, measured data: analogous data. Adjusted for the use of RPE.*
Source: Cobalt. Chemical Safety Report, Sections 9 & 10, 30 June 2021.

A cross-sectional study of 34 workers engaged in thermal spraying at six worksites in the UK was undertaken by Chadwick *et al.* (1997) in order to determine levels of exposure to and uptake of metals during different metal spraying activities. Cobalt exposure levels were determined as 8-h TWA of the inhalable fraction. Concentrations of metals on the filters were determined by ICP-AES (Inductively Coupled Plasma Atomic Emission Spectroscopy). The measured AM by plasma spraying was 23 µg/m³ (n=54, range: 1-390 µg/m³) while it by detonation gun spraying was 27 µg/m³ (n=29, range: 1-80 µg/m³). Detonation gun spraying was always undertaken in totally enclosed booths from which the operator was excluded during spraying. Operators were required to regularly enter the booth, however, to set up the gun, check and replace workpieces and refill the coating powder containers. Where plasma spraying was fully automated and enclosed exposure was below the exposure limit (limit not reported). Exposures were greatest for sprayers using semiautomated or hand-held systems which required the operator to remain in the spray booth and rely on LEV and RPE control measures. The AM for two control groups (workshop control group and office staff) was 2 and 1 μg/m³, respectively with a maximum for the workshop control group at 20 μg/m³.

3.3.5 Summary of exposure data by sector and activity

The available exposure data by sector and activity are shown in Annex C.

A summary of the exposure data used for the further analysis is provided in section 3.3.7.

3.3.6 Exposure levels with and without respiratory protective equipment (RPE)

As indicated in the sections above with sector-specific exposure data, RPE is widely used in many of the sectors for some processes such as raw material handling and cleaning and maintenance. For the calculation of burden of disease for the benefits assessment and the costs of complying with new OELs, exposure concentrations adjusted for the use of RPE are used as this represent the current situation. In order to comply with the general requirements of the CMRD, the companies should, irrespective of an OEL, reduce the exposure as much as technically possible, and RPE is considered the last resort in the hierarchy of RMMs and shall be kept to the strict minimum of time necessary for each worker. Costs of implementation of technical measures in order to reduce the need for RPE under current exposure situations (i.e. provide similar exposure reduction by other RMMs as provided today by the RPE) cannot be considered an impact of the introduction of the OEL. Consequently, the exposure concentrations adjusted for the use of RPE will be used for both the benefits and the costs assessment. It is assumed that the companies would initially continue to use the existing RPE to keep the exposure below the OEL and gradually (where possible) replace the RPE with other measures in accordance with the general requirements of the CMRD and in order 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) it is assumed that the costs of implementing other RMMs is balanced by the saved costs of using the RPE.

For most sectors the exposure data and information on the use of RPE are available for each Worker Contributing Scenarios (WCS), but in general no data are available on the number of workers per WCS (apart from a few sectors where this is available from the stakeholder survey), so it is not possible to use exact calculation methods to derive aggregated exposure distributions. As RPE is used for some WCSs (as shown in the sector-specific sections) but not for others it is likewise not possible to derive reduction factors for the whole sector using exact calculation methods. Typically, the RPE is used for WCSs with higher exposure concentrations but often the duration of these activities is shorter than the activities where no RPE is used. So even the APF for the RPE would be from 10 to several hundred depending on the processes, the aggregated factors are assumed to be significantly lower.

From the dataset submitted by the CoRC, the average assigned protection factor has been calculated. In the absence of data on the number of workers (which would allow to calculate weighted averages based on number of workers) for each sector, averages have been calculated as simple averages of the APF for the WCS and as weighted averages weighted by the number of analysis. As the number of analyses would not indicate the number of workers it cannot be used as an approximation, but the calculation illustrates the uncertainties in determining averages for the sectors. For two of the sectors, the calculated averages differ significantly which reflects that a WCS where RPE with a high APF is used is represented by either relatively many (catalysts) or few (machining) analyses. As the available data do not indicate that the number of samples actually reflect the number of exposes workers it is considered to be most adequate to use the simple average.

Table 3-71 Average assigned protection factors for each sector in the dataset submitted by the CoRC (2023).

Sector		n	Average APF, simple *	Average APF, weighted*
C10.91	Manufacture, feeds	434	12	10
C20.12	Manufacture of dyes and pigments	906	6	6
C20.13-20.14	Manufacture of basic chemicals	1,339	11	9
C20.30	Manufacture of paints and inks	566	13	11
C20.59	Catalysts and other chemicals, catalysts	233	2	5
C20.59	Catalysts and other chemicals, other	844	13	14
C21.20	Pharmaceuticals	2	1	1
C22.11	Production of tyres	378	7	9
C23.1	Glass	276	6	10
C24.45	Manufacture of cobalt and cobalt alloys, manufacture	1,024	12	12
C25.61	Surface treatment of metals	915	7	13
C25.62	Machining	57	11	4
C25.73	Manufacture of tools	845	13	14
C25.99	Manufacture of other fabricated metal products n.e.c.	745	7	6
C26.1	Production of electronic components	745	6	6
C27.2	Batteries	619	17	17
E38.32	Metal recovery	6	10	10
	Biogas	6	1	1
	Welding, etc.	7	10	10

** 'Simple average' is the average of the APF for all WCS within each sector; weighted average is calculated by weighting the APF with the number of measurements for each WCS. Each value represents the average of the average APF for the AM and P95 for the sector.*
Source: Study team calculations based on dataset from the CoRC (2023).

For the sectors included in the dataset from the CoRC, the simple average values shown in the table above will be used.

For other sectors, the following average factors will be used: 8 for sectors where RPE is worn for most of the WCS (as indicated in the CSRs) and where for some of these, RPE with a APF of more that 8 is used, 4 for sectors where RPE is worn for several of the processes, but the APF does not exceed 10, and 1.5 for sectors where RPE in general is not worn except for some cleaning and maintenance processes.

3.3.7 Summary of exposure concentrations used for the further analysis

As shown above, exposure data are for many of the sectors available for each Worker Contributing Scenario. However, data on exposed workforce, as further described in section 3.4, are in general available only for the entire sector and for this reason it has been necessary to assess average exposure concentrations across all Worker Contributing Scenarios.

Exposure concentrations by sector for the inhalable and respirable fraction, with and without adjustment for the use of RPE are provided in the following tables. The statistical parameters for the inhalable fractions are based on log-normal distributions, fitting the available exposure data where the AM and P95 values for existing data have been given particular weight for the fitting (i.e. the distributions better fit these statistical parameters than other parameters.). Statistical parameters are provided for the inhalable fraction without and with adjustment for the use of RPE in Table 3-73 and Table 3-72, respectively. The basis for the adjustment for use of RPE is provided in section 3.3.6.

For the respirable fraction, the parameters have been derived using the sector-specific R:I ratios described in section 3.3.2. It has been assessed that this method provides more correct estimation as the reported data on inhalable fractions are considered to be more representative for an EU average that the data on respirable where data originate mainly from Germany and a few other Member States in Western Europe.

The exposure concentrations are further modified on the basis of the impact of implementation of new OELs for other substances as described in section Impact of the implementation of other OELs4.1.

Table 3-72 Summary of exposure concentrations by sectors for cobalt and inorganic cobalt compounds used for the further analysis. All values in µg Co/m³, inhalable fraction – with adjustment for the use of RPE. This distribution is used for calculating cases of non-cancer endpoints.

Sector		AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	0.3	0.2	0.4	0.8	1.2	2.7
C19.20	Petrochemical, catalyst	3.4	2.2	4.1	7.3	10.3	19.4
C20.12	Manufacture of dyes and pigments	6.5	3.2	7.3	15.6	24.5	57.0
C20.13-20.14	Manufacture of basic chemicals	2.4	1.1	2.5	5.6	9.0	22.0
C20.30	Manufacture of paints and inks	4.0	1.25	3.7	9.8	17.6	52.8
C20.59	Catalysts and other chemicals	0.3	0.1	0.2	0.6	1.0	2.8
C20.59	Formulation other chemicals	2.6	0.8	2.3	6.1	11.0	33.0
C21.20	Pharmaceuticals	0.3	0.0	0.1	0.5	1.0	3.7
C22.11	Production of tyres	1.2	0.2	0.8	2.5	4.8	16.7
C23.1	Glass	3.0	1.5	3.3	6.8	10.5	23.4
C23.4	Ceramics	6.7	3.5	7.7	16.0	24.6	55.0
C23.7	Cutting stone	2.5	0.9	2.5	5.9	10.0	26.6
C24.10	Steel	5.4	2.7	6.0	12.6	19.4	43.7
C24.45	Manufacture of cobalt and cobalt alloys	5.3	2.6	5.9	12.5	19.4	44.5
C25.5	Powder metallurgy	4.8	3.0	5.7	10.3	14.5	27.9
C25.61	Surface treatment of metals	3.2	1.7	3.7	7.3	11.1	23.9
C25.62	Machining	6.3	4.8	7.8	12.2	15.8	25.8
C25.73	Manufacture of tools	4.8	3.0	5.7	10.3	14.5	27.9
C25.99	Manufacture of other fabricated metal products n.e.c.	7.4	4.0	8.7	17.8	27.1	59.8
C26.1	Production of electronic components	7.6	4.2	9.0	17.9	27.0	58.3
C26.51	Humidity indicator cards	0.2	0.1	0.2	0.5	0.7	1.8

Sector		AM	P50	P75	P90	P95	P99
C27.2	Batteries	1.3	0.4	1.2	3.0	5.1	14.2
C28.11	Engines and turbines	6.2	4.7	7.7	12.2	15.9	26.4
C29.10-30	Automotive	3.2	1.7	3.6	7.2	10.9	23.6
C30.30	Air and spacecraft	6.2	4.7	7.7	12.2	15.9	26.4
C32.50	Medical and dental devices	11.5	7.8	14.5	25.2	35.2	65.7
E38.32	Metal recovery	3.8	2.6	4.6	7.9	11.0	19.9
	Biogas	0.0	0.0	0.0	0.0	0.06	0.13
	Welding, etc.	12.9	8.0	16.8	32.7	48.7	100.2

Table 3-73 Summary of exposure concentrations by sectors for cobalt and inorganic cobalt compounds used for the further analysis. All values in µg Co/m³, inhalable fraction – without adjustment for the use of RPE.

Sector		AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	4.0	1.8	4.2	9.0	13.8	31.8
C19.20	Petrochemical, catalyst	27.3	17.6	32.8	58.4	82.0	155.2
C20.12	Manufacture of dyes and pigments	6.5	3.2	7.3	15.6	24.5	57.0
C20.13-20.14	Manufacture of basic chemicals	19.5	8.4	20.0	44.8	72.0	176.0
C20.30	Manufacture of paints and inks	31.7	10.0	29.6	78.4	140.8	422.4
C20.59	Catalysts and other chemicals	2.1	0.4	1.6	4.8	8.0	22.4
C20.59	Formulation other chemicals	21.0	6.0	18.4	48.8	88.0	263.6
C21.20	Pharmaceuticals	1.0	0.2	0.6	1.9	3.9	14.7
C22.11	Production of tyres	9.4	1.6	6.4	19.6	38.4	133.6
C23.1	Glass	23.9	11.6	26.4	54.4	83.6	187.2
C23.4	Ceramics	53.7	28.0	62.0	127.6	196.4	440.4
C23.7	Cutting stone	10.1	3.6	9.8	23.6	39.8	106.4
C24.10	Steel	42.9	21.6	48.4	100.4	154.8	349.6
C24.45	Manufacture of cobalt and cobalt alloys	42.3	20.8	47.6	99.6	155.2	356.0
C25.5	Powder metallurgy	38.0	24.0	46.0	82.0	116.0	222.8
C25.61	Surface treatment of metals	25.9	13.6	29.2	58.4	88.4	191.2
C25.62	Machining	50.2	38.8	62.8	97.2	126.0	206.0
C25.73	Manufacture of tools	38.0	24.0	46.0	82.0	116.0	222.8
C25.99	Manufacture of other fabricated metal products n.e.c.	59.5	32.0	70.0	142.0	216.4	478.8
C26.1	Production of electronic components	60.7	33.6	72.0	143.2	216.0	466.8
C26.51	Humidity indicator cards	0.8	0.2	0.8	1.8	2.8	7.0
C27.2	Batteries	10.6	3.2	9.6	23.6	40.8	113.2
C28.11	Engines and turbines	24.7	18.8	31.0	48.6	63.6	105.6
C29.10-30	Automotive	12.8	6.6	14.4	28.8	43.6	94.4
C30.30	Air and spacecraft	24.7	18.8	31.0	48.6	63.6	105.6
C32.50	Medical and dental devices	46.0	31.2	57.8	100.8	140.8	262.8

Sector		AM	P50	P75	P90	P95	P99
E38.32	Metal recovery	15.2	10.4	18.6	31.8	43.8	79.6
	Biogas	0.0	0.0	0.0	0.0	0.1	0.1
	Welding, etc.	103.6	64.0	134.0	261.2	389.6	801.6

Table 3-74 Summary of exposure concentrations by sectors for cobalt and inorganic cobalt compounds used for the further analysis. All values in µg Co/m³, respirable fraction – with adjustment for the use of RPE. This distribution is used for calculating cases of cancer.

Sector		R:I *	AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	1:4	0.1	0.0	0.1	0.2	0.3	0.7
C19.20	Petrochemical, catalyst	1:4	0.9	0.6	1.0	1.8	2.6	4.9
C20.12	Manufacture of dyes and pigments	1:4	1.6	0.8	1.8	3.9	6.1	14.3
C20.13-20.14	Manufacture of basic chemicals	1:4	0.6	0.3	0.6	1.4	2.3	5.5
C20.30	Manufacture of paints and inks	1:4	1.0	0.3	0.9	2.5	4.4	13.2
C20.59	Catalysts and other chemicals	1:4	0.1	0.0	0.1	0.2	0.3	0.7
C20.59	Formulation other chemicals	1:4	0.7	0.2	0.6	1.5	2.8	8.2
C21.20	Pharmaceuticals	1:4	0.1	0.0	0.0	0.1	0.2	0.9
C22.11	Production of tyres	1:4	0.3	0.1	0.2	0.6	1.2	4.2
C23.1	Glass	1:4	0.7	0.4	0.8	1.7	2.6	5.9
C23.4	Ceramics	1:4	1.7	0.9	1.9	4.0	6.1	13.8
C23.7	Cutting stone	1:4	0.6	0.2	0.6	1.5	2.5	6.7
C24.10	Steel	1:8	0.7	0.3	0.8	1.6	2.4	5.5
C24.45	Manufacture of cobalt and cobalt alloys	1:8	0.7	0.3	0.7	1.6	2.4	5.6
C25.5	Powder metallurgy	1:8	0.6	0.4	0.7	1.3	1.8	3.5
C25.61	Surface treatment of metals	1:4	0.8	0.4	0.9	1.8	2.8	6.0
C25.62	Machining	1:8	0.8	0.6	1.0	1.5	2.0	3.2
C25.73	Manufacture of tools	1:8	0.6	0.4	0.7	1.3	1.8	3.5
C25.99	Manufacture of other fabricated metal products n.e.c.	1:8	0.9	0.5	1.1	2.2	3.4	7.5
C26.1	Production of electronic components	1:4	1.9	1.1	2.3	4.5	6.8	14.6
C26.51	Humidity indicator cards	1:4	0.1	0.0	0.1	0.1	0.2	0.4
C27.2	Batteries	1:4	0.3	0.1	0.3	0.7	1.3	3.5
C28.11	Engines and turbines	1:8	0.8	0.6	1.0	1.5	2.0	3.3
C29.10-30	Automotive	1:4	0.8	0.4	0.9	1.8	2.7	5.9
C30.30	Air and spacecraft	1:8	0.8	0.6	1.0	1.5	2.0	3.3
C32.50	Medical and dental devices	1:8	1.4	1.0	1.8	3.2	4.4	8.2
E38.32	Metal recovery	1:8	0.5	0.3	0.6	1.0	1.4	2.5
	Biogas	1:4	0.00	0.00	0.01	0.01	0.02	0.03

Sector		R:I *	AM	P50	P75	P90	P95	P99
	Welding, etc.	1:2	6.5	4.0	8.4	16.3	24.3	50.1

** 'M' indicates that the parameters are derived by fitting to actual measurements of the respirable fraction. R:I =respirable to inhalable ratio used for calculating respirable concentrations from inhalable.*
Source: Study team.

Table 3-75 Summary of exposure concentrations by sectors for cobalt and inorganic cobalt compounds used for the further analysis. All values in µg Co/m³, respirable fraction – without adjustment for the use of RPE.

Sector		R:I *	AM	P50	P75	P90	P95	P99
C10.91	Manufacture, feeds	1:4	1.0	0.5	1.1	2.3	3.5	8.0
C19.20	Petrochemical, catalyst	1:4	6.8	4.4	8.2	14.6	20.5	38.8
C20.12	Manufacture of dyes and pigments	1:4	1.6	0.8	1.8	3.9	6.1	14.3
C20.13-20.14	Manufacture of basic chemicals	1:4	4.9	2.1	5.0	11.2	18.0	44.0
C20.30	Manufacture of paints and inks	1:4	7.9	2.5	7.4	19.6	35.2	105.6
C20.59	Catalysts and other chemicals	1:4	0.5	0.1	0.4	1.2	2.0	5.6
C20.59	Formulation other chemicals	1:4	5.2	1.5	4.6	12.2	22.0	65.9
C21.20	Pharmaceuticals	1:4	0.3	0.0	0.1	0.5	1.0	3.7
C22.11	Production of tyres	1:4	2.4	0.4	1.6	4.9	9.6	33.4
C23.1	Glass	1:4	6.0	2.9	6.6	13.6	20.9	46.8
C23.4	Ceramics	1:4	13.4	7.0	15.5	31.9	49.1	110.1
C23.7	Cutting stone	1:4	2.5	0.9	2.5	5.9	10.0	26.6
C24.10	Steel	1:8	5.4	2.7	6.0	12.6	19.4	43.7
C24.45	Manufacture of cobalt and cobalt alloys	1:8	5.3	2.6	5.9	12.5	19.4	44.5
C25.5	Powder metallurgy	1:8	4.8	3.0	5.7	10.3	14.5	27.9
C25.61	Surface treatment of metals	1:4	6.5	3.4	7.3	14.6	22.1	47.8
C25.62	Machining	1:8	6.3	4.8	7.8	12.2	15.8	25.8
C25.73	Manufacture of tools	1:8	4.8	3.0	5.7	10.3	14.5	27.9
C25.99	Manufacture of other fabricated metal products n.e.c.	1:8	7.4	4.0	8.7	17.8	27.1	59.8
C26.1	Production of electronic components	1:4	15.2	8.4	18.0	35.8	54.0	116.7
C26.51	Humidity indicator cards	1:4	0.2	0.1	0.2	0.5	0.7	1.8
C27.2	Batteries	1:4	2.6	0.8	2.4	5.9	10.2	28.3
C28.11	Engines and turbines	1:8	3.1	2.4	3.9	6.1	8.0	13.2
C29.10-30	Automotive	1:4	3.2	1.7	3.6	7.2	10.9	23.6
C30.30	Air and spacecraft	1:8	3.1	2.4	3.9	6.1	8.0	13.2
C32.50	Medical and dental devices	1:8	5.8	3.9	7.2	12.6	17.6	32.8
E38.32	Metal recovery	1:8	1.9	1.3	2.3	4.0	5.5	10.0
	Biogas	1:4	0.00	0.00	0.01	0.01	0.02	0.03

Sector		R:I *	AM	P50	P75	P90	P95	P99
	Welding, etc.	1:2	51.8	32.0	67.0	130.6	194.8	400.8

** 'M' indicates that the parameters are derived by fitting to actual measurements of the respirable fraction. R:I =respirable to inhalable ratio used for calculating respirable concentrations from inhalable.*
Source: Study team.

3.3.8 Values used in the benefits and costs models

In both the benefits and costs models, the exposed workers or enterprises with exposed workers are split into five groups representing the groups shown in Table 3-76. The exposure level assumed to be experienced by this group is calculated as shown in Table 3-76 based on the statistical parameters for the exposure concentrations when RPE is taken into account.

Table 3-76 Calculation of exposure levels (inhalable) used in benefits and costs models

Percentiles	Proportion of workers or enterprises	Calculation for exposure level assumed for modelling
0 - 50	50%	50th percentile
51 - 75	25%	Mean of 50th and 75th percentiles
76 - 90	15%	Mean of 75th and 90th percentiles
91 - 95	5%	Mean of 90th and 95th percentiles
96 - 100	5%	Geometric mean of 95th and 100th percentiles

3.3.9 Trends in exposure concentrations

Italy. Analysing data from the SIREP database in Italy, Scarcelli at al. (2020) did not find any significant temporal trend in measured cobalt air levels (geometric mean) during the period 1996 to 2017. The geometric mean for all measurements within one year varied from 0.15 to 1.8 µg/m^3 with no clear trend and an overall geometric mean for the entire period of 0.33 µg/m^3. The authors note that the analysis could indicate an insufficient attention in implementing protection measures but also notes that given the lack of statistical significance, the result must be evaluated with caution.

France. The overalls development in exposure concentrations as reported to the COLCHIC database in France from the period before 2000 to the period after 2000 is shown in Table 3-77. For the personal measurements, the median (P50) concentration was seven times higher for the period before 2000 as compared with the period after 2000 whereas it for the P95 was four times higher. For the stationary samples, the P95 was 6 times higher for the period before 2000 while it for the median cannot be calculated.

Table 3-77 Overall trend in exposure concentrations in France from the period <2000 to the period ≥2000. All concentrations in µg/m^3 without adjustment for RPE.

Sample type	Period	P50	P75	P95	Max
Personal	<2000	14	55	460	23,000
	≥2000	1.9	9.5	120	13,000
Stationary	<2000	4	16	260	49,000
	≥2000	>LOQ	3.8	45	8,200

Source : Sauvé and Mater, 2022.

Finland. The Finnish Institute of Occupational Health gathered exposure concentrations of air pollutants in Finnish workplaces measured by FIOH (FIOH 2021 as cited by ECHA, 2022). Samples were mainly taken from industrial environments, as well as sites of production, transportation and waste disposal. The report from the years 2008-2019 show that the P50 values for cobalt have increased slightly during the years, being 0.35 µg/m^3 for the period 2016-2019 (n=231).

Hardmetal, Austria. Hutter *et al.* (2016), analysed cobalt air levels in the Austrian tungsten industry collected from 1985 to 2012, and human biomonitoring data collected from 2008 to 2014. Both air and urine measurements exhibited an overall decreasing trend over time and the estimated time trend in air concentrations fitted according to the authors the time trend in urine values well. Based on linear regression for the log-transformed data, the overall mean can be estimated to have decreased from approx. 40 µg/m^3 in 1985 to approx. 15 µg/m^3 in 2012 (read from the figure shown in the paper) corresponding to a decline of 4-5% per year. Changes in the use of RPE is not reported.

Manufacture of cobalt. Based on measured concentrations over the period from 1968 to 2014 in a cobalt plant in Finland no clear trend in exposure levels was observed (Sauni *et al.*, 2017). Highest mean cobalt levels were reported for reduction and powder production (around 70 µg/m^3) and sulphating roasting (around 80 µg/m^3) while levels were lower in leaching and solutions purification (around 18 µg/m^3) and chemicals department (around 22 µg/m^3). Respirators were available since the plant started operating and became mandatory in the last ten years in the powder production and chemical departments.

Even higher levels in the past are reported by Swennen *et al.*, 1993). A cross-sectional study was carried out among 82 workers in a cobalt refinery which used a wide variety of raw materials, mainly cobalt metal cathodes and scrap. The geometric mean TWA exposure assessed with personal samplers (n = 82) was about 125 µg/m^3. About 70% of the workers were exposed to a TWA higher than 50 µg/m^3 and about 25% were exposed to a TWA higher than 500 µg/m^3. The possible use of RPE is not reported. For comparison, the most recent data for manufacture of cobalt as reported in the CSRs and shown in section 3.3.4.14 indicates P90 values in the range of 0.5 to 23.6. µg/m^3 for the various Worker Contributing Scenarios. This indicates that the exposure levels 30 years ago were in the order of magnitude of 3-7 times the concentrations today.

Summary. The reported trends in exposure concentrations give no clear indication of the trends. Data from Italy shows no trend in concentrations for the period 1996 to 2017 (Scarcelli *et al.*, 2020) and data from Finland show no clear trend for the period 2008 to 2019 (FIOH 2021 as cited by ECHA, 2022). The study from the Austrian tungsten industry indicates a declining trend in the order of 4-5% per year from 1985 to 2012 (Hutter *et al.*, 2016). Comparing concentrations reported in various studies from the hardmetal industry indicates that the concentration in the beginning of the 1990'ies was likely in the order of 3-7 times the concentrations today. This is in accordance with data on trend in exposure concentrations presented by companies at site visits. No trend in exposure concentration was observed in a cobalt plant in Finland from 1968 to 2014 (Sauni *et al.*, 2017). The French dataset which represents exposure data across many sectors shows that for the personal measurements, the median (P50) concentration was seven times higher for the period before 2000 as compared with the period after 2000 whereas it for the P95 was four times higher.

Based on the available data, given particular weight to the French data representing a large dataset across sectors, a decrease in the concentrations of 4% per year over the last 30 years is assumed for the calculation of current burden of disease in section 3.12.1. This corresponds to a concentration of approximately three times higher 30 years ago as compared with today.

3.4 Exposed workforce

3.4.1 Introduction

The current section assesses the exposed workforce by sector. The section initially present available data on exposed workforce from national databases, stakeholder consultation and other data sources. This is followed by an estimation of exposed workforce by sector. In order to reduce repetition of information, basic information on sectors and number of companies which form background for the estimates is described in section 3.10 on market analysis. To obtain the full understanding of the background for the estimates for each sector it is thus necessary to combine information in this section with information on each sector in section 3.10.

3.4.2 Data on exposed workforce from national databases

Finland. Data from the Finish ASA register as reported in 2014 are shown in Table 3-78. The register does not include data on exposure to cobalt metal but includes exposure to cobalt sulphate and cobalt dichloride only. It should be noted that Finland hosts industries manufacturing cobalt compounds and recycling of cobalt from waste products.

Table 3-78 Workforce exposed to cobalt sulphates and cobalt dichloride in Finland as reported to the ASA register in 2014 (ASA, 2014)

Sectors*	Industry/activity (as reported in ASA 2014)	Cobalt sulphate	Cobalt dichloride
C16	Manufacture of wood and of products of wood and cork	2	
C20	Manufacture of chemicals and chemical products	204	89
C21	Manufacture of basic pharmaceutical products and pharmaceutical preparations		4
C24	Manufacture of basic metals	226	9
C28	Manufacture of machinery and equipment n.e.c.		2
E36	Water collection, treatment and supply		1
E38	Waste collection, treatment and disposal activities; materials recovery	16	
F43	Specialised construction activities	43	27
M71.2	Technical testing and analysis		4
M72	Scientific research and development	3	42
N	Administrative and support service activities		63
O84	Public administration and national defense		34
P	Education	6	22
	Total	500	275

Note: The table shows the data as reported by industry. The summary of the report indicates in total 535 exposed to cobalt sulphate and 263 exposed to cobalt dichloride.
* Indication of sectors added as part of this study.
Source: Translated from ASA (2014)using the corresponding NACE code descriptions

Italy. Data on number of exposed workers in Italy by economic activity compiled from the SIREP database are shown in the table below (Scarselli *et al.*, 2020). The table includes sectors where more than 3 companies have been registered in SIREP and where more than 1% of the total workforce of the sector is registered in SIREP. The data are based on the SIREP 1996-2016 dataset, but the estimate of the number of workers exposed represents the estimated exposed workforce in 2020. Overall, 30,402 workers (72% male) were estimated potentially at risk of exposure to asbestos in the selected industrial sectors. The sectors with most exposed workers were 'Treatment and coating of metals (25.61.0)' with 14,223 potentially exposed workers and 'Manufacture of hand tools, interchangeable parts for machine tools (25.73.1)' with 5,006 potentially exposed workers. The two sectors were also the sectors where the largest percentage of the workforce in companies reporting to SIREP was potentially exposed with values at 39% and 24%, respectively.

The study assumes that the percentage of workers exposed to cobalt in the sectors in Italy are the same as for companies reporting on cobalt exposure to SIREP which as noted by the authors lead to an overestimation. On the other hand, the summary excludes sectors where less than 3 companies have reported to SIREP.

For cobalt and inorganic cobalt compounds the assumption that exposure in the companies reporting to SIREP is representative for the entire sector would probably lead to a quite significant overestimation as cobalt in many sectors are used only for particular purposes.

Table 3-79 Estimates of potentially exposed workers to cobalt in the selected sectors of economic activity (SIREP 1996-2016). Include exposure to both organic and inorganic cobalt compounds.

Sector of economic activity (NACE code)	No of firms [a]	% of firms[b]	No of workers[c]	% of workers[d]	% of exposed[e]	No exposed[f]	% of men[h]
Manufacture of other inorganic basic chemicals (C20.13)	3	1.32	5,883	1.60	13.83	814	79
Manufacture of other organic basic chemicals (C20.14)	3	1.21	10,526	5.84	1.14	120	82
Manufacture of organic chemicals from basic products derived from fermentation processes or vegetable raw materials (C20.59.2)	3	1.97	1,248	7.85	6.12	76	80
Manufacture of other chemical products for industrial use (C20.59.4)	17	2.91	9,913	6.79	19.17	1,900	74
Manufacture of basic pharmaceutical products (C21.10.0)	11	6.79	11,870	18.23	3.97	472	63
Manufacture of pharmaceutical preparations (C21.20.0)	28	4.54	50,855	15.54	3.02	1,538	60
Treatment and coating of metals (C25.61.0)	73	1.73	36,201	3.88	39.29	14,223	77
Manufacture of hand tools, interchangeable parts for machine tools (25.73.1)	3	0.13	20,607	1.72	24.29	5,006	79
Manufacture of other fabricated metal products (C25.99.9)	10	0.21	42,273	2.48	6.10	2,579	72
Manufacture of medical and dental instruments and supplies (C32.50.5) *	3	0.26	18,302	19.37	0.28	52	43
Testing and technical analysis of products (M71.20.1)	7	0.20	15,382	2.95	9.47	1,457	48
Other research and experimental development on natural sciences and engineering (M72.19.0)	10	0.18	17,494	2.86	12.38	2,165	49
Total						30,402	72%

a: Number of firms in SIREP; b: Percentage of total number of firms in Italy registered in SIREP; c: Number of workers reported by firms (exposed + non-exposed) in Italy [the paper indicates number in SIREP but is not in accordance with explanation in the paper]; d: Percentage of total number of workers in the sector represented by the companies registered in SIREP; e: Percentage of exposed workers with respect to non-exposed workers

reported by companies in SIREP; f: Total number of estimated exposed workers in Italy; h: Percentage of exposed workers which are male. * The paper indicates it as 'Manufacture of optical instruments' but the NACE code represents 'Manufacture of medical and dental instruments and supplies' and it is here considered that most likely the indicated NACE code is correct.
Source: Scarselli et al., 2020.

France. The Medical Monitoring Survey of Professional Risks (Surveillance médicale des expositions aux risques professionnels, SUMER) provide extrapolations from a sample of workers who self-declare exposure in a survey administered by company medical officers during the workers' regular compulsory medical examination.

Number of workers exposed to cobalt and cobalt compounds in the SUMER surveys in 2010 and 2016/17 are shown in Table 3-80. The total estimate of exposed workers has nearly halved (from ca. 66,200 to 36,300 workers) between the surveys in 2010 and 2016/17.

It should be noted that the surveys extrapolate the number of workers exposed in France from a limited set of self-declarations. The number of workers in the SUMER dataset should be considered the number 'potentially exposed' rather than exposed to specific concentrations.

The survey include exposure to organic cobalt compounds as well and exposure by other pathways than inhalation.

Table 3-80 Workers exposed to cobalt and cobalt compounds in the SUMER survey, 2010 (Vinck and Emmi, 2015) and 2016/17 (Matinet et al., 2020)

		SUMER survey, 2010*	SUMER survey, 2016/17*
Total no. of workers (% of the workforce)		66,200 (0.3%)	36,300 (0.1%)
Duration of exposure (hours per week)	No indication <2h 2-10h 10-20h >20h	No indication: N/A 43,800 (66.1%) 8,000 (12.1%) 4,800 (7.3%) 6 600 (19.9%)	3,700 (10.2%) 17,300 (47.6%) 12,600 (34.8%) 700 (2.0%) 2,000 (5.4%)
Extent of exposure	Not declared: Very low Low High Very high	22,000 (33.3%) 26,700 (40.3%) 16,300 (24.6%) N/A N/A	4,300 (11.8%) 11,200 (30.8%) 19,900 (54.9%) 900 (2.6%) - (0.1%)

Note: Low exposure: less than 50% of OEL, High exposure: >50% of OEL, very high exposure: may exceed OEL. French OEL for some organic cobalt compounds is 100 µg/m^3.

Number of exposed workers by sector in 2016/2016 is shown in Table 3-81. Similar data are not available in the SUMER survey for 2010.

Table 3-81 Workers exposed to cobalt and cobalt compounds by sector in the SUMER survey 2016/17. Include exposure to cobalt compounds beyond the scope of the current study and exposure at levels below those relevant for the assessed policy options.

Sector	Number of exposed workers 2016/17	Percent of workforce exposed in sector 2016/17
Other manufacturing industries; repair and installation of machinery and equipment	12,500	4.2
Scientific research and development	2,100	1.5
Manufacture of textiles, clothing industries, leather and footwear industry	1,300	1.0

Manufacture of electrical equipment	500	0.6
Manufacture of machinery and equipment n.e.c.	1,200	0.6
Water production and distribution; sanitation, waste management and remediation	800	0.5
Activities for human health	6,400	0.4

Source: Matinet *et al.*, 2020.

Canada. According to CAREX Canada (2022), approximately 25,000 Canadians are exposed to cobalt in their workplaces; 85% of these workers are male. However, in an overview section, CAREX Canada indicates that only 3,000 Canadians are occupationally exposed to cobalt. The background for the difference between the two estimates is not indicated. The main industrial groups exposed are metal ore mining, sawmills and wood preservation (where saw-filers are exposed during grinding), and offices of dentists (where cobalt is used in some dental prosthetics). The largest occupational groups exposed include welders and related machine operators (4,800 workers exposed), dental technologists, technicians and laboratory assistants (2,700 workers exposed), and machinists and machining and tooling inspectors (2,000 workers exposed), and machining tool operators (1,300 workers exposed). The number of workers exposed to cobalt decreased by approximately 7,500 workers from 2006 to 2016 (a 23% decrease). This was according to CAREX Canada driven by a decrease in the total number of workers in the sawmills and wood preservation, medical equipment, and mining industries. Exposure at relatively high level was reported for three industries: production of metal products, machinery production and primary metal manufacturing.

3.4.3 Survey results on average number of exposed workers per site

Number of workers per site responding to the survey is indicated in the table below. Answers represent individual sites; some companies have responded for more than one site and the number of responding companies (indicated by group names) is 44.

In total, the survey results included 7,151 exposed workers. The average number of exposed workers in companies providing this information was 125.

Table 3-82 Survey result for number of workers per company exposed to cobalt and inorganic cobalt compounds for those companies indicating this information.

Sector	Number of answers	Number per site exposed Average (min - max)	Percentage exposed Average (min - max)
C19.20 Petrochemical, catalyst	1	20 (20 - 20)	2% (2% - 2%)
C20.12 Manufacture of dyes and pigments	3	53 (10 - 96)	22% (8% - 39%)
C20.13 Manufacture of other inorganic basic chemicals	6	39 (1 - 93)	29% (0% - 60%)
C20.14 Manufacture of other organic basic chemicals	1	21	72%
C20.30 Manufacture of paints and inks	3	32 (2 - 73)	10% (2% - 16%)
C20.59 Catalysts and other chemical products n.e.c.	6	86 (2 - 159)	42% (10% - 77%)
C21.20 Manufacture of pharmaceutical preparations	1	190	6%
C23.1 Glass	1	9	1%
C23.4 Ceramics	7	32 (1 - 48)	14% (1% - 24%)
C24.10 Steel	1	10	2%
C24.45 Manufacture of cobalt and cobalt alloys	7	142 (50 - 400)	25% (5% - 49%)

Sector	Number of answers	Number per site exposed Average (min - max)	Percentage exposed Average (min - max)
C25.61 Surface treatment of metals	2	17 (4 - 30)	2% (1% - 4%)
C25.73 Manufacture of tools	12	247 (6 - 1280)	45% (13% - 87%)
C26.1 Production of electronic components	1	15	0.004%
C27.2 Batteries	3	130 (60 - 200)	26% (24% - 29%)
C32.50 Medical and dental devices	1	18	4%
F42 Construction	1	400	29%
Total		125	

3.4.4 Exposed workforce by sector

The following section estimates the number of exposed workers by sector. There is an overlap with information provided on number of companies in section 3.10. In order to avoid replication of information, the main basis for estimating the number of companies and resulting estimate on number of exposed workers is provided in section 3.10 with a summary on number of exposed workers in the table below.

Besides the number of workers estimated in the table below, some workers may potentially be exposed to cobalt at levels below the expose levels relevant for the policy options. An estimate of the number potentially exposed at lower levels is provided later in this section. For the non-cancer endpoints the levels would be below the thresholds and not contribute to the current and future burden of disease.

For each sector the most likely range is indicated, but in some cases the actual number may be outside these ranges. It is considered that the uncertainties somewhat balance each other so the uncertainty on the sum is lower than indicated by summing up the minimum and maximum estimates for each sector.

Table 3-83 Estimated number of workers exposed by sector covered by the analysis. The ranges are for some uncertain numbers not evenly distributed around the best estimate indicating the differences in uncertainties regarding the higher and the lower number, respectively.

Sector		Basis	Estimated number of exposed workers (range)
C10.91	Manufacture, feeds	According to consultation response from the European Feed Manufacturers' Federation (FEFAC) 2023), today around 300 sites formulate cobalt-containing preparations or premixtures in the EU which is similar to the number reported for the ECHA Restriction proposal. Compound feed and complementary feed is manufactured in approximately 4,100 sites, but as indicated in section 3.3.4.1, the exposure levels at this stage of the product chain would be below the levels relevant for the assessed policy options and no impacts of introduction of the OELs are expected. Of the 300 sites, it is estimated by FEFAC that approximately 90% are using coated cobalt carbonate which would lead to significant lower exposure concentrations than those reported for these activities. No data are available to demonstrate that the exposure levels when using the coated cobalt compounds would be below the levels of relevance for the assessed OELs. According to FEFAC, about 5-7 persons per site may be exposed to the cobalt compounds	1,800 (1,500 - 2,100)

Sector		Basis	Estimated number of exposed workers (range)
		which leads to an estimate of approximately 1,500 - 2,100 exposed workers; with 1,800 exposed workers used as the medium estimate.	
C19.20	Petrochemical, catalyst	Exposure to cobalt only take place when catalyst reactors are opened for changing the catalyst. According to information provided in section 3.10 cobalt catalysts are typically handled by contractors and the staff in the approximately 82 refinery and GTL sites are supposed not to be in contact with the catalysts. Based on information from one company in the sector, about 20 contractors are operating in this sector with maintenance of various types of catalysts. The number of workers exposed to cobalt by one maintenance operation is approximately 20 in periodic campaigns. Contractors are serving more than one refinery but may have more teams working at the same time, and the total number of workers in the EU exposed is estimated at 400-800. These workers will only be exposed to cobalt occasionally.	600 (400-800)
C20.12	Manufacture of dyes and pigments	The number of companies is according to information provided in section 3.10 estimated at 15 with a total number of sites at 30. For the stakeholder survey, three companies within this sector have responded. The average number of exposed workers in these companies (each reporting for one site) is 53 (range 10-96) representing 22% of the workforce in the companies. Eftec (2023) reports based on responses from 6 companies that the number of exposed workers per site was 75 and per company 138; representing 28% of the workforce of the companies. The average per site is quite similar to the responses to the current study. If this average is used as best estimate, a total of about 2,300 (2,000-2,600) workers would be exposed.	2,300 (2,000-2,600)
C20.13-20.14	Manufacture of basic chemicals	The number of companies is according to information provided in section 3.10 estimated at 30 with 42 sites. For the stakeholder survey, seven companies within this sector have responded. The average number of exposed workers in these companies (each reporting for one site) is 37 (range 1 - 93) representing 29% of the workforce in the companies. The average number of exposed workers in 15 companies representing 27 sites in manufacture of cobalt and/or cobalt substances (including cobalt metal) reporting to the eftec (2023) survey was 92 per site. For the estimation the averages from the eftec (2023) surveys will be used as this represent more companies and, on this basis, the total number is estimated at 2,900 (2,000 - 3,800). In comparison, an extrapolation of Italian data would result in 5,500 exposed workers.	2,900 (2,000 - 3,800)

Sector		Basis	Estimated number of exposed workers (range)
C20.30	Manufacture of paints and inks	Only organic compounds are used as driers in paint and inks, but a few companies use inorganic compounds and convert them in-house to organic compounds used as driers. The number of companies is according to information provided in section 3.10 estimated at 10 with in total 200 exposed workers. The estimate is quite uncertain.	200 (50-500)
C20.59	Catalysts	For the stakeholder survey, six companies within this sector have responded. The average number of exposed workers in these companies (each reporting for one site) is 86 (range 2 - 159) representing 42% of the workforce in the companies. For the eftec (2023 survey), the average reported for three sites is 53 representing 17% of the workforce. The number of exposed workers was estimated by ECHA (2018a) at 800 representing 19% of the workforce in the companies. The number of employees of the companies ranged from 50 to 800 with an average of 290. The average number of exposed workers per site was according to ECHA (2018a) about 60. Assuming 13 sites (see section 3.10) and 70 exposed workers per site, the total number of exposed workers is estimated at 910 (700 - 1,100).	910 (700 - 1,100)
C20.59	Formulation of other chemicals	Based on the information provided in section 3.10 in total 1,700 workers in 35 companies are estimated.	1,700 (1,000- 2,400)
C21.20	Pharmaceuticals	For the stakeholder survey, one company within this sector have responded. The number of exposed workers in the company is 190 representing 6% of the workforce in the company. At the same time, however, the company has indicated that only 2 workers are involved in the relevant process at a time. The number of companies have been assumed to be 8 (see section 3.10) and on this basis the total number of workers is assumed to be 950 (200-2000).	950 (200-2,000)
C22.11	Production of tyres	Exposure by manufacture of tyres and conveyer belts would be to organic cobalt compounds but in at least one company the organic cobalt compounds are produced in-house from inorganic cobalt compounds. It is assumed that 3 companies may undertake this process (see section 3.10). The number of exposed workers would be significantly lower than the number exposed to organic cobalt compounds (on average 565 according to eftec, 2023) and will here be assumed to be no more than hundred per company. The best estimate is thus approximately 300 but it could potentially be significantly higher if in-house production of the organic cobalt compounds take place in more companies.	300 (100 - 3,000)
C23.1	Glass	For the stakeholder survey, one company within this sector have responded. The number of exposed workers in the company is 9 representing 1% of the workforce in the company. It will be assumed that only a small part of the companies using cobalt will use it in this form. The main uses of cobalt substances in	900 (300 - 1,800)

Sector		Basis	Estimated number of exposed workers (range)
		general seems to be in blue coloured container glass and tinted flat glass. In the absence of specific data for the substances within the scope, it will as described in section 3.10.3.10 be assumed that 50 companies use the substances within the scope and the number of exposed workers is 900 (300 - 1,800) same average as assumed by FEVE (2023) but a wider range.	
C23.4	Ceramics	For the stakeholder survey, five companies with seven sites within this sector have responded. The average number of exposed workers per site is 32 (range 1-48) representing 14% of the workforce in the companies. Based on the available information it is assumed that 500 companies in this sector use pigments within the scope (see section 3.10). The average number of workers of responding companies is considered to be higher than the average as the size of the responding companies likely is higher than the average (average number of companies according to Eurostat is on 7 employees). An average of 15 workers exposed will be assumed leading to a total number of 7,500 (2,000-12,000) exposed workers.	7,500 (2,000- 12,000)
C23.7	Cutting stone	Based on information in section 3.10, in the absence of actual information it is assumed that about 300 companies use diamond tools indoors for cutting stone. It will furthermore be assumed that on average 10 workers are exposed in each company which leads to an estimate of 3,000 with a large uncertainty 500-10,000.	3,000 (500-10,000)
C24.10	Steel	For the stakeholder survey, one company within this sector have responded with number of workers. The number of exposed workers in the company is 10 representing 2% of the workforce in the company. Based on the description in section 3.10 the total exposed workforce is estimated at 100.	100 (50-500)
C24.45	Manufacture of cobalt and cobalt alloys	For the stakeholder consultation, two manufacturers of cobalt and cobalt alloys have answered the questionnaire. The average number of workers were 110 representing 44% of the workforce of the companies. As described in section 3.10, the number of companies is assumed to be 6 and the total number of exposed workers is estimated at 660.	660 (300-1000)
C25.5	Powder metallurgy	As described in section 3.10 it is assumed that 30 producers of cobalt-containing powders or products based on powder technology, are not included elsewhere. Based on experience from similar sectors, the average number of exposed workers is estimated at 30 per company leading to a total of 900 exposed workers.	900 (300 - 2,000)
C25.61	Surface treatment of metals	As described in section 3.10, the total number of exposed workers is estimated at 10,400. This is split 50:50 between this sector and the automotive sector.	5,200 (3,200 - 7,200)
C25.62	Machining	As described in section 3.10, a number of 5,000 companies with a total of 30,000 exposed workers is assumed. All companies have been allocated to sector C25.62 but some of the companies may in reality be in other sectors within the metal industry.	25,000 15,000 - 45,000

Sector		Basis	Estimated number of exposed workers (range)
C25.73	Manufacture of tools	The sector is described in section 3.10. For the stakeholder survey, in total 15 companies (representing 18 sites) within C25.73 Manufacture of tools have answered the stakeholder survey. 15 companies with 12 sites within this sector have responded. The average number of exposed workers per site is 247 (range 6 - 1280) representing 45% of the workforce in the companies. These sites represent the segment that produce the sintered hardmetal tools and semi-manufactured parts used by downstream tool manufacturers. The number of sites is estimated at 20-30 and using the average from the survey the total number of exposed workers would be 6,175. No companies from the segment of downstream hardmetal tool producers has answered the stakeholder survey. The number of companies is estimated at 1000-2000 and with an assumed average of 10 exposed workers per company, the total exposed workforce can be estimated at 15,000. The number of hardmetal tool producers is 800-900 of which 90% produce the tools from cobalt powder and diamonds, the process where exposure take place. None of the diamond tool manufacturers has answered the stakeholder survey. Assuming an average number of exposed workers of 10 in those companies where exposure take place, the total number of workers is estimated at 7,650. In total, the number of workers is estimated at 30,000 (23,000-37,000) where the number for the segment sintering the hardmetal is fairly certain, whereas the estimate for the other segment is more uncertain.	30,000 23,000 - 37,000
C25.99	Manufacture of other fabricated metal products n.e.c.	Three companies within the sector have answered the questionnaire. As described in section 3.10, a total of 150 companies with a total of 1,120 exposed workers which represent 20% if the workforce in the companies is assumed.	1,120 (500 - 1,600)
C26.1	Production of electronic components	For the stakeholder survey, one company within this sector has responded. The number of exposed workers in the company is 15 representing 0.004% of the workforce in the company (no indicated at site level) As described in section 3.10, a total number of 200 companies with 3,000 exposed workers is assumed.	3,000 (1,000 - 5,000)
C26.51	Humidity indicator cards	As described in section 3.10, it is here assumed that 5 companies with 100 exposed workers are involved in the production of the cards.	100 30 - 300
C27.2	Batteries	For the stakeholder survey, three companies (each representing one site) within this sector have responded. The average number of exposed workers per site is 130 (range 60 - 200) representing 26% of the workforce in the companies. As described in section 3.10 the number of producers of batteries with cobalt is here estimated at 15 companies with a total of 1,950 exposed workers using the average reported for the stakeholder consultation as the best estimate.	1,950 (1,500 - 2,500)
C28.11	Engines and turbines	No answers to the stakeholder consultation has been obtained from the engines and turbines sector.	2,200 (1,000 - 3,400)

Sector		Basis	Estimated number of exposed workers (range)
		Based on the description in section 3.10, the total number of companies is assumed to be 130 with 2,200 exposed workers.	
C29.10-30	Automotive	As described in section 3.10, the total number of exposed workers is estimated at 10,400. This is split 50:50 between the surface treatment sector and the automotive sector. This gives a total number of exposed from these processes at 5,200. Cobalt may also be used for other purposed in the automotive sector, but it is considered that surface treatment account for the major part.	5,200 (3,200 - 7,200)
C30.30	Air and spacecraft	No answers to the stakeholder consultation has been obtained from the air and spacecraft sector. Based on the description in section 3.10, the total number of companies is assumed to be 130 with 2,200 exposed workers.	2,200 (1,000 - 3,400)
C32.50	Medical and dental devices	For the stakeholder survey, one company within this sector has responded. The number of exposed workers in the company is 18 representing 4% of the workforce in the company. A study in Sweden measured cobalt exposure of 13 dental technicians working in a dental laboratory with 21 employees i Stockholm (Kettelarij *et al.*, 2016). Based on the description in section 3.10, the number of companies in the EU producing medical and dental implants and restorations with cobalt is estimated at 500. Assuming an average of 10 exposed workers per company lead to an estimate of 5,000 workers exposed at EU level.	5,000 (2,500 - 10,000)
E38.32	Metal recovery	Based on the description in section 3.10, the total number of companies is estimated at 15 with a total of 1,100 exposed workers	1,100 (800-1400)
	Biogas	In the absence of more exact data a number of 3,100 companies in industrial and professional biogas production with 5,400 workers exposed, will be applied from the eftec (2023) report. The number of workers is the same as in ECHA (2018a) which indicated the number of sites to be higher than the number of exposed workers.	5,400 (3,500-7,300 4,900 (3,000-6,800) OBS
	Welding etc.	Information on specific welding activities is still pending. Based on preliminary information that consumables for welding in cobalt alloys account for in the order of magnitude of 0.01-0.1% of all consumables (see section 3.10), it is assumed that the number of welders exposed to cobalt at relevant levels is likely in the range of 100-1000.	550 (100-1,000)
	Total		**113,000 (67,000 - 177,000)**

Workers exposed at low levels below the policy options

Workers may be exposed to cobalt by various downstream uses of cobalt-containing chemicals and articles at levels below the policy options and consequently excluded from this assessment. The table below lists some sectors where some information on number of exposed workers have been indicated in various sources.

Besides these sectors/applications, a significant number of workers may be exposed at low levels by use of diamond tools in construction and quarries, but no data allowing an estimate has been identified.

Low levels of exposure to cobalt have been demonstrated in dismantling of electronic waste and it cannot be excluded that low levels of exposure may take place by handling of scrap containing hard metals and cobalt alloys.

Table 3-84 Estimated number of workers exposed to cobalt metal or inorganic cobalt compounds at levels below the policy options in excluded sectors or subsectors

Sector / application area		Number of exposed workers *	Source of information
A01.20	Use of animal feeds	NA	Contact dermatitis has been reported for the use of animal feeds with cobalt, inhalation exposure at low levels cannot be excluded
C20.15 Manufacture of feeds	Manufacture of final feed	12,000	ECHA (2018a) estimates the number of workers in professional manufacture of feed at 14,000 of which 1,800 is covered by this study.
Multiple sectors	Use in fermentation, biotech, scientific research and standard analysis	900 [5 cobalt salts]	ECHA (2018a) estimates the number of workers in fermentation, biotech, scientific research and standard analysis at 900. Also included in eftec (2023). Italian SIREP database indicates about 3,500 exposed in laboratories and R&D activities. French SUMER database indicates 2,100 exposed in R&D.
Multiple sectors	Use of water treatment chemicals	100	ECHA (2018a) indicates that no data are available for this sector. Eftec (2023) indicates the number as 100.
B08.11 Quarrying F41,42, 43 Construction	Use of diamond tools	NA Potentially a large number	Stakeholder consultation
E38 Waste collection and disposal	Handling of electronic waste, scrap, chemical waste	NA	Finnish ASA register
A01.20	Use of animal feeds	NA	Contact dermatitis has been reported for the use of animal feeds with cobalt, inhalation exposure at low levels cannot be excluded
	Total quantified*	13,000	

*Source: Study team estimates on basis of indicated sources. * Rounded to nearest 1000.*

3.4.5 Trends in exposed workforce

No data on the overall past trends in exposed workforce have been identified. The French SUMER database indicates a decreasing trend where the number of exposed workers has nearly halved between the surveys in 2010 and 2016/17 (Vinck and Emmi, 2015; Matinet *et al.*, 2020). However, the numbers are based on a limited database. The number of workers exposed to cobalt in

Canada decreased by approximately 7,500 workers from 2006 to 2016 (a 23% decrease) Carex Canada, 2022).

On the other hand, the consumption of cobalt has been increasing markedly during the last 20 years across sectors. Based on the available data, an overall positive trend in workforce of 2% per year is assumed for the period 1993-2023, but the estimate is very uncertain.

3.4.6 Summary of exposed workforce

A summary of the data on exposed workforce is included in the following tables. Extrapolating the total number of exposed workers from databases in Italy, France and Canada gives similar results. The totals are higher than the totals estimated in this study, but all three estimates include exposure to organic cobalt compounds (e.g. rubber sector, coatings and catalysts in the plastic sector) and inorganic cobalt compounds outside the scope of the CMRD (e.g. glass sector) and include furthermore exposure at any level.

This study's estimate of total exposed workforce is higher than the exposed workforce estimated by eftec (2023) for the Cobalt Institute. The main reason is that eftec (2023) does not include some of the downstream uses with relatively high number of exposed workers such as the service life phases of hardmetal tools and diamond tools, and only partly include downstream uses of cobalt alloys.

Table 3-85 Summary of data on workers exposed to cobalt and cobalt compounds and extrapolated number

Source, year	Geographic coverage	Substances covered	Number estimated	Extrapolated number of workers in the EU27 exposed to the substance
Scarcelli *et al.*, 2020 Around 2020	Italy	All cobalt substances	30,402	230,000
Matinet *et al.*, 2020 2017/2018	France	All cobalt substances	36,300	240,000
Carex Canada, 2022 2016	Canada	All cobalt substances	25,000	292,000
Central Institute for Labour Protection – National Research Institute, Poland, 2019	Poland	All cobalt substances	4,600	54,000
eftec (2023) 2023	EU 27	All cobalt substances, some downstream uses not included	54,200-89,600	54,200-89,600
This study 2023	EU 27	Cobalt and inorganic cobalt compounds within the scope of the CMRD at exposure levels above policy options	113,000 (67,000 - 177,000)	113,000 (67,000 - 177,000)

The estimated number of workers in the EU27 exposed to cobalt and inorganic cobalt compounds in key sectors is summarised in Table 3-86. The main sectors are Manufacture of tools (26.5% of total exposed workforce), Machining (22.1% of total), Ceramics (6.6%), Surface treatment of metals (4.6%), Vehicles (4.6%), Biogas (4.8%), and Medical and dental devices (4.4%).

In the majority of sectors, the exposed workforce account only for a low percentage of the total registered workforce within the sectors. Sectors with the highest percentage of exposed workers are Manufacture of tools (14.7% of total registered workforce within the sector are exposed), Manufacture of dyes and pigments (9.2%), Ceramics (8.0%), Machining (6.4%), Batteries (4.5%), and Manufacture of cobalt and cobalt alloys (manufacture of non-ferrous metals) (4.2%).

Table 3-86 Estimated number of workers in the EU27 exposed to cobalt and inorganic cobalt compounds in key sectors

Sector		Number of exposed workers (best estimate)	% of all exposed workers	Total number of workers in NACE code	% of all workers in NACE code
C10.91	Manufacture, feeds	1,800	1.6%	90,897	2.0%
C19.20	Petrochemical, catalyst	600	0.5%	164,143	0.4%
C20.12	Manufacture of dyes and pigments	2,300	2.0%	25,051	9.2%
C20.13 -20.14	Manufacture of basic chemicals	2,900	2.6%	270,301	1.1%
C20.30	Manufacture of paints and inks	200	0.2%	145,324	0.1%
C20.59	Catalysts	910	0.8%	125,546	2.1%
C20.59	Formulation	1,700	1.5%		
C21.20	Pharmaceuticals	950	0.8%	575,728	0.2%
C22.11	Production of tyres	300	0.3%	101,000	0.3%
C23.1	Glass	900	0.8%	299,659	0.3%
C23.4	Ceramics	7,500	6.6%	94,123	8.0%
C23.7	Cutting stone	3,000	2.7%	139,480	2.2%
C24.10	Steel	100	0.1%	319,174	0.03%
C24.45	Manufacture of cobalt and cobalt alloys	660	0.6%	15,748	4.2%
C25.5	Powder metallurgy	900	0.8%	300,813	0.3%
C25.61	Surface treatment of metals	5,200	4.6%	278,268	3.0%
C25.62	Machining	25,000	22.1%	749,144	6.4%
C25.73	Manufacture of tools	30,000	26.5%	237,392	14.7%
C25.99	Manufacture of other fabricated metal products n.e.c.	1,120	1.0%	370,938	0.3%
C26.1	Production of electronic components	3,000	2.7%	226,199	1.3%
C26.51	Humidity indicator cards	100	0.1%	359,733	0.0%
C27.2	Batteries	1,950	1.7%	43,364	4.5%
C28.11	Engines and turbines	2,200	1.9%	220,000	1.0%
C29.10 -30	Vehicles	5,200	4.6%	2,328,912	0.4%
C30.30	Air and spacecraft	2,200	1.9%	359,401	0.6%
C32.50	Medical and dental devices	5,000	4.4%	542,155	1.4%
E38.32	Metal recovery	1,100	1.0%	196,000	1.3%

Sector		Number of exposed workers (best estimate)	% of all exposed workers	Total number of workers in NACE code	% of all workers in NACE code
	Biogas	5,400	4.8%	NA	NA
	Welding	550	0.5%	NA	NA
	Total (rounded)	**113,000**	**100%**	**8,578,493**	**1.2% (excl. NA)**

Source: Study team; Eurostat Structural Business Statistics (SBS).

The estimated number of workers in the EU27 exposed to cobalt and inorganic cobalt and companies with exposed workers in key sectors is summarised in Table 3-87. The number of companies make reference to section 3.10 where the background for the estimated number of companies is described. The average number of exposed workers per company (with exposed workers) is 7 which corresponds to 13% of the total workforce of the companies. The average number of exposed workers per company ranges from 2 in Biogas to 153 in Manufacture of dyes and pigments.

Sectors in which exposed workers account for more than 25% of the workforce of the companies are: Manufacture of basic chemicals, Manufacture of cobalt and cobalt alloys, Machining, Manufacture of tools, Batteries, Engines and turbines, Vehicles, Air and spacecraft, Medical and dental devices, and Metal recovery. Please note that the percentages in this table represent the percentage of exposed workers in those companies using cobalt, whereas the percentages in the previous table represented the percentage of exposed workers of all registered workers (incl. workers in companies not using cobalt) within the sector as reported in Eurostat SBS.

Table 3-87 Estimated number of workers in the EU27 exposed to cobalt and inorganic cobalt compounds and companies with exposed workers in key sectors

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers in companies *	Number exposed per company	Percentage exposed in companies
C10.91	Manufacture, feeds	1,800	300	9,000	6	20%
C19.20	Petrochemical, catalyst	600	82	88,200	7	1%
C20.12	Manufacture of dyes and pigments	2,300	15	10,500	153	22%
C20.13-20.14	Manufacture of basic chemicals	2,900	30	10,100	97	29%
C20.30	Manufacture of paints and inks	200	10	1,100	20	18%
C20.59	Catalysts	910	13	4,600	70	20%
C20.59	Formulation	1,700	35	8,100	49	21%
C21.20	Pharmaceuticals	950	8	5,100	119	19%
C22.11	Production of tyres	300	3	5,900	100	5%
C23.1	Glass	900	50	8,600	18	10%
C23.4	Ceramics	7,500	500	55,300	15	14%
C23.7	Cutting stone	3,000	1,000	20,900	3	14%
C24.10	Steel	100	7	700	14	14%
C24.45	Manufacture of cobalt and cobalt alloys	660	6	2,200	110	30%

Sector		Number of exposed workers	Number of companies with exposed workers	Total number of workers in companies *	Number exposed per company	Percentage exposed in companies
C25.5	Powder metallurgy	900	30	3,800	30	24%
C25.61	Surface treatment of metals	5,200	470	44,000	11	12%
C25.62	Machining	25,000	6,000	83,300	4	30%
C25.73	Manufacture of tools	30,000	2,300	114,400	13	26%
C25.99	Manufacture of other fabricated metal products n.e.c.	1,120	150	6,400	7	17%
C26.1	Production of electronic components	3,000	250	20,700	12	15%
C26.51	Humidity indicator cards	100	5	1,200	20	8%
C27.2	Batteries	1,950	15	6,900	130	28%
C28.11	Engines and turbines	2,200	130	7,300	17	30%
C29.10-30	Vehicles	5,200	130	17,300	40	30%
C30.30	Air and spacecraft	2,200	130	6,300	17	35%
C32.50	Medical and dental devices	5,000	500	16,700	10	30%
E38.32	Metal recovery	1,100	15	3,300	73	33%
	Biogas	5,400	3,100	36,900	2	15%
	Welding	550	50	4,700	11	12%
Total		113,000	15,334	872,300	7	13%

*Source: Study team, * Rounded figures.*

3.5 Current risk management measures (RMMs)

3.5.1 Types of RMMs

A wide range of RMMs are considered, reflecting the hierarchy of RMMs in the CMRD, as set out in Table 3-88 below. Data on these have been collected both through literature review and consultation.

Table 3-88 Hierarchy of measures to be applied by the employers, as listed in the CMRD

Type of measure	Measures specified in the CMRD
Reducing the quantities of the chemical agents used (substitution and material reduction)	(a) limitation of the quantities of a carcinogen or mutagen at the place of work;
Reducing the number of workers exposed	(b) keeping as low as possible the number of workers exposed or likely to be exposed;
Reducing the concentration of the chemical agents at the workplace	(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;
	(d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;

	(e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
	(f) application of suitable working procedures and methods;
Reducing the exposure of workers by protective measures	(g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
	(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
	(i) information for workers;
	(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;
	(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
Other measures	(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers.

3.5.2 Current use of RMMs by sector

3.5.2.1 Data from Chemical Safety Reports (CSRs)

In order to keep information om applied RMMs together with the exposure concentrations and not repeat the information, information on RMMs from CSRs are reported for each sector and Worker Contributing Scenarios in section 3.3.4. The information from the CSRs is used together with information obtained from the stakeholder survey, interviews and site visits for the cost assessment.

3.5.3 Data from questionnaire survey

The percentage of companies currently using each RMM, and the RMM to which they would change if each of the policy options were implemented is for key RMMs summarised in Annex B. In order not to repeat the information reference is made to the Annex.

3.5.4 Use of personal protective equipment

The exposure of workers to cobalt and inorganic cobalt compounds at a workplace can be further controlled by wearing personal protective equipment (PPE).

Whereas various PPE such as protective clothing, gloves, eye protection, etc. may be useful to protect against e.g. dermal exposure and oral exposure (as reflected by biomonitoring data), only respiratory protective equipment (RPE) would be efficient for protection against exposure by inhalation which is the subject of this study.

According to the CMRD, "*For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already been exhausted*," open for the situation that "*workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker*."

Many of the work processes where workers are exposed to cobalt and inorganic cobalt substances are short term activities where the workers are exposed e.g. by opening a closed system for loading, taking samples, take items in and out of closed systems, etc.

The table below summarising the responses from the stakeholder consultation illustrates that for many of the work processes, where workers are exposed today, they use RPE. This is in accordance with the data provided in the CSRs as shown in section 3.3. The table is together with respondents anticipated use of RPE by introduction of the various policy options also presented and discussed in section 7.2.4.

For many work processes, the respondents answer that more than one type is used so the results should not be interpreted in the way that all workers are wearing RPE (adding the percentages), but RPE is used to some extent by some workers for more than 50% of the work processes.

Table 3-89 Respiratory protective equipment. Percentage breakdown of primary RMMs currently used by enterprises by sector. The numbers represent work processes included in responses.

	Self-cont. breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask
Current situation	5% (8)	37% (61)	26% (43)	46% (75)

Source: Stakeholder survey. HEPA: High-Efficiency Particulate Air

The general trend is that powered air-purifying respirators, where the user is wearing a helmet with air at positive pressure provided by a powered filter worn at the back, is becoming more and more used. As shown in the table, it is reported to be used at least by some of the workers in 37% of the work processes. The equipment has a higher protection factor than conventional masks with HEPA filter or simple disposable masks because of the positive pressure and the helmet is more comfortable for the user than conventional filters. According to information from contacted companies (e.g. by site visits) in many Member States it is accepted that the respirators re used for a full shift contrary to the restricted use of conventional masks. A survey of Member States legislation has not been undertaken but as example in Denmark, the Statutory Order on respiratory equipment states that 'Filtering respiratory protective equipment may therefore only be used 3 hours a day. If the work extends beyond 3 hours, either a filtering respirator with a turbo unit (fan) or an air-supplied respirator must be used from the start of the work' (translated by Study Team)[24].

One of the actions for complying with a new OEL would be to replace existing use of negative pressure masks with HEPA filter or simple disposable masks with the more efficient powered air-purifying respirators. The use of powered air-purifying respirators may, however, like other RPE lead to dermal and oral exposure to the substances if not cleaned and maintained properly and by the introduction of powered air purifying respirators it is necessary also to introduce an efficient regime for cleaning and maintenance of the respirators.

3.5.5 Technical measures

A summary of technical measures applied by work processes from the stakeholder consultation is shown in the table below. The table is together with respondents' anticipated use of technical measures by introduction of the various policy options also presented and discussed in section 7.2.4.

Even general dilution ventilation is probable applied in most processes, it is only indicated for 10% of the processes which reflect the fact that general dilution ventilation may even increase the exposure of those workers which are closest to the dust source (but off cause reduce the background level of the substances in the air in the facility). Full enclosure is indicated for 34% of the work processes which is well in accordance with the information provided in the CSRs (see section 3.3). Whereas the full enclosure prevents the exposure (and has had a major influence on reducing the

[24] https://at.dk/regler/at-vejledninger/aandedraetsvaern-d-5-4/

high levels in the past), some exposure may still occur when the closed equipment is opened for various operations. Reducing the exposure from equipment with full enclosure require further use of automatizations e.g. of sampling for quality control, of emptying by change of batches, or of loading of raw materials, etc. Whereas further automatization typically is implemented in new equipment and new facilities, it may often be challenging to do it on existing equipment.

Table 3-90 Percentage breakdown of technical measures currently used by enterprises by sector. The numbers represent work processes included in responses.

	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	General dilution ventilation
Current situation	34% (56)	44% (72)	63% (102)	9% (15)	10% (16)

Source: Stakeholder survey.

The responses to introduction of an OEL would typically be to replace open hoods and partial enclosures with full enclosures and further segregation of work areas. In existing facilities establishing full enclosure and segregation of work areas are often complicated by the geometry, fire safety considerations, access to the equipment, etc. and may require major changes in the equipment.

3.6 Voluntary industry initiatives

No voluntary industry target for reducing occupational exposure to cobalt have been identified.

Eurometaux has published a guidance on occupational exposure assessment for metals in general (Vetter, 2016).

3.7 Examples of good/best practice

Only a few documents specifically describing best practice as concern exposure to cobalt and inorganic cobalt compounds in the concerned sectors have been identified.

Catalyst Europe has developed a 'Catalyst handling best practice guide' which provides guidance on the handling of catalysts in the safest possible way for human health and the environment (ECMA, 2018). The guide does not specifically concern cobalt-containing catalysts, but the practices are applicable to the use of cobalt catalysts.

Eurometaux has published a guidance on occupational exposure assessment for metals in general (Vetter, 2016). The guidance does not concern best practice as regards the use of RMMs.

More specifically for cobalt, the Cobalt REACH Consortium has published a guidance for its members on the methodology applied in the occupational exposure scenarios for cobalt and cobalt compounds (Vetter *et al.*, 2021). The guidance does not concern best practice as regards the use of RMMs.

Guidance information on the safe use of cobalt and inorganic cobalt compounds is provided by manufacturers and importers of cobalt compounds which are registered under REACH. The guidance is available as part of registration dossiers for the respective substances. It includes information on first-aid measures, fire-fighting measures, accidental release measures, handling and storage, transport and shipping, exposure controls and personal protection, stability and reactivity of the substance and disposal considerations.

3.7.1 Member States

Some Member states have prepared guidance documents for best practice. Examples are the recommendations document: 'Hartmetallarbeitsplätze' [Hardmetal working places] (BGI/GUV-I 790-024, DGUV, 2010) and the Technical Rule on 'Carcinogenic metals' (TRGS 561, 2017), both from Germany.

In France, the toxicological sheet on cobalt and inorganic cobalt substances includes recommended measures for reducing exposure to the substances (INRS, 2022).

3.7.2 Options for making good practice available to stakeholders

Apart from the catalyst handling best practice guide from Catalyst Europe no comprehensive guides on good practice for preventing exposure has been identified. Dissemination of guidance on best practice, which could be organised in cooperation with relevant industry associations and trade unions, would require that a comprehensive guidance was developed.

3.8 Standard monitoring methods/tools

3.8.1 Compliance monitoring

Procedures for monitoring of contaminants in the workplace are typically established by national guidelines prepared by the national working environment authorities. These guidelines would typically refer to European standards to be used for the monitoring.

As concerns the monitoring of substances in the workplace, guidelines refer to two European standards:

- EN 482:2012+A1:2015: Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents.
- EN 689:2018+AC:2019: Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values

The strategy described in EN 689:2018 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.

As described in the Methodological Note, in order to undertake the screening tests, ideally an analytical method with a limit of quantification (LOQ) at 0.1 * OEL would be required; otherwise, it will be necessary to undertake more tests and the costs of monitoring increases. For the lowest of the reference values proposed by RAC this would correspond to 0.1 µg/m^3 for the inhalable fraction and 0.05 µg/m^3 for the respirable fraction.

3.8.2 Available analytical methods

As described in the ECHA scientific report, cobalt and its inorganic compounds in particulates can be monitored in the workplace air using a number of validated methods. The principle of most of the methods is trapping the sample on a suitable filter by using a particle sampler (for inhalable and/or respirable fraction). Afterwards, the cobalt compounds are extracted and further analysed using a suitable technique. The limit of quantification (LOQ) is given as mass of cobalt and can be recalculated into a LOQ in terms of µg Co/m^3 in the workplace air with a defined sample volume.

The main methods reported by 20 companies informing on applied standards used for monitoring cobalt and inorganic cobalt compounds for the stakeholder survey were ISO 30011 (5 respondents), NIOSH 7300 and 7301 (5 respondents) and IFA 7808 (2 respondents) while 8 respondents indicated other standards such as ISO 15202-1:2020, ISO 15202 /IFA 6068, IFA 6015, IFA 7284/4, IFA 8095/6, ISO 11885/10 BGIA 5015, and BGI 505-41. One of the most common method, ISO 30011, is not listed in the ECHA scientific report but listed in the table below for reference. According to stakeholder input from DGUV (Deutsche Gesetzliche Unfallversicherung) to the ECHA stakeholder consultation, sample collection and sample preparation is similar to ISO 15202, but the ISO 30011 has insufficient validation data in the method.

The methods shown in Table 3-91 have (except for method 7) validation data that demonstrate compliance with the requirements of the standard EN 482 or the potential to meet these requirements for some of the proposed OELs. The table indicates whether the method is relevant for the sampling of inhalable fraction, the respirable or both, as reflected in the sample and analysis methods. When a specific particulate sampler (and its associated flow rate) has been recommended, the calculations of the sampling time have used the maximum flow rate recommended by the method. However, the latter does not exclude that the methods have the potential to use other sampler at different flow rates that could achieve lower LOQ or to collect a different aerosol fraction. The methods appearing under 'similar methods' follow a similar principle and analytical technique and may differ in the sample preparation or in details, such as the filter or the sampler used.

According to RAC (RAC, 2022), at the proposed OEL, no measurement difficulties are foreseen. And further "*With current air measurement techniques it is possible to achieve cobalt levels well below 10% of the proposed OELs for the inhalable and respirable fractions. Especially ICP with AES or MS detectors as analytical technique allows reaching a LOQ lower than 10% of the OEL, i.e. 0,083 µg/m^3 for a 480-l sample using the NIOSH 7300 and 7301 sampling methods (NIOSH, 2003a and 2003b) or 0.029 µg/m^3 for a 1,200 l sample using IFA7808 (IFA, 2021).*"

As 10% of the lowest policy option OEL for the respirable fraction is 0.05 µg/m^3, with the sample volumes indicated the table in fact only the IFA 7808 method is applicable for reaching 10% of the OEL. The method is currently used for analyses from some commercial laboratories in Germany.

Schuh *et al.* (2020) describes a method for the determination of cobalt and its compounds in workplace air using atomic absorption spectrometry with the graphite furnace technique (GFAAS) after high-pressure microwave digestion. The validated range of the method is 0.058 to 0.83 µg/m^3 based on an air sample volume of 1,200 l (Schuh *et al.*, 2020).

Table 3-91 Overview of sampling and analytical methods for monitoring cobalt and cobalt compounds (as cobalt) in workplace air, based on digestion of the loaded filter

No	Method/ Fraction	Analytical technique	LOQ and sampling volume and time	Similar methods/ comments
1	IFA 7808 Krebserzeugende Metalle (Arsen, Beryllium, Cadmium, Cobalt, Nickel) und ihre Verbindungen (ICP-Massenspektrometrie) (Inhalable or respirable fraction) (IFA, 2021)	ICP-MS (Inductively Coupled Plasma Mass Spectrometry)	0.029 µg/m^3 for a 1200 l sample (2 hour at a flow rate of 10 l/min)	

No	Method/ Fraction	Analytical technique	LOQ and sampling volume and time	Similar methods/ comments
2	MTA/MA – 065/A16 (INSHT, 2016) (Inhalable and respirable fraction)	ICP-AES (Inductively Coupled Plasma Atomic Emission Spectroscopy)	0.29 µg/m³ (for a 480 l sample) less than 1 hour at a flow rate: 10 l/min/ 4 hours for a flow rate of 2 l/min *	
3	NIOSH 7300 and 7301 ((NIOSH, 2003a) and (NIOSH, 2003b)) Inhalable fraction (sampler not completely fitting the standard)	ICP-AES	0.083 µg/m³ for a 480-l sample (less than 1 hour at a flow rate: 10 l/min/ 4 hours for a flow rate of 2l/min) *	The sampler is not an inhalable sampler. (A sampler fitting the EN 481 could be used instead) A sampler for the respirable fraction could be used if required
4	ISO 15202- parts 1,2, and 3 (ISO, 2020) (Inhalable or respirable fraction)	ICP-AES	0.4 µg/m³ for a 480 l sample (less than 1 hour at a flow rate: 10 l/min / 4 hours for a flow rate of 2 l/min) *	Métropol 003, NIOSH 7300, NIOSH 7301, NIOSH 7303, OSHA ID-125G, OSHA ID-206
5	BGI 505–15E (DFG, 2012b) (Inhalable fraction)	ETAAS (Electrothermal Atomic Absorption Spectrometry)	1.8 µg/m³ for a 1.2 m³ air sample (2 hours at 10 l/min)	A sampler for the respirable fraction could be used if required
6	MDHS 30/2 (HSE, 1996) (Inhalable fraction)	FAAS (Flame Atomic Absorption Spectroscopy	0.8 µg/m³ for a 480-l sample (less than 1 hour at a flow rate: 10 l/min / 4 hours for a flow rate of 2 l/min) *	BIA 6690, MTA/MA-025/A92, NIOSH 7027, OSHA ID-121 A sampler for the respirable fraction could be used if required
7	ISO 30011 (ISO, 2010) (Inhalable and respirable fraction)	ICP-MS	0,003 – 0,057 µg/L (depending on the type of sample dissolution	Sample collection and sample preparation similar to ISO 15202. Insufficient validation data in the method **

** Sampling time calculated for the maximum flow of 10 l/min (maximum flow rate for common inhalable and respirable fraction samplers) and for a flow rate of 2 l/min (common flow rate for inhalable samplers). **Summary from table provided by the German Social Accident Insurance (DGUV) to the ECHA stakeholder consultation. Source: Based on ECHA (2022) here calculated into µg/m³ (except for method 7).*

3.8.2.1 Availability and price of analytical methods

Methods for analysing cobalt at the relevant levels are available using ICP-MS detection.

Based on information from a large international laboratory, the analysis price for cobalt including sample media will typically be the same for both the inhalable and respirable fraction and €200 for each (i.e. €400 for both the inhalable and respirable fraction). With a sampling time of 2 hours the reported detection level of the applied commercial method is reported to be 0.3 µg/m³, i.e. for demonstration of compliance at the lowest policy option higher sampling time or higher air flow would be needed.

3.8.3 Summary of monitoring methods/tools

According to RAC (RAC, 2022), at the proposed OEL, no measurement difficulties are foreseen. Information from an international commercial laboratory indicates that the sampling time or airflow may need to be increased as compared to the conventional method if compliance with the lowest policy option should be demonstrated.

3.9 Intermediate uses not covered by certain REACH procedures

Cobalt and inorganic cobalt substances used as intermediates would not be covered by parts of the REACH registration. Substances which are used as on-site isolated intermediates are not subject to authorisation, and are exempted from restriction (ECHA, 2023b). Transported isolated intermediates are not subject to authorisation but may be subject to evaluation and restriction. Residues of the isolated intermediates, which are not transformed into another substance in a manufacturing process, will typically be discarded or disposed of as waste or recycled as intermediates and are not subject to neither authorisation nor restrictions.

Of the 14 substances within the scope of the CMRD, only six have a registered use as intermediate (Table 3-92). Of these six, four substances have a registered tonnage as intermediate at <10 tonnes/year. For three of these substances, the registered tonnage as intermediate is less than 1% of the total registered volume. For one substance, the registered volumes are not reported but <5 registrants have registered the use as intermediate.

Only for one substance, cobalt sulphate, a significant volume is registered as intermediate by < 5 registrants in a tonnage of 1,000 - 10,000 tonnes/year. For comparison, more than 100,000 tonnes/year is registered for a full registration by 15 registrants.

These quantities are somewhat different from the quantities indicated in the ECHA restriction report for the cobalt salts (ECHA, 2018a) where it is stated that the total tonnage manufactured and imported is estimated at 37,400 tonnes/year, of which 30,000 tonnes/year are used in the EU28 and 7,400 tonnes/year are exported. Approximately 85% of the cobalt salts were used as intermediates in the EU28; 70% of the total volume were used as transported isolated intermediates, whereas it for the rest is not indicated whether they are used as on-site isolated intermediates or are residues of the isolated intermediates (ECHA, 2018a).

As indicated in section 3.10.3.4, the total number of manufacturers of cobalt salts are estimated at 22 i.e. less than 25% of the manufacturers use the substances as intermediate in any significant amount. The total number of workers involved in the manufacture of cobalt salts are estimated at 1,600 and if less than 25% of these are employed in companies using the substances as intermediates, it can be roughly estimated that less than 400 workers would potentially be exposed by intermediate use.

Considering the total number of workers exposed to cobalt and inorganic cobalt compounds in the EU of more than 100,000 (section 3.4.6), it can be estimated that less than 1% of the total number of exposed workers in the EU may be exposed by intermediate use of the substances that would not be covered in case the substances would fall under the authorisation requirements of REACH.

Table 3-92 Registered tonnage for cobalt and inorganic cobalt compounds within the scope of the CMRD which has a registered tonnage as intermediate

Substance (REACH registration name)	EC Number	Registered tonnage, intermediate, t/year	Registered tonnage, full registration, t/year
Cobalt carbonate	208-169-4	<10 (<5 reg)	1,000-10,000 (8 reg)
Cobalt oxide	215-154-6	<10 (<5 reg)	1,000-10,000 (26 reg)
Cobalt dichloride	231-589-4	<10 (<5 reg)	1,000-10,000 (6 reg)
Cobalt sulphate	233-334-2	1,000-10,000 (<5 reg)	>100,000 (15 reg)
Cobalt molybdate	237-358-4	<10 (<5 reg)	10-1000 (<5 reg)
Cobalt dihydroxide	244-166-4	No volumes reported (<5 reg)	>100,000 (19 reg)

3.10 Market analysis

3.10.1 Sources of data on enterprises with exposed workers

3.10.1.1 National databases

Only one published source of data about number of companies was identified. It concerned number of companies reporting on exposure to cobalt to the Italian SIREP database during 1996 to 2016 (Scarselli, 2020). Based on the percentage of companies in the sectors in Italy registered in the SIREP database, the number of enterprises in the EU with workers exposed to cobalt was extrapolated if it is assumed that the percentage in Italy would be representative for the EU as a whole. The extrapolation is uncertain and may underestimate the total as not all companies with exposure to cobalt are reporting to the database, but it is used to obtain an initial estimated of the order of magnitude for sectors where more certain data on the number at EU level have not been obtained. It should be noted that the percentages reported by Scarselli *et al.* (2020) are very different from those that would be obtained by comparing the number reporting to SIREP with the number of companies reported in Eurostat for the sectors. The background for differences is not clear.

Table 3-93 Estimates of potentially exposed workers to cobalt in the selected sectors of economic activity (SIREP 1996-2016)

Sector of economic activity (NACE code)		Enterprises in SIREP with workers exposed to cobalt	% of companies in Italy reporting cobalt exposure to SIREP	Number of enterprises in this sector in EU***	Extrapolated number of enterprises with exposed workers in sector in EU ****
C20.13	Manufacture of other inorganic basic chemicals)	3	1.3%	858	11
C20.14	Manufacture of other organic basic chemicals	3	1.2%	1,949	24
C20.59.2	Manufacture of organic chemicals from basic products derived from fermentation processes or vegetable raw materials	3	2.0%	4,076	110
C20.59.4	Manufacture of other chemical products for industrial use	17	2.9%		

Sector of economic activity (NACE code)		Enterprises in SIREP with workers exposed to cobalt	% of companies in Italy reporting cobalt exposure to SIREP	Number of enterprises in this sector in EU***	Extrapolated number of enterprises with exposed workers in sector in EU ****
C21.10.0	Manufacture of basic pharmaceutical products	11	6.8%	825	56
C21.20.0	Manufacture of pharmaceutical preparations	28	4.5%	3,158	143
C25.61.0	Treatment and coating of metals	73	1.7%	26,393	457
C25.73.1	Manufacture of hand tools, interchangeable parts for machine tools	3	1.2%	15,892	192
C25.99.9	Manufacture of other fabricated metal products	10	2.0%	48,846	962
C32.50.5	Medical and dental instruments and supplies **	3	0.3%	6,457	17
M71.20.1	Testing and technical analysis of products	7	2.9%	7,098	207
M72.19.0	Other research and experimental development on natural sciences and engineering	10	6.8%	5,390	366
	Total	171		120,942	2,545

** As reported by Scarcelli (2020). SIREP includes companies with exposure to one or more carcinogens, i.e. the percentage does not indicate the percentage of all companies within each sector. **Original indicates 'optical instruments' but use the NACE code for medical and dental instruments, and it is here assumed that it is the NACE code which is correct.*
*Source: Two first columns. Scarselli et al., 2020; ***: Eurostat Structural Business statistics. ****Study team.*

3.10.1.2 Information from the Cobalt Institute

The results of the impact assessment by eftec (2023) for the Cobalt Institute / REACH Cobalt Consortium have been used as an input for the market analysis together with other sources and it is specifically indicated in the following where and how information from this assessment has been used. The data from eftec (2023) are summarised in Annex D. The data on number of companies are organised by main uses and not sectors e.g. the use category 'use of metallurgical alloys' cover a number of sectors in the current study. For each use category, the number of enterprises and exposed workers is indicated. As some companies undertake activities related to several use categories they may be included twice or even more. This is taken into account in the reporting by eftec (2023) which presents the total number as 'total upper bound' which includes overlap with other broad uses, which means that summing across multiple uses will lead to double counting and 'total lower bound' using an 'overlap' factor based on respondent data. The total number of companies ranges thus from a total lower bound of 4,960 to a total upper bound of 8,815. For each of the use categories it is not indicated to what extent there is overlap with other categories. For the current study it is attempted to allocate the companies to various sectors taking into account the overlap e.g. it is assumed that there is an overlap between the number indicated for the categories 'Manufacture of other chemicals' and 'Manufacture of precursor chemicals for batteries' when the numbers are allocated to the sector 'C20.12 - 13 Manufacture, basic chemicals.

3.10.2 Study team analysis of Eurostat, survey and industry data

For the sectors covered by the assessment, the number of enterprises with exposed workers is investigated more thoroughly. Each sector is considered in turn following discussions with industry associations and companies in the sector to develop either an estimate based upon one of the following methods:

- Establish and overview of the number of companies by combining information from the eftec survey with information obtained from industry stakeholders. Key stakeholders upstream the supply chains have been asked for best estimates on number of downstream users based on their market intelligence. The methodology proved useful for some sectors (e.g. manufacture of tools) whereas for other sectors companies have been more reluctant in sharing market information. When it comes to use of the final products (e.g. use of hardmetal tools) it has proven very difficult to establish a split by sectors as such information is usually not available because of the very diversified use of the final products.

- Where specific information on the distribution of the companies by size (e.g. refineries and production of catalysts) is available from associations or the eftec survey, these distributions are applied.

- Defining a NACE code into which the sector falls. In general a method of estimating the percentage of companies within each sector that will use cobalt and inorganic cobalt compounds under the scope of the CMRD has not proven useful as companies using cobalt and inorganic cobalt compounds for most sectors account for a low percentage of the companies registered in Eurostat. Eurostat data has been used to define the average number of workers in the companies for the further use of information on turnover and distribution by size of company (for sectors where specific information is not available). For small companies the average number of employees in Eurostat for many sectors is in the range of 4-6 per company. Use of these numbers would result in calculations for small companies where the number of companies is larger than the number of workers. Based on available information, even small companies working with cobalt would typically have 10 or more employees and the average number of employees for small companies has been set at 10 for sectors where it in Eurostat is less than ten. The average turnover has been adjusted accordingly.

- For the metal sector, companies may undertake many processes and it is not well defined which activities should be within which sector. Furthermore end product are used in multiple sectors. The spilt between the different sectors is therefore uncertain whereas the total for all sectors is considered more certain. As an example maintenance of hardmetal tools has primarily been allocated to the sector Machining, but as hardmetal tools are used in multiple sectors (likely more than 20 NACE codes in Eurostat) some of the companies and exposed workers allocated to this sector (and the estimated costs and benefits) would likely be within other sectors.

3.10.3 Assessment by sector

3.10.3.1C10.91 Manufacture, feeds

According to consultation response from the European Feed Manufacturers' Federation (FEFAC) 2023), today around 300 sites formulate cobalt-containing preparations or premixtures in the EU which is similar to the number reported for the ECHA Restriction proposal. Compound feed and complementary feed is manufactured in approximately 4,100 sites, but as indicated in section 3.3.4.1, the exposure levels at this stage of the product chain would be below the levels relevant for the assessed policy options and no impacts of introduction of the OELs are expected. Of the 300 sites, it is estimated that approximately 90% are using coated cobalt carbonate which would lead to significant lower exposure concentrations than those reported for these activities. However, data has not been available to demonstrate that the levels would be below the assessed policy options. Consequently, it is estimated that about 300 sites may have exposure concentrations at a level as reported in 3.3.4.1 which may lead to an overestimation. The total number of exposed workers is estimated at 1,800 which lead to a split between companies of 2% large, 10% medium and 88% small sized companies.

3.10.3.2C19.20 Petrochemical, catalyst

According to manufacturers of catalysts, virtually all refineries in the EU use cobalt catalysts for hydro-treating and desulphurisation. According to available information cobalt catalysts are not used in other refineries such as refineries for biofuels.

According to FuelsEurope (2022), at the end of 2021, 67 mainstream refineries were operating in the EU27. A map prepared by Concawe[25] showing the location of the mainstream and specialised refineries processing crude oil in Europe indicates the number of open mainstream and specialised refineries in 2022 at 81 owned by 46 companies. It has in accordance with this by a catalyst manufacturer been indicated that the number of refineries using cobalt catalysts in the EU is approximately 80.

The distribution by Member States is as follows:

Austria	1	Finland	1	Italy	11	Romania	3
Belgium	2	France	7	Lithuania	1	Slovakia	1
Bulgaria	1	Germany	16	Netherlands	5	Spain	9
Croatia	2	Greece	4	Norway	1	Sweden	5
Czech Republic	2	Hungary	1	Poland	4	Total	81
Denmark	2	Ireland	1	Portugal	1		

Since 2009, 26 mainstream refineries have been closed or transformed. Currently, five refineries in Europe underwent a transformation process, moving away from oil and converting into biorefineries (FuelsEurope 2022).

According to the structural business statistics from Eurostat, in 2020 there were 821 companies in sector C19.20 'Manufacture of refined petroleum products'. According to Eurostat the NACE code cover manufacture of the traditional refinery and steam cracker products such as fuels products for the petrochemical industry but also the manufacture of a number of other products such as road coverings, paraffinic wax, Vaseline, peat briquettes, and hard coal and lignite briquettes. These other products may be produced in a large number of smaller companies which may explain the high number of companies as compared to the reported number of refineries and steam crackers.

According to stakeholder input from FuelsEurope cobalt catalysts are typically handled by contractors and the staff in the refining site are supposed not to be in contact with catalysts. It is however

[25] https://www.concawe.eu/refineries-map/

typically the site which is responsible for the monitoring and for the costs assessment it is assessed that any incremental costs of the contractors' operation will be passed on to the refineries.

Based on information from a company in the sector, about 20 contractors are operating in this sector while another source has indicated a number of around 10. The companies are undertaking the service on various types of catalysts and not specialised in maintenance of cobalt catalyst. As the refineries typically have a number of reactors which are emptied every 2-3 years, the total number of campaigns would likely be in the order of 150-300 per year in EU 27.

Only a few (if any) gas-to-Liquid (GTL) facilities are in operation in the EU (ECHA, 2018b). It has from manufacturers of catalysts not been possible to obtain confirmation that catalysts are produced for GTL today. It has not been possible to identify specific plants. In absence of more specific data, it is assumed that there might be two companies and it is assumed that the few plants can be added to the number of enterprises and workers exposed estimated for the refinery sector.

Based on the available information it is estimated that the cobalt catalysts are used in the 82 refineries and GTL production facilities with a total of 600 exposed workers. The split between large and medium sized companies is assumed to be 50:50 which leads to an average percentage of workers in the companies of 3.7%.

3.10.3.3C20.12 Manufacture, dyes and pigments

Cobalt compounds for dyes, pigments and frits are produced by a number of companies, and registrants are organised in the Frit and Inorganic Pigments Consortium (IP) consortium.

According to the Frit Consortium, the only compound used in frits is tricobalt tetraoxide which is not within the scope of the CMRD. The substance is not used to manufacture substances within the scope of the study. Tow manufacturers of pigments responding to the stakeholder consultations have indicated that they manufacture frits as well, but not which substances are specifically used for the frits. It is here assumed that manufacturers of frits only use substances which are not within the scope of the study (but some may if they also manufacture pigments be included in the number of manufacturers of pigments indicated below).

The Inorganic Pigments Consortium has 25 member companies. Only some of the cobalt pigments are within the scope of this study. According to the IP Consortium, the majority of companies registering the pigments within the scope of this study are manufacturers. There are 14 registrants for the three pigments within the scope; of these at least one is importer. In addition to the manufacture of pigments within the scope, some manufacturers may use some cobalt compounds within the scope to produce other cobalt-containing pigments.

In the study for the Cobalt Institute, eftec (2023) estimate the number of manufacturers of cobalt-containing pigments at 15 with 30 sites. It is indicated that 83% are large companies, and it will here be assumed that 11 of the companies are large and 4 medium-sized. It is not reported which cobalt compounds were used for the manufacture of the pigments, but in the absence of specific data it will be assumed that all 15 companies use or produce substances within the scope.

According to the IP consortium, the number of downstream users is likely in the order of magnitude of hundreds. The main area is manufacture of tiles i.e. companies within sector C23.4 Manufacture of other porcelain and ceramic products.

3.10.3.4C20.13-20.14 Manufacture, basic chemicals

Eftec (2023) estimates that the total number of companies involved in the manufacture or import of cobalt metal and cobalt compounds (organic and inorganic) is 45-80 with 85-145 sites of which 89% involve substances within the scope of the current study. On the basis of responding companies, eftec (2023) estimates the that 38% are SMEs and 62% large sized companies. The dataset is derived from responses from 14 companies and combined with information from a value chain report from 2019 (eftec, 2019) and feedback from webinars. The 2023 report does not allow for distinguishing between manufacture of chemicals and metal or between manufacture or import. The total number of workers employed is estimated at 56,900 - 89,600 of which 4,800-8,000 are potentially exposed to cobalt substances (both within and outside the scope). The total number of workers is indicated to be based on the eftec (2019) report, however that report, as shown on the table below, estimates the total number of workers, when taking into account that some companies import or manufacture more than one substance, at 28,000 for both importers and manufacturers. The number of importers is significantly higher than the number of manufacturers, but the distribution of workers between importers and manufacturers cannot be derived. According to the eftec (2023) report, the upper bound of 89,600 employees are based on the eftec (2019) report without correcting for double counting (as done by the eftec, 2019 report). However, the total without taking double counting into account and just summing up the number indicated for each substance group only reach 66,800 (the total of 89,600 include 20,100 twice). The approach used by the eftec (2023) report leads to a significant overestimation of the total number of exposed employees.

A more detailed presentation was included in the eftec (2019) report. The number of manufacturers and importers supplying to the EU market for cobalt metal, 5 cobalt salts, 5 cobalt oxides and 11 cobalt carboxylates as reported by eftec (2019) are shown in the table below. The cobalt carboxylates are likely produced from cobalt compounds within the scope of this study and exposure to substances within the scope may consequently take place. The table does not include manufacture of cobalt pigments (included in previous sector) but include oxides and salts not within the scope of this study.

Table 3-94 Number of manufacturers and importers supplying to the EU market

	Number of manufacturers and supplying to the EU market				Data on M/Is	
Cobalt substances	**Manufacturer only (M)**	**Importer only (I)**	**Both M and I**	**Total**	**Total number of sites in the EU**	**Total number of people directly employed in the EU ***
Cobalt metal	6	58	7	71	84	20,100
5 cobalt salts	22	8	3	33	33+	5,300
5 cobalt oxides	9	36	8	53	15 - 36	13,400
11 cobalt carboxylates	4	9	2	15	15 - 36	7,900
Highest value from any cobalt compound group	22	58	8	71 (sum = 88)	84	20,100
All cobalt substances, best estimate, total number	26	67	9	100	120	28,000

** The total number of people employed includes all workers within the company (e.g. sales, HR and finance) and not only the number of workers involved with the manufacture of the cobalt compound(s). See eftec (2019) for further details about the estimations.*
Source, eftec, 2019.

The total number of companies in the eftec (2019) report, manufacturing cobalt compounds and/or cobalt metal is 26 while the number of sites is not indicated specifically for manufacturers. Eftec (2023) estimate, as mentioned, the number of manufacturers and importers of both cobalt metal and cobalt compounds 45-80 companies i.e. lower than estimated in the eftec (2019) report.

If Italian SIREP data (section 3.10.1.1) are extrapolated to the entire EU, a total number of 35 companies with 5,500 exposed workers can be estimated.

Considering that the eftec (2023) report include importers of cobalt compounds and import and manufacture of cobalt metal addressed in section 3.10.3.14, it is considered that the number of companies producing the basic cobalt compounds can better be based on the eftec (2019) report and a total number of 30 companies in 36 sites will be assumed. The distribution is assumed to be 22% small, 37% medium and 41% large. As discussed in section 3.4.4, the total number of exposed workers in the companies is here estimated at 2,900.

The data are analysed with Eurostat data for manufacture of both organic and inorganic basic chemicals as the companies may manufacture both organic and inorganic compounds.

3.10.3.5C20.30 Paints and similar coatings

Cobalt compounds are widely used as drying agents in paint. The cobalt-based driers are organic compounds. Eftec (2019) indicated that 500 t/year cobalt metal and 1,600 t/year organic cobalt compounds was used for driers while no inorganic cobalt compounds were used.

For the stakeholder survey, one company has indicated that it uses inorganic cobalt compounds to produce organic cobalt compounds for paint driers, but none of the compounds manufactured for this purpose are inorganic. The company is here included under manufacture of basic chemicals.

The CSRs for a number of the inorganic cobalt compounds include exposure scenarios for the use in paints which indicate that these compounds may to some extent be used for some purposes.

Two companies identifying themselves as included under C20.30 Paints and similar coatings were in fact included under C20.14 manufacture of dyes and pigments.

Eftec (2023) estimates that 100 companies with 600 exposed workers use cobalt compounds for the manufacture of driers and paints but does not provide information on the substances used. The eftec (2023) also include organic substances.

According to information obtained through the stakeholder consultation, a few large manufacturers of paint may buy inorganic cobalt compounds and convert them in-house to organic compounds used as dryers or accelerators in paint. The number is not known but it is indicated as a few. The exposure scenario for these companies would be different from the scenarios for companies using the organic compounds as exposure to the inorganic compounds would only be for the step of converting the inorganic compounds into organic compounds.

In the absence of specific data on the number of manufacturers that in-house convert inorganic compounds to organic, it will be assumed it could be 10% of all manufacturers and a number of 10 companies with 200 exposed workers is used as a best estimate. The assumption is based on the information that it is relatively few companies which do the conversion in-house. The distribution is set at 1 large, 3 medium and 6 small.

3.10.3.6 C20.59 Catalysts

According to ECHA (2018b) the cobalt salts are used as intermediates which are chemically transformed to produce catalyst precursors or active catalyst substances at 11-15 sites in Europe (the number is indicated differently in various sections of the report). The number of catalysts manufacturers organised today in Catalysts Europe is 14. However, not all catalysts manufacturers manufacture cobalt catalysts.

A dataset provided by Catalysts Europe for the stakeholder consultation covered 7 companies and 11 sites. According to information obtained for the current stakeholder consultation approximately 8 catalysts manufacturers manufacture catalysts with cobalt, but the number of sites is not indicated. A number of 13 sites will be used as best estimate.

eftec (2023) assume a total number of companies and sites of 15 based on previous studies.

Based on the reported range and average it will be assumed that the spilt with 6 large and 7 medium sized companies.

3.10.3.7 C20.59 Formulation of other chemical products

It is uncertain which activities should be included under this sector apart from production of catalyst, but in this study all activities concerning preparation of formulations for various downstream uses have been included here. These activities have been separated from production of catalysts because production of catalyst is well-described and the estimates quite certain, whereas for the rest of activities very limited information has been available.

eftec (2023) estimates the on the basis of survey responses from five companies, the total number of companies involved in the production of formulations for surface treatment at 10 at 15 sites. The share of companies that are SME is estimated at 90%. The total number of exposed workers is estimated at 200 corresponding to 9% of the workforce in the companies. The number of companies is quite well in accordance with the 20-25 companies previously reported by ECHA (2018a).

eftec (2023) estimate that 5 companies with 1,500 exposed workers are involved in the formulation of water treatment chemicals, oxygen scavengers, and corrosion inhibitors. The number of exposed workers seems very high considering that only estimated 100 workers are estimated to be exposed by use of these chemicals. The explanation may be that the companies are formulating cobalt chemicals for other purposes also.

For the biogas sector no specific data for the formulation step is provided in eftec which aggregate formulation and industrial use (2023). The number if here assumed to be similar to the number of water treatment chemicals.

The number of companies is in eftec (2023) indicated by broad use area, but to the extent companies have activities in more application areas they are counted twice (or more). In order to reduce double counting, the number of manufacturers of chemical reported in eftec (2023) under 'Manufacture and/or import of cobalt and/or cobalt substances' here reduced to those producing the basic chemicals which should reduce the risk of double counting.

On the basis of above, the total number of companies involved in the manufacture of formulations for various sectors is estimated at 35 with a total of 1,700 exposed workers. Based on the distribution reported for production of surface treatment chemicals, the distribution between large, medium and small-sized companies is set at 40%, 30% and 30%.

3.10.3.8C21 Pharmaceuticals

For the estimation of cancer cases, ECHA (2018a) assumes that 300 companies with 900 exposed workers are involved in the use of cobalt salts in fermentation, biotech, scientific research and standard analysis. No distribution by sector is provided. eftec (2023) which assumes on basis of older data the number of companies is 100. As shown in section 3.10.1.1 based on Italian data a total number of companies of about 200 in this sector can be extrapolated from the Italian data, but it is not clear whether the use of cobalt in the companies have been for fermentation or production of pharmaceuticals. No exposure data are presented in the Italian dataset which might indicate the levels are low.

As indicated in the section on exposure concentrations, the exposure concentrations by use of cobalt compounds for fermentation is considered to be below the relevant levels for the policy options (the substances are added in closed bags).

For the stakeholder survey one pharmaceutical company has indicated the use of cobalt compounds for production of pharmaceutical preparations (specific preparation not indicated). Cobalt is used as a constituent of various veterinary products for cattle (likely with the same effect as when it is used in feed).

No data are available to assess how many companies could be involved in the manufacture of veterinary medicinal products, but in the absence of more specific data it is assumed that the number could be 8. They are all assumed to be large companies.

3.10.3.9C22.11 Production of tyres

Organic cobalt compounds are the main cobalt compounds used as rubber additives. The main use is in the production of tyres but use in the production of steel cord conveyor belts is also reported. According to the stakeholder input from the European Rubber Chemicals Association (ERCA) members of ERCA do not provide any additives with cobalt compounds within the scope of the study. Communication with the European Tyre & Rubber Manufacturers' Association (ETRMA) and a conference call with a number of manufacturers has not revealed any specific information on the use of cobalt compounds within the scope of the current study. ETRMA has expressed concern that production of tyres and other rubber products would be impacted e.g. as consequence on how the OELs are transposed into national legislation and this is discussed in Annex F.

The CSRs for some of the inorganic cobalt compounds include an exposure scenario for use in rubber production, and eftec (2019) indicates some use of inorganic compounds for this sector. Eftec (2023) does not indicate any use of inorganic compounds for this sector. The report indicates that 27% of the companies may be directly or indirectly within the scope but this is not substantiated with data showing that substances within the scope is used in the sector.

According to information from the Stakeholder Consultation, at least one company in the sector produce the organic cobalt compounds used in the production of tyres from inorganic cobalt compounds. This means that exposure to substances within the scope of the current study may take place at this stage in the production, whereas for other contributing scenarios indicated in the CSRs exposure would be for organic cobalt compounds only.

eftec (2023) estimates the total number of companies at 20 with 100 sites.

In the absence of data indicating that more than one company in the sector produced the organic compounds in-house it will here be assumed that 3 large companies may undertake this process. The number of exposed workers would be significantly lower than the number exposed to organic cobalt compounds (on average 1,372 per company according to eftec, 2023) and will here be assumed to be no more than hundred per company and 300 in total.

3.10.3.10 C23.1 Glass

According to stakeholder input from the European Container Glass Federation (FEVE, 2023), cobalt compounds are generally used as colouriser in the form of tricobalt tetraoxide (Co_3O_4 outside the scope), but sometimes cobalt oxide (CoO) or cobalt sulphate ($CoSO_4$) is used. It is not indicated if cobalt oxide or cobalt sulphate is used by only a few companies or only for some specific applications. Furthermore, cobalt-containing frits, outside the scope of the study, may be added. It is not indicated how common the use of cobalt oxide (CoO), or cobalt sulphate ($CoSO_4$) is and the number of companies using these substances is not known. For the questionnaire survey, one company has reported on the use of cobalt oxide in the production of glass. In a conference call with Glass Alliance Europe and a number of companies concern was raised to what extent tricobalt tetraoxide by the transposition in the Member States could be within the scope and the sector in this way may be affected. None of the participants indicated any use of other substances than tricobalt tetraoxide.

FEVE represents 60 corporate members with 162 manufacturing sites across Europe. FEVE (2023) estimates that probably less than half of sites are using cobalt compounds, so about 70 sites which each use between 100 kg and 5,000 kg of cobalt per year. In total the container glass industry is estimated to use about 100-200 tonnes Co/year. It is not indicated how many of the companies use cobalt oxide (CoO) or cobalt sulphate. FEVE (2023) estimates that in total 850-1,700 workers could be exposed to cobalt (all cobalt substances) within the container glass sector.

Information on the use of cobalt in glass has also been submitted by Glass Alliance Europe (2020) which states that cobalt compounds are used as colourant by the flat, container, domestic and special glass sectors. No specific information from the other glass sectors have been obtained. In the glass production, cobalt is added to give the glass a distinctive blue colour, but cobalt compounds are also used for decolouring of some specialty glasses.

The study of eftec (2023) does not address use in glass.

The total number of companies in the EU under NACE code C23.1 is 13,813. If shaping and procession of flat glass and production of fibre glass is subtracted the total is 7,057. Production of container glass is together with production of drinking glass included in the NACE code C23.13 on manufacture of hollow glass with 3,137 enterprises in the Eurostat SBS.

The available information indicates that cobalt oxide and cobalt sulphate is used to a small extent only and it will be assumed that only a small part of the companies using cobalt will use it in this form. The main uses of cobalt substances in general seems to be in blue coloured container glass and tinted flat glass. In the absence of specific data for the substances within the scope, it will be assumed that 50 companies use the substances within the scope. The distribution between large, medium and small sized are set at 15% large, 30% medium and 55% small.

Cobalt is furthermore used for mould/plunger maintenance activities (polishing, grinding, welding) in the container glass sector. This takes place in separate workshops, either on-site or off-site. According to the FEVE (2023) it seems that only a very small number of plants are concerned by this activity. Glass Alliance Europe (2020) indicate the same application for the container glass sector but do not indicate similar applications in other of the glass sectors. As the activity take place in a few companies only, it will here for simplicity be assumed that the possible impacts will be covered by the cross-sectoral activity of welding.

3.10.3.11 C23.4 Ceramics

According to the IP consortium, the number of downstream users of cobalt pigments in the scope of the study is likely in the order of magnitude of hundreds and not thousands. A manufacturer of pigments for the ceramics industry indicated the number as 'a lot'. The main area is manufacture of wall and floor ceramics. According to European Ceramic Industry Association (CerameUnie, 2021), wall and floor ceramic tiles constitute the biggest sector in terms of turnover among European ceramic industries. Although Italy and Spain are by far the two biggest producers in the EU, significant production also exists in Poland, Portugal, Germany, France, Bulgaria, Romania, the Netherlands, Czech Republic and Hungary [26]. One third of the production in ceramic tiles is exported outside of the EU.

For the stakeholder consultation, five manufacturers of ceramic tiles representing seven sites has responded. All are from Italy. The number of exposed workers in the sites range from 1 to 48 with an average of 32 exposed workers (total of 224 exposed workers) representing 14% of the workforce in the companies. Three responding companies are large, one medium and one small.

Manufacture of ceramics is not included in the eftec (2023) study.

Exposure in the ceramics sector is not indicated in summaries of national databases in Finland, France, Italy and Canada (see section 3.4.4) which might indicate that this is not a key sector as to number of exposed workers.

The number of employees in the ceramic tiles sub-sector is 59,146 representing 28% of the entire ceramics sector[27]. For the entire ceramics sector, 80% of the companies are SME. Based on the available information, it is assumed that only a minor part of the companies would use cobalt pigments within the scope of this study. In the absence of more specific data, the number of companies is assumed to be about 500. For the overall distribution of the sector in Eurostat, small enterprises account for 98% of the sector, but for the production of wall and floor ceramic tiles large and medium-sized companies is assumed to account for a larger share as also indicated by the stakeholder responses. The distribution between large, medium and small-sized companies is set at 9%, 21% and 70%.

3.10.3.12 C23.7 Cutting of stone

Diamond tools are used by virtually all companies in the natural stone industry for processing of natural stone, starting with the block extraction in the quarries and ending with polishing operations for the finished product and all production steps in between. The activity in this sector is particularly high in Italy, Spain, Germany and Poland. The European & International Federation of Natural Stone Industries (Euroroc) has not answered the request, and no responses have been obtained from companies.

Based on information from a key player, the number of companies using diamond tools for natural stones is likely in the range of 2,500 to 4,000 companies at EU level. The majority of the

[26] https://cerameunie.eu/members/sectors/

[27] https://www.ceramicroadmap2050.eu/chapters/the-european-ceramic-industry-in-numbers/

companies are reported to be SMEs. The total number of companies in the sector is 33,363 with an average of 4 employees. It is uncertain to what extent work is undertaken outdoors and workers are exposed to levels relevant for the assessed policy options.

Cutting of stone is not included in the eftec (2023) study.

Exposure by cutting of stone is not mentioned in any of the summaries of national databases, indicating that this is not a major exposure category, but it cannot be excluded that workers may be exposed at levels of relevance for the lower of the policy options. Significant exposure levels are reported from the use of diamond tools for cutting of diamonds, but an older paper also indicates significant levels when cutting stone indoors. It will here be assumed that exposure at the exposure levels used for the calculations will only be relevant when the tools are used indoors and likely also only when cutting in hard stone. In the absence of actual information it will be assumed that about 10-25% of the companies use the tools indoors leading to an estimate of about 1,000 companies. The distribution between large, medium and small-sized companies is set at 1%, 2% and 97%.

3.10.3.13 C24.10 Steel

No specific information on number of producers of steel alloys with a high content of cobalt has been obtained. The trade organisation Eurofer had no specific information on production of high-cobalt steel. According to Eurofer, stainless steel and specialty steels are produced at 37 sites in the EU producing about 6 million tonnes of steel per year. [28] 'Other metallic uses' which include steel is in Figure 3-1 indicated to account for 0.3% of the total consumption of cobalt for production in the EU corresponding to 72 tonnes cobalt or 1,200 tonnes steel with a cobalt content of 6%. This indicates that high-cobalt steels could account 0.02% of the stainless and speciality steel market. Considering the cobalt steels are a niche market, it is assumed that no more than 5 companies produce the steels, and the number of exposed workers is no more than 100.

Steel with high cobalt compounds is mainly used for various cutting tool and it is assumed that the sectors with exposure are the same as for hard-metal tools.

3.10.3.14 C24.45 Manufacture, cobalt and cobalt alloys

For the stakeholder consultation, two manufacturers of cobalt and cobalt alloys have answered the questionnaire. The average number of workers were 110 representing 44% of the workforce of the companies. In addition to these, one company with two sites for manufacture of copper answered the questionnaire (sector excluded). Two companies involved in recycling of cobalt scrap have indicated themselves as being within this sector, but are in the current assessment included in E38.32 Metal recovery.

According to Latunussa *et al.* (2020), refined cobalt is produced by four plants in the EU in Finland (two plants), Belgium and France. The majority is refined in Finland which supply 54% of the EU demand for refined cobalt (Latunussa *et al.*, 2020). Eftec (2019) indicates the number of producers of cobalt metal at 6 and indicates that the producers of the cobalt metal is also the main producers of alloys.

Besides these, a number of companies produce powder alloys for use in various powder metallurgy. Even the alloys are produced in the process, the companies consider themselves under

[28] https://www.eurofer.eu/issues/eurofer-stainless-and-specialty-steel/

C25.99 Manufacture of other fabricated metal products and are consequently included in this sector in this study.

eftec (2023) does not provide specific information on producers of alloys but indicate the number of downstream users of alloys at 170 companies in 395 sites based on RPA (2020) which base it on limited specific information. Furthermore, the manufacture of cobalt metal is together with manufacture of cobalt compounds estimated at 45-80 without specification of the number specifically involved in the manufacture of cobalt metal.

Based on the available information, the number of manufacturers of cobalt and cobalt alloys is assumed to be six. All are assumed to be large companies. Using the average number from the stakeholder consultation of 110 per company, the total number of exposed workers is estimated at 660.

3.10.3.15 C25.5 Powder metallurgy

Power metallurgy is used for a number of applications including many covered by other sectors such as production of hardmetal and diamond tools and additive manufacturing under manufacture of other fabricated metal products. Besides these applications, an introduction to powder metallurgy (EPMA, 2008) lists of relevance here magnetic components and special high-duty alloys. A major part of the listed applications includes cobalt.

None of the respondents to the questionnaire have indicated this NACE code which among other applications include powder metallurgy. Two respondent producing powders have answered the questionnaire but identified themselves under other NACE codes.

It is considered here that production of cobalt powder (apart from those used for tools) is included here together with manufacture of magnets and products of special high-duty alloys.

A Guide to Powder Metallurgy Manufacturers and Suppliers 2022 from the European Powder Metallurgy Association (EPMA, 2022) lists 32 metal powder manufacturers from the EU and 57 manufacturers and suppliers of powder metal components. Several of these provide powders for the hardmetal and diamond tool industry or produce such tools whereas others provide powders or products without cobalt.

Eftec (2023) estimate all downstream uses of metallurgical alloys to be 170 companies in 395 sites. This would include the number indicated in the current study covering the following sectors: Powder metallurgy, Manufacture of other fabricated metal products, Medical and dental devices, Air and spacecraft, and Engines and turbines. The total number of companies estimated for these sectors in the current study are 940. As the number provided by eftec (2023) is based on very limited data, it is considered that the number estimated in the current study is less uncertain.

In absence of more specific data, it is assumed that 30 producers of cobalt-containing powders or products based on powder technology, are not included elsewhere (the powders are used in many other sectors). Based on experience from similar sectors, the average number of exposed workers is estimated at 30 per company leading to a total of 900 exposed workers. The distribution between large, medium and small companies is assumed to be 10%, 55% and 35%.

3.10.3.16 C25.61 Surface treatment of metals

Surface treatment include two processes: Plating and passivation. The process take place in several sectors but as data are available for the process without a split on sectors it is described within this sector.

According to ECHA (2018a) the German trade association ZVO (Zentralverband Oberflächentechnik e.V.) indicated that there are around 20-25 companies undertaking formulation of the cobalt salts and between 600-800 companies in Europe using cobalt salts in the surface treatment sector for passivation and corrosion resistance, with approximately 50% of this use occurring in Germany. The use of cobalt salts in the surface treatment sector is predominantly located in countries with a large automotive sector, such as Germany, although it is noted that production in Poland and the Czech Republic is growing. The estimation for the number of sites in Europe is an extrapolation from the number of sites estimated in Germany. The data presented by eftec (2018a, as cited by ECHA, 2018a) suggests a higher value, with the number of sites using cobalt salts in the surface treatment sector estimated as being up to 3,000. It is not clear what the cause of this discrepancy is. eftec (2023) estimate the number of companies on the basis of RPA (2020), that base it on the estimate from ZVO. As shown in section 3.10.1.1, a total of 457 companies in the EU can be estimated if the Italian data are extrapolated to the entire EU.

Based on eftec (2023), the total number of companies is estimated at 750 companies (1,350 sites) in passivation sector with 5,900 exposed workers representing 3% of the workforce in the companies. The total number of companies in the plating sector is estimated at 190 companies (530 sites) with 4,500 exposed workers representing 33% of the workforce in the companies. The number of exposed workers per company is estimated on the basis of five stakeholder responses from each of the sectors. For both sectors the share of companies responding being SMEs are indicated at 60%. The total for the two types is 940 companies with 10,400 workers. This will here be used as a best estimate.

The surface treatment is to a large extent undertaken in departments in other sectors first of all the automotive sector. This is clearly indicated by the data for the passivation sector where the exposed workers account for only 3% of the workforce in the companies. Whereas the total workforce in the 940 companies is estimated at 251,000, the total workforce in sector C25.61 is about 278,000 in about 26,000 companies. For passivation, the final products are predominantly used in the automotive sector, but data are not available for a distribution on sectors. In the absence of actual data it is assumed that the 940 companies are distributed 50:50 between the automotive sector (C29) and this sector. The number of exposed workers is distributed likewise whereas it is assumed that the companies in the automotive sector is larger than in the surface treatment sector (e.g. the percentage of the exposed is higher in the surface treatment sector)

The number of companies within this sector will here be estimated at 470 with a split between large, medium and small companies at 10%, 20% and 70%.

3.10.3.17 C25.62 Machining

Tools with hardmetal part are used in a large number of companies within many sectors including machining, automotive, aerospace, energy, mining and general engineering. No data are available for estimating the split between the different sectors. Occupational exposure at levels relevant for the assesses policy options will mainly take place by sharpening of the tools which is done by the use of diamond tools. Not all tools would need sharpening, but sharpening of drills and saws are reported. According to a key player in the diamond tools market, about 10% of the diamond tools will be used for sharpening of hard-metal parts. The diamond tools are used for the rough part while ceramic tools are used for the finer part. Exposure will be both to cobalt from the diamond tools and from the hard-metal parts sharpened. According to stakeholders, sharpening of hard-metal tools most often takes place in closed systems and with cooling liquids so the exposure will be very limited. Sharpening may take place in specialised department in larger companies using the tools but is also provided as a service by specialised companies.

The use of hardmetal tools is not addressed in eftec (2023).

As described in section 3.3.4.17, a number of older studies demonstrates significant exposure by sharpening of tools and exposure concentrations from CSRs, the Cobalt REACH Consortium, the French COLCHIC database, IARC and the German guidance on hardmetal working places all point at significant exposure by sharpening of hardmetal tools (see section 3.3.4.17). It is assumed that exposure at relevant levels only take place by sharpening, but it cannot be excluded that under certain conditions, also the use of the tools may lead to exposure at relevant levels as the data reported for the CSRs do not specifically indicate that the activities concerned are sharpening only.

A recent study by Paganelli *et al.* (2020) studied occupational exposure of 132 hardmetal tool sharpeners from 17 companies (on average 8 per company) in the province of Brecia, Italy. The exposure levels are relevant for the lowest of the policy options. The sector of the companies is not reported, but the companies are apparently specialised in sharpening of tools. According to the authors, hardmetal tool sharpening plants are often small factories employing less than 10 workers each which indicate that the 8 exposed workers is in the high end. About 29% of the sharpeners were not using cutting fluids.

In an older study, Imbrogno *et al.* (1994) investigated exposure of sharpeners in 80 factories in the Lombardia Region (10 million inhabitants), Italy, which may indicate that in some regions, the number of companies may be significant. In this study, the number of exposed workers was 5 per company. Mosconi *et al.* (1994) identified 2039 factories in the Bergamo region in Italy where sharpening of hardmetal tool with diamond wheels or production of diamond wheels potentially took place. A total of 110 companies with 403 confirmed exposed workers were identified by inspection; of these, at least 76 exposed workers were involved in grinding.

It will here be assumed that cutting fluids and closed systems are in general used in larger companies and the exposure level will be below the levels relevant for the policy options. Julander *et al.* (2014) report that in a company for development and manufacturing of components for gas turbines and space propulsion, exposure to cobalt took place in the department for sharpening of hardmetal drills, cutting tips and blades (provides no air exposure data), but notes that exposure via skin contact with the materials was more important than via airborne metals.

An order of magnitude of the number of companies at EU level can be obtained by assuming that the 17 analysed companies represented all such companies in the province of Brescia (1.3 million inhabitants) and extrapolated on population basis, the total number of companies at EU level would be approximately 6,000 companies. Extrapolation from the number in Lombardia mentioned above would lead to less companies and the number of exposed workers per company is 5 which will be used for the estimate. In the absence of other data, a number of 5,000 companies with a total of 25,000 exposed workers will be applied. The number correspond to 5% of the companies within this sector.

It is unclear if the companies would actually be within this sector or within other subsectors in the overall metal sector and some may even be in wood processing sectors.

3.10.3.18 C25.73 Manufacture of tools

This sector comprises two types of tools, hardmetal tools and diamond tools, with separate supply chains. The European Cutting Tools Association which represents manufacturers of cutting tools and clamping devices and their national associations have not answered requests from the study team.

The hardmetal tool sector can be divided into two segments:

- 1) Companies that prepare the sintered materials from tungsten/carbide and cobalt powders. This is at this stage workers are exposed in a large number of contributing scenarios (those described under exposure concentrations). The percentage of exposed workers of the total workforce is at this stage approximately 45%. The companies partly produce final tools and other hardmetal products, partly produce semi-manufactured sintered part for downstream manufacturers; first of all, hardmetal tool manufacturers. Based on the available information the number of companies involved in production of hardmetal powders and sintering hardmetals for and at this stage is approximately 15 with 20-30 sites. In total 15 companies (representing 18 sites) within C25.73 Manufacture of tools has answered the stakeholder survey. Many of the companies are subsidiaries of large groups. Except two, they were all involved in the production of hardmetal powder or sintered parts for hardmetal tools. Data presented in the section on exposure concentrations represent this part of the sector. All companies are large companies. The average number of exposed workers as reported for the stakeholder survey for the companies producing the hardmetal parts is 247 per site. This segment is dominated by three large groups with production facilities across the EU.

- 2) Companies that use the sintered parts (so-called blanks) for production of various tools e.g. by mounting the hardmetal part on the tip of a drill or on the teeth of a circular saw. At this stage the sintered material is solid, and inhalation exposure would only take place by grinding of the tools or by connecting parts e.g. by welding in closed systems. The same operations are undertaken in the companies preparing the sintered materials as these companies also to some extent produce the final tools. The processes are typically undertaken in closed processes with very limited exposure. Based on information from key players in the sector, the total number of downstream manufacturers of the tools is estimated at 1,000-2,000 companies. No answers have been obtained from manufacturers working at this stage. The percentage of exposed workers are at this stage much lower as exposure would only take place by a few operations. In the absence of specific information, it will be assumed that on average 10 workers are exposed in these companies.

For the manufacture of diamond tools, the supply chain differs as the majority of the manufacturers actually do the sintering of the materials. According to a key player in the diamond tools subsector, the number of producers of diamond tools in the EU is approximately 800-900 of which 90% start with the cobalt alloy powder and diamonds. In the 10% not working with the powder no significant exposure would take place so they are not further considered. About 1% of the companies are large while a large majority are relatively small companies with 10-15 employees. Especially in Southern Europe many small companies produce the tools for the local or regional customers in the natural stone industry or construction. Apart from the 1% large companies, the rest is assumed to be distributed between small and medium companies with the same distribution between the two types in the sector as reported by Eurostat. No answers have been obtained but based on information from suppliers to the sector, it is assumed that on average about 10 workers are exposed in each company.

Eftec (2023) estimates the total number of companies (without distinguishing between subsector and stages in the supply chain) at 630 companies with 720 sites. The total number of exposed workers is estimated at 9,700 (13 per site). The total number of workers in the companies is estimated at 25,600 workers, corresponding to 11% of the 237,392 workers registered for this sector in Eurostat.

It is here considered that the estimate of number of companies provided on the basis of key players is more robust.

On this basis of above description, the total number of companies is estimated at 2,300 with a total of 30,000 exposed workers. The distribution of the companies across the three segments is set at 2% large, 10% medium and 88% small companies.

3.10.3.19 C25.99 Manufacture of other fabricated metal products n.e.c.

According to the description for the NACE code in Eurostat, permanent batteries should be included here together with a long list of other products. Additive manufacturing may also be listed under this code. One respondent for the stakeholder consultation with an aggregated response for several sectors lists three sites under this NACE code involved with 3-D printing and production of metal alloy powders, but do not specify the number of exposed workers specifically for this sector (average for all sites in the aggregated answer is 116 exposed workers representing 36% of the workforce in the companies).

The SIREP database in Italy include 10 companies under this NACE code. Scarcelli *et al.* (2020) extrapolate from the percentage of workers exposed in the reporting companies (6.1%) the number of exposed workers in Italy at 2,579. The number of workers in the 10 reporting companies is not indicated. If the reported percentage of companies with exposed workers in Italy is extrapolated to the entire EU, a total of 962 companies could be estimated. A simple extrapolation of the 10 companies in the SIREP database would result in 76 companies (i.e. extrapolated from those actually known to have exposure to cobalt).

The total number of companies in this sector in the Eurostat SBS is 48,846 with 257,715 workers, but likely only a very small part would be involved in activities with cobalt.

In the absence of specific data, with a view to the 10 companies reported in the SIREP database and three companies reporting to the stakeholder survey, the total number of companies is assumed to be 150 with a total of 1,120 exposed workers which represent 20% if the workforce in the companies assuming. The distribution between large, medium and small size companies is set at 5%, 20% and 75%.

3.10.3.20 C26.1 Electronic components and boards

Cobalt is present in various components of electronic equipment. According to the Cobalt Institute (2023) and other sources, most integrated circuits are likely to contain cobalt which provides wear resistance and electrical resistivity, and cobalt is also used in magnetic recording thin films, magnetic storage devices, and metal leads and used in semi-conductors. As an example, electrolytes for hard gold coatings with cobalt is marketed in the EU for electrical contacts and edge connectors on printed circuit boards. The CSR for cobalt includes an exposure scenario for production of resistors, a semiconductor (the exposure scenario combine resistors and magnets) which has been used for estimating exposure concentrations.

Electronic components are manufactured by relatively few companies in the EU. The European Semiconductor Industry Association (ESIA) has 15-16 members and represents most manufacturers in the EU. According to the association it has no specific information on the use of cobalt in the industry. The European Passive Components Industry Association (EPCIA) which include manufacture of resistors have 16 members. The number of producers of printed circuit boards in the EU is reported to have dropped from 1,400 to about 230.[29]

One large company has responded to the stakeholder consultation with very limited information indicating that cobalt may be used in one department.

Eftec (2023) estimate the number of companies at 200 (200 sites) with 1,300 exposed workers. As the background for the estimate is not provided it is not possible to assess to what extent these applications would lead to exposure to cobalt. ECHA (2018a) does not mention any applications of the cobalt salts in production of electrical and electronic products (apart from batteries and magnets included elsewhere). According to Table 3-10 based on eftec (2019), the annual volume used for production of 'electronics' is indicated at <50 tonnes/year. Of the summaries of the national databases in Finland, France, Italy and Canada, the only indication of exposure within this field is exposure of 500 workers in France by 'Manufacture of electrical equipment', but it is not specified if this could be manufacture of batteries as batteries do not have its own category in the French survey.

Considering that the number of manufacturers of electronic components and boards has decreased, and considering the number estimated by eftec (2023), a total number of 200 companies and 3,000 exposed workers is assumed. The distribution is set at 5% large, 20% medium and 75% small sized enterprises. It is not known to what extent the applied exposure concentrations would be representative for the processes.

3.10.3.21 C26.51 Humidity indicator cards

ECHA (2018a) quote one company which for the stakeholder consultation had indicated the use of cobalt for production of humidity indicator cards. On the basis of limited information, eftec (2023) assume that 5 companies with 5 sites with 100 exposed workers are involved in the production of the cards. In the absence of specific data, the same will be assumed here.

3.10.3.22 C27.2 Batteries

Batteries that contain cobalt are nickel-cadmium (Ni-Cd), nickel metal hydride (Ni-MH), and lithium-based batteries.

The supply chain for the production of cobalt-containing batteries consists of two steps: Manufacture of the cathodic material and production (assembly) of the batteries.

According to ECHA (2018b), there were more than 20 plants identified in Europe that use the cobalt salts as the starting material for the manufacture of cathodic material for batteries, although several of them have limited production, for niche or specialty markets. Several of the manufacturers of cathodic material are included in the sector for manufacture of basic chemicals, and produce also chemicals for other purposes, but it cannot be excluded that some specialised companies could be included in this sector. According to ECHA (2018b) quoting the Cobalt Institute, the exact

[29] https://www.raypcb.com/pcb-manufacturing-in-europe/

number of workers exposed to cobalt salts in plants that manufacture cathodic material for batteries is not known but according to industry it could be estimated at below 100 workers.

ECHA further notes that approximately 1,500 workers are expected to be exposed to cobalt-containing substances (including the cobalt salts) in the manufacturing and recycling of batteries.

According to the OELs 4 report on nickel compounds, approximately ten companies were involved in the production of nickel-containing batteries in the EU and the number of exposed workers was estimated at 500.

Based on stakeholder input from Eurobat and other available information, the total number of producers of lithium-based batteries currently in operation is five.

For the stakeholder consultation, three producers of batteries have answered. The average number of exposed workers was 130 (60 - 200) representing 27% of the workforce of the companies.

Eftec (2023) does not address production of batteries. It is estimated by eftec (2023) that 20 companies with 70 sites and 2,000 workers are involved in the manufacture of precursor chemicals for batteries. However, it is also indicated that 'insufficient respondent data' were available for this use area. Furthermore, it is not indicated to what extent the same companies are also included under other use areas. In correspondence with the information from ECHA (2018b), it is here assumed that the same companies are involved in the manufacture of other chemicals and included under manufacture of basic chemicals.

Based on the available data, the total number of producers of batteries is here estimated at 15 companies with a total of 1,950 exposed workers using the average reported for the stakeholder consultation as the best estimate. The split between large and medium sized is set at 50:50.

3.10.3.23 C28.11 Engines and turbines

The main use of cobalt in this sector is cobalt-based alloys in the manufacture of components of gas turbines and engines. The main use of cobalt alloys is split between gas turbines, aerospace and medical/dental implants. A top down approach of collecting information on the market of cobalt alloys from providers of the alloys has so far not been successful and no specific information is provided in eftec (2023). Three areas where alloys may be used are power and motive (4% of total cobalt consumption), energy (4%), and aerospace (4%) (Cobalt Institute, 2022). Furthermore, alloys are used for the medical and dental sector.

The European gas and steam turbine industry association (EUTurbines) have 7 members; all large companies. The association has not answered the request and no companies in this sector have responded to the questionnaire.

Cobalt is used for various applications in the sector. As an example, Julander *et al.* (2014) at an industry for development and manufacturing of components for gas turbines and space propulsion where exposure to cobalt took place by job tasks in the three departments: (i) Sharpening of hardmetal drills, cutting tips and blades (tungsten carbides containing cobalt); (ii) production of nozzles and other combustion structures (metal alloys containing nickel, cobalt, and chromium); and (iii) thermal application of different surface layers on solid metal items (powders containing nickel, cobalt, and chromium).

RPA (2020) report that no information on the number of companies using cobalt in this sector was obtained during the consultation, so the study team assumed it was 30 enterprises.

The total number of companies in the sector in Eurostat SBS is 1,300 with a distribution of large, medium and small companies at 6%, 13% and 81% and in total employment of 220,000 workers.

In the absence of specific data it will be assumed that 10% of the companies are using cobalt alloys (130 companies) and 10% of the employees are exposed to cobalt resulting in a total of 2,200 exposed workers. The assumed distributions between companies are the same as for the entire sector.

3.10.3.24 C29.10-30 Automotive

No companies in this sector have responded to the questionnaire and the European Automobile Manufacturers' Association (ACEA) has not responded to the request. One interviewed car manufacturer company interviewed has informed on the use of cobalt for R&D activities regarding batteries.

The use of cobalt for surface treatment has been described under sector C25.61 in section 3.10.3.16. As described, it is assumed that 470 of the 940 companies undertaking surface treatment would be within the automotive sector (which also include companies producing part for motor vehicles).

The split between large, medium and small sized companies will here be estimated at 7%, 10% and 83%. For the further analysis, all companies are allocated to C29.30 Manufacture of parts and accessories for motor vehicle.

3.10.3.25 C30.30 Air and spacecraft

No companies in this sector have responded to the questionnaire and AeroSpace and Defence Industries Association of Europe (ASD) has not answered the request. Relevant application areas are similar to those described for engines and turbines, and based on information on the distribution of cobalt use by end uses it is estimated that the activities in this sector could be similar to those in production of engines and turbines sector.

The total number of companies in the sector in Eurostat SBS is 1,417 (similar to the engine and turbines sector) with a distribution of large, medium and small sized companies at 8%, 12% and 80% and in total employment of 359,401.

In the absence of specific data, it will initially be assumed that the companies are using cobalt alloys is the same as for the engines and turbines sector (130 companies) and 10% of the employees are exposed to cobalt resulting in a total of 2,200 exposed workers. The assumed distribution between companies is the same as for the entire sector. The distribution is set at 5% large, 8% medium and 87% small sized companies.

3.10.3.26 C32.50 Medical and dental devices

The European Dental Industry (FIDE) and Association of German Dental Manufacturers (VDDI) have submitted a note on the use of cobalt alloys in dental devices (VDDI, 2021), but did not hold any data on number of companies undertaking these activities. The note make reference to five companies which are all large companies. Today the membership of VDDI comprises almost 200 German manufacturers of dental-medical and dental-technical products. It is not indicated how many of these produce dental implants and restorations.

For the stakeholder consultation one large company has responded to the questionnaire. The company has 18 exposed workers corresponding to 4% of the workforce of the company. Kettelarij *et* *al.* (2016) measured cobalt exposure of 13 dental technicians working in a dental laboratory i Stockholm with 21 employees, but it is not indicated if the measurement included all exposed technicians.

For dental restorations a limited number of companies are manufacturing pre-sintered dental blanks in an industrial process; while the finalization of the dental restoration on basis of the blanks is done in dental laboratories (a supply chain quite similar to the supply chain for hardmetal tools although the material is different). The exposure situations by the two processes are very different as the production of the blanks include handling of powder raw materials and sintering processes. No data are available to estimate the number of companies undertaking the two types of processes.

In France, the SUMER survey 2016/17 (Matinet *et al.*, 2020) indicates that the number exposed in 'Activities for human health' was 6,400 but it is not indicated which activities. The French COLCHIC database 2007-2017 include 104 measurements for dental workers representing 9% of the measurements in the dataset indicating that the number of exposed may be significant (Emili *et al.*, 2019). The SCOLA dataset for 2000-2020 include 307 samples for the sector which is one of three sectors in France with most data (Sauvé and Mater, 2022).

In Italy, the Italian Dental Industry has more than 100 members of which 33 are registered under the headline 'Implants'[30]. It is not indicated how many of these use cobalt alloys. Extrapolated to the entire EU, it corresponds to 250 companies. In Denmark, the association of Danish Dental Laboratories has 26 members typically with 5-20 employees, but it is not indicated how many make implants or restorations using cobalt.

Considering that not all producers of implants and restorations are members of the associations and that the number of companies producing medical implants may be of a similar size as the number producing dental implants, the number of companies in the EU producing medical and dental implants with cobalt is estimated at 500. This corresponds to approximately 1% of the companies registered in this sector in Eurostat SBS. Assuming an average of 10 exposed workers per company leads to an estimate of 5,000 workers exposed at EU level.

According to the Eurostat SBS, 98% are small companies, but based on the available data the distribution of large, medium and small sized producers of medical and dental implants is assumed to be 10%, 30%, 60%.

3.10.3.27 E38.32 Metal recovery

No companies from this sector have answered the stakeholder survey but one company specialised in recycling of hardmetal scrap has answered the consultation but indicates the sector as 27.45 Other non-ferrous metal production. The number of exposed workers is 76 representing 22% of the workforce.

Based on responses from seven companies involved in recycling, eftec (2023) estimated that the total number of companies involved in recycling of materials containing cobalt for recovery of the cobalt or recycling of the cobalt-containing materials (e.g. hardmetal materials) is 25-45 with 35-65 sites. The total number of exposed workers is 4,400-7,300 corresponding to about 170 per company. The share of SMEs is by eftec set at 33%.

[30] https://www.unidi.it/en/list-of-members

A major part of these companies are also involved in other parts of the life cycle and are e.g. included in the sectors for manufacture of basic chemicals, manufacture of cobalt and hardmetal tools. According to eftec (2023) half of the manufacturer respondents indicated that they also recycle cobalt-containing material, and this was used as a starting point for estimating the number of cobalt recyclers in the EU-27. Based on feedback from stakeholders, eftec (2023) estimates there are only a few specialist recycling companies (i.e., companies that specialise in the recovery of a variety of metals but do not necessary manufacture/refine the cobalt) and estimate the number to be five.

For the current stakeholder consultation, it is reported that about 10 companies are involved in the recovery of scrap of hardmetals, but it is not reported to what extent these companies are undertaking other activities and are covered elsewhere.

According to Latunussa *et al.* (2020), there were in 2020 five plants in the EU where cobalt was recovered from batteries. The plants were located in Belgium, Finland, Germany and France (2 sites). These sites are involved in other parts of the life cycle of cobalt and included elsewhere in this report.

In in order not to underestimate the number of companies involved in metal recovery, it will here be assumed that the number of companies which are not included in other sectors may is 15. It is assumed that 8 are large companies and 7 are medium-sized.

Assuming that the average number of exposed workers per company is 76, as reported by one specialised company for this survey (the average from the eftec (2023) survey is higher but cover companies also involved in other activities), the total number of exposed workers in the 15 companies can be estimated at 1,100.

3.10.3.28 Cross-sectoral: Biogas

Eftec (2023) estimates that the total number of companies involved in the formulation, industrial and professional use of mixtures at 3,100 companies with 10,000 workers exposed. No companies had answered the eftec (2023) survey. The total number of companies is based on RPA (2020) which estimate the number of companies at 3,100 on the basis of 13,800 sites in the ECHA (2018a) restriction proposal. Of these, the ECHA (2018a) report assumed that 10% (1,380) is allocated to formulation and industrial use in biogas production and 90% (12,420) to professional use in biogas production. The formulation of the mixtures is in the current study included under C20.50 Formulation of other chemicals. The industrial use is in the dedicated biomethane producing facilities of which there according to the European Biogas Association was 1,322 by April 2023 [31]. None of the sources define the professional use, but it is likely biogas production in farms and sewage sludge digestors. The Eftec (2023) report assume a SME percentage of 33% (i.e. large companies take up 67%) based on responses for other sectors, but this is not in accordance with the indicated average number of workers in the companies of 9 employees per company.

The number of exposed workers is in the ECHA (2018a) report estimated at 4,860 in 13,800 sites. It leads to an estimate of less than one exposed worker per site which is not further explained. RPA (2020) does not estimate number of workers and the estimate of 4,900 workers in the eftec (2023) is based on average number of exposed workers per site reported for other sectors. In the

[31] https://www.europeanbiogas.eu/strongnew-record-for-biomethane-production-in-europebrshows-eba-gie-biomethane-map-2022-2023-strong/

absence of more exact data a number of 3,100 companies with 10,000 workers exposed, applied from the eftec (2023) report will be used as best estimate.

A number of EDTA-based cobalt substances (outside the scope of the CMRD, see section 3.11.12) are marketed for use in biogas plants, but as no data are available to estimate the percentage of biogas plants using cobalt compounds within the scope, it will be assumed that all use substances within the scope.

As described in section 3.2.1, in Denmark 54% of the biogas facilities was based on agricultural biproducts, 7% based on sewage sludge, 15% based on non-hazardous waste and landfill gas and 4% take place within industry. In industry, the process would typically take place in larger companies.

In the absence of more specific data the following distribution between large, medium and small sized companies will be assumed 4%, 9%, and 87% respectively.

3.10.3.29 Cross-sectoral: Welding

Interviews have been conducted with the International Institute of Welding and the European Welding Association. Available information indicates that welding of cobalt alloys may take place in those sectors where the cobalt alloys are used such as the air and spacecraft and engines and turbines sectors, but specific data are not available. Data on exposure levels in the literature concern welding of moulds for ceramic tiles and aircraft parts (section 3.3.4.28) and it is also reported that welding may be applied for cobalt alloys used in the hollow glass sector.

Available information suggests that consumables for welding cobalt alloys account for the order of magnitude of 0.01-0.1% of the consumables market and the total number of welders in the EU of approximately 1 million (see OELs 3 report on welding), the number of welders (calculated as full-time welders) 100-1,000. This is calculated as full time welders and the number of workers doing some welding from time to time could potentially be higher. Brazing would typically take place in the same sectors as welding but is also used separately in some industrial processes.

A first estimate until more information is obtained is that in total 550 workers are exposed by welding and brazing. In comparison the OELs 4 report on nickel estimated the number of welders of stainless steel at 2,510 in 251. Welding likely take place in sectors already covered and there is a risk of double counting, however, to be able to analyse welding separately it is assumed that welding takes place in 50 companies with the same split between large, medium and small companies at 5%, 15% and 80%.

3.10.4 Summary of enterprises with exposed workers

A summary of enterprises with exposed workers is shown in Table 3-95. For most of the sectors, cobalt substances within the scope are used by a few percent of all registered companies within the sector. For five sectors, the percentage of registered companies account for more than 7%: Manufacture of feed (8%), petrochemical sector (10%), production of tools (14%), production of engines and turbines (10%) and production of aircraft (9%). In total across the sectors, cobalt was used in about 3% of the registered companies.

Table 3-95 Estimated number of EU enterprises with workers exposed to cobalt and inorganic cobalt compounds using Eurostat, survey and industry data

Sector		Number of enterprises in EU (Eurostat) *	% of enterprises with exposed workers **	Estimated enterprises with exposed workers in EU **
C10.91	Manufacture, feeds	3,786	8%	300
C19.20	Petrochemical, catalyst	821	10%	82
C20.12	Manufacture of dyes and pigments	485	3%	15
C20.13	Manufacture of basic inorganic chemicals	858	3%	30
C20.30	Manufacture of paints and inks	3,247	0.3%	10
C20.59	Catalysts + Formulation	4,076	1%	48
C21.20	Pharmaceuticals	825	1%	8
C22.11	Production of tyres	1,460	0.2%	3
C23.1	Glass	13,813	0.4%	50
C23.4	Ceramics	14,029	4%	500
C23.7	Cutting stone	33,363	3%	1,000
C24.10	Steel	2,769	0.3%	7
C24.45	Manufacture of cobalt and cobalt alloys	522	1%	6
C25.5	Powder metallurgy	13,732	0.2%	30
C25.61	Surface treatment of metals	26,393	2%	470
C25.62	Machining	126,791	5%	6,000
C25.73	Manufacture of tools	15,892	14%	2,300
C25.99	Manufacture of other fabricated metal products n.e.c.	48,846	0.3%	150
C26.1	Production of electronic components and boards	7,301	3%	250
C26.51	Humidity indicator cards	9,073	0.1%	5
C27.2	Batteries	551	3%	15
C28.11	Engines and turbines	1,300	10%	130
C29.30	Automotive, parts	9,427	1%	130
C30.30	Air and spacecraft	1,417	9%	130
C32.50	Medical and dental devices	64,571	1%	500
E38.32	Metal recovery	16,900	0.1%	15
	Biogas	NA	NA	3,100
	Welding	NA	NA	50
	Total	422,248	3% (excl. NA)	15,334

*Sources: * Eurostat SBS; **Study team.*

3.10.5 Enterprises with exposed workers by sector and by size of enterprise

Distribution of EU enterprises by sector and by size of enterprise based on Eurostat SDS is shown in Table 3-96. The Eurostat database does not provide percentages by size of company at the 4-digit level (C20.12 'Manufacture of dyes and pigments) but only at 3-digit level (e.g. 20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms'). The split by size of company for the 4-digit level has therefore been calculated on the basis of the split for the 3-digit level.

Distribution of EU enterprises by sector and by size of enterprise according to Eurostat is shown in Table 3-96. In total for the concerned sectors 98% are small, 1.8% medium and 0.3% large-sized companies. For most of the concerned sectors, small companies account for more than 85% of the total number of companies. The data on distribution of EU enterprises by sector has been used together with information obtained from the stakeholder consultation and other sources for estimating the distribution by sector of companies with workers exposed to cobalt and cobalt compounds which is shown in Table 3-97.

Table 3-96 Distribution of EU enterprises by sector and by size of enterprise according to Eurostat. Please note that data are provided for each sector, whereas for some sectors these are grouped in the current study.

Sector, short name used in this report		Total number of enterprises	Percentage of enterprises		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
C10.91	Manufacture, feeds	3,786	91%	7%	1%
C19.20	Petrochemical, catalyst	821	83%	8%	9%
C20.12	Manufacture of dyes and pigments	485	86%	10%	4%
C20.13	Manufacture of basic inorganic chemicals	858	86%	10%	4%
C20.14	Manufacture of basic organic chemicals	1,949	86%	10%	4%
C20.30	Manufacture of paints and inks	3,247	86%	11%	4%
C20.59	Formulation of other chemical products	4,076	89%	9%	2%
C21.20	Pharmaceuticals	825	78%	13%	9%
C22.11	Production of tyres	1,460	91%	6%	2%
C23.1	Glass	13,813	95%	4%	2%
C23.4	Ceramics	14,029	98%	1%	0%
C23.7	Cutting stone	33,363	100%	0%	0%
C24.10	Steel	2,769	91%	4%	5%
C24.45	Manufacture of cobalt and cobalt alloys	522	84%	10%	6%
C25.5	Powder metallurgy	13,732	92%	7%	2%
C25.61	Surface treatment of metals	26,393	98%	2%	0%
C25.62	Machining	126,791	98%	2%	0%
C25.73	Manufacture of tools	15,892	97%	2%	0%
C25.99	Manufacture of other fabricated metal products n.e.c.	48,846	96%	3%	1%
C26.1	Production of electronic components and boards	7,301	93%	5%	2%
C26.51	Humidity indicator cards	9,073	89%	8%	2%
C27.2	Batteries	551	82%	10%	8%
C28.11	Engines and turbines	1,300	81%	13%	6%
C29.1	Manufacture of motor vehicles	2,067	88%	5%	6%
C29.30	Automotive, parts	9,427	77%	13%	10%

Sector, short name used in this report		Total number of enterprises	Percentage of enterprises		
			Small <50 employees	Medium 50-249 employees	Large >249 employees
C30.30	Air and spacecraft	1,417	80%	13%	8%
C32.50	Medical and dental devices	64,571	98%	1%	0%
E38.32	Metal recovery	16,900	97%	3%	0%
	Biogas	NA			
	Welding	NA			
	Total	1,384,064			

The estimated number of EU enterprises with exposed workers by sector and by size of enterprise shown in the table below follow a similar pattern but only 80% are small, 15% medium and 5% is large-sized companies. It reflects that the processes involving cobalt in many sectors are only used at industrial scale. As an example, for manufacture of catalysts, large and medium-sized companies account for 100% of the companies with exposed workers whereas for the overall C20.59 'Formulation of other chemical products', medium-sized and large companies account for 11% only.

Examples where none of the companies are small-scale are the petrochemical sector where all the refineries are part of medium and large-sized companies, manufacture of dyes and pigments, catalysts and manufacture of pharmaceuticals. Sectors with no SMEs with exposed workers are production of pharmaceuticals, production of tyres, and manufacture of cobalt and cobalt alloys.

Table 3-97 Estimated number of EU enterprises with exposed workers by sector and by size of enterprise

Sector		Number of enterprises			
		Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
C10.91	Manufacture, feeds	264	30	6	300
C19.20	Petrochemical, catalyst	0	41	41	82
C20.12	Manufacture of dyes and pigments	0	4	11	15
C20.13-20.14	Manufacture of basic chemicals	12	11	7	30
C20.30	Manufacture of paints and inks	6	3	1	10
C20.59	Catalysts	0	7	6	13
C20.59	Formulation of other chemical products	14	11	11	35
C21.20	Pharmaceuticals	0	0	8.0	8
C22.11	Production of tyres	0	0	3	3
C23.1	Glass	28	15	7.5	50
C23.4	Ceramics	350	105	45	500
C23.7	Cutting stone	970	20	10	1,000
C24.10	Steel	2	4	1	7
C24.45	Manufacture of cobalt and cobalt alloys	0	0	6	6
C25.5	Powder metallurgy	11	17	3	30

Sector		Number of enterprises			
		Small <50 em-ployees	Medium 50-249 employees	Large >249 employees	Total
C25.61	Surface treatment of metals	329	94	47	470
C25.62	Machining	4,800	900	300	6,000
C25.73	Manufacture of tools	2,024	230	46	2,300
C25.99	Manufacture of other fabricated metal products n.e.c.	113	30	8	150
C26.1	Production of electronic compo-nents and boards	188	50	13	250
C26.51	Humidity indicator cards	3	1	1	5
C27.2	Batteries	-	8	8	15
C28.11	Engines and turbines	105	17	8	130
C29.30	Automotive, parts	108	13	9	130
C30.30	Air and spacecraft	113	10	7	130
C32.50	Medical and dental devices	300	150	50	500
E38.32	Metal recovery	-	7	8	15
	Biogas	2,697	279	124	3,100
	Welding	40	8	3	50
	Total	**12,476**	**2,063**	**795**	**15,334**

Source: Study team.

Table 3-98 Estimated number of EU enterprises with exposed workers by sector and by size of enterprise, in percentage

Sector		Percentage of enterprises			
		Small <50 em-ployees	Medium 50-249 employees	Large >249 employees	Total
C10.91	Manufacture, feeds	88%	10%	2%	300
C19.20	Petrochemical, catalyst	0%	50%	50%	82
C20.12	Manufacture of dyes and pig-ments	0%	27%	73%	15
C20.13-20.14	Manufacture of basic chemicals	41%	37%	22%	30
C20.30	Manufacture of paints and inks	60%	30%	10%	10
C20.59	Catalysts	0%	54%	46%	13
C20.59	Formulation of other chemical products	40%	30%	30%	35
C21.20	Pharmaceuticals	0%	0%	100%	8
C22.11	Production of tyres	0%	0%	100%	3
C23.1	Glass	55%	30%	15%	50
C23.4	Ceramics	70%	21%	9%	500
C23.7	Cutting stone	97%	2%	1%	1,000
C24.10	Steel	29%	57%	14%	7
C24.45	Manufacture of cobalt and co-balt alloys	0%	0%	100%	6
C25.5	Powder metallurgy	35%	55%	10%	30
C25.61	Surface treatment of metals	70%	20%	10%	470

Sector		Percentage of enterprises			
		Small <50 em-ployees	Medium 50-249 employees	Large >249 employees	Total
C25.62	Machining	80%	15%	5%	6,000
C25.73	Manufacture of tools	88%	10%	2%	2,300
C25.99	Manufacture of other fabricated metal products n.e.c.	75%	20%	5%	150
C26.1	Production of electronic compo-nents and boards	75%	20%	5%	250
C26.51	Humidity indicator cards	60%	20%	20%	5
C27.2	Batteries	0%	50%	50%	15
C28.11	Engines and turbines	81%	13%	6%	130
C29.30	Automotive, parts	83%	10%	7%	130
C30.30	Air and spacecraft	87%	8%	5%	130
C32.50	Medical and dental devices	60%	30%	10%	500
E38.32	Metal recovery	0%	47%	53%	15
	Biogas	87%	9%	4%	3,100
	Welding	80%	15%	5%	50
	Total	81%	13%	5%	15,334

Source: Study team.

3.10.6 Enterprises with exposed workers by Member State

The estimated number of EU enterprises with exposed workers by Member State is summarised in Table 3-99. The table is generated from the list of estimated number of EU enterprises with exposed workers in Table 3-95 and data from the Eurostat SDS on the overall distribution by sector and Member State for the entire sectors. As the companies with exposed workers account for a small percentage of all companies within each sector, a distribution by sector and Member State is quite uncertain, but the uncertainty is reduced by aggregating across all sectors. As welding and biogas are not allocated to a specific sector, these use areas are not included in this table and the next.

The most pronounced difference to the distribution of Member States by capita is an overrepresentation of Czech Republic, Italy, Poland and Slovakia, which may reflect an extensive metal industry in these Member States, and an underrepresentation of France, Romania, and Spain.

Table 3-99 Estimated number of EU enterprises with exposed workers by Member State (excl. biogas and welding)

Member State	Number of enterprises	Percentage of listed**
Austria	124	1.0%
Belgium	232	1.9%
Bulgaria	154	1.3%
Croatia	104	0.9%
Cyprus	14	0.1%
Czechia	891	7.3%
Denmark	122	1.0%
Estonia	29	0.2%
Finland	139	1.1%

Member State	Number of enterprises	Percentage of listed**
France	833	6.8%
Germany	1,950	16.0%
Greece	140	1.2%
Hungary	402	3.3%
Ireland	141	1.2%
Italy	2,054	16.9%
Latvia	29	0.2%
Lithuania	71	0.6%
Luxembourg	4	0.0%
Malta	6	0.0%
Netherlands	551	4.5%
Poland	1,643	13.5%
Portugal	382	3.1%
Romania	166	1.4%
Slovakia	647	5.3%
Slovenia	209	1.7%
Spain	703	5.8%
Sweden	426	3.5%
Total (excl. welding and biogas)	**12,166***	

** Due to rounding the number is slightly different from the total number of companies excl. welding and biogas. ** Percentage for all sectors excl. welding and biogas.*
Source: Study team on the basis of estimated number of companies and Eurostat SBS.

The estimated number of companies by key sector and Member State is shown in Table 3-100. The table is generated from the list of estimated number of EU enterprises with exposed workers by sector Table 3-95 and data from the Eurostat SDS on the overall distribution by sector and Member State for the entire sectors. As the companies with exposed workers account for a small percentage of all companies within the sector, the distribution by sector and Member State is quite uncertain and should be taken as indicative only. For sectors with few companies with exposed workers the table may be misleading. Data have not been available for adjusting the distribution with actual information on the distribution of companies with exposure to cobalt.

Table 3-100 Estimated number of enterprises with exposed workers by key sector and by Member State (excl. welding and biogas)

MS	Manufacture, feeds	Petrochemical, catalyst	Manufacture of dyes and pigments	Manufacture of basic chemicals	Manufacture of paints and inks	Catalysts	Formulation	Pharmaceuticals	Production of tyres	Glass	Ceramics	Cutting stone	Steel	Manufacture of cobalt and cobalt alloys
	C10.91	C19.20	C20.12	C20.13 20.14	C20.30	C20.59	C20.59	C21.20	C22.11	C23.1	C23.4	C23.7	C24.10	C24.45
BE	13	8	2	3		1			1	3	21			2
BG	7	41	8	15		1				5	8			
HR	17	16	3	6				1	7	40	45			5
CY	3	12	2	5		1				3	3			1
CZ	28	4	1	2	1	10	2		5	34	156	1	3	3
DK	1									1	2			
ES	9					1			1	5	10	1		
FI	13					2			1	18	28			
FR	53				1	6	1		3	28	92	1		3
DE	16				1	3	1		5	128	76			4
EL	3					1			1	4	17			
HU	28				2	9	1		12	72	222	1	1	3
IE	3									1	3			
IT	2									2	5			
LV	2									12	19			
LT														
LU	8					1			1	16	19			
MT											2			
NL	10					2	1		3	11	13			1
AT	5					1				5	18			1
PL	33				1	4	1		4	25	133			2
PT	8					2			1	33	49			2
RO	11					1			2	6	20			
SK	1									2	8			
SI	18					2			1	13	19	2		
ES	5					1				3	6			
SE	4					1			1	31	8			1

ext.

MS	Powder metallurgy	Surface treatment of metals	Machining	Manufacture of tools	Manufacture of other fabricated metal	Production of elec-tronic components	Humidity indicator cards	Batteries	Engines and turbines	Automotive	Air and spacecraft	Medical and dental devices	Metal recovery
	C25.5	C25.61	C25.62	C25.73	C25.99	C26.1	C26.51	C27.2	C28.11	C29.10-30	C30.30	C32.50	E38.32
BE	13	9	123	22	1	3			2	4	4	9	1
BG	7	3	45	8	3	3			1		1	5	
HR	17	52	623		4	25		1	9	6	8	23	
CY	3	5	42	24	1	2			12	1	2	3	
CZ	28	61	849	564	10	56	1	3	19	20	24	93	1
DK	1	2	15	4	1	1				1		1	
ES	9	1	87	15	1	2			2	2	2	2	
FI	13	6	20	28	3	3			3	1	2	12	
FR	53	26	227	177	5	16		1	8	7	9	39	
DE	16	30	294	165	4	16		1	5	10	18	51	5
EL	3	4	36	24	2	2			3	1	3	3	
HU	28	78	810	560	39	47		2	19	6	15	124	3
IE	3		5	1								1	
IT	2	2	11	3	1	1					1	1	
LV	2	2	20	11	1	1						3	
LT	-		3	1									
LU	8	10	228	84	1	7		1	4	4	3	15	
MT	-		2	2									
NL	10	18	387	48	2	9		1	13	10	6	16	
AT	5	4	32	40	1	3			3	1	3	7	
PL	33	95	1,114	114	8	21		2	10	10	14	51	1
PT	8	7	93	163	4	3			2	2	4	9	
RO	11	4	70	24	2	5			3	2	3	12	1
SK	1	4	125	57	2	3			1	1	2	3	
SI	18	29	416	49	50	11			1	29		7	
ES	5	5	74	31	2	4			2	2	1	3	
SE	4	12	250	81	3	7		1	5	10	5	6	

Source: Study team on the basis of estimated number of companies and Eurostat SBS.

3.10.7 Cross border aspects

This section provides information on cross border aspects which form background for the analysis of market effects in chapter 8. Particular focus is on the sectors where introduction of OELs would have the highest impact or sectors with relatively few companies and specific information is available.

Information on cross border aspects e.g. the number/proportion of firms operating in more than one Member State is not available from the Eurostat Structural Business Statistics but has been collected from various sources such as stakeholder input, company websites, trade associations' websites, and the literature. For some sectors, no information on cross border aspects has been available, and in the case the sectors are not among the highest impacted sectors, it has not been prioritised to collect this information by further contact to individual companies as a large number of contacts would be required in order to obtain a statistically significant result.

The available information is summarised by sector in the table below.

Table 3-101 Information on cross-border aspects by sector

Sector		Information on cross-border aspects
C10.91	Manufacture, feeds	No data on industry structure of the manufacture of feed premixes industry have been identified.
C19.20	Petrochemical, catalyst	A map prepared by Concawe showing the location of the mainstream and specialised refineries processing crude oil in Europe indicates the number of open mainstream and specialised refineries in 2022 at 81 owned by 46 companies (it has not been investigated to what extent the listed companies are owned by larger groups). Of the 46 companies, 8 (17%) have refineries in more than one Member State.
C20.12	Manufacture of dyes and pigments	It is estimated that 15 companies in 30 sites use or produce substances within the scope. A search of the websites of registered companies indicates that the majority are companies in Spain, Italy and Germany which seems not to have production sites in other Member States. Three registrants are internationally operating companies with many locations within and outside the EU: Ferro, Sun chemicals, and Heubach Pigment Manufacturing GmbH.
C20.13-20.14	Manufacture of basic chemicals	The total number of companies involved in the manufacture or import of cobalt metal and cobalt compounds (organic and inorganic) is 45-80 companies with 85-115 sites. Of these 62% are large companies. No specific data are available on the part manufacturing cobalt compounds specifically, but it is here assumed that 30 companies are manufacturing the compounds. A search on the websites of registrants for inorganic cobalt compounds shows that many are international chemical companies with production sites in several Member States. Only for a few of the companies it is confirmed that they have manufacturing sites for cobalt compounds in more than one Member State.
C20.30	Manufacture of paints and inks	No specific information on which companies may use substances within the scope is available.
C20.59	Catalysts	It is estimated that cobalt catalysts are produced by 8 companies in 13 sites. The specific companies are not known. The majority of manufacturers members of Catalysts Europe are companies with production sites in more Member States and/or outside the EU. It is on this basis assumed that half of the companies producing cobalt-based catalysts have production sites in more than one Member State.
C20.59	Formulation of other chemicals	Limited specific information is available for the estimated 35 companies in this category which are involved in formulation of other chemicals and formulation of mixtures for various purposes (surface treatment chemicals, water treatment chemicals, biogas additives, etc.). No data on industry structure of the formulation of chemicals industry has been identified.

Sector		Information on cross-border aspects
C21.20	Pharmaceuticals	The number of companies are estimated at 8 on basis of limited information. No data on the distribution of production sites by Member States are available.
C22.11	Production of tyres	No specific information on which companies may use substances within the scope is available.
C23.1	Glass	It is estimated that in total 50 companies in the glass sector use cobalt; first of all in the container glass sector. Based on information on members of the European Container Glass Federation (FEVE) listed on the website, a major part of the sites belongs to larger groups with production sites in more than one Member State including: Ardagh Group, BA GLASS, Vidrale, O-I, Saver Glass, and Vetropack. It has not been investigated whether all the listed companies use cobalt.
C23.4	Ceramics	The cobalt pigments are mainly used in the ceramic tiles sector with an estimated 500 companies using the cobalt pigments within the scope. A major part of the production takes place in Spain and Italy. Major producers have production sites in one Member State only and it is assumed that the majority of companies produce in one Member State only.
C23.7	Cutting stone	No data on industry structure of the natural stone industry using cobalt-containing tools have been identified. It is assumed that 97% of the companies are small and most of these are likely operating in one Member State only.
C24.10	Steel	No specific information on the estimated five companies producing cobalt-containing steel has been available.
C24.45	Manufacture of cobalt and cobalt alloys	The number of manufacturers of cobalt and cobalt alloys is assumed to be six. According to Latunussa *et al.* (2020) refined cobalt is produced by four plants in the EU in Finland (two plants), Belgium and France. The companies are international companies but according to available information only one of the companies produce cobalt and cobalt alloys in more than one Member State.
C25.5	Powder metallurgy	A Guide to Powder Metallurgy Manufacturers and Suppliers 2022 from the European Powder Metallurgy Association (EPMA, 2022) lists 32 metal powder manufacturers from the EU and 57 manufacturers and suppliers of powder metal components. A number of these are also included in other sectors first of all manufacture of tools. Apart from those involved in the manufacture of tools, a search of company websites indicates that the majority have manufacturing sites in one Member State only.
C25.61	Surface treatment of metals	No data on industry structure of companies involved in surface treatment of metals have been available.
C25.62	Machining	No detailed data on industry structure for sharpening hardmetal tools have been identified. The companies involved in the sharpening of hardmetal tools at the reported exposure levels are assumed mainly to serve the local/regional metal industry and it is assumed that the majority of companies have sharpening workshops in one Member State only.

Sector		Information on cross-border aspects
C25.73	Manufacture of tools	The structure is different for the various segments. The number of manufacturers of the sintered blanks for hard metal tools is estimated at 20-30. This part of the sector is dominated by large companies with production sites in more than one Member State and/or outside the EU. Suppliers of tungsten carbide powder and suppliers of hardmetal / cemented carbide are listed at the website of the International Tungsten Industry Association [32]. Information on sites have been obtained from company websites. Major manufacturers of blanks with sites in more Member States and indicated in a list of larger global players are Kennametal, Sandvik and Ceratizit. Other companies, either manufacturers of powder or blanks, with production sites in more than one Member State (not necessarily for cemented carbide) include Höganäs, OMCD Group, Umicore, Epiroc Drilling Tools AB, and HC Starck Tungsten GmbH. In addition some listed companies have facilities in one Member State only. For the stakeholder consultation, in addition to the listed companies, five German companies involved in the production of powder or blanks with production sites with 105-400 employees have responded. These companies apparently have production sites in Germany only. On the basis of available information it is assessed that more than half of the companies have sites in more than one Member State and that these companies represent by far the majority of the total volume. For the further downstream use of the blanks, with an estimated number of companies of 1,000-2,000, no specific information on the industry structure of has been available. For the production of diamond tools, the number of companies producing the tools from powder is estimated at 720-810. According to a key stakeholder, about 1% of the companies are large while a large majority are relatively small companies with 10-15 employees. Large companies listed in various market reports on the diamond tool industry include Husqvarna AB, Bosch Tool, LEUCO, Hilti, Tyrolit, and Saint Gobain. These are large manufacturers of tools in general. These companies typically have production sites in more EU Member States (not necessarily producing diamond tools). It is on the basis of the available information assessed that the majority of the companies are small companies with production sites in one Member State only. No data are available to evaluate the share of the market volume represented by large companies with production sites in more than one Member State.
C25.99	Manufacture of other fabricated metal products n.e.c.	No data on industry structure of the sector om 'Manufacture of other fabricated metal products n.e.c.' have been identified.
C26.1	Production of electronic components	No specific information on the estimated 250 companies producing cobalt-containing electronic components have been available.
C26.51	Humidity indicator cards	The number of companies is indicated at 5 in five sites; consequently all companies have sites in one Member State only.
C27.2	Batteries	The total number of companies is estimated at 15. Based on producers' websites, two major companies involved in the manufacture of lithium batteries in the EU, Saft and CATL, have production sites in more than one Member States and also outside the EU. According to a report from Transport & Environment (2023) half of the Li-ion battery cells used in electric vehicles and energy storage systems in the EU were produced in the EU in 2022, notably in Poland, Hungary, and to a lesser extent in Germany and Sweden. According to the report from Transport & Environment (2023) close to 50 lithium-ion battery factories are planned for Europe by 2030. According to

[32] https://www.itia.info/suppliers-of-tungsten-tungsten-carbide-powder.html

Sector		Information on cross-border aspects
		the report 68% of potential battery production capacity in Europe (1.2TWh) is at risk of being delayed, scaled down or not realised if further action is not taken. Among the EU Member States, Germany, Hungary, Spain, and Italy have the largest shares of battery cell capacities at risk. Companies with the largest production output in 2030 include according to the study CATL, Freyr, Northvolt, LG Chem, Tesla, ACC, and Volkswagen Group. Almost 60% of European production in 2030 would be from European companies, while Chinese companies would account for around 20% of production. The report does not indicate to what extent the projected battery production would be accounted for by cobalt-free batteries. Looking further into battery components, two-thirds of all the cathode active material (the most valuable part of the battery that contains metals such as cobalt and nickel) can be produced in Europe by 2027 already, with largest projects in Germany, Poland and Sweden (Transport & Environment, 2023).
C28.11	Engines and turbines	Total number of companies is estimates at 130. No specific information on the industry structure have been available.
C29.10-30	Automotive	Total number of companies is estimates at 470. No specific information on the industry structure have been available.
C30.30	Air and spacecraft	Total number of companies is estimates at 130. According to the European Commission[33], "*although the large aeronautical enterprises are located in a few Member States (in particular in France, Germany, Italy and Spain) the industry is characterised by an extended supply chain and a fabric of dynamic small- and medium- sized enterprises throughout the EU, some of them world leaders in their domain*". Among the registrants for cobalt are four companies in the aerospace sector which are all international companies (or subsidiaries of large international companies) with production facilities in and outside the EU: Honeywell Aerospace, GE Aviation, GE Avio S.r.l., and Howmet SAS. The European Aerospace, Security and Defence Industries have 22 direct company members (none of the four listed above) which are mainly large international companies.
C32.50	Medical and dental devices	Total number of companies is estimated at 500. The percentage of SME is estimated at 90% and it is assumed that the majority of companies operate in one Member State only. As the companies operating in more than one Member State are generally large companies it cannot be excluded that these companies take up a major part of the total market volume. Examples of large-sized companies in the dental implant sector with sites in more Member States are: CeraRoot, Institut Straumann AG, Kulzer GmbH, Dentsply Sirona, Dentaurum GmbH & Co. KG, and ETK (Euroteknika). For the medical sector where the cobalt-containing implants constitute a small part of the medical devices sector no data on industry structure has been available. According to RPA (2023) it is suspected that some major European producers in the dental/medical sector may have significant metal working operations in the EU, but the largest firms do maintain manufacturing outside the EU as well.
E38.32	Metal recovery	Eftec estimates the total number of companies involved in recycling of cobalt-containing waste at 25-45 with 35-65 sites. The number of companies involved in the recovery of cobalt from waste only, and not involved in other part of the life cycle, is here estimated at 15 but may be lower. These are assumed all to be medium or large-sized companies. No data are available to estimate the percentage of companies which have recycling sites in more than one Member State. According to the OEL report for nickel compounds there are recycling activities for Ni-Cd batteries by a number of companies: SAFT (Sweden), SNAM (France); VEOLIA Environnement (France), Accurec (Germany), Umicore (Belgium), and Redux (Germany). These are in general international companies with facilities in more Member

[33] https://defence-industry-space.ec.europa.eu/eu-aeronautics-industry_en

Sector		Information on cross-border aspects
		States but it has not been investigated if recycling of cobalt take place in more than one Member State. Several of the large companies involved in manufacture of cobalt, cobalt alloys and hardmetal tools have sites in more Member States; among these also facilities for recycling of cobalt-containing waste.
	Biogas	Of the estimated 3,100 companies using cobalt for biogas only a small percentage would operate biogas facilities in more than one Member State. A list of top companies in the biogas sector lists a few companies operating in more than one Member State and typically in the same region (e.g. the Nordic Countries)
	Welding etc.	No information on the structure of companies undertaking welding of cobalt alloys has ben available.

Source: Study team on basis of sources indicated in the table.

Trade flows in articles and materials

Godoy Leon *et al.* (2022) has undertaken a Material System Analysis of cobalt in the EU from 2012 to 2016. Detailed results are provided for the year 2016. Results regarding import and export in articles and materials are shown in Table 3-102. An analysis of the trend in import and export from 2012 to 2017 indicated that the EU became more dependent on imports in downstream stages of the supply chain.

Table 3-102 Trade flows (EU external trade) of cobalt in articles and materials by application in the EU in 2016

Application	Imported Tonnes Co/year	Exported Tonnes Co/year
Portable batteries	3,600	0
Mobility batteries	890	440
Industrial batteries	310	0
Catalysts	280	280
Intentionally dissipative uses	450	1,760
Hardmetals	1,330	440
Magnets	4,830	420
Superalloys	10,180	8,720
Other uses	30	20
Total	21,900	12,080

Source. Godoy Leon et al., 2022

3.10.7.1 Increased costs

None of the interviewed or visited companies with production sites in more than one Member State have indicated it to be a problem that the facilities have to comply with different national OELs. Some of the interviewed companies have indicated that they apply the OEL of the Member State where the group is headquartered in all sites (if they hereby also comply with the national OEL) whereas other companies have indicated that each site comply with the OEL of the Member State where it is located.

In previous OEL studies it has been assumed that the resulting simplification of establishing an OEL at EU level would be particularly beneficial to companies operating in more than one Member State as they would be faced with a reduced range of requirements to which they would have to adhere. This would reduce the need to research OEL requirements across the EU for companies wishing to operate in more than one Member State, saving on both research costs as well as design costs through facilitating the adoption of common solutions to reduce exposure across plants in different locations instead of having to design facilities to meet with different OEL requirements. However, it has not been reported from the stakeholder consultations that the different OEL requirements across the EU for companies wishing to operate in more than one Member State result in any significant costs to the companies.

3.10.7.2 Lack of level playing field in the internal market

In total 19% of 57 companies responding to the stakeholder survey question regarding benefits of an OEL indicated level playing field as a benefit of establishing an OEL. The companies represent one third of the sectors represented by the survey: C20.59 Catalysts and other chemical products, C24.45 Manufacture of cobalt and cobalt alloys, C25.61 Surface treatment of metals, C25.73 Manufacture of tools; C26.1 Production of electronic components and boards, and C27.2 Batteries. It has not been analysed if companies indicating this as a benefit are located in Member States with relatively low OELs, but in interviews companies in Member States with a relatively low OEL have clearly indicated that they consider it to be a benefit to introduce an OEL at EU level.

The Cobalt Institute has in a presentation for the WPC August 2023 indicated that they support establishing an OEL in order to have a level playing field.

3.10.7.3 Risk of relocation of firms to another Member State

Questions regarding risk of relocation have not been included in the stakeholder survey. No evidence of past location decisions due to introduction of national OELs have been identified. It should be noted that most likely, companies would not specifically indicate lower protection level of workers as a driver for a relocation.

Furthermore, no evidence of significant costs of implementation of national OELs that could trigger relocation has been identified.

3.10.8 Market trends

Manufacture of cobalt. The domestic production of primary cobalt in the EU (from mining in the EU) have during the period 1955 to 2020 fluctuated between zero and approximately 2,200 tonnes of cobalt per year (Godoy León *et al.*, 2021). In 2019 it was 1,400 tonnes. The domestic production of cobalt (refinery production from domestic and imported raw materials) in EU-27 were during the period 1960 to 1990 stable at a level of about 2,000 tonnes/year. From 1990 to 2019 the domestic production has increased steadily to a level of 14,000 tonnes/year in 2019 (Godoy León *et al.*, 2021). The study was done for current Member States of the EU (EU27).

End uses. Detailed data on the current consumption of cobalt by application area is provided in section 3.2.2. As indicated in the section, quite different split by application areas is provided by different sources.

A number of studies include projections of future use of cobalt (described in section 4.5) and these typically also include some figures illustrating the past trends, but with a resolution that do not allow for a detailed analysis. No detailed overview of the trend in cobalt consumption in the EU the last 20 years have been identified.

Eftec (2019;2013) have provided some estimates on the annual consumption of cobalt in 2011-2013 (for EU 28) and 2023 (for EU 27) as shown in the table below. The two studies do not use exactly the same categories but for five categories the data are comparable. For cobalt-containing alloys, hardmetal and diamond tools and magnetic alloys the total consumption in 2023 was more than twice the consumption in 2011-2013 with the highest increase for cobalt-containing alloys (2.9 times). It should, however, be noted that another assessment by Matos *et al.* (2020) estimated the consumption of cobalt with cobalt-containing alloys at 8,640 tonnes/year and with hardmetals at 3,360 tonnes/year in 2016. This may indicate that the consumption in 2011-2013 has actually been underestimated by eftec (2019) and the increase in consumption has been less pronounced.

Table 3-103 Estimated consumption of cobalt for key use areas in 2011-13 and 2023. Tonnes Co/year

	Consumption 2011-13 EU28 *	Consumption 2023 EU27 **
Cobalt-containing alloys (metals)	1,300	3,800
Hardmetal and diamond tools (metals)	1,900	4,800
Magnetic alloys (metals)	900	1,300
Catalysts - used as catalyst precursor (metals and salts)	2,300	2,300
Use in surface treatment (metals and salts)	700	1,110

*Sources: * eftec, 2019; ** eftec, 2023.*

3.11 Alternatives

Substitution is a key risk management measure for companies having difficulty achieving an OEL. Therefore, it is important to know whether alternatives exist for cobalt and inorganic cobalt compounds in each sector. The possible alternatives are discussed below.

3.11.1 Cobalt alloys

According to a study on the EU's list of critical raw materials for the European Commission (Latunussa *et al.*, 2020), potential substitutes to cobalt alloys include composites (e.g. fibre-reinforced metal matrix composites, carbon-carbon and ceramic-ceramic composites), titanium-aluminides, nickel-based alloys, and iron-based superalloys. In some cases, cobalt can be also substituted by niobium, rhenium, and PGMs (platinum group metals) in superalloys.

All the above alternatives may replace to some extent cobalt-containing alloys used in applications such as jet aircraft engines, turbine blades for gas turbines, space vehicles or chemical equipment but with reduced overall performance e.g. loss of performance at high temperatures in some cases (Tercero Espinosa *et al.*, 2018; Cobalt Institute, 2018; Harald Ulrik Sverdrup, Ragnarsdottir, and Koca 2017 as cited by Latunussa *et al.*, 2020). Substitution of cobalt in turbine engine components by nickel has been evaluated from poor (Espinosa *et al.*, 2018) to adequate (Alves Dias *et al.*, 2018 as cited by Latunussa *et al.*, 2020).

Eftec (2023) does not include a detailed assessment for metallurgical alloys but note that molybdenum may be used as alternative in alloys used for heat resistance and nickel and iron may be used where cobalt is used as binder in wear-resistant powders. They furthermore assess that at an OEL of 20 µg/m^3 29% of the sites not in compliance would go for substitution while the percentages at OELs of 10 and 1 µg/m^3 is 14 and 11% respectively. This clearly indicate that feasible alternatives are available for some applications.

3.11.1.1 Dental alloys

According to a stakeholder input from the Association of German Dental Manufacturers (VDDI, 2021), as a main component, cobalt is responsible in dental cobalt-chromium alloys for the high corrosion resistance (in combination with chromium and molybdenum/tungsten) and strength. Main application areas are crowns, bridges, metal denture bases (frameworks), clasps, retainers und friction-pins and wires. The following is based on the stakeholder input and represent the view of VDDI (2021).

In the past, nickel-chromium alloys and beryllium alloys were alternatives to cobalt-chromium. Both alloys are viewed very critically due to their considerable allergenic potential. Nickel is unsuitable as a substitute for cobalt because of the observed allergenic potential. Precious metal alloys can release ions to a comparable and also greater extent. The mechanical properties of precious metal alloys are also lower than those of cobalt-chromium alloys. The high precious metal prices also reduce a general acceptance. While reimbursement of cobalt-chromium alloys as dental restorations in Germany is covered by statutory health insurance, the high-gold-content alloy must be borne privately by the patient. Use of elemental titanium and titanium alloys for fabricating dental restorations is well known. However, these metals are inferior to cobalt-chromium alloys with regard to the modulus of elasticity.

According to VDDI (2021) there are no alternatives available to cobalt-chromium alloys in the area of metal denture bases and clasps due to their exceptional mechanical properties (spring-hard, flexible, corrosion resistance, bending strength).

High-gold-content alloys, titanium and titanium alloys, or zirconium dioxide-based ceramics can be considered for use with bridges in principle. Apart from the costs, high-gold-content alloys do not exhibit the same strength as the corresponding cobalt-chromium alloys, meaning wall thicknesses and connector dimensions must be strengthened. The same applies for titanium and titanium alloys. If titanium-based materials are used, there is the added difficulty that the connection to the ceramic is more problematic for the dental technician. The increased space requirement of ceramics in comparison with metal frameworks means that as a rule more tooth structure is removed, which counteracts the minimally invasive approach and places additional stress on the patient. For several decades there have been alternative materials for cobalt-chromium crowns in the indication single crown that are strong and corrosion resistant and exhibit a high standard of aesthetics (glass ceramics, translucent zirconium dioxides). Strength plays a subordinate role with single crowns. Other alternatives for single crowns include veneered precious metal alloy.

Latunussa *et al.* (2020) do not address alternatives to cobalt in all dental applications but mention that palladium is an essential component of alloys used for dental restorations such as inlays, bridges and crowns. Palladium provides strength, stiffness and durability to the dental alloy while the other metals of the alloy (i.e. gold, silver, zinc and copper in varying proportions) improve malleability. In low gold alloys used in dentistry, palladium content typically ranges from 50% to 80% by weight. According to Latunussa *et al.* (2020), the use of palladium-containing alloys varies widely from country to country depending on customer preferences.

3.11.2 Hardmetal tools

According to Espinosa *et al.* (2018), the addition of cobalt to the carbide increases resistance to wear, hardness and toughness, essential qualities for cutting tools, metal rollers and engine components. Researchers have investigated using other elements as binders, including nickel and iron. No other metal fulfils the characteristics mentioned above. Despite most of the competing matrix materials having a lower cost, there is a certain loss of performance. Therefore, cobalt is practically irreplaceable in cemented carbides and in the hard metal industry (Espinosa *et al.*, 2018). Eftec (2023) reach the same conclusion.

Several ongoing research projects aim at developing alternatives to cobalt-containing hardmetal in the mining sector such as the FASTRAM project 34, a R&D project supported by Sweden's Innovation agency[35] and a project to develop an additive manufacturing process for producing cobalt-free hardmetal parts funded by US Department of Defence[36].

3.11.3 Diamond tools

Some alternatives to diamond tools with cobalt are marketed.

According to Konstanty (2021), until the early 1990s the diamond tool industry had been mainly threatened by the very high cost of diamond, whereas the price of other raw materials, e.g. cobalt and cobalt-based matrix powders, used in most professional and non-professional applications, had remained at an acceptable level. The rise in the price of cobalt initiated an intensive search for cheaper matrix materials. To meet these objectives, efforts were directed toward substituting cobalt matrix with iron-base and copper-base alloys, overcoming poor diamond retention and achieving its better distribution in the matrix. According to Konstanty (2021), recent figures reveal for the Italian market a decreasing use of cobalt, which accounts for 25% of 350 tons of powders consumed annually by the diamond tool industry. It is not indicated if the tools with cobalt are used for specific segments of the market.

According to eftec (2023), the diamond tool industry has viable alternatives to the use of cobalt as a binder such as iron or bronze which are already in use in Europe. According to eftec (2023), the diamond tools that do not use cobalt are of inferior quality. According to eftec (2023) "*Previously, when diamonds were more expensive, it was important to extend the lifetime of the diamond tool and use cobalt (as a superior binder) to ensure it. However, during consultations, the industry explained that nowadays diamonds are cheaper so buying two cheaper diamond tools is better than buying one more expensive one. As diamonds are far cheaper, it's the cobalt which is making them more expensive and a candidate for substitution*". So, the inferior quality is today counterbalanced by the cheaper price of alternatives.

Kymera International and Ecka Granules have introduced new premixed products for diamond tools without cobalt as described by Zanon *et al.* (2022). The authors conclude: "*A systematic R&D effort was undertaken, by a vast experimentation program focused on the Fe-Cu-Ni system. The result is a new family of cobalt-free bonds, with property levels comparable to the well-known 'prealloys' but manufactured via a simpler, scalable and environmentally friendlier processing route. Hardness spans over the typical range for stone cutting, further adjustable in both harder/softer direction. Standard versions are suitable for free-sintering within 910 – 930 °C, while LT versions are also suitable for hot pressing, due to their lower consolidation temperature. The high compressibility and thus low dimensional change, down to -4%, allows for substantially improved dimensional precision and net shape manufacturing via free-sintering. A new alternative is being offered to the diamond tool industry, contributing to retain its competitiveness under the current challenging market conditions*". The prealloys are commercially available from Kymera

[34] https://www.pm-review.com/fastram-project-offers-alternative-to-wc-co-hardmetals-for-mining-sector/
[35] https://im-mining.com/2022/12/19/sandvik-working-with-kth-and-boliden-on-high-strength-steel-as-a-cobalt-alternative-in-rock-drill-bits/
[36] https://3dprintmagazine.eu/desktop-metal-develops-high-volume-manufacturing-process-for-cobalt-free-hardmetal-parts/

International. Cobalt-free diamond tools are also marketed as the DTOX tool line including saw blades and core drills from the German company Kern Daudiam[37].

3.11.4 Magnets

According to Alves Dias *et al.* (2018) there is some potential for substitution of cobalt-alloyed magnets by nickel-iron alloys or neodymium-iron-boron (Nd-Fe-B) magnets. The substitution seems to be difficult though, especially in high temperature applications. Other potential substitutes include barium or strontium ferrites (Alves Dias *et al.,* 2018). Nd-Fe-B magnets have the highest energy density compared to other permanent magnets, making it the material of choice in high-performance applications where the size and weight are key requirements (Pavel *et al.*, 2016). However, weaknesses are still present in high-temperature applications, which have been addressed by coating techniques with the addition of cobalt (Cobalt Institute, 2019c).

According to eftec (2023), while some alternatives are available such as iron, nickel, and rare-earth metals such as neodymium and samarium, these alternatives lack the same functionality as cobalt-based alloys.

3.11.5 Use in steel

No information on alternatives to cobalt in high-speed steel has been identified.

3.11.6 Glass

Tricobalt tetraoxide (out of scope) is used for similar applications in glass as substances within the scope. It has not been investigated to what extent tricobalt tetraoxide could replace the current use of cobalt oxide (CoO) or cobalt sulphate ($CoSO_4$); the stakeholder inputs from industry associations have not indicated whether the two substances are used for particular applications.

3.11.7 Catalysts

Catalysts Europe has for this study submitted a confidential report on alternatives to cobalt catalysts (DHI, 2018). The report has for the hydrotreating/desulphurisation catalysts and Gas to liquid (GTL) catalysts been quoted by ECHA (2018b) as 'ECMA (2018)'. According to Catalysts Europe the information provided is still up-to-date and consequently ECHA's description is directly quoted in the following. The conclusion by eftec (2023) is based on the DHI (2018) report as well.

3.11.7.1 Hydrotreating/desulphurisation catalysts

Used in the petrochemical sector (C19.20), in the production of hydrotreating/hydrodesulphurisation catalysts, it is also indicated by industry that there are no suitable alternatives. It was noted that there are continuous R&D efforts to improve catalyst products to prepare and performance-test new possible catalyst production recipes. Through this work an industrially realistic substitute for cobalt has not been found to date.

One catalyst manufacturer (pers. comm., 12/01/18) interviewed indicated that cobalt carbonate is considered the best solution as, unlike other alternatives, it leaves no unwanted trace of counter ions and produces only CO2. There are no other suitable alternatives according to downstream users interviewed. ECMA (2018) note that for hydrotreating catalysts in oil refining (which represents the main application of cobalt in heterogeneous catalysts), most transition metals can catalyse the process. The ECMA (2018) report identifies nickel-molybdenum (Ni-Mo), iron-molybdenum (Fe–Mo), molybdenum (Mo) and ruthenium (Ru) as potential alternatives.

[37] https://kern-deudiam.de/en/dtox-diamond-tools/

Industry stakeholders interviewed indicate the main potential alternative to cobalt is nickel. It is considered that Ni-based catalysts are very good hydrodenitrogenation and hydrogenation catalysts, relative to Co-based catalysts but give rise to a relatively high hydrogen consumption, with Co-based catalysts being the superior hydrodesulphurisation catalyst. ECMA (2018) notes that although nickel-molybdenum (NiMo) catalysts are very active in hydroprocessing processes it is highly unlikely that a drop-in replacement alternative to CoMo based on nickel will be possible due to both technical and economic (i.e. associated with refinery redesign) constraints.

Switching from Co-based to Ni-based catalyst is considered possible for only a very limited number of operations because this generally leads to products with higher degrees of hydrogenation and lower octane number. Refiners with lower pressure capabilities may not be able to use Ni-based catalysts, according to their response. Industry also expressed concern that the use of these NI-based alternatives would not allow the current levels of desulphurisation of fuels, as required by European fuel quality legislation.

Eijsbouts et al (2013) have reviewed and tested the potential alternatives for alumina supported Co/Ni–Mo/W catalysts in hydrotreating units used in oil refining. However, the number of options is shown to be limited as many alternative compositions are either very expensive or are known to be toxic.

It is reported that several compositions have sufficiently high activities for the process (e.g. those based on Ru, Rh, Os and Ir sulphides), but their feasibility as an alternative is limit ed because the costs are several orders of magnitude higher than those of a commercial Co–Mo catalyst (Eijsbouts, 2013). For example, ECMA (2018) indicate that ruthenium is the most active hydroprocessing catalyst and attractive from a technical perspective; however, due the very limited availability and the resulting high market prices ruthenium is not regarded as a realistic alternative to CoMo catalysts. Indeed, it is reported by industry that that the cost of Ru catalyst is over 400 times higher and can also lead to unwanted reactions. The metals used in these catalysts may also not be available in sufficient amounts for commercial use. For example, industry noted that ~5 tonnes of Ru is mined globally per year, with the industry requiring ~5000 tonnes if this were to be used as an alternative.

While Fe–Mo/W catalysts are attractive from a health and cost perspective, their activity is reportedly too low for commercial application (Eijsbouts, 2013). ECMA (2018) also indicate that alternatives, iron-molybdenum and molybdenum-based catalysts, have significantly lower desulphurisation activities than CoMo catalysts. It was also noted that Fe–Mo/Al2O3 and Mo/Al2O3 catalysts are the only Co- and Ni-free alternative compositions exhibit ing appreciable activity, but the activity levels are still substantially lower than those of the Co- and Ni-promoted catalysts (Eijsbouts, 2013).

One company reported that a catalyst based on a combination of iron and molybdenum, for instance, can reach at the very best half the activity of the cobalt-molybdenum based systems, resulting in much higher costs. One company (CfE 516) also describe the alternative catalysts considered in oil refinery processes. A literature review by Toulhoat and Raybaud (2003) is cited, which concluded that catalysts containing iron and molybdenum compounds, zinc and molybdenum compounds, and copper and molybdenum compounds have very low activity compared to catalysts containing cobalt and molybdenum compounds. Catalysts containing nickel and molybdenum instead of cobalt and molybdenum have also been considered but these reportedly suffer from lower stability and faster deactivation compared to cobalt-containing catalysts, resulting in more frequent change-outs and resulting higher costs. One trade association (CfE 494) consider that, at present, there is no other effective alternative for HDS catalysts applied in the low-pressure desulphurisation processes of middle distillates than the combination of Co/ Mo sulphides." (entire section ECHA 2018a)

Considering the challenges in substitution of cobalt it is considered unlikely that substitutions would be the preferred risk management measure in order to comply with a new OEL.

3.11.7.2Gas to liquid (GTL) / Fischer-Tropsch catalysts

One trade association (CfE 494) report that the current commercial GTL plants are geared towards the use of cobalt and modification of the plants would be very costly to industry. Iron- and ruthenium-based catalysts have been highlighted as potential alternatives to cobalt salts in this process (ECMA, 2018).

ECMA (2018) note that iron is relatively inexpensive option, and reduces the overall hazard related to the use of a CMR substance and is suitable for a low hydrogen/carbon monoxide ratio as in coal gasification. However, cobalt is considered more suitable for higher H_2/CO ratios, as in natural gas-based plants, where iron catalysts have significantly shorter lifetimes compared to cobalt-based catalysts (months rather than years). The use of iron would also result in much higher emissions of CO_2 as a significant portion of the oxygen from CO dissociation would be discarded as CO_2 rather than H_2O as is the case with the cobalt salts. Using iron-based catalysts will lead to much higher costs in natural gas-based operations due to reactor modifications to operate at higher pressures required (ECMA, 2018).

It is indicated that ruthenium catalysts have the highest activity, function at the lowest reaction temperatures, and produce the highest molecular weight hydrocarbons (ECMA, 2018). However, there is currently no ruthenium-based solution available for industrial scale use in this sector, mainly due to technical and economic constraints. It is highlighted by industry that ruthenium catalysts are extremely sensitive to poisoning by impurities, reducing the efficiency, as well as being expensive. Furthermore, the global supply is reported as being too scarce to supply this use (ECMA, CfE 505). ECMA (2018) note that, technically it is challenging to use ruthenium-based catalysts because ruthenium(IV) oxide is highly reactive and volatile, meaning ruthenium recycling is difficult, resulting in losses up to 25%. "(entire section, ECHA 2018a)

Considering the challenges in substitution of cobalt it is considered unlikely that substitutions would be the preferred risk management measure in order to comply with a new OEL.

3.11.8 Batteries

Cobalt-free lithium iron phosphate (LFP) batteries account for an increasing share of the market for batteries for electric vehicles.

According to the 'Global EV (electric vehicle) Outlook' from the International Energy Agency (IEA, 2023), "*In 2022, lithium nickel manganese cobalt oxide (NMC) remained the dominant battery chemistry with a market share of 60%, followed by lithium iron phosphate (LFP) with a share of just under 30%, and nickel cobalt aluminium oxide (NCA) with a share of about 8%. Lithium iron phosphate (LFP) cathode chemistries have reached their highest share in the past decade. This trend is driven mainly by the preferences of Chinese OEMs. Around 95% of the LFP batteries for electric LDVs went into vehicles produced in China, and BYD*[38] *alone represents 50% of demand. Tesla accounted for 15%, and the share of LFP batteries used by Tesla increased from 20% in*

[38] BYD: Chinese car producer

2021 to 30% in 2022. Around 85% of the cars with LFP batteries manufactured by Tesla were manufactured in China, with the remainder being manufactured in the United States with cells imported from China."

No production of LFP batteries in the EU has been identified.

LFP batteries contrast with other chemistries in their use of iron and phosphorus rather than the nickel, manganese and cobalt found in NCA and NMC batteries. The downside of LFP batteries is that the energy density is lower than that of NMC. The advantages mentioned are that the LFP batteries last longer and can stand charging to 100% in every charging cycle. The LFP batteries are cheaper than NMC batteries (IEA, 2023).

According to IEA, in recent years, other alternatives to Li-ion batteries have been emerging, notably sodium-ion (Na-ion). The Na-ion battery do not contain cobalt. This battery chemistry has the dual advantage of relying on lower cost materials than Li-ion, leading to cheaper batteries, and of completely avoiding the need for critical minerals. It is currently the only viable chemistry that does not contain lithium. The Na-ion battery developed by the Chinese car producer CATL is estimated to cost 30% less than an LFP battery. Conversely, Na-ion batteries do not have the same energy density as their Li-ion counterpart (IEA, 2023).

According to IEA (2023), on a global scale, the demand for cobalt for other batteries was nearly the same as for batteries for electrical vehicles. IEA (2023) does not include information on alternatives to use of cobalt in other types of batteries. No information on the use of LFP batteries for non-automotive applications have been identified.

No information on cobalt-free Ni-MH (nickel metalhydride) and Ni-Cd (nickel cadmium) batteries have been identified. The use of cobalt in these batteries allows them to charge more quickly and hold charge for a longer period (eftec, 2023).

3.11.9 Surface treatment

According to ECHA (2018a), cobalt salts themselves are considered by industry stakeholders an alternative to the more hazardous chemicals that have historically been used in the surface treatment sector. In passivation/corrosion resistance, the use of cobalt salts has replaced hexavalent chromium surface treatment applications. According to ECHA (2018a), industry considers the use chromium (III) in combination with cobalt dinitrate or cobalt sulphate to be the most viable option to meet customer demand.

According to ECHA (2018a), in relation to passivation/corrosion resistance, one company indicate that some cobalt-free passivation processes have already been developed; however long-term experience in the field is not yet available, or not yet representative.

Foster *et al.* (2021) characterised cobalt-containing and cobalt-free trivalent chromium passivations on γ-ZnNi coated steel substrates and demonstrated that after 1000 hours of salt-spray exposure, cobalt-free passivations had visible white rust on 4% of the surface area while cobalt-containing passivations had 22% of the surface area covered by white rust.

According to ECHA (2018a), industry considered there to be no viable alternatives for cobalt salts in metal alloy electroplating as this was the only alloy that will allow the required electrical conductivity and mechanical resistance, where metals like gold and silver are used. According to ECHA (2018a), one company interviewed noted that, while some alternatives are available, it may not be difficult for them to penetrate the market due to specific safety standards in the automotive sector, which require the use of specified chemicals. Cobalt-phosphate plating is also a candidate under evaluation as a replacement for chrome plating. In metal alloy plating, the use of cobalt salts is considered an alternative to gold-cadmium alloys, which are themselves under regulatory scrutiny (ECHA, 2018a). It can reportedly take a long term for new alternatives to pass the standards and obtain the required qualifications. There is also a cost implication in having the tests for qualification which means companies can be reticent to pay for these as there is no immediate benefit to do so.

According to eftec (2023), substitution in coatings is feasible for some markets depending on the specific properties and requirements of the coating. It is noted that sulphate can serve as an alternative to cobalt for black chromating. By increasing the concentration of sulphate in the process bath, the addition of cobalt can be eliminated with no noticeable difference in the final product. However, it is also noted that this substitution method is only applicable to processes where cobalt is solely used for decorative purposes, such as providing a certain colour or appearance. In other applications where cobalt provides a specific functionality, such as corrosion resistance, no viable substitutes have been found yet. It is further noted that using alternative metals would require a complete process change and end-product re-qualification, resulting in significant time and costs.

3.11.10 Pigments

According to Latunussa *et al.* (2020), substitution of cobalt in pigments is straightforward and alternatives with very good performance are available. Cerium, acetate, iron, lead, manganese, or vanadium can all be used as substitutes, but unfortunately not necessarily with the same results (USGS as cited by Tercero Espinoza *et al.*, 2018).

According to eftec (2023), there are no alternatives to cobalt that meet the requirements for some specialist uses where the exact colour is necessary, a specific technical function is required (e.g., solubility and stability of the cobalt-containing colourant), or where cultural significance is attached to cobalt blue. The statement concerns all cobalt pigments, however, many of the cobalt pigment (among these cobalt blue, EC No 1345-16-0) are not within the scope of the assessed OEL.

Cobalt pigments within the scope may to some extent be replaced by other cobalt pigments but they would likely not provide exactly the same colour. This has not been further investigated.

3.11.11 Electronic components

The five cobalt salts, which were addressed by the REACH restriction proposal, are under consideration for inclusion in Annex II of the RoHS Directive. According to a ROHS Annex II Dossier (Öko-institut, 2019) for the five salts, information on possible alternatives for cobalt dichloride and cobalt sulphate in the surface treatment processes is scarce. According to Ökoinstitut (2019), *"the available information does not indicate substitutes that can be considered to be practical in light of the hazardousness of such substitutes*".

No other information on alternatives to cobalt metal in electronic products have been identified.

3.11.12 Use in biotechnological processes, feeds, fertilizers, etc.

Cobalt is used as a precursor of vitamin B12 synthesis.

Animal feeds. According to ECHA (2018b), there is reportedly no alternative to the supplementation of feed with cobalt for ruminants, horses and animal species with hindgut fermentation (rabbits) as cobalt is an essential component for the synthesis of Vitamin B12 by these animals.

The primary alternative solution is the coating of the cobalt salts in order to reduce occupational exposure when adding the cobalt salts to the feed.

Fermentation, biogas production and biotechnological processes. According to ECHA (2018b), no alternative techniques or end-products have been identified by industry and stakeholder respondents for the same reasons as encountered above.

Cobalt is an essential element in these biotechnology processes and when absent cell growth and yield is reduced. However, the cobalt does not necessarily be in a form of substance within the scope of the OEL. For biogas production, e.g. a number of EDTA-based chelates are marketed such as EDTA-cobalt diammonium (EC No: 304-038-1), EDTA-cobalt disodium (EC No 239-198-0), EDTA-cobalt dihydrogen (EC No 825-116-6), and EDTA-cobalt dipotassium (EC No 237-864-5).[39]

3.11.13 Manufacture of humidity indicator cards

According to ECHA (2018a), cobalt dichloride-free humidity indicator cards have been developed and are available on the market and it has been demonstrated that humidity indicator cards free of cobalt dichloride can meet some of the appropriate standards for use such as the accuracy required by international JEDEC (Joint Electron Device Engineering Council) standards. In Internet search, May 2023 demonstrate a wide range of humidity indicator cards marketed as 'cobalt-free'. The cobalt-free humidity may be based on polystyrene sulphonic acid, organic dye and hygroscopic inorganic salt. However, ECHA (2018a) noted that there are certain industrial and military applications where the chemical cobalt dichloride is integrated in the required specifications and use of cobalt dichloride based products will continue. The same is noted by eftec (2023).

3.11.14 Summary of availability by sector

A summary of availability of alternatives by sector is provided in the table below.

Alternatives are available for the following sectors where substitution may be a preferred action for some companies, especially for the lower policy options: Production of batteries (at least for lithium batteries for electrical vehicles), some applications of alloys, manufacture and use of pigments (would however require that all used pigments within the scope are replaced in the company), biogas (replaced with cobalt compounds outside the scope), and diamond tools. Alternatives to cobalt in humidity indicator cards are readily available but cobalt-containing indicator cards are required in some international standards and the remaining uses of indicator cards with cobalt are expected to remain.

Table 3-104 Summary of availability of alternatives by sector

NACE code	Short description	Availability of alternatives
C10.91	Manufacture, feeds	Alternatives to cobalt not available. Coated cobalt salts may be used in order to reduce exposure but the substance used will still be within the scope.
C19.20	Petrochemical, catalyst	Switching from Co-based to Ni-based catalyst is considered possible for a very limited number of operations because this generally leads to products with higher degrees of hydrogenation and lower octane number.
C20.12	Manufacture, dyes and pigments	Cerium, acetate, iron, lead, manganese, or vanadium can all be used as substitutes for cobalt but not necessarily with the same results.

[39] https://www.gold-mann.de/chelated-cobalt-and-nickel/

NACE code	Short description	Availability of alternatives
		Cobalt compounds within the scope may to some extent be replaced with cobalt compounds outside the scope.
C20.13-20.14	Manufacture, basic chemicals	Alternatives mentioned for downstream uses.
C21	Pharmaceuticals	Alternatives to cobalt not available as cobalt is added as an essential element. The form of cobalt used in the final pharmaceuticals is not within the scope of the OEL, substances within the scope are used in the production process.
C20.59	Catalysts and other chemical products	Same as indicated for C19.20 petrochemical, catalyst
C23.1	Glass	Tricobalt tetraoxide (out of scope) is used for similar applications in glass as substances within the scope. It has not been investigated to what extent tricobalt tetraoxide could replace the current use of cobalt oxide (CoO) or cobalt sulphate ($CoSO_4$).
C23.4	Ceramics	Same as indicated for manufacture of dyes and pigments.
C23.7	Cutting of stone	Some alternatives available as indicated for manufacture of tools.
C24.10	Steel	No specific information.
C24.45	Manufacture, cobalt and cobalt alloys	Alternatives to cobalt alloys depends on application. Molybdenum may be used as alternative in alloys used for heat resistance and nickel and iron may be used where cobalt is used as binder in wear-resistant powders.
C25.5	Powder metallurgy	Alternatives depends on alloys (hundreds of different alloys used). Alternatives mentioned under cobalt alloys may be used for certain applications.
C25.61	Surface treatment of metals	For passivation some cobalt-free trivalent chromium passivations are available for some applications. No viable alternatives for plating.
C25.62	Machining	No alternatives are readily available for hardmetal tools. For sharpening, some diamond tools with alternatives are available.
C25.73	Manufacture of tools	No alternatives are available for hardmetal tools. Diamond tools using alternative binder material are marketed available; the quality is lower, but this is counterbalanced by lower prices.
C25.99	Manufacture of other fabricated metal products n.e.c.	Same as indicated for hardmetal tools and cobalt alloys.
C26.1	Electronic components	No information on alternatives to cobalt in electronic components have been available.
C26.51	Humidity indicator cards	Alternatives are readily available but cobalt-containing indicator cards are required in some international standards.
C25.9	Other fabricated metal products	Same as for cobalt alloys.
C27.2	Batteries	Cobalt-free lithium batteries for automotive applications are readily available and accounted for 27% of the market for batteries for electrical vehicles in 2022. No data on alternatives to cobalt in other types of batteries have been identified.
C28.11	Engines and turbines	Same as for cobalt alloys.
C29.10-30	Vehicles	Same as for surface treatment.

NACE code	Short description	Availability of alternatives
C30.30	Air and spacecraft	Same as for cobalt alloys.
C32.50	Medical and dental devices	Alternatives are available but at higher costs and not the same performance.
E38.21	Biogas	Alternative EDTA-based cobalt compounds are available.
E38.32	Metal recovery	Alternatives not relevant - depends on alternatives for uses.
	Welding	No information has been available.

Source: Study team.

3.12 Current disease burden (CDB)

The current burden of disease is estimated using the data in the preceding sections for exposed workers and exposure levels as well as data on the exposure risk relationship (ERR) and dose response relationship (DRR) described in section 2.4. The overall methodology used for the estimations are provided in the Methodological Note.

3.12.1 Past trend in exposure concentrations and exposed workforce

For health endpoints with a latency time, the current burden of disease is based upon data from past. In the case of lung cancer, an average latency period of 30 year is assumed (see next section). It means that the exposures, which lead to lung cancer today, took place in the 1980's and 1990's and the estimation of number of cases of ill health will depend on exposure levels and workforce at that time.

The reported trends in exposure concentrations described in section 3.3.9 gives no clear indication of the trends. As described in the section, based on the available data a decrease in the concentrations of 4% per year is assumed for the calculation. Using this rate, the average exposure concentration 30 years ago would be about 3 times the average today. The main drivers for reducing the exposure concentrations are assessed to be establishment of national OELs (and similar limit values in some Member States), implementation of the CMRD, implementation of risk and exposure assessments done as part of the REACH registration and communication within the supply chain, and the classification of cobalt and inorganic cobalt compounds as carcinogenic and reprotoxic substances. The harmonised classification of cobalt metal as carcinogenic and reprotoxic substances entered into force March 2020, but the self-classification of cobalt as metal has included inhalation carcinogenicity since December 2013.

As reviewed in section 3.4.5, no data on overall trend in exposed workforce have been identified. Data from France and Canada indicate a decrease in the exposed workforce, but the estimates seem to be based on limited actual data. As the consumption of cobalt has been increasing steeply during the period, an overall positive trend in workforce of 2% per year over the 1993-2023 period is used (see section 3.4.5).

The estimates presented above only relate to the sectors with current exposure to inorganic cobalt compounds at levels relevant for the assessed policy options. As indicated in section 3.4.6, in addition to the total workforce exposed the levels of relevance for the policy options, some workers would be exposed at lower levels. These may contribute to the total burden of disease of past occupational exposure. Considering the low number of additional exposed workers as compared to the number included in the assessment and the low exposure concentrations, it is estimated that the contribution from these other exposure groups would be insignificant and no further attempt for estimation the potential contribution from additional exposure groups has been done.

3.12.2 Latency, workforce turnover and MaxEx

The ERR and DRRs are estimated on the basis of 40-years exposure, but the majority of workers would not work in the relevant sectors and be exposed to cobalt for so long time. The estimations are consequently, as described in the Methodological Note depending on the workforce turnover and the maximum exposure duration needed to reach the maximum risk (MaxEx). If the MaxEX is e.g. 10 years, additional exposures would not lead to further risk beyond the risk expressed by the ERR and DRRs and a worker who has been exposed for 10 years would have the same risk of developing the endpoint as a worker exposed for 40 years.

As a default value, it has in the previous OEL studies been assumed that there is a staff turnover of 5% per year corresponding to an average employment in a sector of 10 years (in 20 years the entire workforce is replaced). 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. 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. On this basis, the default staff turnover of 5% per years used in the previous studies seems to be adequate and also used in this study.

The time required for the endpoints to develop over an average working life takes into account the maximum time required to develop the condition (MaxEx) and the distribution of new cases between these two points in time, combined with the latency period with which the effects are diagnosed.

Table 3-105 Latency and maximum exposure duration to develop a condition (MaxEx)

Endpoint	MaxEx (years)	Latency (years)
Lung cancer	40	30
Restrictive lung disease	1	0
Upper airway irritation	1	0

Source: Source: Study team - See Methodological Note for more details

3.12.3 Current disease burden

The current disease burden for the three assessed endpoints is summarised in Table 3-106.

The current burden of disease (i.e. the number of cases diagnosed in 2023) is estimated on the basis of historical exposure. For lung cancer with 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.

For reprotoxic toxicity (male/female fertility and developmental toxicity) effects are not expected at the current exposure levels, but it cannot be excluded that some new cases may derive from past exposure at higher levels. In general, however, no data on latency periods for the non-cancer endpoints are available and as default, a latency period of 0 years have been applied i.e. number of new cases are calculated on the basis of the current exposure situation. Apart from the two endpoints restrictive lung disease and upper airway irritation, asthma may develop at the relevant concentrations, but the data have not been sufficient for developing a DRR.

*Table 3-106 Current burden of disease in EU27 due to past exposure to cobalt and inorganic cobalt compounds**

Endpoint	New cases per year (incidence) in 2023
Lung cancer	12
Restrictive lung disease	100
Upper airway irritation	350

**For lung cancer the estimates are based on exposure level and workforce 30 years ago; for non-cancer endpoints it is based on current exposure levels and workforce.*
Source: Study team.

3.12.4 Comparison with data on recognised cases and epidemiological data

Cancer

Limited information on recognised cases of cancer endpoints from exposure to cobalt and inorganic cobalt compounds have been identified from national databases in Finland, Poland, France and Belgium.

The French health insurance organisation (l'Assurance Maladie, 2021) has three entries of causes of lung cancer from occupational exposure to cobalt. Recognised cases are recorded for exposure to cobalt dust combined with tungsten carbide before sintering (Table 3-107), whereas no cases are recorded for exposure to sintered or molten metal carbides containing cobalt (hardmetal) or to cobalt and cobalt compounds. For the period 2005 - 2019 on average about one case was recorded per year, whereas no cases are recorded for 2019 and 2020. The three other databases do not include any recognised cases.

Table 3-107 Recognised cases of lung cancers in France caused by inhalation of cobalt

Cause	Disease	2005-2009	2010-2014	2015-2019	2019	2020
Inhalation of cobalt dust combined with tungsten carbide before sintering	Primary bronchopulmonary cancer	3	5	7	0	0

Source: l'Assurance Maladie, 2021

A number of epidemiological studies have been analysed by meta-analysis by Marsh *et al.* (2017) and Zhang *et al.* (2021).

Marsh *et al.* (2017) conducted a pooled mortality follow-up among 32,354 hard-metal production workers from 17 manufacturing sites from five countries. Special emphasis was on lung cancer risk, but some data on mortality from non-malignant respiratory diseases (NMRD) were also reported (see further below). The authors conclude that they found evidence that duration, average intensity, or cumulative exposure to tungsten, cobalt, or nickel, at levels experienced by the workers examined, increases lung cancer mortality risks. They also found no evidence that work in these facilities increased mortality risks from any other causes of death.

RAC (2022) includes a discussion of the results of this meta-analysis of epidemiological studies and the ERR derived from animal studies. According to RAC (2022) "*The above rough estimations indicate that the risk estimates by the ERR may result in overestimation. However, the effects of assumptions concerning the ratio respirable/inhalable particles, duration of exposure in the cohorts vs the assumed 40 career used in the ERR and effect of potential confounding, especially by smoking, as well as the effect of use of personal respiratory protective equipment in the actual exposure levels experienced by the cohorts cannot be fully assessed assumption by assumption, while they might operate to different directions. It is, however, also important to underline the overall lack a significantly increased risk in the cohorts, i.e., the point estimate in the Marsh et al. (2017) highest exposure category was not statistically significantly deviating from unity and no significant trend of increasing risk by increasing mean or cumulative exposure was observed and Sauni et al. (2017) did not observe an increased risk of lung cancer with an upper 95% confidence limit quite close to unity. To be noted that there is no obvious indication that healthy worker effect would have biased the lung cancer risk estimates of Marsh et al. (2017) or Sauni et al. (2017), see section 7.7.1. Given the above, it seems robust to conclude that at exposure levels experienced by the workers of the Marsh et al. (2017) and Sauni et al. (2017) studies, humans are not more sensitive to carcinogenic risks than the predictions made by the animal data derived ERR indicate. There is some indication that at such exposure levels the animal data derived ERR may somewhat overestimate the risk. However, as pointed out by ECHA (2020) it is to be noted that detecting or excluding with confidence low levels of relative risk in an epidemiological study is challenging."*

Zhang *et al.* (2021) conducted a systematic review and meta-analysis of published, peer-reviewed epidemiologic studies among approximately 1 million individuals across a number of countries and spanning several decades. The study found no association between cobalt exposure through orthopaedic implants or in occupational settings and overall cancer risk in analyses that included either only high-quality studies or studies irrespective of NOS (Newcastle-Ottawa Scale) quality ratings. According to the authors, occupational cohort studies among workers exposed to cobalt particles in occupational settings provided long-term data of cobalt exposure to several cobalt forms among humans via the inhalation route and the meta-analysis also found no increased risk of overall cancer even among studies evaluating individuals with more than 20 years of follow-up.

Non-cancer endpoints

For the non-cancer endpoints, the DRRs are based on results of epidemiological studies and in this respect are representative for the actually observed health effects.

According to the information received by ECHA from three Member States (representing approximately 3% of the population of the EU) for the restriction proposal for five cobalt salts, there are one to three registered cases per year of occupational skin diseases and zero to one cases per year of asthma due to occupational exposure to cobalt. The RAC and SEAC opinion on the restriction proposal for five cobalt salts concludes on this basis "*Although, the current data do not allow setting of a NOEC for asthma, based on the data available from three Member States and from an industry survey, asthma caused by cobalt seems to be uncommon nowadays"* ECHA (2020). According to Annex 1 to the RAC opinion, "*a more extensive literature search indicates that large epidemiological studies on cobalt asthma are lacking, and the knowledge is largely based on case reports or small series often with limited analysis of risk by level of exposure." (ECHA, 2022)*

No data on the prevalence of other non-cancer endpoints in Members States is available.

The study by Marsh *et al.* (2017) found a statistically significant excess in NMRD overall, when comparing to regional rates which was primarily due to an excess of emphysema (lung condition that causes shortness of breath) affecting mainly workers with less than a year of employment in hard-metal production. Among workers with at least 1 year of employment, the mortality of NMRD was not increased. Among these workers, there was no evidence of an occupationally related risk for the NMRD subcategory ‘other NMRD’, in which ‘hard-metal disease’ and pneumoconiosis are contained.

3.13 Summary of the current situation

3.13.1 Risk to workers' health

Relevant exposure routes are oral exposure and inhalation. Inhalation absorption is highly dependent on the particle size of cobalt. As a metal, cobalt is not metabolised in the body. Excretion after inhalation exposure is highly dependent on the solubility of the cobalt substance; the more soluble the substance is, the more rapidly it is eliminated via the lungs by transfer to the blood and excretion via urine and faeces.

Cobalt and several inorganic cobalt compounds have a harmonised classification for carcinogenicity according to Annex VI of the CLP Regulation (Canc. 1A or B). Numerous studies on carcinogenic effects of cobalt have been published. However, the epidemiological evidence can be considered as inconsistent mainly due to the presence of confounding factors or limitations of the studies. RAC considers carcinogenicity in animal studies and non-cancer related respiratory effects in exposed workers as the critical toxicological endpoints after cobalt exposure. For carcinogenicity they did not identify a threshold. However, RAC believes that a ‘break point’ for the carcinogenic effects can be established at 0.5 µg/m³ and derived an ERR for lung cancer (RAC, 2022). This ERR is also applied in the present report.

The main critical non-cancer endpoints after inhalation exposure are respiratory effects observed in exposed workers.

RAC considers three occupational exposure settings in the context of the OEL derivation. These are a) production and use of cobalt and cobalt compounds, b) production and use of hard-metal and c) polishing of diamonds. According to RAC, exposure to cobalt is associated with diseases like asthma, whereas exposure to cobalt-containing hard-metal is an established cause of parenchymal lung disease. Parenchymal lung disease is also reported in workers from the diamond-polishing industry. Numerous studies from different industrial sectors describe decreased lung function and respiratory tract irritation in association with cobalt exposure.

For the current report, the effects observed were assigned to conditions that can be summarised as ‘restrictive lung diseases’ and ‘upper airway irritation’ as indicated in the table below.

Cobalt metal and several cobalt compounds also have a harmonised classification as Repr. 1B (H360F) or are notified by the registrants as Repr. 1B (H360) or Repr. 1A (H360) as significant effects on the male reproductive system can be observed. These classifications are based on animal data (e.g. reduced sperm motility) as no relevant epidemiological data are available investigating fertility or developmental toxicity effects in humans. The effects are observed at levels well above the current exposure levels and therefore not assessed.

Effects mainly observed after oral cobalt exposure or in non-occupational settings (cardiovascular diseases, thyroid-related, haematological and nervous/sensory effects) are not considered for the current assessment.

Table 3-108 Health effects caused by cobalt and inorganic cobalt compounds and major occupational exposure routes

Carcinogen	Health effects caused by inhalation at current exposure levels	Major occupational exposure routes
Cobalt and inorganic cobalt compounds	Lung cancer Restrictive lung disease Upper airway irritation Astma (not quantified)	Inhalation and dermal route

Source: Study team.

The following table summarises carcinogenic and non-carcinogenic endpoints and their use for deriving ERRs and DRRs

Table 3-109 Relevant carcinogenic and non-carcinogenic endpoints and their use for deriving ERRs and DRRs

Endpoint	Assessment
Lung cancer	Considered quantitatively for ERR
Other cancer sites (upper respiratory tract, pheochromocytomas and pancreatic cancer)	Not considered (not relevant or secondary to lung cancer)
Restrictive lung disease	Considered quantitatively for DRR
Parenchymal lung disease	Not considered (unlikely to occur in concentration range below 100 µg/m³)
Upper airway irritation	Considered quantitatively for DRR
Asthma (Respiratory Sensitisation)	Not considered (no dose response data available for DRR derivation)
Reproductive toxicity – male fertility	Not considered quantitatively for DRR (only relevant above highest policy option)
Reproductive toxicity – female fertility	Not considered quantitatively for DRR (only relevant above highest policy option)
Reproductive toxicity - developmental toxicity	Not considered quantitatively for DRR (only relevant above highest policy option)
Cardiovascular effects, thyroid effects, nervous/sensory effects and haematological effects	Not considered (effects only considered relevant in a non-occupational setting)

Source: Study team.

The current exposure concentrations and number of exposed workers by sector at relevant exposure levels used for estimating the current disease burden are shown in Table 3-110 and used as background for estimating the future disease burden in section 4.9 and the benefits assessment in Chapter 6. The main sectors in terms of number of exposed workers are manufacturing of tools and use of the tools. The table also shows the number of companies with exposed workers which is used for the further assessment of costs of the various policy options in chapter 7.

Table 3-110 Summary of exposure concentrations (not adjusted for the use of RPE), exposed workforce and number of companies by sectors for cobalt and inorganic cobalt compounds, inhalable fraction

Sector		Exposure concentration			Number of exposed workers	Number of companies
		AM	P50	P95		
C10.91	Manufacture, feeds	4.0	1.8	13.8	1,800	300
C19.20	Petrochemical, catalyst	27.3	17.6	82.0	600	82

Sector		Exposure concentration			Number of exposed workers	Number of companies
		AM	P50	P95		
C20.12	Manufacture of dyes and pigments	6.5	3.2	24.5	2,300	15
C20.13-20.14	Manufacture of basic chemicals	19.5	8.4	72.0	2,900	30
C20.30	Manufacture of paints and inks	31.7	10.0	140.8	200	10
C20.59	Catalysts	2.1	0.4	8.0	910	13
C20.59	Formulation	21.0	6.0	88.0	1,700	35
C21.20	Pharmaceuticals	1.0	0.2	3.9	950	8
C22.11	Production of tyres	9.4	1.6	38.4	300	3
C23.1	Glass	23.9	11.6	83.6	900	50
C23.4	Ceramics	53.7	28.0	196.4	7,500	500
C23.7	Cutting stone	10.1	3.6	39.8	3,000	1,000
C24.10	Steel	42.9	21.6	154.8	100	7
C24.45	Manufacture of cobalt and cobalt alloys	42.3	20.8	155.2	660	6
C25.5	Powder metallurgy	38.0	24.0	116.0	900	30
C25.61	Surface treatment of metals	25.9	13.6	88.4	5,200	470
C25.62	Machining	50.2	38.8	126.0	25,000	6,000
C25.73	Manufacture of tools	38.0	24.0	116.0	30,000	2,300
C25.99	Manufacture of other fabricated metal products n.e.c.	59.5	32.0	216.4	1,120	150
C26.1	Production of electronic components	60.7	33.6	216.0	3,000	250
C26.51	Humidity indicator cards	0.8	0.2	2.8	100	5
C27.2	Batteries	10.6	3.2	40.8	1,950	15
C28.11	Engines and turbines	24.7	18.8	63.6	2,200	130
C29.10-30	Vehicles	12.8	6.6	43.6	5,200	130
C30.30	Air and spacecraft	24.7	18.8	63.6	2,200	130
C32.50	Medical and dental devices	46.0	31.2	140.8	5,000	500
E38.32	Metal recovery	15.2	10.4	43.8	1,100	15
	Biogas	0.0	0.0	0.1	5,400	3,100
	Welding	103.6	64.0	389.6	550	50
	Total				113,000	15,334

Source: Study team.

The current disease burden from past exposure is summarised in Table 3-111.

Table 3-111 Current disease burden related to occupational exposure to cobalt and inorganic cobalt compounds (number of cases)

Carcinogen	Health effects caused	Current disease burden Incidences in 2023
	Lung cancer	12
	Restrictive lung disease	100

Carcinogen	Health effects caused	Current disease burden Incidences in 2023
Cobalt and inorganic cobalt compounds	Upper airway irritation	350

Source: Study team

3.13.2 Relationship with other EU policies

For cobalt and inorganic cobalt compounds within the scope of this study, no restrictions nor authorisation requirements have been established under REACH.

3.13.3 National OELs

The status of current national OELs is summarised below. In summary, none of the Member States have OELs for both inhalable and respirable fraction with a scope similar to the scope of the proposed OEL. The most common level OEL observed among those Member States having an OEL is set at 20 µg/m³ for the inhalable fraction, but the scope of the OEL as to the substances covered differs.

Table 3-112 Summary of national OELs in EU Member States

Carcinogen	Lowest (strictest) national binding OEL (µg/m³)	Highest (least strict) national binding OEL (µg/m³)	Member States with no OEL or defined risk levels
Cobalt and inorganic cobalt compounds	10 µg/m³ In DK, total dust	500 µg/m³ In LT, inhalable fraction	5: Italy, Luxembourg, Malta, Portugal, Slovenia

Source: Study team based on Table 5-1.

The scope of the national OELs can be summarised as shown in the table below.

*Table 3-113 Scope of current limit values in Member States***.*

Scope compared to reference OELs	Scope	Member States	Number
Similar scope **	Cobalt and inorganic cobalt compounds	Bulgaria *, Denmark *, Estonia *, Finland, Hungary *, Lithuania*, Poland *, Spain, Sweden *	9
Wider scope - organic cobalt compounds included	Cobalt and its compounds	Croatia, Czechia *, Greece *, Ireland, Slovakia *	5
More narrow scope - some inorganic cobalt compounds excluded	Cobalt and cobalt alloys, cobalt oxide, cobalt sulphate and cobalt sulphide	Austria *	6
	Cobalt metal (dust and fume) and hardmetal of cobalt and tungsten carbide	Belgium *	
	Cobalt, metal dust and fumes	Cyprus *	
	Cobalt, cobalt (II) and (III) oxide	Latvia *	
	Cobalt (dust and smoke)	the Netherlands *	
	Cobalt, cobalt oxide	Romania *	
Wider for some substances, narrower for others	Cobalt and cobalt compounds classified as Carc 1A and 1B	Germany (stipulated risk levels) *	2

Scope compared to reference OELs	Scope	Member States	Number
	Cobalt compounds, excluding hardmetals	France (recommended risk levels)	
No OEL		Italy, Luxembourg, Malta, Portugal, Slovenia	5

** Indicates the limit value is binding.*
*** Uncertain to what extent inorganic cobalt compounds outside the scope of the CMRD would be included.*
****Include both OELs and other occupational limit values such as risk values.*
Source: Study team based on Table 5-1.

The occupational limit values in three Member States concern the respirable fractions, whereas in the rest of Member States, where an OEL or other occupational limit value is established, the OEL concerns the inhalable fraction, or no fraction is specified. None of the Member States have currently binding limit values for both respirable and inhalable fraction.

*Table 3-114 Respirable vs. inhalable fraction covered by the occupational limit values**. An * indicates that the limit value has a binding character.*

Scope compared to reference OELs	Member States	Number
Respirable fraction	Belgium *, Germany *, Czechia *	3
Inhalable or nothing specified	Austria *, Bulgaria *, Croatia, Denmark *, Estonia *, Finland, France, Greece *, Hungary *, Ireland *, Latvia *, Lithuania *, the Netherlands *, Poland *, Romania*, Slovakia *, Spain, Sweden *	18
No OEL	Cyprus, Italy, Luxembourg, Malta, Portugal, Slovenia	6

** Indicates the limit value is binding.*
*** Include both OELs and other occupational limit values such as risk levels.*
Source: Study team based on Table 5-1.

3.13.4 Potential for lowering exposure to cobalt and inorganic cobalt compounds

Based on the available information and data collected by the stakeholder consultation, the main options for lowering exposure to cobalt and inorganic cobalt compounds are a combination of a range of measures in order to reduce generation of dust and spread of dust in the facilities. In many of the larger facilities with a high number of exposed workers, processes such as manufacture of powder or catalyst or sintering of hardmetal parts takes place in closed systems. Dust is generated mainly by transferring dusty material from one container to another (raw material handling, packaging, product preparation, waste handling, etc.), by opening of closed systems (for loading or changing between batches, sampling for quality control, maintenance, etc.) and by cleaning and maintenance operations. Exposure can be reduced by better dust household and typically companies would apply a combination of a range of measures in order to reduce exposures:

- Training of workers in work procedures that reduce generation and spread of dust and in procedures that reduce the personal exposure (e.g. correct use of PPE and keeping distance to sources);
- Reduce spread of dust from sources by local ventilation at dust generating points, automatization (e.g. of sampling for quality control and transfer of substances), further use of close systems, etc.

- Reduce spread of dust in facilities with further segregation of work areas, further use of hoover systems to remove dust, reduce area of horizontal surfaces, paint surfaces with easy-to-clean paints, etc.
- Reduce personal exposure by rotation (reduced time in areas with exposure), use of better RPE (e.g. powered air-purifying respirators).

Based on the result of the stakeholder consultation, it is the consultant's impression, that the best performing companies which have been working on reduction of cobalt exposure for decades and have newer facilities, with some improvements would be able to comply with a level of 5 µg/m^3 for the inhalable fraction provided that RPE is still used for some work operations. This may be regarded as the limit for the technical feasibility, but it should be noted that for companies with older facilities it may require major changes of equipment, buildings, work processes, etc. because the necessary technical measures in some cases cannot be implemented in the existing facilities. For some of the down-stream sectors where exposure to cobalt take place in a limited part of the facility, the limit of technical feasibility would be lower than for the up-stream sectors.

4 BASELINE SCENARIO

The baseline scenario describes how the problem is expected to evolve in case no further action is taken at EU level.

This chapter comprises the following sections:

- Section 4.1: Impact of the implementation of other OELs
- Section 4.2: Effects of forthcoming changes in national OELs or protective regulation, self-regulatory initiatives
- Section 4.3: Effects of REACH
- Section 4.4: Effects of EU Strategic Foresight megatrends
- Section 4.5: Future trend in use and recycling of the substances
- Section 4.6: Future trend in exposure concentrations due to technical improvements
- Section 4.7: Future trend in exposed workforce
- Section 4.8: Other factors of importance for the baseline
- Section 4.9: Future disease burden (FDB)
- Section 4.10: Summary of the baseline scenario

4.1 Impact of the implementation of other OELs

Establishing OELs for PAHs, 1,4-dioxane and isoprene is not considered to influence the benefits and costs of establishing an OEL for cobalt and cobalt substances as co-exposure to cobalt and inorganic cobalt compounds and the three substances/substance groups is considered insignificant. Furthermore, possible inclusion of welding fumes into Annex I to the CMRD will likely have no significant impact on the costs and benefits of introduction of an OEL for cobalt and cobalt compounds.

A number of OELs have in recent years been established under the CMRD and the implementation of some of these OELs may influence the levels of exposure to cobalt and inorganic cobalt compounds as compared to the reported current levels.

OELs for the following substance groups are considered to potentially influence the exposure levels and cost of compliance: Nickel compounds, chromium VI compounds, and cadmium and cadmium compounds. The timeline for implementation of the OELs are shown in Table 4-2.

As part of the stakeholder survey, companies have been asked about the possible impacts of the implementation of new OELs for other substance groups on the exposure to cobalt and inorganic cobalt compounds. The results are summarised in the table below. The table shows the positive results only while the respondents may have answered either ‘no impact’ (33 for nickel, 41 for chromium VI, cadmium was included in an ‘other’ group) or did not answer the question. In total 14 of the respondents (24%) in 8 sectors answered that implementation of the OEL for nickel would reduce the cobalt exposure concentrations compared to those reported in the questionnaire. One company answered that the OEL for chromium (VI) would have an impact while two companies in the battery sector answered that the OEL for cadmium and inorganic cadmium compounds would have an impact.

For three sectors, at least one respondent has indicated a decrease of more than 50% by introduction of the OEL for nickel: Manufacture of other inorganic basic chemicals, glass and batteries.

Table 4-1 Companies' expected reduction in exposure to cobalt and inorganic cobalt compounds as consequence of implementation of new OELs under the CMRD. Number of companies answering positive indicated in brackets.

Sector		Nickel compounds	Chromium VI compounds	Cadmium and cadmium compounds
C20.13	Manufacture of other inorganic basic chemicals	>50% (1) <50% (1)		
C20.30	Manufacture of paints and inks	<50% (1)		
C20.59	Catalysts and other chemicals	<50% (3)		
C23.1	Glass	>50% (1)	>50% (1)	
C24.10	Steel	<50% (1)		
C24.45	Manufacture of cobalt and cobalt alloys	<50% (2)		
C25.73	Manufacture of tools	<50% (2)		
C27.2	Batteries	>50% (1) <50% (1)		>50% (2)

Source: Stakeholder survey.

The possible impact of the introduction of new OELs on the exposure concentrations for the substances concerned has been assessed on the basis of the stakeholder consultation responses and previous impact assessments (OELs 3 and OELs 4 studies) by estimating the exposure reduction needed to comply with the OELs introduced for the different application areas (see Table 4-2) and to what extend the RMMs would have the potential for a similar reduction in the exposure to cobalt and inorganic cobalt compounds.

C20.13 Manufacture of other inorganic basic chemicals. Two respondents (out of seven) indicate an impact of the implementation of the OEL for nickel compounds on the exposure concentration for cobalt and cobalt compounds. One indicated the reduction to be >50% and one indicated it at <50%. Sector C20.13 was excluded from the OEL study for nickel compounds and the possible reduction factor cannot be established. As only two out of seven indicate a reduction, the overall reduction is assumed to be well below 50%. For the baseline scenario it is expected that the exposure concentrations will be reduced to 80% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force.

C20.30 Manufacture of paints and inks. One company has indicated an effect of the implementation of the OEL for nickel compounds on the exposure concentration for cobalt and cobalt compounds. The specific application area is the use of cobalt oxide in frits. Manufacture of frits and glazes is also included in this NACE code. In the manufacture of paints and inks, cobalt compounds within the scope of the OELs are expected to be used by a few companies for in-house manufacture of organic cobalt compounds used as driers. Other manufacturers of paint use only organic cobalt compounds and furthermore, the Frit Consortium has informed that only tricobalt tetraoxide (out of scope of the study) is used for frits. According to the OEL report for nickel, the P95 level with RPE for frits was 0.06 mg/m^3 for the inhalable fraction - slightly above the new OEL for the inhalable fraction (see the table below). As the information on impacts of the OEL for nickel is based on one response only and it has been informed that substances within the scope is in general not used for frits, the exposure concentrations have not been adjusted for the baseline scenario.

C20.59 Catalysts. Three respondents have indicated that the OEL for nickel may reduce the exposure concentrations for cobalt and inorganic cobalt compounds by <50%. Nickel and cobalt are typically not used together in catalysts, but the same production lines are used for production of nickel and cobalt-containing catalysts. According to the OEL report for nickel, the P95 level for catalysts (both with and without RPE) was 0.05 mg/m^3 for the inhalable fraction - the same level as the new OEL for the inhalable fraction (see the table below). However, some costs and benefits of establishing an OEL 0.05 mg/m^3 were calculated, as 5% of the workers and companies were estimated to have exposure levels above the P95 level. For the baseline scenario it is expected that the exposure concentrations will be reduced to 80% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force.

C23.1 Glass. One respondent indicates that both the OEL for nickel compounds and chromium (VI) would reduce the exposure concentration for cobalt and cobalt compounds by more than 50%. The company, however, does not provide any information on actual exposure concentrations. Nickel compounds, chromium (VI) and cobalt compounds are typically not use together in the manufacture of glass, but the same equipment may be used for the process indicated as 'Mixing or blending in batch processes'. Considering that only one answer is provided without indication of exposure concentrations, the exposure concentrations have not been adjusted for the baseline scenario.

C24.10 Steel. One respondent (out of two) indicates that the OEL for nickel compounds would reduce the exposure concentration for cobalt and cobalt compounds by less than 50%. According to the OEL report for nickel, the P95 level for 'C24 Metals' (without RPE) was 0.61 mg/m^3 for the inhalable fraction; more than 10 times the new OEL. Cobalt-containing steels would not typically contain nickel, but the same equipment may be used for producing cobalt and nickel containing steel in batch processes. For the baseline scenario it is expected that the exposure concentrations have been reduced to 90% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force.

C24.45 Manufacture of cobalt and cobalt alloys. Two respondents (out of five) indicates that the OEL for nickel compounds would reduce the exposure concentration for cobalt and cobalt compounds by less than 50%. Cobalt alloys would not typically contain nickel, but some do and the same equipment may be used for producing cobalt alloys and nickel alloys in batch processes. For the baseline scenario it is expected that the exposure concentrations have been reduced to 90% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force.

C25.61 Surface treatment of metals. No responses from companies within the sector C25.61 Surface treatment of metals were obtained which may explain the absence of the sector from the table below. Both nickel compounds and cobalt compounds are used in surface treatment. However, they are not typically used together, and no data are available to assess to what extent the substances are used in the same companies and same processes. Consequently, the exposure concentrations have not been adjusted for the baseline scenario.

C25.73 Manufacture of tools. Two respondents (out of 12 all producing hardmetal tools) indicates that the OEL for nickel compounds would reduce the exposure concentration for cobalt and cobalt compounds by less than 50%. Co-exposure to cobalt and nickel have been reported in some studies from the hardmetal industry (e.g. Kraus *et al.*, 2001; Linauskiene *et al.*, 2021) whereas e.g. Klasson *et al.* (2016) report that nickel was not present and according to the information available to the authors not used in the Swedish hard metal plants. The OEL report on nickel compounds does not specifically address nickel in hard metals. As only 2 out of 12 respondents have answered that the OEL for nickel compounds would reduce the exposure concentration for cobalt and cobalt compounds and it is indicated as less than 50% reduction, the exposure concentrations have not been adjusted for the baseline scenario.

C27.2 Batteries. For Ni-Cd batteries, two responses to the stakeholder consultation have indicated an expected reduction in exposure concentration due to the implementation of the OEL for cadmium of >50% whereas the reduction due to the implementation of the OEL for nickel is indicated by the two companies at <50% and >50%, respectively. A comparison between the P95 reported for the OELs study on cadmium and the new OEL would indicate a reduction potential of a factor of 3. As the consumption of cobalt for the production of Ni-Cd batteries only account for a part of the total cobalt consumption for the battery sector (the main part is for lithium batteries), the effect on the average concentrations for the entire sector should be significantly smaller. For the baseline scenario it is expected that the exposure concentrations have been reduced to 80% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force.

Welding. For welding both the OEL for nickel compounds and chromium VI compounds may have some influence on the exposure to cobalt as most cobalt alloys would also include either nickel or chromium or the welders are welding both cobalt alloys and stainless steel using the same equipment. No answers for the stakeholder survey concerned welding was obtained. It has for the stakeholder consultation been confirmed that the RMMs implemented in order to reduce nickel and chromium VI would similarly reduce cobalt concentrations. The estimated reduction factors are 1.7 for nickel compounds and 5 for chromium VI compounds based on the OEL studies for the two substance groups. Overall, it will be assumed that the exposure levels for welding are reduced to 50% of the current (reported) levels before the OEL for cobalt and inorganic cobalt compounds is going into force. The nickel and chromium VI OELs do not apply to nickel metal and chromium metal and consequently it is not expected that the implementation of the OELs will have any impact on the exposure to cobalt and inorganic cobalt compounds for other processes than high-temperature processes.

Table 4-2 OELs coming into force and possible impact on sectors with exposure to cobalt and inorganic cobalt compounds

Substance group	Timing	Sectors with cobalt exposure which might be impacted	Adjusted concentration, percentage of reported level
Nickel compounds	Member States shall bring the OELs for the inhalable fraction at 0.1 mg/m^3 into force before 5 April 2024. After 18 January 2025 it is reduced to 0.05 mg/m^3. For the respirable fraction, an OEL of 0.01 mg/m^3 shall apply from 18 January 2025. The OEL does not apply to nickel metal.	C20.13 Manufacture of other inorganic basic chemicals	80%
		C20.30 Manufacture of paints and inks	No adjustment
		C20.59 Catalysts	80%
		C23.1 Glass	No adjustment
		C24.10 Steel	90%
		C24.45 Manufacture of cobalt and cobalt alloys	90%
		C25.61 Surface treatment of metals	No adjustment

Substance group	Timing	Sectors with cobalt exposure which might be impacted	Adjusted concentration, percentage of reported level
		C25.73 Manufacture of tools	No adjustment
		C27.2 Batteries (affect only cobalt used for nickel cadmium batteries). Indicated percentage is average for all battery types	80%
		Welding	50%
Chromium VI compounds	The current (into force before 20 February 2021) limit value for chromium VI is 0.025 mg/m³ in welding, plasma cutting or similar work processes that generate fume is reduced to 0.005 mg/m³ by 17 January 2025 (factor of 5 reduction).	Welding	50%
Cadmium and its inorganic compounds	Limit value reduced from 0.004 mg/m³ to 0.001 before 11 July 2027 mg/m³ (factor of 5 reduction).	C27.2 Batteries (affect only cobalt used for nickel cadmium batteries). Indicated percentage is average for all battery types	80%

** Estimated by comparing the P95 of the substances concerned as indicated in the OELs report for nickel compounds, cadmium and its inorganic compounds, respectively. ** Reduction factor based on reduction in OEL; P95 values different for different processes in OEL report for chromium VI in welding.*
Source: Study team on basis of stakeholder survey and previous OEL studies.

The exposure concentrations used for the estimation of costs and benefits have in accordance with the percentages shown in the table above been adjusted from the exposure concentration shown in Table 3-72.

4.2 Effects of forthcoming changes in national OELs or protective regulation, self-regulatory initiatives

No information on forthcoming changes in national OELs for cobalt and inorganic cobalt compounds have been available.

In Germany, in January 2023 the AGS has changed the 4:10,000 risk factor from 5 µg Co/m³ (AGS 2017) to 2 µg Co/m³ (AGS, 2023) for the respirable fraction. This risk factor forms basis for the defined acceptable cancer risk as defined in TRGS 910 but is still not implemented in the technical rules. At the same time the 4:100,000 risk factor, the tolerable risk level, has been changed from 0.5 to 0.2 µg Co/m³ for the respirable fraction. The corresponding OEL analogue values are set at 2 µg Co/m³ for the respirable fraction and 20 µg Co/m³ for the inhalable fraction (AGS, 2023). The change in risk factors will probably result in lower exposure concentrations in Germany in the future.

In France, no OEL (Valeurs limites d'exposition professionnelle, VLEP value) is established for cobalt and inorganic cobalt compounds. The French Expert Committee on Expert appraisal for recommending occupational exposure limits for chemical agents and the Working Group on biomarkers of exposure has in 2015 proposed a pragmatic OEL at 2.5 µg Co/m³ and a STEL at 12.5 µg Co/m³ for cobalt and its compounds with the exception of cobalt associated with tungsten carbide (ANSES, 2015). No information on the further plan for establishing a binding OEL value has been identified.

No information on self-regulatory initiatives, e.g. forthcoming voluntary industry targets, or new protective regulation in Member States, which may lead to lower exposure to cobalt and inorganic cobalt compounds, have been identified.

It may be expected that in case of no action at EU level, more Member States would lower their OELs or establish OELs as consequence of the assessment and proposed OEL in the RAC opinion.

4.3 Effects of REACH

No policy actions under REACH are in the pipeline for the substances within the scope of the study.

The registries of restriction intentions, SVHC (Substance of Very High Concern) intentions and CLH (Registry of classification and labelling) intentions do not include any inorganic cobalt compounds which are still under assessment.

The harmonised EU classification of cobalt metal as of 1 October 2021 may have some consequence for the risk assessments undertaken in accordance with REACH. According to a Q&A from the Cobalt Institute regarding the new harmonised classification, the self-classification of cobalt metal has included inhalation carcinogenicity since December 2013 (Cobalt Institute, 2020). With the new harmonised classification, the cobalt metal is classified carcinogenic by all exposure routes and according to the Cobalt Institute (2020) it may in particular result in the need for additional risk management measures for reduction of exposure by the oral and dermal route. It cannot be ruled out that these measures may to some extent also reduce the exposure by the inhalation route.

No effects of REACH on the baseline in the nearest future scenario is anticipated. Possible effects in the long term (after 10 years) cannot be assessed.

4.4 Effects of megatrends

The baseline scenario may be affected by at least three megatrends [40]:

- Climate change and environmental degradation
- Aggravating resource scarcity
- Accelerating technological change and hyperconnectivity

Climate change and environmental degradation
According to the report 'Occupational safety and health in Europe - state and trends 2023' from the European Agency for Safety and Health at Work, major environmental changes and policies influence OSH (EASHW, 2023). The enhanced and accelerated introduction of environmental technologies is widely supported by national and EU policies. Consequently, the number of workers in some of these sectors may increase and impact the working conditions of many workers. Sectors/enterprises dealing with sustainable technologies grow fast, for example, decentralised and carbon-free energy production, green products, waste and recycling, green mobility and transport, and energy saving buildings' renovation. These 'green jobs' have gained a relevant and sometimes essential share in several economic areas (EASHW, 2023). Possible effects of growing demand for

[40] As defined at the Megatrend Hub at: https://knowledge4policy.ec.europa.eu/foresight/tool/megatrends-hub_en

sustainable technologies, first of all batteries and magnets, on the demand for cobalt is described in the section 4.5.

Securing and diversifying supply of critical raw materials
Cobalt is considered a critical raw material. According to Alves Dias *et al.* (2018) "*Potential disruptions in cobalt supply can arise from the near-monopolistic supply structures for both mined and refined cobalt, unethical practices in producing countries, the long lead-time for developing new mining projects, and the fact that cobalt is mainly mined and recovered as a co- or by-product of copper and nickel."*

This may affect the demand for cobalt as users may look for alternatives with less critical supply perspectives. An example is the growing use of cobalt free batteries for electrical vehicles that may partly have been driven by the risk of supply shortages in the future. This is further assessed in section 4.5.

Accelerating technological change and hyperconnectivity
According to the report 'Occupational safety and health in Europe - state and trends 2023', "*digital technologies can enhance prevention at workplaces. They can help to separate workers from hazardous working situations, facilitate better and innovative ways of monitoring exposure, and might improve the quality of work by relieving workers from repetitive or routine tasks*" (EASHW, 2023). Further automatization, e.g. automatic sampling for quality control and automatic loading from one container to another, may also result in lower exposure levels and shorter duration of exposures.

While accelerating technological change likely has some impact on exposure concentrations and exposed workforce, no quantitative data illustrating this have been identified. The possible effect of automization and other technological changes is further assessed in section 4.6.

4.5 Future trend in use and recycling of the substances

The future trend in the use of the substance may affect the baseline in terms of changes in the number of companies affected by establishing the OEL and the number of workers exposed.

The overall consumption of cobalt and inorganic cobalt substances has increased steeply in the recent years and this trend is expected to continue. The steady growth in cobalt demand in the last two decades, is according to Latunussa *et al.* (2020) reflecting the increased use in superalloys and catalysts, whereas in recent years the growth has primarily been driven by the demand for cobalt for batteries.

According to Tercero Espinoza *et al.* (2020) when looking at the collective effort currently undertaken by politics and industry to create a competitive and sustainable manufacturing value chain for batteries in Europe, the base scenario with constant market shares in rechargeable lithium ion batteries fabrication needs to be complemented with additional scenarios taking this European Battery Alliance and Europe's Strategic Action Plan on Batteries into consideration.

Combined scenarios for cobalt demand dependent on the development of the European fabrication of lithium ion batteries are shown below. As illustrated, the overall trend is totally depending on the trend in use of cobalt for manufacture of batteries in the EU.

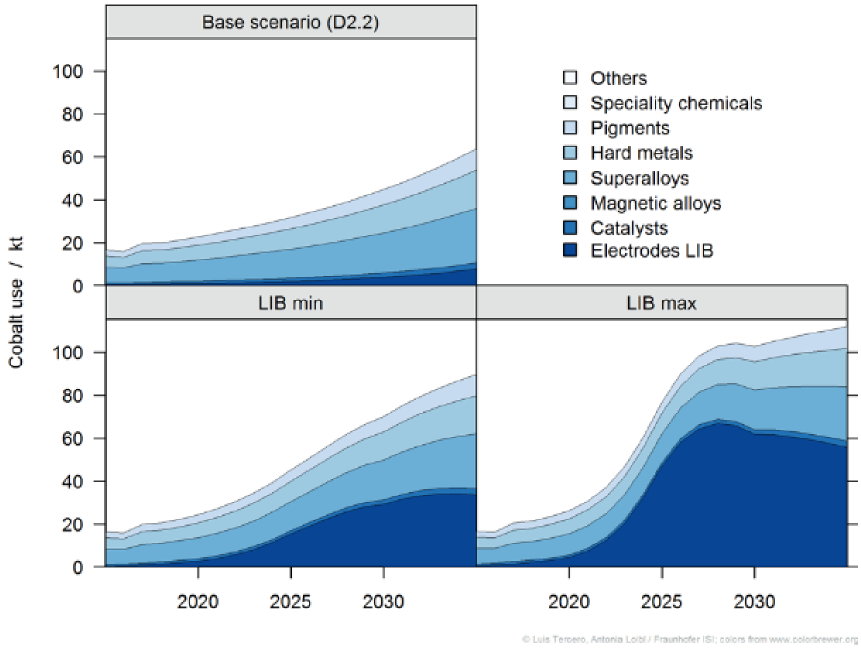

Figure 4-1 *Comparison between projections for the future European cobalt use with different scenarios for the development of the European fabrication of lithium ion batteries (LIB) Electrodes LIB refers to the use in lithium-ion batteries. Source: Tercero Espinoza et al. (2020) (making reference to Neef & Thielmann 2018; Thielmann et al. 2015).*

According to a study on the EU's list of Critical Raw Materials, cobalt is a crucial raw material for the implementation of the EU long-term strategy for the climate-neutral economy by 2050 as it is employed in the manufacture of rechargeable batteries for electric vehicles and energy storage systems (Latunussa *et al.*, 2020). The direct use of cobalt in the EEA (European Economic Area) (in applications such as batteries, alloys, catalysts, binding agents, and others) is forecasted to increase from just over 19,000 tonnes Co in 2019 to 26,500 tonnes Co in 2028 (base case demand).

Quite similar estimates are provided by the Cobalt Institute (2019) where the use of cobalt in final end-user products manufactured in the EEA is forecasted to increase from almost 20,600 tonnes Co in 2019 to more than 29,100 tonnes in 2028 corresponding to an 41% increase over ten years.

A Foresight Study on Critical Raw Materials for Strategic Technologies and Sectors in the EU projects that the additional material consumption for batteries, fuel cells, wind turbines in renewables and e-mobility only, in 2030 and 2050 compared to current EU consumption of the material in all applications, is 5 times and 14 times, respectively (Bobba *et al.*, 2020). The main part of the increase is assumed to be for batteries.

In the report 'Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study', Carrara *et al.* (2023) provides forecasts for a Low Demand Scenario (LDS) and a High Demand Scenario (HDS). The forecasts are divided on batteries for the automotive sector and renewable technologies. For 2030, the material demand forecast for cobalt for the automotive sector for EU is 40,388 tonnes/year for the LDS and 53,469 tonnes/year for the HDS. For 2050, the forecast is 36,308 tonnes/year and 40,202 tonnes/year for the two scenarios, respectively. The starting point in 2020 is set at 8,102 tonnes/year (note this is significantly lower than reported in the eftec (2023) impact assessment). The forecasted cobalt demand for batteries is nearly similar. Carrara *et al.* (2023) assumes that the resource efficiency of batteries will increase in time for both scenarios, although in the LDS scenario, the share of non-cobalt-based Li-ion batteries (LIBs) will increase faster than in the HDS, as well as the content of cobalt in cobalt-based batteries will decrease in time. This forecast for the EU differs from the forecast for the global demand where the demand in 2050 is forecast to be approximately two times the demand in 2030. The difference between the EU and global forecast for cobalt is not described. Regarding the use of cobalt in lithium-ion batteries (LIB) the authors note: "*Also due to their cost and to social aspects, the use of high-cobalt content LIBs is expected to decrease in favour of nickel-rich batteries or new chemistries. Lithium iron phosphate (LFP) batteries are currently mainly used in Asian countries. As LFP performance increases and the chemistry is more widely deployed, they will compete with fertiliser production for phosphates (Epstein, 2022).*" (Carrara *et al.*, 2023). According to Carrara *et al.* (2023) li-ion batteries are expected to dominate the global and the EU battery market for the next two decades even though novel battery types are expected to arise (e.g. sodium batteries).

Carrara *et al.* (2023) provide aggregated forecasts for the renewable energy technologies. These include in particular wind turbines, electrolysers, solar photovoltaics (PV), heat pumps and batteries for energy storage. From an estimated 143 tonnes/year in 2020, the demand is forecast at 3,250-4,452 tonnes/year (LDS-HDS) in 2030 and at 8,707-11,577 tonnes/year (LDS-HDS) in 2050. According to the authors, cobalt is currently crucial for batteries and energy storage, for which demand is rising as energy markets move away from oil and gas. It is not indicated how much of the demand is for batteries for energy storage.

According to a study for the industry organisation Eurometaux (Gregoir, 2022), the world's energy transition would require an annual 4-6% increase in average cobalt demand between 2020 and 2050. Despite these rates being high, they have according to the authors been achieved in the past, with the market growing on average by 5.5% per year since 1990. The world's pace of climate action may have a big impact on future cobalt demand (Gregoir, 2022). Given, Europe's energy transition, cobalt demand could grow significantly by 2040, if Europe is successful in developing battery cathode production (Gregoir, 2022). Europe's 2030 energy transition goal is projected to require between 10,000-20,000 tonnes of cobalt in 2030, rising to 50,000-60,000 tonnes in 2050. Europe today consumes relatively low volumes of cobalt compared to other parts of the world because lithium batteries are mainly imported. As also highlighted by other studies, Europe's success rate in developing battery cathode manufacturing capacity will determine the growth in cobalt demand (Gregoir, 2022). The development of a European battery value chain, including cathode production capacity, would increase Europe's cobalt demand. The European cobalt market has the potential to grow to 30,000 - 50,000 tonnes in 2030 and 80,000-100,000 tonnes in 2050 (Gregoir, 2022).

Quoting Gregoir (2022), the EU 2022 Strategic Foresight Report on twinning the green and digital transitions in the new geopolitical context states that a 330% increase in the use of cobalt by 2050 is expected (European Commission, 2022).

Below is presented further information for three application areas where information on scenarios for future trends have been available: Production of batteries (C27.2), use and production of catalysts (C19.20 and C20.59, respectively) and recovery of cobalt from scrap materials (E38.32).

Batteries

Some forecasts for the cobalt demand for production of lithium-ion batteries have been reviewed in the previous section. The demand for batteries for the electrical vehicles sector is expected to increase in the coming years. To what extend this would also imply an increase in the consumption of cobalt for battery production in the EU depends on several factors: To what extent cobalt content of the batteries may be reduced, or the cobalt be replaced by other constituents and to what extent the cathodes for batteries used for vehicles produced in the EU will be imported from countries outside the EU of produced within the EU.

Figure 4-2 illustrates the trend in cobalt demand for batteries in electric vehicles sold in the EU based on European Road Transport Research Advisory Council (ERTRAC) deployment scenarios under the assumption that the cobalt content of the batteries resemble the content of today.

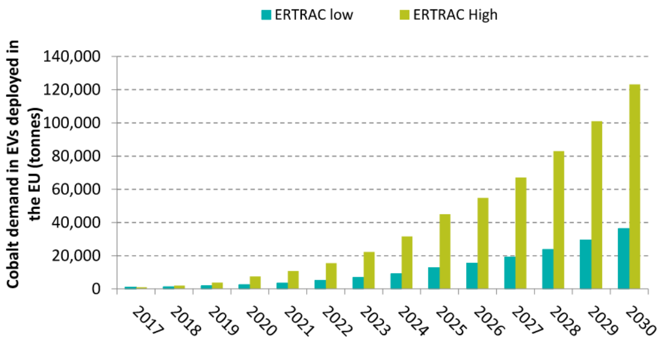

Figure 4-2 *Annual cobalt demand in the European electrical vehicles sector, estimated based on European Road Transport Research Advisory Council (ERTRAC) deployment scenarios. Source: Alves Dias et al., 2018.*

As described above, according to Carrara *et al.* (2023), the use of high-cobalt content lithium-ion batteries is expected to decrease in favour of nickel-rich batteries or new chemistries and Carrara *et al.* (2023) assume a decreasing trend in the use of cobalt for batteries from 2030 to 2050.

This is in accordance with the newest trends in the use of cobalt in lithium-ion batteries. The share of cobalt-free LFP batteries of the total market for batteries for electric vehicles has increased steeply from 3% in 2019 to 27% in 2022 (IEA, 2023). LFP batteries are less expensive than cobalt-containing lithium batteries per unit of energy capacity (IEA, 2023). Several market analyses foresee that LFP batteries will be the dominant battery chemistry over nickel manganese cobalt batteries (NMC) by 2028 (e.g. [41]).

Besides the shift to other battery types, the cobalt content of lithium-ion batteries has been decreasing. According to Gregoir (2022), producers continue to reduce the cobalt content in their batteries, but the required demand remains strong in the next decade. According to IEA (2023) the variability in price and availability of critical minerals can explain some of the developments in battery chemistry from the last few years. Battery chemistries using an equal ratio of nickel, manganese, and cobalt were popular until 2015. Since then, cobalt price increased and concerns affecting public acceptance of cobalt mining have contributed to a shift towards lower-cobalt ratios in battery types which are nevertheless more difficult to manufacture.

According to a report on batteries for energy storage in the European Union from the Joint Research Centre there is continuation of the trend to reduce the cobalt content in the batteries increasing the share of nickel (Bielewski *et al.*, 2022). According to the report "*The global trends in battery R&I[42] show general shift to low cobalt chemistries (NMC811, 955, NCA, NMCA, and LNO) and cheap LFP. Also new chemistries, like solid state, LNP or iron trifluoride may play an important role in the future*". The report quotes two scenarios for the development of the batteries for energy

[41] https://www.energy-storage.news/lfp-to-dominate-3twh-global-lithium-ion-battery-market-by-2030/

[42] R&I: Research & Innovation

storage. In both scenarios cobalt is projected to be replaced by cheaper and easier available metals such as nickel, iron and manganese within 20 to 30 years (Bielewski *et al.*, 2022).

Based on the available data it is considered highly likely, that the cobalt demand for manufacturing of batteries in the EU will increase considerably during the 40-years assessment period which may lead to increases in the number of workers exposed in the batteries sector even the trend is very uncertain after 2030. For the baseline scenario, an annual trend in the use of cobalt of 5% per year will be assumed.

Catalysts

The main use of cobalt catalysts is for the refinery sector. Due to the transition from fossil fuels to alternatives a decrease in refinery capacity is expected. According to a report from McKinsey & Co (Ding *et al.*, 2022), the refinery capacity in Europe will depending on scenario decrease by 19-58% (current trajectory of 46%) of the 2019 capacity by 2040. As consequence of the ban of sale of new diesel and gasoline driven cars and vans from 2035, the decrease is expected to continue after 2040. It will for the baseline be expected that the refinery capacity in the EU will decrease by 6% per year corresponding to a decrease to 36% of today's level after 20 years and to 14% of today's level by the end of the 40 years' assessment period. The exposed workforce and costs of RMMs are expected to decrease similarly.

As cobalt catalysts (based on cobalt compounds within the scope) are mainly used for the refinery sector, a similar decrease of 6% per year in the consumption of cobalt for manufacture of the catalysts will be expected.

Recycling

The steep growth in the cobalt demand in the past 30 years have resulted in increased amount of cobalt in materials and articles disposed of for waste management. The trend in battery and non-battery recycling volume demand for 2010-2028 is illustrated in Figure 4-3. The recycling of cobalt in batteries is illustrated by three different scenarios, but still small compared to recycling of cobalt alloys and cobalt from other applications but is expected to significantly increase in the coming years.

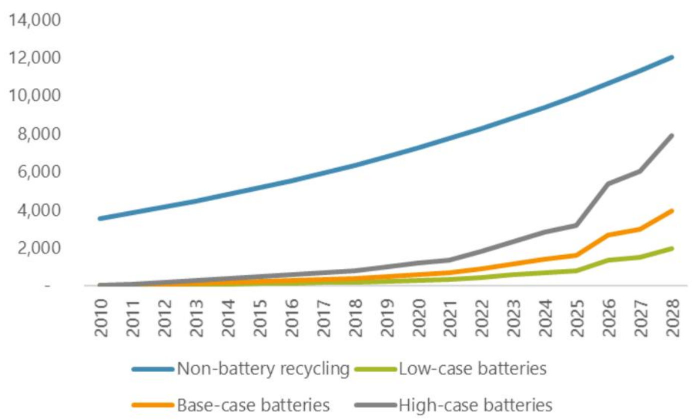

Figure 4-3 Battery and non-battery recycling volume demand scenario 2010-2028 (tonnes cobalt). Source: Cobalt Institute, 2019.

According to Gregoir (2022), European secondary supply has the potential to reach 20,000 tonnes by 2040 and 60,000 tonnes by 2050.

The forecast for cobalt quantities recycled with batteries is less uncertain than the forecast for battery production as this is not sensitive to assumptions on the trend in domestic production vs. import of cathode materials. For the baseline scenario an annual trend in the amount of recycled cobalt of 5% per year will be assumed.

4.6 Future trend in exposure concentrations due to technical improvements

Technical improvements such as further automatization and further use of closed systems may lead to decreased exposure concentrations.

Data demonstrating that technical improvement to a significant degree in itself has led to lower exposure to cobalt and inorganic cobalt compounds have not been identified. Based on information from site visits and other stakeholder consultation, lowering the concentrations have mainly been a result of the companies' intentional work on reducing the risk to the workers from exposure to cobalt substances and other hazardous substances in order to comply with national OELs and other OSH legislation or driven by the companies' internal targets for workers protection.

Past trends in exposure concentrations are described in section 3.3.9 where an overall trend of -4% over the last 30 years is used for the calculation of current burden of disease. Data from national databases in Italy and Finland do not indicate any significant trends for the last 10-15 years. Contrary to this, data from the manufacture of tools sector in several countries indicates a clear decreasing trend. The difference may reflect that cobalt salts have been classified carcinogenic for more years than cobalt metal and that the decrease in exposure concentrations for cobalt salts took place more years ago. As described in section 3.3.9, the main drivers for reducing the exposure concentrations in the past are assessed to be establishment of national OELs (and similar limit values in some Member States), the classification of cobalt and inorganic cobalt compounds as carcinogenic and reprotoxic substances and the implementation of the requirements of the CMRD as well as implementation of REACH. The harmonised classification of cobalt metal as carcinogenic and reprotoxic substances entered into force March 2020 but the self-classification of cobalt as metal has included inhalation carcinogenicity since December 2013. Some cobalt salts have been classified carcinogenic since 2004 (under Council Directive 67/548/EEC). Risk management measures have to a large degree already been implemented in response to these drivers and the decrease in concentrations is expected to be lower than seen the past 30 years.

The introduction of OELs for other hazardous substances will for some sectors, as described in section 4.1, result in some decreases in exposure levels as the implemented RMMs may also lower exposure to cobalt and inorganic cobalt compounds. The changes are assumed to take place before a potential new OEL for cobalt and inorganic cobalt compounds come into force and have been factored into the applied exposure concentrations as described in section 4.1.

Although the decreasing trend in exposure concentrations is assumed to be lower, some reduction is still foreseen. Information obtained by site visits and the stakeholder survey responses indicates that many companies expect that the exposure levels would be further decreased. It is common that at least large companies have internal targets for exposure reduction and reports e.g. in the Annual Report on the progress in reducing exposure (based on air monitoring or biomonitoring data). It has not been possible to identify any studies on the expected exposure reduction rates for cobalt or other carcinogenic substances for the next 40 years. The previous OEL studies have assumed no reduction in the exposure concentrations, but several studies note that some exposure reduction may take place.

For the quantitative assessments of costs and benefits it is however still assumed that the exposure levels remain constant over the assessment period. It is considered that a reduced exposure trend will affect both costs and benefits and not change the relative assessment of alternative policy options. Combining this with the practical reason that the cost model used for this study does not allow for taking a reduction of exposure into account supports the assumption of doing the assessment with no trend.

The considerations on the expected development in the exposure level includes a number of issues presented in the following. It can be assumed that the reduction in exposure level will be lower than the 4% per year applied for the last 30 years and in principle likely higher than 0%. As described in section 4.2, some Member States may in the absence of an OEL at EU level introduce a national OEL (if not already established) or lower the national OEL. As described in section 4.2, Germany has recently lowered acceptance and tolerance levels for cobalt and cobalt substances. In the absence of actual data to build a projection on, the reduction rate is assumed to be in the range of one to two percent per year. It roughly corresponds to a halving in exposure levels over 40 years. However, an annual reduction in exposure concentrations of one to two percent per year would require some investments and recurrent costs which should be subtracted in case the reduction is factored into the estimation of the total number of cases and the benefits. Some reduction may come for ‘free’ as consequence of investments with other objectives such as automatic sampling, but in many cases, the objective of the investments would actually be exposure reduction. The cost model used for the study does not include a common methodology for taking the cost reduction into account. A halving of the exposure concentrations over 40 years can broadly be compared to the costs of compliance with the highest policy option where the cost/benefit ratio is approximately 2. Even some of the reduction in exposure concentration would be the consequence of investments with other objectives than reduction of the exposure to cobalt and inorganic cobalt compounds, the costs would likely be in the same range as the benefits. In order not to screw the cost/benefit ratio of the policy options, neither the benefits nor the costs of the reduction in exposure levels have been subtracted from the calculated costs and benefits, but it is noted that both costs and benefits would overestimate the actual costs and benefits of the introduction of the OELs. Hence, for assessment purposes, it a trend of 0% is used.

4.7 Future trend in exposed workforce

Based on the description of the future trends in the consumption and recycling of cobalt, the following trends in workforce will be applied for the baseline analysis under the assumption that the trend in exposed workforce follows the trend in the consumption and recycling of cobalt. For the following sectors, a trend in workforce has been factored into the assessment. The values are the annual increase (+) or decrease (-):

- C27.2 Batteries: +5%
- C19.20 Petrochemical, catalyst: -6%
- C20.59 Catalysts: -6%
- E38.32 Metal recovery: +5%

The four sectors represent together about 1% of all companies with exposed workers and about 4% of the exposed workforce. As the trends to some extent counterbalance each other these trends consequently have a very small effect on the total estimated benefits and costs.

Further automatization and introduction of robots for work processes with exposure to hazardous substances can potentially reduce the number of exposed workers. An example is the use of industrial welding robots instead of manual welding. However, data demonstrating that automatization have had a significant impact on the number of workers exposed to cobalt the last ten years have not been identified. Considering that the cobalt consumption may be slightly increasing for other applications than batteries, a possible effect of further automatization may be counterbalanced by increased use of cobalt for other applications.

It is therefore assumed that the number of exposed workers is stable in these sectors, and the trend is set at 0%.

4.8 Other factors of importance for the baseline

No other factors of importance for the baseline have been identified.

4.9 Future disease burden (FDB)

4.9.1 Future disease burden from current and future exposure

The future disease burden is given below as the cases over the next 40 years (2023-2062) and is the number of cases generated by exposure in over the next 40 years (and not the number of cases actually happening in the next 40 years). Latency may cause many of the cases caused by exposure in the next 40 years, particularly of cancer, to occur beyond the 40 year period. For this reason, the number of cases is not divided by 40 to indicate a number of cases per year as this would be misleading.

The future burden of disease does not include cases that are the result of legacy exposure in previous years. These are included in next section on future disease burden from legacy exposure. The future burden of disease is also lower than what could be expected from the current disease burden's figures as exposure concentrations have kept declining.

The estimations take into account the trend in workforce described in section 4.6.

The number of cases for the future burden of disease is shown in Table 4-3 while the number by sector is summarised in section Table 4-4. The present value of the healthcare costs over 40 years for both a static discount rate and a declining discount rate are shown in Table 4-5 and Table 4-7, respectively. The estimates in the table below assume a workforce turnover at 5% per year. This means that the workforce is replaced in 20 years and that the average employment time is 10 years.

A mean latency period of 30 years is assumed for lung cancer and 0 for non-cancer endpoints.

The predicted number of cases is around 76 for lung cancer, 4,365 for restrictive lung disease, and 14,152 for upper airway irritation over a 40-year period for a workforce of around 113,000.

Table 4-3 Baseline future burden of disease; staff turnover of 5% for all sectors. Trend in workforce varies by sector

Endpoint	Number of cases over 40 years
Lung Cancer	76
Restrictive Lung disease	4,365
Upper airway Irritation	14,152

Source: Study team

Table 4-4 Baseline future burden of disease by sector; staff turnover of 5% for all sectors. Trend in workforce varies by sector

Sector		Number of cases over 40 years			Percent of total cases
		Lung cancer	Restrictive lung disease	Upper airway irritation	
C10.91	Manufacture, feeds	0	0	2	0.0%
C19.20	Petrochemical, catalyst	0	5	20	0.1%
C20.12	Manufacture of dyes and pigments	4	139	387	2.8%
C20.13-20.14	Manufacture of basic chemicals	1	29	107	0.7%
C20.30	Manufacture of paints and inks	0	7	19	0.1%
C20.59	Catalysts	0	0	2	0.0%
C20.59	Formulation other chemicals	1	34	100	0.7%
C21.20	Pharmaceuticals	0	1	3	0.0%
C22.11;	C22.19 Rubber adhesion	0	2	7	0.0%
C23.1	Glass	1	16	57	0.4%
C23.4	Ceramics	12	468	1,315	9.7%
C23.7	Cutting stone	1	51	164	1.2%
C24.10	Steel	0	4	12	0.1%
C24.45	Manufacture of cobalt and cobalt alloys	0	26	79	0.6%
C25.5	Powder metallurgy	0	29	102	0.7%
C25.61	Surface treatment of metals (specialised)	3	101	366	2.5%
C25.62	Machining (specialised)	15	1,073	3,948	27.1%
C25.73	Manufacture of tools	13	960	3,410	23.6%
C25.99	Manufacture of other fabricated metal products n.e.c.	1	80	221	1.6%
C26.11	Production of electronic components	5	220	606	4.5%
C26.51	Humidity indicator cards	0	0	0	0.0%
C27.2	Batteries	1	30	117	0.8%
C28.11	Engines and turbines	1	94	342	2.4%
C29.10-30	Vehicles	3	99	360	2.5%
C30.30	Air and spacecraft	1	94	342	2.4%
C32.50	Medical and dental devices	7	629	1,619	12.1%
E38.32	Metal recovery	1	109	275	2.1%

Sector		Number of cases over 40 years			Percent of total cases
		Lung cancer	Restrictive lung disease	Upper airway irritation	
Cross	sectoral - Biogas	0	0	0	0.0%
Cross	sectoral - welding, etc.	3	66	167	1.3%
	Total	**76**	**4,365**	**14,152**	**100**

** Multiply of trend in workforce and exposure concentration*
Source: Study team

Table 4-5 Baseline future burden of disease (PV40), 5% turnover of workforce a year, static discount rate

Sector		PV40 over 40 years, static discount rate Range of Method 1 – Method 2 (€ million)			
		Lung cancer	Restrictive lung disease	Upper airway irritation	Total
		M1 – M2	M1 – M2	M1 – M²	High - Low
C10.91	Manufacture, feeds	0.0-0.0	0.0-0.0	0.0-0.0	0.1-0.0
C19.20	Petrochemical, catalyst	0.2-0.1	0.1-0.1	0.1-0.1	0.3-0.3
C20.12	Manufacture of dyes and pigments	2.9-1.5	1.9-2.1	1.1-1.4	5.9-5.0
C20.13-20.14	Manufacture of basic chemicals	0.9-0.4	0.4-0.4	0.3-0.4	1.5-1.3
C20.30	Manufacture of paints and inks	0.1-0.1	0.1-0.1	0.1-0.1	0.3-0.2
C20.59	Catalysts	0.0-0.0	0.0-0.0	0.0-0.0	0.0-0.0
C20.59	Formulation other chemicals	0.8-0.4	0.5-0.5	0.3-0.4	1.5-1.2
C21.20	Pharmaceuticals	0.0-0.0	0.0-0.0	0.0-0.0	0.0-0.0
C22.11;	C22.19 Rubber adhesion	0.0-0.0	0.0-0.0	0.0-0.0	0.1-0.1
C23.1	Glass	0.4-0.2	0.2-0.2	0.2-0.2	0.8-0.7
C23.4	Ceramics	9.5-5.0	6.3-7.0	3.7-4.6	19.5-16.6
C23.7	Cutting stone	1.2-0.6	0.7-0.8	0.5-0.6	2.3-2.0
C24.10	Steel	0.0-0.0	0.1-0.1	0.0-0.0	0.1-0.1
C24.45	Manufacture of cobalt and cobalt alloys	0.2-0.1	0.4-0.4	0.2-0.3	0.8-0.8
C25.5	Powder metallurgy	0.3-0.2	0.4-0.4	0.3-0.4	1.0-1.0
C25.61	Surface treatment of metals (specialised)	2.7-1.4	1.4-1.5	1.0-1.3	5.1-4.2
C25.62	Machining (specialised)	12.3-6.4	14.5-16.0	11.0-13.9	37.7-36.3
C25.73	Manufacture of tools	10.8-5.6	12.9-14.3	9.5-12.0	33.2-31.9
C25.99	Manufacture of other fabricated metal products n.e.c.	0.7-0.4	1.1-1.2	0.6-0.8	2.5-2.4
C26.11	Production of electronic components	4.2-2.2	3.0-3.3	1.7-2.1	8.9-7.6
C26.51	Humidity indicator cards	0.0-0.0	0.0-0.0	0.0-0.0	0.0-0.0
C27.2	Batteries	0.7-0.4	0.3-0.4	0.3-0.3	1.3-1.1
C28.11	Engines and turbines	1.1-0.6	1.3-1.4	1.0-1.2	3.3-3.2
C29.10-30	Vehicles	2.7-1.4	1.3-1.5	1.0-1.3	5.0-4.1
C30.30	Air and spacecraft	1.1-0.6	1.3-1.4	1.0-1.2	3.3-3.2

Sector		PV40 over 40 years, static discount rate Range of Method 1 – Method 2 (€ million)			
		Lung cancer M1 – M2	Restrictive lung disease M1 – M2	Upper airway irritation M1 – M2	Total High - Low
C32.50	Medical and dental devices	5.5-2.9	8.5-9.4	4.5-5.7	18.5-17.9
E38.32	Metal recovery	0.7-0.3	1.5-1.6	0.8-1.0	2.9-2.9
Cross-sectoral	Biogas	0.0-0.0	0.0-0.0	0.0-0.0	0.0-0.0
Cross-sectoral	Welding, etc.	2.0-1.1	0.9-1.0	0.5-0.6	3.4-2.6
Grand	**Total**	**61.3-32.0**	**58.7-64.9**	**39.5-49.8**	**159.5-146.6**

Source: Study team

Table 4-6 below presents the baseline costs of ill health for workers (M1 and M2), employers and public authorities associated with the three health endpoints modelled for cobalt and inorganic cobalt compounds. These figures represent the cost prior to any intervention being put in place to reduce exposure to cobalt and inorganic cobalt compounds and reduce the number of resulting cases.

Table 4-6 Baseline costs of ill health for workers (M1 and M2), employers and public administrations (€ millions)

Sector	Workers and families (M1)	Workers and families (M2)	Employers	Public Authorities	Grand total (M1)	Grand total (M2)
C10.91 Manufacture, feeds	0.05	0.03	0.000	0.00	0.05	0.04
C19.20 Petrochemical, catalyst	0.30	0.24	0.002	0.01	0.32	0.26
C20.12 Manufacture of dyes and pigments	5.58	4.65	0.056	0.26	5.89	4.96
C20.13-20.14 Manufacture of basic chemicals	1.47	1.18	0.013	0.07	1.54	1.25
C20.30 Manufacture of paints and inks	0.27	0.23	0.003	0.01	0.29	0.25
C20.59 Catalysts	0.02	0.01	0.000	0.00	0.02	0.01
C20.59 Formulation other chemicals	1.41	1.17	0.014	0.06	1.49	1.25

Sector	Workers and families (M1)	Workers and families (M2)	Employers	Public Authorities	Grand total (M1)	Grand total (M2)
C21.20 Pharmaceuticals	0.05	0.04	0.000	0.00	0.05	0.04
C22.11; C22.19 Rubber adhesion	0.09	0.08	0.001	0.00	0.09	0.08
C23.1 Glass	0.77	0.62	0.007	0.03	0.81	0.67
C23.4 Ceramics	18.44	15.51	0.185	0.86	19.48	16.56
C23.7 Cutting stone	2.21	1.83	0.021	0.10	2.33	1.95
C24.10 Steel	0.12	0.11	0.001	0.01	0.12	0.12
C24.45 Manufacture of cobalt and cobalt alloys	0.76	0.74	0.009	0.04	0.81	0.79
C25.5 Powder metallurgy	0.94	0.90	0.010	0.06	1.01	0.96
C25.61 Surface treatment of metals (specialised)	4.84	3.95	0.043	0.22	5.10	4.21
C25.62 Machining (specialised)	35.26	33.79	0.380	2.09	37.74	36.27
C25.73 Manufacture of tools	31.05	29.74	0.339	1.83	33.23	31.91
C25.99 Manufacture of other fabricated metal products n.e.c.	2.29	2.21	0.028	0.13	2.45	2.37
C26.11 Production of electronic components	8.40	7.13	0.086	0.40	8.88	7.61
C26.51 Humidity indicator cards	0.00	0.00	0.000	0.00	0.00	0.00
C27.2 Batteries	1.24	1.00	0.011	0.06	1.31	1.06
C28.11 Engines and turbines	3.11	2.96	0.033	0.18	3.32	3.18
C29.10-30 Vehicles	4.77	3.88	0.042	0.22	5.02	4.14
C30.30 Air and spacecraft	3.09	2.95	0.033	0.18	3.31	3.17

Sector	Workers and families (M1)	Workers and families (M2)	Employers	Public Authorities	Grand total (M1)	Grand total (M2)
C32.50 Medical and dental devices	17.32	16.74	0.215	0.99	18.53	17.95
E38.32 Metal recovery	2.71	2.74	0.036	0.17	2.91	2.94
Cross-sectoral - Biogas	3.23	2.48	0.029	0.13	3.39	2.63
Cross-sectoral - welding, etc.	0.05	0.02	0.000	0.00	0.05	0.02
Total	**149.82**	**136.93**	**1.599**	**8.12**	**159.54**	**146.65**

Source: Study team.

Notes: Values for workers and values are calculated using two different methodologies (M1-M2), for more information on the differences between these methods, please see the methodological note. Grand total (M1) is the sum value of Workers & Families (M1), Employers, and Public Authorities. Grand total (M2) is the sum value of Workers & Families (M2), Employers, and Public Authorities.

4.9.2 Legacy burden of disease

Previous OEL studies have not included the calculation of future burden of disease from legacy exposure. The reason is that this burden of disease would not be affected by the assessed policy options and just be added to all scenarios and will make differences in the scenarios less prominent.

A mean latency period of 30 years is assumed for lung cancer. This means that exposure before 2023 may lead to cancer cases for a period of 30 years i.e. from 2024-2054. The total number of cases are calculated in the same way as described for the current burden of disease where the total burden for each year due to exposure during the period 1994-2023 is calculated using the past trends in workforce and exposure concentrations as described in section 3.12.1.

For the non-cancer endpoints, the latency time is assumed to be 0 years and past exposure would not lead to future cases.

The future burden of disease from past exposure is reported in the table below but is not presented with the policy options.

Table 4-7 Legacy burden of disease that will occur in the next 40 years due to exposure in the last 40 years

Endpoint	Number of cases over 40 years due to legacy exposure
Lung cancer	200
Restrictive lung disease	0
Upper airway irritation	0

Source: Study team

4.10 Summary of the baseline scenario

A summary of the baseline scenario is presented in the table below.

Table 4-8 Baseline scenario over 40 years for cobalt and inorganic cobalt compounds

Item	Detail	
Chemical agent	Cobalt and inorganic cobalt compounds	
Classification	Carc. 1A or 1B (most of substances) Repr. 1B (most of substances)	
Sectors	C10.91	Manufacture, feeds
	C19.20	Petrochemical, catalyst
	C20.12	Manufacture of dyes and pigments
	C20.13-20.14	Manufacture of basic chemicals
	C20.30	Manufacture of paints and inks
	C20.59	Catalysts
	C20.59	Formulation
	C21.20	Pharmaceuticals
	C22.11	Production of tyres
	C23.1	Glass
	C23.4	Ceramics
	C23.7	Cutting stone
	C24.10	Steel
	C24.45	Manufacture of cobalt and cobalt alloys
	C25.5	Powder metallurgy
	C25.61	Surface treatment of metals
	C25.62	Machining
	C25.73	Manufacture of tools
	C25.99	Manufacture of other fabricated metal products n.e.c.
	C26.1	Production of electronic components and boards
	C26.51	Humidity indicator cards
	C27.2	Batteries
	C28.11	Engines and turbines
	C29.10-30	Automotive
	C30.30	Air and spacecraft
	C32.50	Medical and dental devices
	E38.21	Biogas
	E38.32	Metal recovery
Period for estimation	40 years	
Types of cancer caused	Lung cancer	
Other adverse health effects	Restrictive lung disease (decrease in lung function) Upper airway irritation	
No. of exp. workers	113,000 (67,000 - 177,000)	
Change exp. level	Assumes 0% in the assessment though a small decrease could be expected.	
Change no. of exp. workers	C27.2 Batteries: 5% C19.20 Petrochemical, catalyst: -6% C20.59 Catalysts: -6% E38.32 Metal recovery: 5% Other: 0%	
Current disease burden (CDB) - no. of cancer cases/year	12	

Item	Detail
Future disease burden (FDB) from current and future exposure - no. of cancer cases over 40 years	76
Future disease burden from past (legacy) exposure - no. of cancer cases over 40 years	200
Current disease burden CBD - no. of restrictive lung disease cases/year	110
FDB - no. of restrictive lung disease cases over 40 years	4,365
Future disease burden from past (legacy) exposure - no. of restrictive lung disease cases over 40 years	0
Current disease burden CBD - no. of Upper airway irritation cases/year	350
FDB - no. of Upper airway irritation cases over 40 years	14,152
Future disease burden from past (legacy) exposure - no. of Upper airway irritation cases over 40 years	0
Estimated deaths due to FDB cancer over 40 years	60
Estimated deaths due to FDB non cancer endpoints over 40 years	0
Monetary value FDB cancer over 40 years	32 - 61 € million
Monetary value FDB other adverse health effects over 40 years	98 – 115 € million

The next table summarises the baseline data on number of exposed workers, number of cancer and non-cancer cases and finally the estimate health costs. Note that total health costs are not just the sum of cancer and non-cancer health costs displaying the previous table[43].

Table 4-9 *Estimated number of exposed workers, expected number of cancers and other hazardous diseases cases and related health costs in case no action is taken (baseline scenario), over a 40 year period*

Carcinogen	No. of exposed workers	Expected no. of cancer cases	Expected no. of cases of other adverse health effects	Estimated health costs, €million	Possible underestimations (non exhaustive list)
Cobalt and inorganic cobalt compounds	113,000 (current level) For some sectors increasing trend for others decreasing)	76	18,517	147 - 160	Some health endpoints (astma) could not be quantified

[43] The range is based on the two approaches for monetisation. For cancer health costs M1 provides the highest value, while for the non-cancer health costs, M2 estimates the highest costs.

5 POLICY OPTIONS

The ACSH has in its 'Opinion on limit value setting for non-threshold carcinogens, a Risk-Based Approach' agreed on the following regarding the levels of OELs:

- *'In the future, limit values for non-threshold substances will be set in between the predetermined 'upper risk level' and the 'lower risk level'. It is agreed that the upper risk is 4:1 000 (corresponding to 4 predicted cancer cases in 1 000 employees) and the lower risk level is 4:100 000. This assumes exposure occurs over 8 hours per day, 5 days a week and 40 years of working life.'* (ACSH, 2022)

Risk estimate based on the ERR for respirable fraction derived by RAC is shown in the table below (see further description of the ERR in sections 2.2).

Table 5-1 Risk estimate based on the ERR for respirable fraction derived by RAC

Risk estimate	Cobalt concentration (µg/m³, respirable fraction, long-term mean value, 40 years of workplace exposure)
Risk 4:1 000	4.20
Risk 4:10 000	0.69
Risk 4:100 000	0.38

Source: Study team om basis of ERR derived by RAC.

Based on the above, throughout the analysis of benefits and costs, four policy options are taken for the sets of OELs, and these are shown in the table below. For the final report, an additional set of levels may be added if the ACSH decides on a set of OELs not covered by the initial analysis.

Table 5-2 Policy options acting as reference points for this study for cobalt and inorganic cobalt compounds (see comments in the body text)

OEL, Inhalable / respirable fraction measured as Co		Reason for inclusion	
mg Co/m³	µg Co/m³	Inhalable	Respirable
0.001 / 0.0005	1 / 0.5	OEL at the level proposed by the RAC opinion	OEL at the level proposed by the RAC Close to risk level 4:100,000
0.005 / 0.00125	5 / 1.25	Intermediate level	Intermediate level
0.010 / 0.0025	10 / 2.5	Minimum binding OEL as observed among those Member States where an OEL exists	Intermediate level
0.020 / 0.0042	20 / 4.2	Mode of OELs observed among those Member States where an OEL exists – is used in more than half of Member States where an OEL exists	Risk level 4:1,000
To be decided		Proposed EU-OEL(s) adopted by the ACSH	

No STELs or BLVs are proposed by RAC and not assessed in this study.

Biological guidance values (BGV) are not listed in the CMRD and consequently, the potential impacts of the BGVs suggested by RAC is not included in the assessed policy options.

The residual risks for the policy options are included below.

Table 5-3 Estimate of residual risks

Respirable fraction µg	Residual risk	4:xxxx
4.2	0.00396562	4: 1009
2.5	0.0021677	4: 1845
1.25	0.0008457	4: 4730

Source: Study team

6 BENEFITS OF THE MEASURES UNDER CONSIDERATION

This chapter comprises the following sections:

- Section 6.1: Summary of the assessment framework
- Section 6.2: Improved welfare, assumptions and avoided cases of ill health
- Section 6.3: Benefits to workers & families
- Section 6.4: Benefits to employers
- Section 6.5: Benefits to the public sector
- Section 6.6: Summary of the benefits of the measures.

6.1 *Summary of the assessment framework*

6.1.1 *Summary of the key features of the model*

The model developed to estimate the benefits in terms of reduced costs takes into account the cost categories set out in Table 6-1 below. More details are presented in the Methodological Note.

Table 6-1 The benefits framework

Category		Benefits	Notes
Direct	Improved welfare	Reduced healthcare costs	Avoided cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc. Avoided private direct and indirect medical costs and rehabilitation costs
		Reduced informal care costs[44]	Avoided 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 ill health)
		Reduced cost for employers	E.g. avoided costs due to insurance payments and absence from work
		Environment	See Chapter 9, not monetised
	Improved market efficiency	Cost savings	Include higher economic productivity, improved allocation of resources, removal of regulatory or market failures or cost savings but and.
		Improved information	Includes improved information availability
		Wider range of products/services	Enhanced product and service variety and quality for end consumers
Indirect	Indirect compliance benefits	Reduced mortality – productivity loss.	Avoided costs to society due to premature death
		Reduced morbidity – lost working days.	Avoided earnings and output due to absence from work due to illness or treatment
		Other indirect benefits to workers and families	
		Indirect benefits to administrations	Avoided tax revenue losses Avoided administrative and legal costs Avoided costs linked to the process of defining a national OEL

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

Category		Benefits	Notes
	Wider economic benefits	including higher GDP, productivity enhancements, greater employment rates, improved job quality etc.	Employment may increase as a result of industry 'clean up' due to better perception of workplaces and increased acceptability of risks
	Other, non-monetary benefits	Protection of fundamental rights, social cohesion, reduced gender discrimination, international and national stability	
Intangible	Improved welfare	Approach 1 WTP[45]: Mortality	A monetary value of the impact on quality of life of affected workers Avoided moral pain and suffering Avoided loss of present and future income Avoided cost of time claiming benefits, waiting for treatment etc. Reduction in insurance contributions
		Approach 1 WTP: Morbidity	
		Approach 2 DALY[46]: Mortality	
		Approach 2 DALY: Morbidity	

The abbreviations are explained in Table 6-2 below.

6.2 Improved welfare, assumptions and avoided cases of ill health

6.2.1 Benefits categories for improved welfare

Table 6-2 Overview of benefits categories for improved welfare

Category	Code	Cost to be avoided	Workers and families	Employers	Public administration
Direct	*Ch*	Healthcare			100%
	Ci	Informal care	100%		
	Ce	Total cost to an employer		100%	
Indirect	*Cp*	Productivity loss due to mortality		20%	80%
	Cl	Lost earnings due to morbidity	80%	20%	
Intangible	*Cvsl*	Value of statistical life	100%		
	Cvsm	Value of cancer morbidity/value of statistical morbidity	100%		
	Cdaly	Value of DALYs	100%		

The benefit model provides the following two outputs:

- The number of new cases for each health endpoint assigned to a specific year in the 40-year assessment period; and
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

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45 WTP = Willingness to Pay. The maximum sum an individual is willing to pay for a service/goods in order to avoid loss, in this case, in terms of health treatment.

46 DALY = Disability Adjusted Life Year. DALY is whereby one year of health is lost. It is used to calculate the gap between current health status and the ideal health situation (WHO, accessed Feb 2018).

The model assumes an annual staff turnover of 5%. This corresponds to a situation where the whole workforce is replaced every 20 years, and within the time period of 40 years, more than two cohorts of workers are exposed to the substances. In addition, workforce growth is assumed in two sectors, as outlined in section 4.7, where the battery and metal recovery sectors are expected to grow 5 percent annually, while the refinery and catalyst sectors are assumed to decrease with an annual rate of 6 percent.

A detailed overview of the key features of the model for the estimation of the benefits and the assumptions underpinning it are set out in the Methodological Note.

6.2.2 Relevant health endpoints for cobalt and inorganic cobalt compounds

The substance assessment for cobalt and inorganic cobalt compounds entails three endpoints:

- Lung cancer;
- Restrictive lung disease;
- Upper airway irritation.

6.2.3 Method 1 vs Method 2

Two estimates of the cost savings from ill health avoided under the different policy options (Methods 1 and 2) are presented in this report. These estimates rely on two different monetisation approaches. Both monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect (productivity/lost earnings) impacts. However, they use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.). The results of both approaches should be considered together and treated as indicative of the general order of magnitude of the cost savings. A detailed explanation of these approaches is provided in the Methodological Note.

For non-cancer endpoint, there are no WTP directly available. The approach used here is based on combining a disability weight for each endpoint with the valuation of one life year (one DALY). For Method 1, a general one-off WTP for the non-cancer endpoints could be calculated using the assumption on the number of years with the disease.

The values given in the sections below are for the present value (PV) discounted over 40 years.

6.2.4 Summary of the key assumptions for cobalt and inorganic cobalt compounds

6.2.4.1 Onset of the disease

The time required for the endpoints to develop over an average working life takes into account the maximum time required to develop the condition (MaxEx) and the distribution of new cases between these two points in time, combined with the latency period with which the effects are diagnosed.

Table 6-3 Latency and maximum exposure duration to develop a condition (MaxEx)

Endpoint	MaxEx (years)	Latency (years)
Lung cancer	40	30
Restrictive lung disease	1	0
Upper airway irritation	1	0

Source: See Methodological Note for more details

6.2.4.2 The effects of the disease

The key assumptions on the effects of the disease entering the model are summarized below:

- Treatment period;
- Years lived with disability of the disease (YLD);
- Fatality rate;
- Additional life expectancy at death; and
- Disability weights during treatment and after treatment.

The tables below present the treatment period, YLD, fatality rate, and additional life expectancy at death for the health endpoints. Neither of the non-cancer endpoints have a potentially fatal outcome.

For restrictive lung disease, it is assumed that it is a chronic disease and that workers will live for around 30 years with the disease. For upper airway irritation it is assumed that the worker exposed will experience symptoms of the illness throughout their employment, which is assumed to be 10 years on average based on the assumed turnover of workers of 5% per year; described above in 3.12.2.

Table 6-4 Treatment period, YLD, fatality rate, and additional life expectancy at death in years

Type of illness	Treatment period (years)	Years lived with disability/disease (YLD)	Fatality rates (MoR)	Additional life expectancy at death (years)
Lung cancer	5	5	0.8	22
Restrictive lung disease	1	30	0	0
Upper airway irritation	1	10	0	0

Source: See Methodological Note for more details

The disability weight for lung cancer is outlined in the Methodological Note.

The disability weight for restricted lung disease is based on the global burden of disease study from 2019[47], where a disability weight of 'Mild interstitial lung disease and pulmonary sarcoidosis' is being considered. Here it is assumed that it is a mild interstitial lung disease corresponding to the symptoms outlined in section 2.2.3.1. It is assumed that an infected person can receive treatment which will make the symptoms less prevalent. It is assumed that after one year, the disability weight is 0.011 equivalent to low end of range for this disease. This is a relatively low disability weight corresponding to very mild symptoms. In the sensitivity assessment, an alternative weight is used. As a sensitivity assessment, the high end of the estimated disability weights is used. It has a value of 0.033 which is three times higher than the value used here.

For the upper airway irritation, a disability weight of 0.005 is used both during treatment and after treatment. Again, there is no disease included in the disability weight studies, which exactly matches the upper airway irritation. Diseases with mild symptoms that does not affect daily

[47] https://ghdx.healthdata.org/record/ihme-data/gbd-2019-disability-weights

activities are typically included with a disability weight of this order. The disability weights applied in the benefit assessment are presented in the below table.

Table 6-5 Disability weights

Type of illness	During treatment	After treatment
Lung cancer	0.265	0.515
Restrictive lung disease	0.019	0.011
Upper airway irritation	0.005	0.005

Source: See Methodological Note for more details.

6.2.4.3 Cost of treatment

The basis for the costs of lung cancer is described in the Methodological Note as it is common for all substances where lung cancer is one of the health endpoints.

For the restrictive lung disease, there are no data on the likely direct health costs. Based on what has been used for similar health points, it is estimated that the disease will require visits to the General Practitioner and specialists though no specific treatment can be offered. This is estimated at an order of €1,000 per case. It might cover regular visits to the medical service given that the disease is chronic.

For the upper airway irritation, there is also limited data. It is assumed to be a milder disease with less symptoms. Still, it will require visits the General Practitioner or specialists. The costs are estimated in the order of €500 per case. For lung cancer there is also a cost of informal health care which is assumed to be €3000 per case.

Table 6-6 Cost of healthcare treatment

Type of illness	Unit cost in €
Lung cancer	11,500
Restrictive lung disease	1,000
Upper airway irritation	500

Source: See Methodological Note for more details

6.2.4.4 Willingness to Pay (WTP) values

The willingness to pay estimates are presented in the below table. For lung cancer, the WTP is the value of a statistical life; details are presented in the Methodological Note.

For the non-cancer health endpoints, no WTP has been identified. For the restrictive lung disease, the disability weight is 0.011 and it is assumed that the worker will live with disease for 30 years. Given that one life year is estimated to have WTP of €100,000, the annual WTP is €1100. Then, the WTP for avoiding getting the disease can be estimated at around €21,000.

A form of a sense check on this value can be done by considering what it would mean in terms of the willingness to pay for workers being exposed to cobalt. As presented above in Section 2.2.3 on the DRR for non-cancer effects, the risk of getting the restrictive lung disease is in the order of 4-5% at the estimated average concentration levels. It means, that on average, a person should be willing to pay a little less than €1,000[48] when asked about her/his WTP.

[48] Estimated as 4.5% of €21,000 is equal to €945.

Table 6-7 WTP for a statistical life, one life lost and restricted activity days

Type of illness	WTP, €	Comment
Lung cancer	4,710,00	Value of a statistical life
Lung cancer	100,000	Value of one life year lost (the value of DALY)
Restrictive lung disease	21,000	This is based on the discounted value of DALY of €100,000 and a disability weight of 0.011 and a remaining life of 30 years.
Upper airway irritation	4,250	This is based on the discounted value of DALY of €100,000 and a disability weight of 0.005 and a disease period of 10 years.

Source: See Methodological Note for more details.

6.2.4.5 Summary

In addition to the costs of treatment and the intangible welfare loss described above, there are direct and indirect costs for employers and for society in lost productivity. The direct costs for employers include for example lost productivity, administrative costs, insurance costs etc. These costs have been estimated at €13,200 per cancer case[49]. For the restrictive lung disease, a minor cost of €500 per case has been assumed. The indirect costs related to mortality and morbidity includes the lost working days. These costs have been estimated at €5000 for fatal lung cancer cases and €1000 for non-fatal lung cancer cases[50]. For the restrictive lung disease, a value of €500 for lost working days have been assumed.

The unit costs are summarised in the table below.

Table 6-8 Unit costs used for the benefits assessment

Category	Code		Cost, €/case		
			Lung cancer	Restrictive lung disease	Upper airway irritation
Direct	*Ch*	Healthcare	11,500	1,000	500
	Ci	Informal care	3,000	0	0
	Ce	Cost for employers	13,200	500	0
Indirect	*Cp*	Mortality – productivity loss due to mortality	5,000	0	0
	Cl	Morbidity – lost working days due to morbidity	1,000	500	0
Intangible	*Cvsl*	Approach 1 WTP: Value of statistical life	4,710,00	4,710,00	4,710,00
	Cvsm	Approach 1 WTP: Value of cancer morbidity/value of statistical morbidity	455,000	21,000	4,250
	Cdaly	Approach 2 DALY: Value of DALYs	100,000	100,000	100,000

[49] See the Methodological note – Section 4.3.2.3.5 (Cost savings for employers) for details of the estimation.
[50] See the Methodological note – Section 4.3.2.3.6 for more details.

6.2.5 Avoided cases of ill health and residual risk (cancer and non-cancer)

The method for calculation of avoided cases of ill health is described in the Methodological Note.

As described in the section of future burden of disease, the number of cases of cancer is based on the exposure concentrations for the respirable fraction while the number of noncancer cases is based on the inhalable fraction. The simple way to calculate the number of cases would be to assume that companies comply with the OELs for respirable fraction and calculate the number of cases on this basis. In the same way the number of cases for non-cancer endpoints could be calculated by assuming that companies comply with the OELs for the inhalable fraction. But this would not reflect the real situation. As described in section 3.3.2 the respirable to inhalable fraction varies by sector and is different from the ratios between inhalable to respirable fraction of the four policy options. If a company in the metal sector comply with a respirable to inhalable fraction of 1:8 should comply with the policy options 1 / 0.5 µg Co/m^3, the respirable fraction would in reality be reduced to 0.125 µg Co/m^3 when the exposure concentration of the inhalable fraction is in compliance with the OEL of 1 µg Co/m^3.

If this is not taken into account the benefits of complying with the combined sets of OELs would be underestimated. In order to prevent this underestimation the calculations are adjusted for the respirable to inhalable ratios for the three different segments (use as metal, use as chemical and welding).

For the use of metals, the OEL for the inhalable fraction will be the determining whereas it is the opposite for welding. For use as chemical it varies with policy options.

It should be noted that for the uses as metal or chemical, compliance with the OEL for the inhalable fraction at 1 µg Co/m^3 would result in a concentration for the respirable fraction at 0.125 or 0.25 µg Co/m^3, respectively, which is below the 4:100 000 Risk of 0.38 µg Co/m^3 established from the ERR (see chapter 5 on policy options).

Table 6-9 Adjusted concentrations when in compliance with the policy options taking into account the respirable to inhalable fraction for three different segments. All values in µg Co/m^3.

Policy option	Uses as metal R:I = 1:8		Use as chemical R:I = 1:4		Welding R:I = 1:2	
	I	R	I	R	I	R
1 / 0.5 µg Co/m^3	**1**	0.125	**1**	0.25	1	**0.5**
5 / 1.25 µg Co/m^3	**5**	0.625	**5**	1.25	2.5	**1.25**
10 / 2.5 µg Co/m^3	**10**	1.25	**10**	2.5	5	**2.5**
20 / 4.2 µg Co/m^3	**20**	2.5	16.8	**4.2**	8.4	**4.2**

Source: study team. Values marked in bold are similar to the policy options.

The number of avoided cases over 40 years by the different policy options is shown in the table below. The number of cases is further plotted in a continuous form in the figure below.

Table 6-10 Avoided cases over 40 years for each policy option

Policy option	Lung cancer (Respirable)	Restrictive lung disease (Inhalable)	Upper airway irritation (Inhalable)
Baseline	0	0	0
1 / 0.5 µg Co/m^3	71	4,365	14,152
5 / 1.25 µg Co/m^3	51	4,365	12,266
10 / 2.5 µg Co/m^3	27	2,842	7,363

Policy option	Lung cancer (Respirable)	Restrictive lung disease (Inhalable)	Upper airway irritation (Inhalable)
20 / 4.2 µg Co/m³	15	1,000	2,135

Source: Study team.

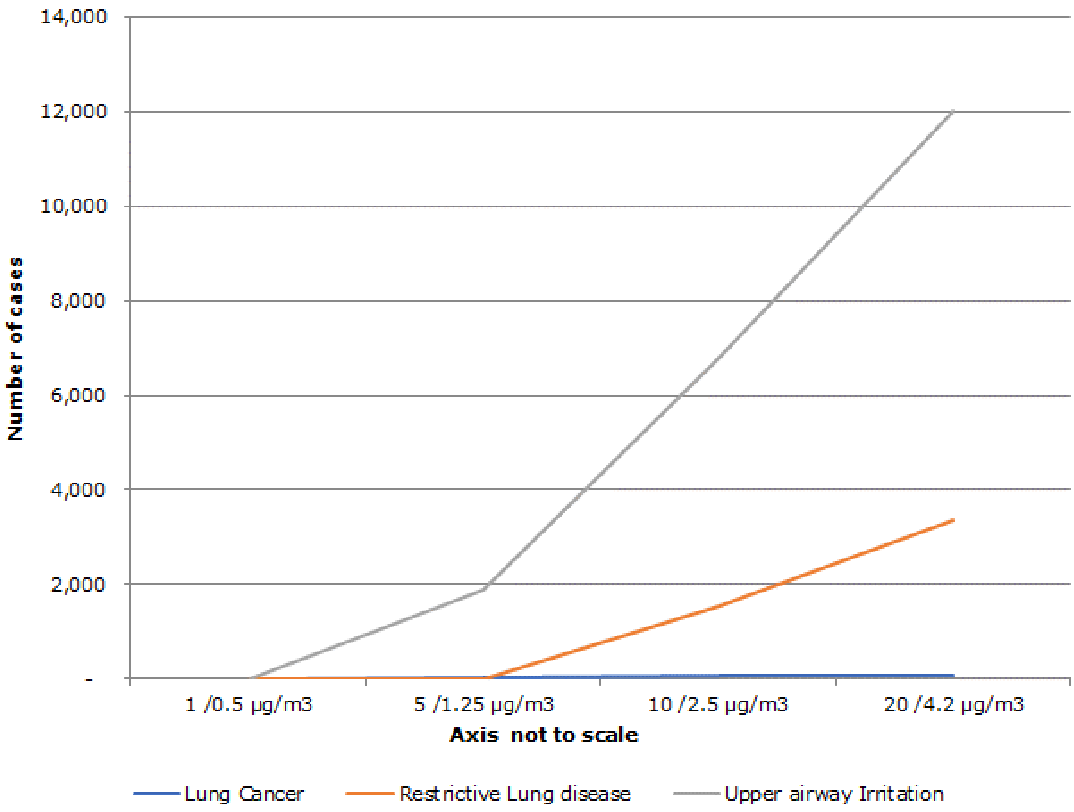


Figure 6-1 Cases over 40 years due in relation to different OEL levels. Axis not to scale

The residual risk, the difference between the baseline and the number of avoided cases, by the different policy options is shown in Table 6-11.

Table 6-11 Estimated number of cases (residual risk) by the different policy options.

Policy option	Lung cancer (Respirable)	Restrictive lung disease (Inhalable)	Upper airway irritation (Inhalable)
Baseline	76	4,365	14,152
1 / 0.5 µg Co/m³	5	-	-
5 / 1.25 µg Co/m³	25	-	1,921
10 / 2.5 µg Co/m³	53	1,555	6,849
20 / 4.2 µg Co/m³	64	3,612	12,488

Source: Study team.

6.3 Benefits to workers & families

6.3.1 Avoided costs of ill health

The benefits that will be realised by exposed workers and their families are first of all intangible benefits of reduced mortality rates. All the categories are presented in the table below.

Table 6-12 Benefits for workers and their families (avoided cost of ill health)

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+Cl+Cdaly*

The benefits of each policy option (relative to the baseline) are summarised below. Method 1 relies on WTP values for mortality and morbidity, with the resulting estimates given in Table 6-13 and Figure 6-2.

Table 6-13 METHOD 1: Benefits to WORKERS & FAMLILIES (policy options, relative to the baseline), € million

Policy option	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 / 0.5 µg Co/m^3	56	55	35	146
5 / 1.25 µg Co/m^3	41	55	31	126
10 / 2.5 µg Co/m^3	22	36	18	75
20 / 4.2 µg Co/m^3	12	13	5	29

Note: *Workforce turnover 5% per year. Source: Study team.*

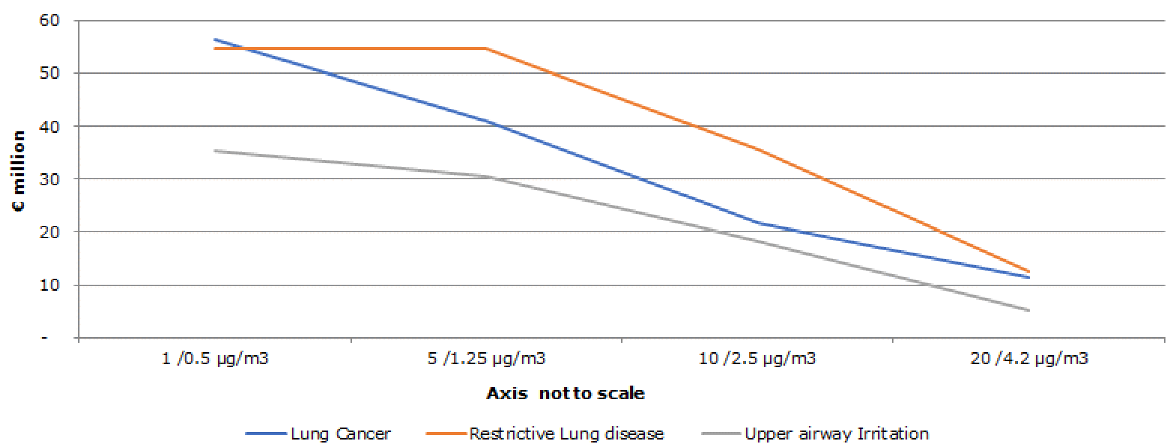


Figure 6-2 METHOD 1: Benefits to WORKERS & FAMILIES (policy options, relative to the baseline). Axis not to scale.

Method 2 relies on the valuation of DALYs as explained above. The resulting benefits estimates for lung cancer is lower when using Method 1. For the non-cancer endpoints, the Method 2 gives more or less the same results.

Table 6-14 METHOD 2: Benefits to WORKERS & FAMLILIES (policy options, relative to the baseline), € million

Policy option	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 / 0.5 µg Co/m³	29	61	46	135
5 / 1.25 µg Co/m³	21	61	40	121
10 / 2.5 µg Co/m³	11	40	24	74
20 / 4.2 µg Co/m³	6	14	7	27

Note: Workforce turnover 5% per year. Source: Study team.

6.3.2 Other benefits to workers and families

There are no other benefits that have been estimated.

6.4 Benefits to employers

6.4.1 Avoided costs of ill health

The benefits (avoided costs of ill health relative to the baseline) accrued by employers are calculated using the method summarised below.

Table 6-15 Benefits to EMPLOYERS (avoided cost of ill health)

Stakeholder group	Costs	Method of summation
Employers	Ce, Cp	*CtotalEmployer=Ce+0.8*Cp*

The benefits of each policy option are summarised below in Table 6-16 and depicted in Figure 6-3. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 6-16 Benefits to EMPLOYERS (policy options, relative to the baseline), € million

Policy option (Inhalable)	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 / 0.5 µg Co/m³	0.3	1.3	0	1.6
5 / 1.25 µg Co/m³	0.2	1.3	0	1.5
10 / 2.5 µg Co/m³	0.1	0.9	0	1.0
20 / 4.2 µg Co/m³	0.1	0.3	0	0.4

Source: Study team.

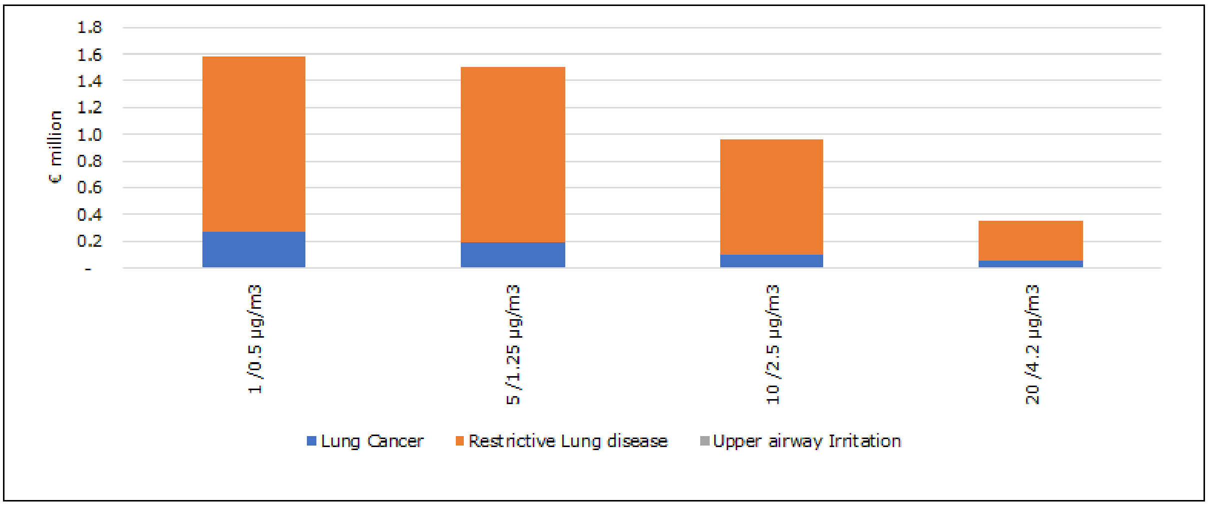


Figure 6-3 Benefits to EMPLOYERS (Policy options, relative to the baseline)

6.4.1.1 Result of stakeholder survey regarding other benefits

Companies' answers to the question "*Do you think your company will benefit from any of these indirect benefits if an EU-wide OEL for cobalt and its inorganic compounds is introduced*?" are summarised in the table below. Of those answering the question, 67% indicated there will be no benefit. Benefits for which more than 10% answered 'Yes' were healthier staff (25%), improved public image (21%) and level playing field with EU competitors (19%). The benefit of healthier staff is covered by the sections above, whereas some of the other benefits will be briefly described below.

Table 6-17 Companies' survey answer to question regarding benefits of establishing an OEL.

Sector	Percent answering yes (number of respondents)
Healthier staff	25% (14)
Increased productivity of workers	4% (2)
Improved public image	21% (12)
Easier to recruit staff	7% (4)
Easier to retain staff	7% (4)
Reduced cost of recruitment	2% (1)
Easier monitoring of exposure	9% (5)
Savings because company currently has multiple locations in different Member States with different regulations or OELs	4% (2)
Level playing field with EU competitors	19% (11)
Other indirect benefits, please specify	2% (1)
There will be no indirect benefits	67% (38)
Number of responses *	57

** Two companies did not answer this question.*

Better company image, public perception

In total 21% of companies responding to this question indicated improved public image as a benefit of establishing an OEL. It has not been possible to monetise this benefit.

Level playing field

In total 19% of 57 companies responding to the question indicated level playing field as a benefit of establishing an OEL. The companies represent one third of the sectors represented by the survey: C20.59 Catalysts and other chemical products, C24.45 Manufacture of cobalt and cobalt alloys, C25.61 Surface treatment of metals, C25.73 Manufacture of tools; C26.1 Production of electronic components and boards, and C27.2 Batteries. It has not been possible to monetise this benefit.

One set of limit values across all Member States

Only one company responding to this question indicated savings because company currently has multiple locations in different Member States with different regulations or OELs. The company is within the sector C32.50 Medical and dental devices. Many of the responding companies from other sectors are known to also have multiple locations. Information obtained from interviews and site visits both within this study and previous OEL studies indicates that it is common that larger companies with multiple sites have their own company standards and try to comply with the most stringent OELs among those Member States where they operate. Some companies, however, use different OELs depending on the national OELs in the Member States where facilities are located. In cases where companies take over sites in other Member States with higher or no OELs it may take some years to implement the necessary measures to comply with the company standards. It has not been possible to monetise this benefit.

6.5 Benefits to public administrations

6.5.1 Avoided costs of ill health

The benefits (avoided costs of ill health, relative to the baseline) for the public administrations are calculated using the method summarised Table 6-18 and shown in Figure 6-4. These costs include healthcare treatment costs, which assume that the costs are borne by the public administrations. These costs do not include informal care costs, which are costs for workers and families covered in section 6.3. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 6-18 Benefits to the PUBLIC ADMINISTRATIONS (avoided cost of ill health)

Stakeholder group	Costs	Method of summation
Governments	Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue)	*CtotalGov=Ch+0.2(Cp+Cl)* *(Note 1)*

Note: 1 Assumes 20% tax

The benefits of each policy option (relative to the baseline) are summarised in Table 6-19 below and depicted in Figure 6-4.

Table 6-19 Benefits to the PUBLIC ADMINISTRATIONS (Policy option, relative to the baseline), € million

Policy option (Inhalable)	Lung cancer	Restrictive lung disease	Upper airway irritation	Total (€ million)
1 / 0.5 µg Co/m^3	0.9	2.9	4.3	8.1
5 / 1.25 µg Co/m^3	0.7	2.9	3.7	7.2
10 / 2.5 µg Co/m^3	0.4	1.9	2.2	4.4
20 / 4.2 µg Co/m^3	0.2	0.7	0.6	1.5

Source: Study team.

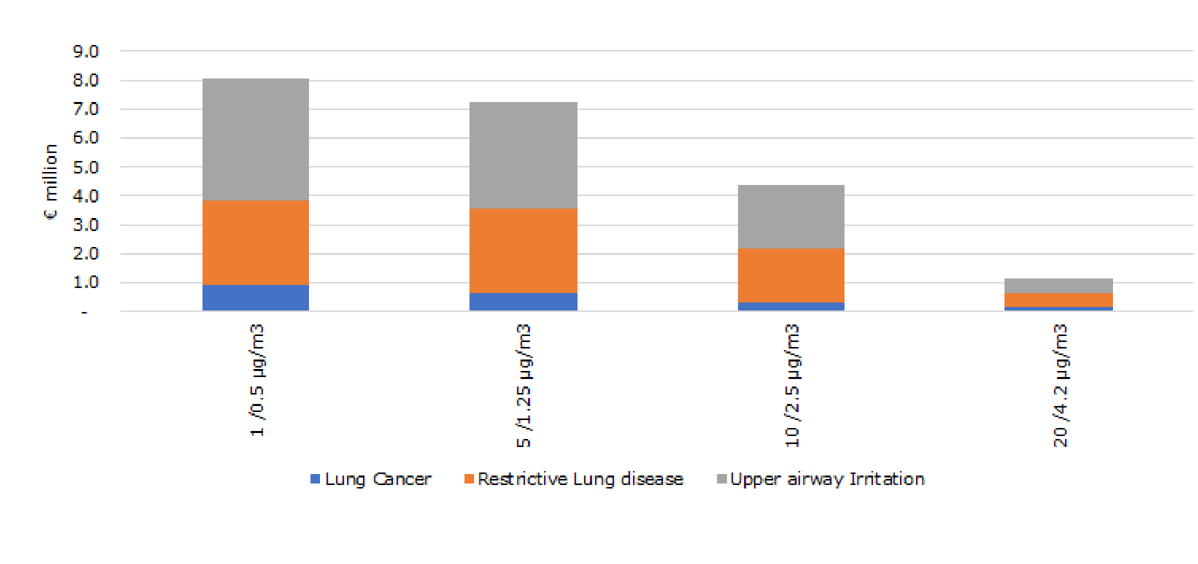


Figure 6-4 Benefits to the PUBLIC ADMINISTRATIONS (Policy options, relative to the baseline)

6.5.2 Other benefits to public administrations

6.5.2.1 Avoided costs linked to the process of defining a national OEL

An indirect benefit for Member State authorities is that if they have no OELs there are cost involved in assessing the impact of an OEL value and introducing it.

Of the 27 EU Member States, research carried out for this study has confirmed that five of the Member States (Cyprus, Italy, Luxembourg, Malta, Portugal, Slovenia) have no OEL (or having similar risk-based levels). The study takes €100,000[51] per Member State not having an OEL (or similar) as an approximation of the general order of magnitude of the applicable costs of introducing an OEL for Member States where there is currently no OEL for cobalt and inorganic cobalt compounds.

For Member States with an existing OEL, there is the possibility that they might revise their OEL at some point over the assessment period[52]. The study takes €50,000[53] per Member State requiring alteration of an existing OEL as an approximation of the general order of magnitude of the applicable costs of amended their limit values where there are some limit values in place for cobalt and inorganic cobalt compounds. However, the study team believes that only a small fraction of the avoided cost for Member States requiring alteration of an existing OEL should be considered realistic because it is unlikely that any Member State would ever bring in both a respirable and inhalable OEL, and a STEL. As it is impossible to estimate this element of the avoided cost, it is not included any further in the calculation of benefits: the study team does not believe that it would significantly increase any of the overall benefits calculations as these are all given in € millions.

[51] This is an expert estimate, and it is slightly higher than what is used for other substances due to the fact that there are two fractions.

[52] See the methodological note, Section 4.7

[53] See the methodological note, Section 4.7

Table 6-20 Avoided costs of implementing OELs for Member State authorities (same for all policy options)

Member State situation	Number of Member States	Avoided costs per Member State, €	Total avoided costs across the EU, €
Member States with no OEL or similar limit values	5	100,000	500,000
Member States with an existing OEL	22	50,000	(1,100,000) *
Total			500,000

Source: Study team
*Notes: * Only the avoided costs for Member States with no OEL or similar limit value are taken forward into the main benefits calculations*

6.6 Summary of the benefits of the measures

6.6.1 Benefits from avoided ill health

The benefits split by all the sectors and by policy options are presented in Table 6-21.

Table 6-21 METHOD 1: Benefits from avoided ill health by sector by policy options, relative to the baseline (€ Million)

Sector	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 µg Co/m³				
C10.91 Manufacture, feeds	0.02	0.01	0.01	0.03
C19.20 Petrochemical, catalyst	0.16	0.07	0.07	0.31
C20.12 Manufacture of dyes and pigments	2.88	1.87	1.08	5.83
C20.13-20.14 Manufacture of basic chemicals	0.75	0.39	0.30	1.44
C20.30 Manufacture of paints and inks	0.14	0.09	0.05	0.28
C20.59 Catalysts	0.00	0.00	0.00	0.01
C20.59 Formulation other chemicals	0.75	0.45	0.28	1.49
C21.20 Pharmaceuticals	0.02	0.01	0.01	0.04
C22.11; C22.19 Rubber adhesion	0.03	0.03	0.02	0.08
C23.1 Glass	0.40	0.22	0.16	0.78
C23.4 Ceramics	9.31	6.31	3.67	19.29
C23.7 Cutting stone	1.08	0.68	0.46	2.22
C24.10 Steel	0.03	0.05	0.03	0.12
C24.45 Manufacture of cobalt and cobalt alloys	0.22	0.35	0.22	0.79
C25.5 Powder metallurgy	0.30	0.39	0.29	0.98
C25.61 Surface treatment of metals (specialised)	2.55	1.36	1.02	4.93
C25.62 Machining (specialised)	11.40	14.45	11.03	36.88

Sector	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
C25.73 Manufacture of tools	9.74	12.93	9.53	32.20
C25.99 Manufacture of other fabricated metal products n.e.c.	0.71	1.08	0.62	2.41
C26.11 Production of electronic components	4.16	2.96	1.69	8.81
C26.51 Humidity indicator cards	0.00	0.00	0.00	0.00
C27.2 Batteries	0.49	0.33	0.26	1.08
C28.11 Engines and turbines	1.03	1.27	0.96	3.25
C29.10-30 Vehicles	2.51	1.33	1.01	4.85
C30.30 Air and spacecraft	1.01	1.27	0.96	3.23
C32.50 Medical and dental devices	5.37	8.47	4.52	18.36
E38.32 Metal recovery	0.59	1.47	0.77	2.83
Cross-sectoral - Biogas	0.00	0.00	0.00	0.00
Cross-sectoral - welding, etc.	2.03	0.89	0.47	3.38
Grand Total	**57.68**	**58.72**	**39.48**	**155.89**
5 µg Co/m³				
C10.91 Manufacture, feeds	0.00	0.01	0.00	0.01
C19.20 Petrochemical, catalyst	0.12	0.07	0.05	0.24
C20.12 Manufacture of dyes and pigments	2.63	1.87	0.98	5.48
C20.13-20.14 Manufacture of basic chemicals	0.34	0.39	0.12	0.85
C20.30 Manufacture of paints and inks	0.12	0.09	0.05	0.26
C20.59 Catalysts	0.00	0.00	0.00	0.01
C20.59 Formulation other chemicals	0.75	0.45	0.28	1.49
C21.20 Pharmaceuticals	0.01	0.01	0.00	0.02
C22.11; C22.19 Rubber adhesion	0.02	0.03	0.01	0.05
C23.1 Glass	0.29	0.22	0.11	0.61
C23.4 Ceramics	8.51	6.31	3.34	18.16
C23.7 Cutting stone	0.74	0.68	0.29	1.71
C24.10 Steel	0.02	0.05	0.03	0.10
C24.45 Manufacture of cobalt and cobalt alloys	0.13	0.35	0.19	0.67
C25.5 Powder metallurgy	0.15	0.39	0.24	0.78
C25.61 Surface treatment of metals (specialised)	1.93	1.36	0.74	4.02
C25.62 Machining (specialised)	6.36	14.45	9.81	30.63
C25.73 Manufacture of tools	5.13	12.93	8.16	26.22
C25.99 Manufacture of other fabricated metal products n.e.c.	0.59	1.08	0.57	2.24

Sector	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
C26.11 Production of electronic components	3.85	2.96	1.56	8.37
C26.51 Humidity indicator cards	0.00	0.00	0.00	0.00
C27.2 Batteries	0.28	0.33	0.07	0.67
C28.11 Engines and turbines	0.57	1.27	0.85	2.69
C29.10-30 Vehicles	1.88	1.33	0.72	3.94
C30.30 Air and spacecraft	0.57	1.27	0.85	2.69
C32.50 Medical and dental devices	4.72	8.47	4.30	17.49
E38.32 Metal recovery	0.07	1.47	0.48	2.03
Cross-sectoral - Biogas	0.00	-	-	0.00
Cross-sectoral - welding, etc.	2.00	0.89	0.45	3.33
Grand Total	**41.76**	**58.72**	**34.26**	**134.74**
10 µg Co/m³				
C10.91 Manufacture, feeds	0.00	0.00	0.00	0.00
C19.20 Petrochemical, catalyst	0.03	0.01	0.00	0.03
C20.12 Manufacture of dyes and pigments	2.07	1.46	0.77	4.30
C20.13-20.14 Manufacture of basic chemicals	0.17	0.10	0.04	0.31
C20.30 Manufacture of paints and inks	0.08	0.06	0.03	0.16
C20.59 Catalysts	0.00	0.00	0.00	0.00
C20.59 Formulation other chemicals	0.75	0.45	0.28	1.49
C21.20 Pharmaceuticals	0.01	0.00	0.00	0.01
C22.11; C22.19 Rubber adhesion	0.01	0.01	0.00	0.02
C23.1 Glass	0.02	0.02	0.01	0.05
C23.4 Ceramics	6.75	4.95	2.64	14.34
C23.7 Cutting stone	0.39	0.21	0.08	0.68
C24.10 Steel	0.01	0.03	0.02	0.06
C24.45 Manufacture of cobalt and cobalt alloys	0.05	0.22	0.12	0.39
C25.5 Powder metallurgy	0.03	0.22	0.12	0.36
C25.61 Surface treatment of metals (specialised)	0.34	0.32	0.13	0.79
C25.62 Machining (specialised)	0.86	9.20	5.34	15.40
C25.73 Manufacture of tools	1.54	7.19	3.91	12.64
C25.99 Manufacture of other fabricated metal products n.e.c.	0.25	0.89	0.47	1.61
C26.11 Production of electronic components	3.15	2.44	1.29	6.87
C26.51 Humidity indicator cards	0.00	0.00	0.00	0.00
C27.2 Batteries	0.16	0.08	0.03	0.28
C28.11 Engines and turbines	0.07	0.81	0.47	1.35

Sector	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
C29.10-30 Vehicles	0.29	0.27	0.12	0.68
C30.30 Air and spacecraft	0.08	0.81	0.47	1.36
C32.50 Medical and dental devices	3.01	7.53	3.73	14.27
E38.32 Metal recovery	0.04	0.19	0.08	0.31
Cross-sectoral - Biogas	0.00	-	-	0.00
Cross-sectoral - welding, etc.	1.89	0.80	0.40	3.09
Grand Total	**22.03**	**38.25**	**20.56**	**80.85**
20 µg Co/m³				
C10.91 Manufacture, feeds	0.00	0.00	0.00	0.00
C19.20 Petrochemical, catalyst	0.01	0.01	0.00	0.02
C20.12 Manufacture of dyes and pigments	1.08	0.59	0.24	1.91
C20.13-20.14 Manufacture of basic chemicals	0.09	0.04	0.02	0.15
C20.30 Manufacture of paints and inks	0.01	0.02	0.01	0.04
C20.59 Catalysts	0.00	0.00	0.00	0.00
C20.59 Formulation other chemicals	0.75	0.45	0.28	1.49
C21.20 Pharmaceuticals	0.00	0.00	0.00	0.00
C22.11; C22.19 Rubber adhesion	0.00	0.00	0.00	0.01
C23.1 Glass	0.05	0.02	0.01	0.09
C23.4 Ceramics	3.58	2.01	0.84	6.43
C23.7 Cutting stone	0.23	0.10	0.04	0.38
C24.10 Steel	0.00	0.01	0.00	0.02
C24.45 Manufacture of cobalt and cobalt alloys	0.03	0.06	0.02	0.10
C25.5 Powder metallurgy	0.01	0.04	0.02	0.07
C25.61 Surface treatment of metals (specialised)	0.38	0.15	0.06	0.59
C25.62 Machining (specialised)	0.25	1.02	0.41	1.68
C25.73 Manufacture of tools	0.71	1.32	0.52	2.55
C25.99 Manufacture of other fabricated metal products n.e.c.	0.12	0.43	0.20	0.75
C26.11 Production of electronic components	1.91	1.18	0.53	3.62
C26.51 Humidity indicator cards	0.00	0.00	0.00	0.00
C27.2 Batteries	0.09	0.04	0.01	0.14
C28.11 Engines and turbines	0.02	0.10	0.04	0.15
C29.10-30 Vehicles	0.36	0.15	0.06	0.57
C30.30 Air and spacecraft	0.02	0.10	0.04	0.16
C32.50 Medical and dental devices	0.30	4.92	2.29	7.52
E38.32 Metal recovery	0.01	0.15	0.06	0.22
Cross-sectoral - Biogas	0.00	-	-	0.00
Cross-sectoral - welding, etc.	1.72	0.57	0.27	2.56

Sector	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
Grand Total	**11.78**	**13.46**	**5.96**	**31.20**

Source: Study team.

Method 1 relies on WTP values for morbidity, with the results presented in Table 6-22 below. The total net benefits calculated on the basis of Method 1 are depicted in Figure 6-5. The workforce turnover is 5% per year and a static discount rate of 3% is used.

Table 6-22 METHOD 1: Benefits from avoided ill health (Policy options, relative to the baseline), € million over 40 years

Policy option (Inhalable)	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 / 0.5 µg Co/m^3	58	59	39	156
5 / 1.25 µg Co/m^3	42	59	34	135
10 / 2.5 µg Co/m^3	22	38	21	81
20 / 4.2 µg Co/m^3	12	13	6	31

Source: Study team.

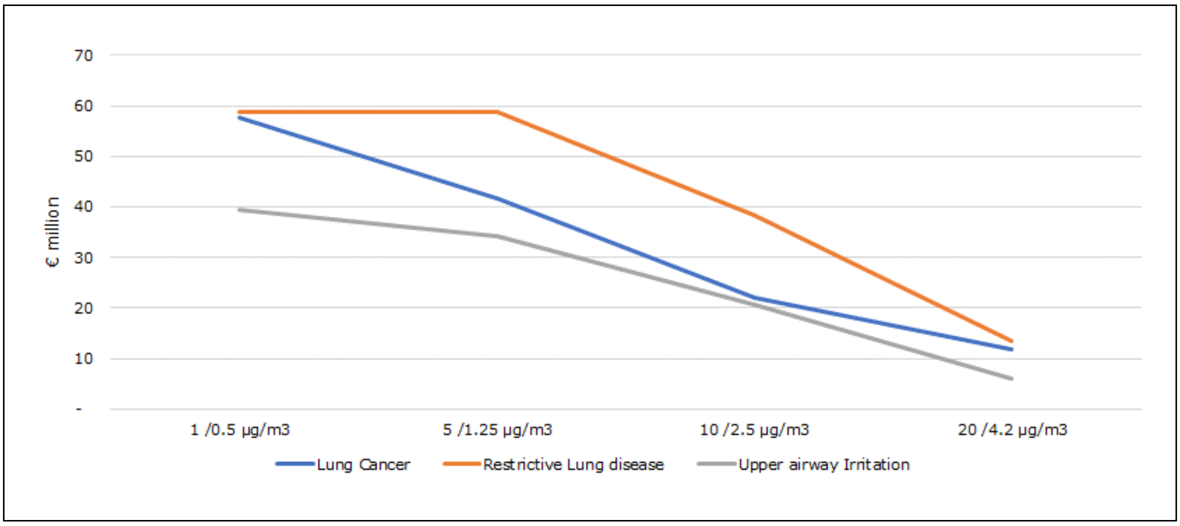


Figure 6-5 METHOD 1: Benefits from avoided ill health (Policy options, relative to the baseline)

Table 6-23 illustrates the benefits from avoided ill health relying on Method 2.

Table 6-23 METHOD 2: Benefits from avoided ill health (Policy options, relative to the baseline), € million over 40 years

Policy option (Inhalable)	Lung cancer	Restrictive lung disease	Upper airway irritation	Total
1 / 0.5 µg Co/m^3	30	65	50	145
5 / 1.25 µg Co/m^3	22	65	43	130
10 / 2.5 µg Co/m^3	11	42	26	80
20 / 4.2 µg Co/m^3	6	15	8	29

The total benefits from avoided ill health are shown below by who receives the benefits.

Table 6-24 Overview of benefits (total for all provisions), € million over 40 years (without transition measures)

Description	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Avoided costs for workers & families M1	146	126	75	29
Avoided costs for workers & families M2	135	121	74	27
Avoided costs for employers	2	2	1	0
Avoided costs for public administrations	8	7	4	1
Totals (based on M1)	**156**	**135**	**81**	**31**
Totals (based on M2)	**145**	**130**	**80**	**29**

Source: Study team.
Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

6.6.2 Other benefits

The assessment has identified that there might be some additional benefits. For companies, one benefits are related to improved public image from lower worker exposure to hazardous substances. This benefit cannot be quantified. For companies, there is also a possible benefit from a more level playing fields across EU. Finally, there could be a potential cost saving from companies that have multiple production sites across different Member States. Having to comply with a common OEL might save costs due to more standardisation and streamlining across the companies. These other benefits cannot be quantified and overall, based on the information from the industry stakeholder consultation, they are assessed to be minor compared to the health benefits.

6.6.3 Total benefits

Aggregated benefits of the policy options are summarised in Table 6-25. No other than the health and safety benefits are included, and other benefits are assessed to be of minor importance, see above on other benefits.

The benefits of the alternative OELs vary from around 30 € million for the policy option of 20 / 4.2 µg Co/m³ up around 150 € million for the policy option of 1 / 0.5 µg Co/m³. The majority of the benefits are the avoided costs for workers and their families.

Table 6-25 Overview of aggregated benefits (total for all provisions), € million over 40 years (without transition measures)

Description		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³	Comments
Health and safety	Avoided costs for workers & families M1	146	126	75	29	
	Avoided costs for workers & families M2	135	121	74	27	
	Avoided costs for employers	2	2	1	0	
	Avoided costs for public administrations	8	7	4	1	
Other benefits	Avoided costs for workers & families					No other benefits identified

Description		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³	Comments
	Avoided costs/benefits for employers	Improved public image, more level playing fields, potential cost saving for companies with muliple sites across EU				
	Avoided costs for public administrations	0.6	0.6	0.6	0.6	MSs with no OELs avoid costs of introducing national OEL
Total		**145 - 156**	**130 - 135**	**80-81**	**29-32**	

Source: Study team.
Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

7 COSTS OF THE MEASURES UNDER CONSIDERATION

This chapter comprises the following sections:

- Section 7.1: The cost framework
- Section 7.2: Direct adjustment costs for companies
- Section 7.3: Indirect costs for companies
- Section 7.4: Costs for public administrations
- Section 7.5: Impact of transitional periods on costs
- Section 7.6: Summary of the costs of the measures

7.1 The cost framework

The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are presented Table 7-1 below.

Table 7-1 Impact of costs on different stakeholders

Type of cost		Consumers	Workers	Business	Public administrations
Direct costs					
Direct compliance costs	Adjustment costs			✓	
	Administrative costs			✓	
	Charges				
Enforcement costs	Transposition				✓
	Information & monitoring			✓	✓
	Inspections and sanctions			✓	✓
	Complaint handling			✓	✓
	Adjudication/litigation			✓	✓
Hassle costs				✓	✓
Indirect costs					
Indirect compliance costs		✓		✓	
Other indirect costs	Offsetting/substitution effects	✓		✓	
	Transaction costs	✓		✓	
	Opportunity costs	✓		✓	
	Reduced competition	✓		✓	
	Reduced market access	✓		✓	
	Reduced investment/innovation	✓		✓	

7.2 Direct compliance costs to companies

The following sections present the compliance costs. First, the adjustment costs are described (section 7.2.1 to 7.2.11) followed by the monitoring costs (section 7.2.12) and the administrative costs (section 7.2.13).

7.2.1 Introduction

Adjustment costs are defined as the additional costs of complying with a limit value such as the costs incurred by companies in bringing down their exposure to levels below the limit value. This depends on the number of companies above the limit value and the cost for each company of reducing the exposure concentration to a level below the limit value. The costs for each company depend on the size of the relevant activities such as the number of machines and number of workers, and the gap between the actual exposure and the limit value, as well as the type of risk management measures required to bridge the gap.

A cost model developed for the previous OELs studies was used to estimate the adjustment costs of complying with the different limit value options. In summary, the characteristics of the relevant sectors, the RMMs in place, the sizes of the companies, and the required reduction in exposure, are used to propose suitable RMMs for each company. The model subsequently selects the cheapest of the suitable options. The results are summed up across all companies and sectors. A detailed description of the model is provided in the Methodological Note.

For this study of cobalt and inorganic cobalt compounds, the model is run separately for:

- the OELs policy options and exposure concentrations for the inhalable fraction, and
- the OELs policy options and exposure concentrations for the respirable fraction.

For the estimation of the total adjustment costs of compliance with the policy options, for each policy option and sector, a new model has collected the highest value of the two values calculated for the respirable and the inhalable option, respectively and sum up all the highest values. In this way double counting is prevented, and the total adjustment costs reflect that for some sectors the OEL for the inhalable fraction is most challenging to comply with whereas for other sections the respirable may be most challenging. It is in the sector specific tables for the adjustment costs indicated whether the OEL for the inhalable or respirable have been the determining for the adjustment costs.

7.2.2 Summary of the key features of the adjustment cost model

The cost model is described in the Methodological Note accompanying this report. The cost model takes several inputs and calculates the predicted costs incurred for a range of policy options. There are eleven types of inputs:

- Limit value options, see Table 3-1;
- Number of small, medium and large enterprises at each of the current exposure concentrations for each sector, see section 7.2.3;
- Estimated breakdown of primary risk management measures (RMM) used by enterprises for each sector, see section 7.2.4;
- Characteristics of cobalt and inorganic cobalt compounds and type of work, see section 7.2.7;

- Effectiveness of RMMs, see the Methodological Note;
- Cost of RMMs, see the Methodological Note;
- Discount rates, see the Methodological Note;
- Level of compliance with the policy option, see the Methodological Note;
- Discontinuation costs per sector, see section 7.2.7;
- Estimated average number of exposed workers per company, see section 7.2.5; and
- Estimated average number of workstations using cobalt and cobalt compounds in small, medium and large enterprises, see section 7.2.6.

The output is the cost of implementing the OELs split by:

- Sector;
- Company size: small, medium and large; and
- Capital expenditure (one-off) and operating expenditure (recurrent).

7.2.3 Number of enterprises at current exposure levels

The key input parameters for both the cost and benefit estimation models developed for this study are the distribution of the actual exposure levels across enterprises or workers, respectively. Whilst the distribution function for the benefit model focuses on the distribution of the workforce over different exposure concentrations, the key parameter for the cost function is the distribution of companies across different exposure levels. Although the ideal parameter would be the number of same exposure groups (SEGs), factory lines or facilities/sites operated by the different companies, such data are not available for most applications of cobalt and inorganic cobalt compounds and the number of companies together with their distribution across the different size bands is taken as a proxy in the cost model.

It is not taken into account in the determination of the exposure concentration distributions that some Member States have already implemented OELs at different levels as this is reflected in the reported exposure concentrations which are considered to represent and EU average. Consequently, the cost of adjustment costs already takes into account that some companies would not need any adjustment costs at the OEL levels of some of the policy options. The monitoring costs model, in contrary takes into account that some companies already have to comply with an OEL at a certain level.

The exposure data for cobalt and inorganic cobalt compounds were collected through questionnaires, CSRs, data from the Cobalt REACH Consortium and the literature. The exposure data was analysed to provide exposure concentration distributions on which basis percentile values can be estimated.

The cost model is based on three sizes classes of enterprises: small, medium and large.

To obtain a cost estimate for each sector, the numbers of small, medium and large companies affected by cobalt and inorganic cobalt compounds at different exposure levels are entered into the model for each policy option. These numbers are based upon the estimated numbers for each sector and size class from section 3.10. The numbers of companies allocated to each exposure level for the inhalable fraction is shown in Table 7-2.

The cost model has been run independently for the inhalable and respirable fraction and for each sector, and the highest value is selected in order to calculate the overall costs. Please note that the number of companies by exposure level is estimated based on the total number of companies and the percentage distribution by exposure levels. It means that number of companies are not estimated as an integer. The table shows rounded values – meaning that is shows numbers as integers. Then, for some sectors where the number of companies are small (typically for large companies) the result value is less than one company and here the table display the number with one decimal. It means that the sum of the displayed number of small, medium and large companies might not add up to the displayed total. Overall, the calculation of the number of companies can be understood as only a part of a company being affected. It is done for the estimation purposes as the cost model can work with number of companies not being an integer.

The table shows that the majority of the companies are in the lower exposure levels. There are few companies above 20 µg Co/m³, but relatively many above the lowest policy option of 1 µg Co/m³.

Table 7-2 Number of enterprises with workers exposed to cobalt and inorganic cobalt compounds at current exposure levels by size of enterprise by sector. The bold numbers are total number of enterprises with exposed workers for each sector.

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
C10.91 Manufacture, feeds	**264**	**30**	**6**	**300**
0.15	132	15	3	150
0.25	66	8	2	75
0.55	40	5	1	45
0.95	13	2	0.3	15
1.75	13	2	0.3	15
C19.20 Petrochemical, catalyst	**0**	**41**	**41**	**82**
2.20	0	21	21	41
3.15	0	10	10	21
5.70	0	6	6	12
8.78	0	2	2	4
14.10	0	2	2	4
C20.12 Manufacture of dyes and pigments	**0**	**4**	**11**	**15**
3.20	0	2	6	8
5.27	0	1	3	4
11.48	0	1	2	2
20.05	0	0	0.6	1
37.39	0	0	0.6	1

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
C20.13-20.14 Manufacture of basic chemicals	**12**	**11**	**7**	**30**
1.05	6	6	3	15
1.78	3	3	2	8
4.05	2	2	1	5
7.30	1	1	0.3	2
14.07	1	1	0.3	2
C20.30 Manufacture of paints and inks	**6**	**3**	**1**	**10**
1.25	3	2	1	5
2.48	2	1	0	3
6.75	1	0	0	2
13.70	0	0	0.1	1
30.48	0	0	0.1	1
C20.59 Catalysts	**0**	**7**	**6**	**13**
0.05	0	0	0	7
0.13	0	2	2	3
0.40	0	1	1	2
0.80	0	0	0.3	1
1.67	0	0	0.3	1
C20.59 Formulation other chemi-cals	**14**	**11**	**11**	**35**
0.75	7	5	5	18
1.53	4	3	3	9
4.20	2	2	2	5
8.55	1	1	0.5	2
19.04	1	1	0.5	2
C21.20 Pharmaceuticals	**0**	**0**	**8**	**8**
0.04	0	0	4	4
0.09	0	0	2	2
0.31	0	0	1	1
0.73	0	0	0.4	0
1.90	0	0	0.4	0
C22.11; C22.19 Rubber adhesion	**0**	**0**	**3**	**3**
0.20	0	0	2	2

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
0.50	0	0	1	1
1.63	0	0	0	0
3.63	0	0	0.2	0
8.95	0	0	0.2	0
C23.1 Glass	**28**	**15**	**8**	**50**
1.45	14	8	4	25
2.38	7	4	2	13
5.05	4	2	1	8
8.63	1	1	0.4	3
15.64	1	1	0.4	3
C23.4 Ceramics	**350**	**105**	**45**	**500**
3.50	175	53	23	250
5.62	88	26	11	125
11.85	53	16	7	75
20.25	18	5	2.3	25
36.76	18	5	2.3	25
C23.7 Cutting stone	**970**	**20**	**10**	**1,000**
0.90	485	10	5	500
1.68	243	5	3	250
4.17	146	3	2	150
7.93	49	1	0.5	50
16.27	49	1	0.5	50
C24.10 Steel	**2**	**4**	**1**	**7**
2.70	1	2	1	4
4.37	1	1	0	2
9.30	0	1	0	1
15.95	0	0	0.1	0
29.08	0	0	0.1	0
C24.45 Manufacture of cobalt and cobalt alloys	**0**	**0**	**6**	**6**
2.60	0	0	3	3
4.27	0	0	2	2
9.20	0	0	1	1

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
15.93	0	0	0.3	0
29.38	0	0	0.3	0
C25.5 Powder metallurgy	**11**	**17**	**3**	**30**
3.00	5	8	2	15
4.37	3	4	1	8
8.00	2	2	0	5
12.38	1	1	0.2	2
20.10	1	1	0.2	2
C25.61 Surface treatment of metals (specialised)	**329**	**94**	**47**	**470**
1.70	165	47	24	235
2.68	82	24	12	118
5.47	49	14	7	71
9.18	16	5	2.4	24
16.25	16	5	2.4	24
C25.62 Machining (specialised)	**4,800**	**900**	**300**	**6,000**
4.85	2,400	450	150	3,000
6.35	1,200	225	75	1,500
10.00	720	135	45	900
13.95	240	45	15.0	300
20.14	240	45	15.0	300
C25.73 Manufacture of tools	**2,024**	**230**	**46**	**2,300**
3.00	1,012	115	23	1,150
4.37	506	58	12	575
8.00	304	35	7	345
12.38	101	12	2.3	115
20.10	101	12	2.3	115
C25.99 Manufacture of other fabricated metal products n.e.c.	**113**	**30**	**8**	**150**
4.00	56	15	4	75
6.37	28	8	2	38
13.25	17	5	1	23
22.40	6	2	0.4	8
40.24	6	2	0.4	8

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
C26.1 Production of electronic components	**188**	**50**	**13**	**250**
4.20	94	25	6	125
6.60	47	13	3	63
13.45	28	8	2	38
22.45	9	3	0.6	13
39.69	9	3	0.6	13
C26.51 Humidity indicator cards	**3**	**1**	**1**	**5**
0.05	2	1	1	3
0.13	1	0	0	1
0.33	0.5	0.2	0.2	0.8
0.58	0	0	0.1	0
1.11	0	0	0.1	0
C27.2 Batteries	**0**	**8**	**8**	**15**
0.40	0	4	4	8
0.80	0	2	2	4
2.08	0	1	1	2
4.02	0	0	0.4	1
8.49	0	0	0.4	1
C28.11 Engines and turbines	**105**	**17**	**8**	**130**
4.70	53	8	4	65
6.22	26	4	2	33
9.95	16	3	1	20
14.03	5	1	0.4	7
20.49	5	1	0.4	7
C29.10-30 Vehicles	**108**	**13**	**9**	**130**
1.65	54	7	5	65
2.63	27	3	2	33
5.40	16	2	1	20
9.05	5	1	0.5	7
16.04	5	1	0.5	7
C30.30 Air and spacecraft	**113**	**10**	**7**	**130**
4.70	57	5	3	65

Sector and exposure levels µg Co/m³, inhalable fraction	Small	Medium	Large	Total
6.22	28	3	2	33
9.95	17	2	1	20
14.03	6	1	0.3	7
20.49	6	1	0.3	7
C32.50 Medical and dental devices	**300**	**150**	**50**	**500**
7.80	150	75	25	250
11.13	75	38	13	125
19.83	45	23	8	75
30.20	15	8	2.5	25
48.09	15	8	2.5	25
E38.21 Biogas	**2,697**	**279**	**124**	**2,697**
0.01	1349	140	62	1550
0.02	674	70	31	775
0.03	405	42	19	465
0.05	135	14	6	155
0.09	135	14	6	155
E38.32 Metal recovery	**0**	**0**	**5**	**5**
2.60	0	0	3	3
3.63	0	0	1	1
6.30	0	0	1	1
9.45	0	0	0.3	0
14.76	0	0	0.3	0
Cross-sectoral - Welding	**40**	**8**	**3**	**50**
8.00	20	4	1	25
12.38	10	2	1	13
6.30	6	1	0.4	8
40.67	2	0.4	0.1	2.5
69.86	2	0.4	0.1	2.5
Total	**12,476**	**2,056**	**792**	**15,324**

Source: Study team.
Note: Totals may not be the sum of all sectors due to rounding in the presentation - for the calculations numbers are not rounded.

7.2.4 Estimated breakdown of RMMs used by enterprises

The model requires a profile of the primary risk management measure used by enterprises in each sector. This is based upon the information on the current use of RMM gather through the industry survey and stakeholder consultation (see section 7.2.10.1), data from the CSRs described for each sector in section 3.3 together with detailed examination of the survey data and information from interviews and site visits. Most companies use several RMMs, but the distribution reflects the primary RMMs used for various work processes with risk of exposure.

Table 7-3 Percentage breakdown of primary RMMs currently used by enterprises by sector

Sector/		Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
C10.91	Manufacture, feeds	10%	30%	30%	0%	0%	0%	10%	10%	0%	10%	0%
C19.20	Petrochemical, catalyst	0%	0%	30%	0%	0%	0%	20%	40%	0%	10%	0%
C20.12	Manufacture of dyes and pigments	10%	30%	40%	0%	0%	0%	0%	10%	0%	10%	0%
C20.13 -20.14	Manufacture of basic chemicals	10%	30%	30%	0%	0%	0%	20%	0%	0%	10%	0%
C20.30	Manufacture of paints and inks	10%	20%	30%	0%	0%	0%	30%	0%	0%	10%	0%
C20.59, 1	Catalysts	10%	40%	35%	0%	0%	0%	5%	0%	0%	10%	0%
C20.59, 2	Formulation	10%	40%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C21.20	Pharmaceuticals	40%	20%	20%	0%	0%	0%	10%	0%	0%	10%	0%
C22.11	Production of tyres	10%	30%	30%	0%	0%	0%	30%	0%	0%	0%	0%
C23.1	Glass	10%	40%	20%	0%	0%	0%	20%	0%	0%	10%	0%
C23.4	Ceramics	0%	40%	35%	0%	0%	0%	15%	0%	0%	10%	0%
C23.7	Cutting stone	0%	20%	20%	0%	0%	0%	20%	10%	0%	10%	20%
C24.10	Steel	10%	20%	20%	0%	0%	0%	20%	20%	0%	10%	0%
C24.45	Manufacture of cobalt and cobalt alloys	10%	30%	25%	0%	0%	0%	15%	0%	0%	20%	0%
C25.5	Powder metallurgy	10%	25%	25%	0%	0%	0%	20%	10%	0%	10%	0%
C25.61	Surface treatment of metals	10%	30%	20%	0%	0%	0%	10%	30%	0%	0%	0%
C25.62	Machining	0%	0%	70%	0%	0%	0%	10%	0%	0%	0%	20%
C25.73	Manufacture of tools	30%	20%	20%	0%	0%	0%	10%	20%	0%	0%	0%

Sector/		Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Breathing apparatus	HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
C25.99	Manufacture of other fabricated metal products n.e.c.	10%	30%	20%	0%	0%	0%	10%	30%	0%	0%	0%
C26.1	Production of electronic components ad boards	10%	30%	10%	0%	0%	0%	30%	10%	0%	10%	0%
C26.51	Humidity indicator cards	10%	30%	20%	0%	0%	0%	0%	20%	0%	20%	0%
C27.2	Batteries	10%	45%	20%	0%	0%	0%	15%	0%	0%	10%	0%
C28.11	Engines and turbines	20%	30%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C29.10 -30	Automotive	20%	30%	25%	0%	0%	0%	15%	0%	0%	10%	0%
C30.30	Air and spacecraft	10%	30%	25%	0%	0%	0%	15%	20%	0%	0%	0%
C32.50	Medical and dental devices	0%	20%	25%	0%	0%	0%	15%	20%	0%	20%	0%
E38.21	Biogas											
E38.32	Metal recovery	10%	20%	25%	0%	0%	0%	15%	20%	0%	10%	0%
	Welding	0%	20%	25%	0%	0%	0%	45%	0%	0%	10%	0%

Source: Study team

7.2.5 Estimated average number of exposed workers per enterprise

The model requires an estimate of the average number of exposed workers per enterprise by size of enterprise in each sector. These estimates made by the study team are based upon the information in Table 3-85 and data in Table 3-96 split by size of enterprise according to Eurostat data about employees and the size of enterprise for which they work. It has for the estimates been assumed as a default that the percentage exposed is the same for all size classes.

For some sectors, the distribution of exposed workers may, however, be different as the small companies tend to be specialised for the specific activity involving cobalt (e.g. subcontractors to large companies in the transportation sector or a biogas reactor in a large industry), whereas in larger companies these activities are undertaken in special departments only. In order to take this into account for some sectors, the split between number of exposed workers has been adjusted by the study team. This concerns the following sectors/activities: Machining, steel, engines and turbines, automotive, air and spacecraft, medical and dental devices, and biogas. By the adjustment, the average number of exposed workers are closer to the average assumed in the costs of various RMMs by company size.

Table 7-4 Estimated average number of exposed workers per enterprise by size of enterprise by sector

Sector		Number of exposed workers per company		
		Small	Medium	Large
C10.91	Manufacture, feeds	1.5	21	133
C19.20	Petrochemical, catalyst		1	14
C20.12	Manufacture of dyes and pigments		19	202
C20.13	Manufacture of basic inorganic chemicals	2.9	35	375
C20.14	Manufacture of basic organic chemicals	1.8	21	126
C20.30	Manufacture of paints and inks		21	127
C20.59	Formulation of other chemical products	2.1	23	136
C21.20	Pharmaceuticals			119
C22.11	Production of tyres			100
C23.1	Glass	1.0	11	95
C23.4	Ceramics	1.4	14	123
C23.7	Cutting stone	1.4	15	131
C24.10	Steel	1.4	8	66
C24.45	Manufacture of cobalt and cobalt alloys			110
C25.5	Powder metallurgy	2.4	25	156
C25.61	Surface treatment of metals	1.2	12	78
C25.62	Machining	3	7	13
C25.73	Manufacture of tools	2.6	48	298
C25.99	Manufacture of other fabricated metal products n.e.c.	1.7	13	72
C26.1	Production of electronic components and boards	1.5	16	154
C26.51	Humidity indicator cards	0.8	9	88
C27.2	Batteries		32	228
C28.11	Engines and turbines	3.0	50	132
C29.1- 30	Automotive	3.0	28	496
C30.30	Air and spacecraft	3.5	33	226

Sector		Number of exposed workers per company		
		Small	Medium	Large
C32.50	Medical and dental devices	3.0	18	28
E38.32	Metal recovery		18	122
	Biogas	1.5	4	4
	Welding	1.2	21	139
	Average (weighted for entire dataset)	2.6	16	80

Source: Study team

7.2.6 Estimated average number of workstations per enterprise

The model requires an estimate of the average number of workstations per enterprise by size of enterprise in each sector. These estimates made by the study team are based upon the information in Table 7-4 and the assumption that there will be five exposed employees per workstation; the numbers of workstations are rounded to the nearest integer and all values of 0.5 or lower are set to 0.5.

Table 7-5 Estimated average number of workstations per enterprise by size of enterprise by sector

Sector		Number of workstations per enterprises		
		Small	Medium	Large
C10.91	Manufacture, feeds	0.8	11	67
C19.20	Petrochemical, catalyst		1	7
C20.12	Manufacture of dyes and pigments		10	101
C20.13-20.14	Manufacture of basic chemicals	1.5	18	188
C20.30	Manufacture of paints and inks	0.9	11	63
C20.59	Catalysts		11	64
C20.59	Formulation of other chemical products	1.1	12	68
C21.20	Pharmaceuticals			60
C22.11	Production of tyres			50
C23.1	Glass	0.5	6	48
C23.4	Ceramics	0.7	7	62
C23.7	Cutting stone	0.7	8	66
C24.10	Steel	0.7	4	33
C24.45	Manufacture of cobalt and cobalt alloys			55
C25.5	Powder metallurgy	1.2	13	78
C25.61	Surface treatment of metals	0.6	6	39
C25.62	Machining	0.5	4	22
C25.73	Manufacture of tools	1.3	24	149
C25.99	Manufacture of other fabricated metal products n.e.c.	0.9	7	36
C26.1	Production of electronic components and boards	0.8	8	77
C26.51	Humidity indicator cards	0.5	5	44
C27.2	Batteries		16	114
C28.11	Engines and turbines	1.5	25	66
C29.30	Automotive, parts	1.5	14	248
C30.30	Air and spacecraft	1.8	17	113
C32.50	Medical and dental devices	1.5	9	14
E38.32	Metal recovery		9	61

Sector		Number of workstations per enterprises		
		Small	Medium	Large
	Biogas	0.8	2	2
	Welding	0.6	11	70

Source: Study team. Empty cell indicates no exposed workers in the sector, size class.

7.2.7 Discontinuation costs

A part of the cost of compliance is the cost of a company discontinuing if either the model can find no risk management measures that can comply with the policy option, or the costs of the risk management measures is higher than the cost of discontinuing. The discontinuation cost is taken as the loss of profit taken over 20 years and the average profit is assumed to be 10% of turnover of an average company in sector[54]. The average turnover of small, medium and large companies in the key sectors is shown in Table 7-6.

It is assumed that if the company has to discontinue activities using cobalt and cobalt compounds that this would mean the closure of a small or medium sized company, and the closure of a division representing 10% of a large company. The lost profit is therefore assumed to be 10% of annual turnover for 20 years for small and medium sized companies, discounted. For large companies, it is assumed to be 1% of annual turnover for 20 years, discounted.

Companies enter and exit the market continually and ideally discontinuations would be compared with the general level of companies leaving. The study team has not been able to identify any data on the typical number of firms leaving the market under normal circumstances. Whilst it would be possible to identify the number of firms in specific sectors and identify trends over time, these can be influenced by a multitude of different factors and represent net figures (they also include firms entering the market).

Further detail about discontinuation costs and the normal rate of insolvencies is described in the Methodological Note.

Table 7-6 Average turnover by size of enterprise by sector in € million

Sector		Average turnover in € millions		
		Small	Medium	Large
C10.91	Manufacture, feeds	4.1	74.6	500.1
C19.20	Petrochemical, catalyst	2.9	73.5	4,043.0
C20.12	Manufacture of dyes and pigments	1.2	30.7	381.4
C20.13-20.14	Manufacture of basic chemicals	4.6	114.5	1,434.9
C20.30	Manufacture of paints and inks	1.7	31.9	209.8
C20.59	Catalysts	2.9	53.5	367.8
C20.59	Formulation of other chemical products	2.9	53.5	367.8
C21.20	Pharmaceuticals	1.6	46.7	362.4
C22.11	Production of tyres	1.9	41.0	699.2
C23.1	Glass	0.2	7.3	119.9
C23.4	Ceramics	0.1	9.9	86.4

[54] 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.' The study team makes the assumptions of profits being an average of 10% of turnover and that the losses are taken over 20 years.

Sector		Average turnover in € millions		
		Small	Medium	Large
C23.7	Cutting stone	0.3	14.2	97.4
C24.10	Steel	1.0	54.8	873.8
C24.45	Manufacture of cobalt and cobalt alloys	0.6	20.3	142.2
C25.5	Powder metallurgy	0.8	18.3	145.6
C25.61	Surface treatment of metals	0.7	18.7	123.1
C25.62	Machining	0.3	9.5	61.7
C25.73	Manufacture of tools	0.5	22.2	217.6
C25.99	Manufacture of other fabricated metal products n.e.c.	0.3	9.2	63.7
C26.1	Production of electronic components and boards	1.0	23.2	409.6
C26.51	Humidity indicator cards	1.0	20.0	241.5
C27.2	Batteries	1.2	26.2	384.0
C28.11	Engines and turbines	4.0	60.4	883.3
C29.30	Automotive, parts	1.0	27.0	5,530.2
C30.30	Air and spacecraft	1.0	14.2	1,143.2
C32.50	Medical and dental devices	0.3	15.0	255.7
E38.21	Biogas			
E38.32	Metal recovery	1.3	36.7	276.6
	Welding *	0.6	32.2	551.6

*Source: Eurostat (2023). For sectors in this study covering where more two NACE codes, averages for the NACE codes are used. * Turnover for construction used for welding*

7.2.8 Costs of changing to alternatives

As described in section 3.11, alternatives are available for various applications, but the quality of alternatives are typically inferior to the use of cobalt for most uses. As cobalt is a relatively expensive metal, it is mainly used for applications where it adds quality to the materials.

The stakeholder survey has not included questions regarding alternatives and to what extent respondents would expect that substitution would be a realistic response to the introduction of an OEL. The eftec (2023) survey for the Cobalt Institute has included this question. Substitution has been indicated by respondents as a possible response for three use areas: Metallurgical alloys, diamond tools and recycling. At an OEL for the inhalable fraction of 20 µg/m^3, of those sites not in compliance, 29% within the use category metallurgical alloys and 25% within the use category cemented carbide/diamond tools (in practice diamond tools) expect that substitution would be the most likely response. Furthermore, 14% of sites involved recycling of materials indicates substitution as the most likely option; however, the meaning may in this case be that the sites would cease recycling of cobalt-containing materials and do other activities instead. This will not here be considered substitution. At an OEL for the inhalable fraction of 10 µg/m^3, of those not in compliance, 14% in the use category metallurgical alloys and 19% in the use category cemented carbide/diamond tools expect that substitution would be the most likely options. At an OEL for the inhalable fraction of 1 µg/m^3 the corresponding percentages would be 11% and 26%, respectively. The lower percentages at 1 µg/m^3 is a consequence of a higher percentage of companies expected to discontinue. For the metallurgical alloys, the current study has divided the application into a number of end-use sectors and the available information does not allow to determine if substitution would be more feasible in some sectors than in others.

The cost model calculates that a number of companies within the ceramics sector would discontinue production at the lower OELs. Alternatives exists but not with exactly the same colours and it is assumed that substitution would not be the preferred option at OELs where the major part of the companies could continue to use the pigments within the scope and products with the these colours would be available at the market.

The percentages represent those sites which would not expect to be in compliance at the various OEL levels. For the OELs for the inhalable fraction of 20 and 10 µg/m^3 more than half of the sites within the two use categories would according to eftec (2023) be in compliance and could continue manufacture/use of the cobalt substance without any additional costs (i.e. the percentage of sites actually substituting the substances would be about 10%). As alternatives are typically technically inferior it will here be assumed that customers would still request cobalt-containing materials and articles, and discontinuation of the production would be more likely than substitution because there is no market for the alternatives. An exception would be diamond tools where the inferior quality of the cobalt-free diamond tools for less demanding applications is counterbalanced by the lower price. It has been indicated by a market actor that it is likely that cobalt-free diamond tools will be used as substitutes for cobalt-containing tools except for the most demanding applications. In the current study, if substitution is not taken into account, the sector 'manufacture of tools' represents about half of the companies that have to discontinue production. It is considered that these companies are mainly producers of diamond tools and that some of the companies will move to production of cobalt-free tools. It may also be expected that some of the users of the tools would request cobalt-free tools in order to reduce the cobalt exposure by the use of the tools.

Based on above information it will be assumed that half of the companies within the production of tools sector which would otherwise discontinue will change to production of cobalt-free alternatives. Eftec (2023) estimated an average substitution cost for all companies (both SMEs and large companies) of € 0.2 million per company over 40 years.

At 1 µg/m^3, the situation would differ for some of the sectors as most of the companies would have additional costs of compliance with the OEL and the price of the cobalt-containing products would increase. Without taking substitution into account, the cost model calculates that about 1,100 companies (or departments in larger companies) would discontinue. In this situation, more of the companies may instead substitute the cobalt-containing materials/substances in case the market changes due to marked increases in the cobalt-containing materials and articles. More than half of companies expected to discontinue are within the manufacture of tools sector and are assumed to mainly represent production of diamond tools. At this OEL level it will be expected that the majority of the producers of diamond tools will change to cobalt-free tools; partly in response to a demand for cobalt-free products driven by the aim at reducing the exposure to cobalt by the use of the tools. Replacement of cobalt in diamond tools will also impact the exposure to cobalt during the service life of hardmetal tools as diamond tools are used in the sharpening of the hardmetal tools and responsible for a part of the exposure to cobalt by the sharpening of the tools. Cobalt-free alternatives may also be an option for batteries, but the model does not estimate that any of the battery producers would discontinue and no data indicating the costs of establishing production facilities for alternative batteries have been available.

To what extent companies will discontinue or substitute the cobalt within other sectors and applications is not known and substitution will only be considered for diamond tools. This may lead to an overestimation of the costs as the costs of substitution (for those applications where substitution is possible) in general is expected to be lower than discontinuation.

7.2.9 Characteristics of cobalt and inorganic cobalt compounds and type of work

The use of cobalt and inorganic cobalt compounds in each sector identified in section 3.2.3 has certain characteristics and certain types of work during which exposure occurs. This information helps to determine the type of risk management measures that are suitable. These characteristics are split into three groups:

- Duration of exposure over one day;
- Form of cobalt and inorganic cobalt compounds to which workers are exposed; and
- Extent to which cobalt and inorganic cobalt compounds to disperse or spread when emitted.

The amount of exposure is split into works where the worker is exposed to cobalt and inorganic cobalt compounds 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 cobalt and inorganic cobalt compounds. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use respiratory protective equipment (RPE) such as masks with filters or breathing apparatus.

It should be noted that the use of powered air-purifying respirators (with positive pressure) in recent years in many companies has taken over from conventional half and full facemasks (negative pressure respirators) and disposable respirators (FFP masks). The powered air-purifying respirators have a higher assigned protection factor and are more convenient to use and it is in many Member States (if not all) accepted that these respirators can be worn for a full shift. All companies visited as part of the stakeholder consultation used these respirators for maintenance work and for a number of work activities where exposure may be elevated for a shorter time such as loading of closed equipment, taking samples for quality control, opening of barrels, etc. For many operations, the equipment is worn independently of the exposure concentrations under normal conditions to avoid elevated exposure in case of accidental leakages. The current version of the cost model does not include an upgrade to powered air-purifying respirators. This might lead to an overestimation of the costs. As these masks provide a high protection factor, they would be selected instead of more expensive RMMs. It is not likely to be a major overestimation.

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 recommended for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: Dust which also includes fibres; and gas which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM, and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine/equipment and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area, and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and cause exposure to workers beyond the area where the substance is being used. The risk of diffuse spread is also dependent on the size distribution of the articles with a higher tendency of the respirable fraction to spread diffusive compared to the inhalable. The risk of spread of diffusive dusts is therefore considered to some extent to reflect the respirable to inhalable ratio with the highest risk for welding and other high-temperature processes.

Furthermore, it is considered that dust generated by open processes such as open cutting in stone will have a high risk of spread of the dust over longer distances.

In Table 7-7 below, the percentage split for each characteristic used in the analysis is given for each sector. These values are built into the cost model.

Table 7-7 Cobalt and inorganic cobalt compounds: Amount of exposure, form of substances and extent of spread by sector

Sector		Amount		Form		Spread		
		<1h	>1h	Dust	Gas	Local	Dif-fuse	Periph-eral
C10.91	Manufacture, feeds	20%	80%	100%	0%	80%	20%	0%
C19.20	Petrochemical, catalyst	80%	20%	100%	0%	80%	20%	0%
C20.12	Manufacture of dyes and pigments	30%	70%	100%	0%	70%	30%	0%
C20.13 -20.14	Manufacture of basic chemicals	30%	70%	100%	0%	70%	30%	0%
C20.30	Manufacture of paints and inks	30%	70%	100%	0%	70%	30%	0%
C20.59	Catalysts	30%	70%	100%	0%	70%	30%	0%
C20.59	Formulation of other chemical products	30%	70%	100%	0%	80%	20%	0%
C21.20	Pharmaceuticals	20%	80%	100%	0%	80%	20%	0%
C22.11	Production of tyres	30%	70%	100%	0%	80%	20%	0%
C23.1	Glass	30%	70%	100%	0%	80%	20%	0%
C23.4	Ceramics	30%	70%	100%	0%	80%	20%	0%
C23.7	Cutting stone	10%	90%	100%	0%	50%	40%	10%
C24.10	Steel	30%	70%	100%	0%	80%	20%	0%
C24.45	Manufacture of cobalt and cobalt alloys	30%	70%	100%	0%	80%	20%	0%
C25.5	Powder metallurgy	30%	70%	100%	0%	80%	20%	0%
C25.61	Surface treatment of metals	20%	80%	100%	0%	80%	20%	0%
C25.62	Machining	50%	50%	100%	0%	80%	20%	0%
C25.73	Manufacture of tools	30%	70%	100%	0%	80%	20%	0%
C25.99	Manufacture of other fabricated metal prod-ucts n.e.c.	30%	70%	100%	0%	80%	20%	0%
C26.1	Production of electronic components and boards	20%	80%	100%	0%	80%	20%	0%
C26.51	Humidity indicator cards	20%	80%	100%	0%	70%	30%	0%
C27.2	Batteries	20%	80%	100%	0%	70%	30%	0%
C28.11	Engines and turbines	20%	80%	100%	0%	80%	20%	0%
C29.30	Automotive, parts	20%	80%	100%	0%	80%	20%	0%
C30.30	Air and spacecraft	20%	80%	100%	0%	80%	20%	0%
C32.50	Medical and dental de-vices	20%	80%	100%	0%	80%	20%	0%
E38.32	Metal recovery	30%	70%	100%	0%	60%	40%	0%
E38.21	Biogas	100%	10%	100%	0%	60%	40%	0%
	Welding *	80%	20%	50%	50%	80%	20%	0%

7.2.10 Survey and stakeholder consultation data on adjustment costs

7.2.10.1 Survey - RMMs needed to achieve compliance

The percentage of companies by sector currently using each RMM, and the RMM to which they would change if each of the policy options were implemented is for key RMMs summarised in Annex B.

In order to provide an overview, the data are summarised across the sectors below divided on three types of RMMs. The tables include more RMMs than the detailed overview by sector in Annex B.

The technical measures are summarised in the table below. The main RMM to be further installed, in particular at the lower policy options, is installation of full enclosure.

Table 7-8 Technical measures and 'no action'. Percentage breakdown of primary RMMs currently used by enterprises by sector and expected RMMs to be further implemented (or improved) by the four policy options. The numbers represent work processes included in responses.

Policy option (number of work processes = 163)	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	General dilution ventilation
Current situation	34% (56)	44% (72)	63% (102)	9% (15)	10% (16)
20 / 4.2 µg/m^3	26% (43)	15% (24)	10% (17)	4% (7)	2% (4)
10 / 2.5 µg/m^3	21% (34)	10% (17)	12% (19)	6% (9)	5% (8)
5 / 1.5 µg/m^3	20% (32)	15% (25)	11% (18)	4% (7)	1% (2)
1 / 0.5 µg/m^3	39% (64)	9% (14)	12% (19)	6% (10)	2% (4)

The table below illustrates the RPE currently used and indicated to be further used in order to comply with the policy options. For many work processes the respondents answer that more than one type is used so the results should not be interpreted in the way that all workers are wearing RPE, but RPE is used to some extent for more than 50% of the work processes. At the policy options of 20 / 4.2 µg/m^3 and 10 / 2.5 µg/m^3 further use of self-containing breathing is the most common as action which is well in accordance with the assumptions of the general cost model, that one of the RMMs applied is to step up in the use of RPE to RPE with higher protection factor. At the higher policy options further use of powered air-purifying respirators become a common action. The increase in the use of HEPA filter at the lowest policy option (1 / 0.5 µg/m^3) is somewhat contradictory with the general pattern but may explain that respondents expect that a larger part of the workforce at that policy option may need to wear RPE.

Table 7-9 Respiratory protective equipment. Percentage breakdown of RPE currently used by enterprises by sector and expected RMMs to be further implemented (or improved) by the four policy options. The numbers represent work processes included in responses.

Policy option (number of work processes = 163)	Self-cont. breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask
Current situation	5% (8)	37% (61)	26% (43)	46% (75)
20 / 4.2 µg/m^3	2% (3)	20% (33)	7% (11)	12% (19)
10 / 2.5 µg/m^3	2% (3)	15% (24)	4% (6)	10% (17)
5 / 1.5 µg/m^3	6% (10)	7% (12)	2% (4)	11% (18)
1 / 0.5 µg/m^3	10% (17)	11% (18)	18% (30)	4% (7)

Substitution and reduction of the use of the substances and organisational measures are summarised in the table below. By lower policy options the percentage that would substitute the substances or discontinue the processes using the substance increases and at the lowest policy option the respondents expect that 36% of the processes where the substance is currently used should discontinue.

Table 7-10 Substitution and organisational measures. Percentage breakdown of primary RMMs currently used by enterprises by sector and expected RMMs to be further implemented (or improved) by the four policy options. The numbers represent work processes included in responses.

Policy option (number of work processes = 163)	Substitution of substances	Reduce amount of substance	Discontinuation of process using the substance	Continuous monitoring	Formal/ external RPE cleaning and filter changing regime	Cleaning	Training and education
Current situation		26% (42)		9% (15)	63% (103)	99% (161)	98% (160)
20 / 4.2 µg/m³	2% (4)	1% (2)	1% (1)	14% (23)	18% (30)	23% (37)	31% (50)
10 / 2.5 µg/m³	5% (8)	4% (6)	8% (13)	10% (17)	14% (23)	21% (35)	29% (47)
5 / 1.5 µg/m³	14% (23)	6% (9)	19% (31)	11% (18)	10% (17)	28% (45)	31% (50)
1 / 0.5 µg/m³	23% (37)	9% (14)	36% (58)	17% (28)	18% (30)	28% (46)	34% (55)

The companies by sector indicating that no further RMMs would be needed for the four policy options are shown below. At 20 / 4.2 µg Co/m³ the reponsents indicates that no action is required for 43% of the work processes. This gradually decrease to 6% for the 1 / 0.5 µg Co/m³ policy option.

Table 7-11 Proportion of respondents that are already achieving the policy option (indicated by respondent 'no action needed'). Number in parentheses refers to number of processes included in the responses and not number of responders.

Sector (n)	1 / 0.5 µg Co/m³	5 / 2.5 µg Co/m³	10 / 1.25 µg Co/m³	20 / 4.2 µg Co/m³
C19.20 Petrochemical, catalyst				100% (1)
C20.12 Manufacture of dyes and pigments				83% (5)
C20.13 Manufacture of other inorganic basic chemicals			20% (4)	5% (1)
C20.14 Manufacture of other organic basic chemicals				25% (1)
C20.30 Manufacture of paints and inks		14% (1)	71% (5)	100% (7)
C20.59 Manufacture of other chemical products n.e.c. (24)		21% (5)	38% (9)	50% (12)
C23.1 Glass				100% (1)
C23.4 Ceramics			100% (15)	100% (15)
C24.10 Steel				75% (3)
C24.45 Manufacture of cobalt and cobalt alloys	25% (4)	19% (3)	25% (4)	50% (8)
C25.61 Surface treatment of metals	25% (1)	25% (1)	25% (1)	25% (1)
C25.73 Manufacture of tools		10% (4)	13% (5)	15% (6)
C27.2 Batteries	50% (5)	60% (6)	80% (8)	90% (9)

Sector (n)	1 / 0.5 µg Co/m³	5 / 2.5 µg Co/m³	10 / 1.25 µg Co/m³	20 / 4.2 µg Co/m³
Grand Total	**6% (10)**	**13% (21)**	**31% (51)**	**43% (70)**

Source: Stakeholder survey

7.2.10.2 Survey - Companies' estimated costs of compliance

In the consultation survey, respondents were asked to estimate the magnitude of both one-off investment and annual recurrent costs required to achieve the policy options.

Aggregated results for initial investment costs are displayed in Table 7-12 while estimates for the recurrent costs are presented in Table 7-13. The tables show summary results of all respondents and data for four sectors with more than three respondents.

Values in Table 7-12 represent number of companies by enterprise size and cost range, followed by the number of respondents in the last three columns to the right. The table summarises data for four sectors with more than three answers.

In total 38 companies responded with costs estimates. It should be noted that some respondents have not indicated costs at the lower policy options as they considered the options not to be technically feasible and no costs could consequently be estimated.

The costs indicated would be for companies which would not be in compliance at the various OELs levels.

For the large companies which represent the largest part of the answers, there is a tendency toward larger costs by lower policy options. For all large companies, more than half of the respondents indicated cost of initial investments at >€10 million at the 1 / 0.5 µg Co/m³ policy options while the majority of the small and medium-sized companies indicated costs in the €1-10 million range. For the sectors C25.73 Manufacture of tools and C24.45 Manufacture of cobalt and cobalt alloys, where a major part of the companies' activities involves use/handling cobalt, all large companies except one indicate initial costs at >€10 million for all three policy options while one indicates the €1 -10 million range for the 1 / 0.5 and 5 / 1.25 µg Co/m³ policy options.

Still 3 companies indicate costs at €10,000 - €100 range but none of these are from the four sectors. For the sector C23.4 Manufacture of other porcelain and ceramic products, all large companies indicate cost in the €1 -10 million range for 1 / 0.5 µg Co/m³ policy options and the €100,000 - €1 million range for the 5 / 1.25 µg Co/m³ policy options and no costs for the 10 / 2.5 µg Co/m³ policy options.

A similar pattern but with lower estimated costs is seen for the medium-sized companies.

The results for the recurrent costs in Table 7-13 show as similar rise in costs with each step down in policy options.

Table 7-12 Companies' anticipated cost range for RMM initial investment costs per site required to achieve policy options, by company size (values = number of respondents). All companies include also respondents also in sectors not indicated in the table.

Sector	< €10,000			€10,000 - €100,000			€100,000 - €1 million			€1 -10 million			> €10 million			Number of responses		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
All companies																		
1 / 0.5 µg Co/m^3		1		1		3		1	1	2	4	7		6	12	3	12	23
5 / 1.25 µg Co/m^3		1	1	1	1	1	1	4	8	1	1	4		3	9	3	10	23
10 / 2.5 µg Co/m^3	1	2	3					4	5	1	5	2		1	8	2	12	18
C20.59 Manufacture of other chemical products																		
1 / 0.5 µg Co/m^3											1	1		2			3	1
5 / 1.25 µg Co/m^3								1	1					2			3	1
10 / 2.5 µg Co/m^3			1					1			1			1			3	1
C23.4 Ceramics																		
1 / 0.5 µg Co/m^3										1	2	4				1	2	4
5 / 1.25 µg Co/m^3							1	2	4							1	2	4
10 / 2.5 µg Co/m^3																		
C24.45 Manufacture of cobalt and cobalt alloys																		
1 / 0.5 µg Co/m^3											1				6		1	6
5 / 1.25 µg Co/m^3					1							1			5		1	6
10 / 2.5 µg Co/m^3		1													5		1	5
C25.73 Manufacture of tools*																		
1 / 0.5 µg Co/m^3				1										3	3	1	3	3
5 / 1.25 µg Co/m^3				1							1	1		1	3	1	2	4
10 / 2.5 µg Co/m^3	1										4	1			2	1	4	3

*Source: Consultation survey. * For manufacture of tools some aggregated responses were provided, so some of the answers concern more sites.*

Table 7-13 Companies' anticipated annual cost range for recurrent costs per site required to achieve policy options, by company size (values = number of respondents). All companies include also sectors not indicated in the table

Sector	< €1,000			€1,000 - €10,000			€10,000 - €100,000			> €100,000			Number of re-sponses		
	S	M	L	S	M	L	S	M	L	S	M	L	S	M	L
All companies															
1 / 0.5 µg Co/m³	1		1	1	3	2		6	5		3	10	2	12	18
5 / 1.25 µg Co/m³			1	1	2	2	1	4	9		4	11	2	10	23
10 / 2.5 µg Co/m³					3	4	1	8	18	1	1	1	2	12	23
C20.59 Manufacture of other chemical products															
1 / 0.5 µg Co/m³			1					2			1			3	1
5 / 1.25 µg Co/m³								2	1		1			3	1
10 / 2.5 µg Co/m³					1			2	1					3	1
C23.4 Ceramics															
1 / 0.5 µg Co/m³															
5 / 1.25 µg Co/m³							1	2	4				1	2	4
10 / 2.5 µg Co/m³							1	2	4				1	2	4
C24.45 Manufacture of cobalt and cobalt alloys															
1 / 0.5 µg Co/m³					1							5		1	5
5 / 1.25 µg Co/m³					1				1			5		1	6
10 / 2.5 µg Co/m³								1	6					1	6
C25.73 Manufacture of tools*															
1 / 0.5 µg Co/m³				1	1			1	1		2	2	1	4	3
5 / 1.25 µg Co/m³			1	1							2	3	1	2	4
10 / 2.5 µg Co/m³					1			2	3	1			1	3	3

*Source: Consultation survey * For manufacture of tools some aggregated responses were provided, so some of the answers concern more sites.*

In order to indicate the size of the costs estimates as compared to the cost estimates undertaken using the cost model of this study, the answers were calculated into average discounted costs over 40 years. In accordance with the methodology of the cost model, the initial costs are expected to be incurred twice; at year 0 and year 20. For the ranges, the mid-point of the range was used, while for the upper range for investment of € >10 million a value of € 20 million has been used and for recurrent costs an upper value of € 200,000 million is used. This may for the lover policy options underestimate the upper level. However, for the policy option 1 / 0.5 µg Co/m^3 the median value for large companies is still below € 10 million, which would indicate that the arithmetic mean, if it is assumed that the data are normal distributed, should be below € 10 million per company, i.e. lower than the average value of about € 12 million calculated here.

Table 7-14 Average initial investment costs and recurrent costs per company as indicated by respondents to questionnaire survey, € 1000

Policy option	Initial investment costs, € 1000			Recurrent costs, € 1000/year		
	Small (n= 3)	Medium (n=12	Large (n=23)	Small (n= 3)	Medium (n=12	Large (n=23)
1 / 0.5 µg Co/m^3	3,685	11,880	12,140	3	79	127
5 / 1.25 µg Co/m^3	2,035	6,776	8,977	30	103	118
10 / 2.5 µg Co/m^3	2,753	4,143	9,654	128	55	53

Source: Study team on the basis of questionnaire responses

The average discounted costs over 40 years calculated as indicated above is shown in the table below. The reported costs estimates are presented together with the costs estimated using the cost model for this study in section 7.2.16.

Table 7-15 Total average adjustment costs per company as indicated by respondents to questionnaire survey discounted over 40 years, € million

Policy option	Total costs per company discounted over 40 years, € million		
	Small (n= 3)	Medium (n=12	Large (n=23)
1 / 0.5 µg Co/m^3	5.8	20.4	21.9
5 / 1.25 µg Co/m^3	3.9	13.0	16.8
10 / 2.5 µg Co/m^3	7.4	7.8	16.3

Source: Study team on the basis of questionnaire responses.

7.2.10.3 Survey - Lowest technically possible and economically feasible option

As part of survey, respondents were asked for their view of the lowest technically possible, and economically feasible policy options for their organisation using cobalt and inorganic cobalt compounds. The following two tables provide an overview of the responses for the inhalable fraction. The answers are typically in the high end of the range e.g. answers in the >5 - 10 µg Co/m^3 range are all 10 Co/m^3. Some of the responders indicate the economically feasible level lower than the technically possible; likely because they have mixed up the questions and answered for the technically possible level for the respirable fraction. The manufacture of tools sector stands out as a large percentage indicated both the technically possible and economically feasible level at higher than 20 µg Co/m^3. It should be noted than many companies consider a new OEL at EU level as the level in the workplace without taking RPE into account i.e. for all processes/activities where RPE is used today, the concentration in all workplaces should be lowered so RPE is not required. For maintenance and various activities of shorter duration it would require heavy investments if the OEL should be complied with without use of RPE. It is common in Member States (and in accordance with the CMRD which used the term 'For certain activities such as maintenance...') that RPE can be used for some maintenance and shorter processes where the OEL cannot be complied with and technical preventive measures for limiting workers' exposure has already been exhausted.

Only a few responses were obtained for the respirable fraction. Seven responses from the ceramics sector (several from same group) all answered that 0.5 µg Co/m³ would be technically feasible but indicated the economically feasible level at 2.5 µg Co/m³ for the respirable fraction (these companies did not provide levels for the inhalable fraction).

Table 7-16 Companies' anticipated lowest technically possible OEL (µg Co/m³), inhalable fraction

Sector (n)	Lowest technically possible OEL for inhalable fraction					
	<=1	>1 - 5	>5 - 10	>10 - 15	>15-20	>20
C19.20 Petrochemical, catalyst				1		
C20.12 Manufacture of dyes and pigments				1		
C20.13 Manufacture of other inorganic basic chemicals			2	2		
C20.14 Manufacture of other organic basic chemicals					1	
C20.30 Manufacture of paints and inks		1	2			
C20.59 Manufacture of other chemical products n.e.c.		2	1	1		
C24.10 Steel		1				
C24.45 Manufacture of cobalt and cobalt alloys		1	1	1	2	
C25.61 Surface treatment of metals	1					
C25.73 Manufacture of tools	3	1	1		1	5
C27.2 Batteries	1					

Source: Consultation survey, Notes: n = number of responses.

Table 7-17 Companies' anticipated economically feasible OEL (µg Co/m³), inhalable fraction

Sector (n)	Lowest economically feasible OEL for inhalable fraction					
	<=1	>1 - 5	>5 - 10	>10 - 15	>15-20	>20
C19.20 Petrochemical, catalyst						
C20.12 Manufacture of dyes and pigments				1		
C20.13 Manufacture of other inorganic basic chemicals					1	1
C20.14 Manufacture of other organic basic chemicals						1
C20.30 Manufacture of paints and inks	1			1	1	
C20.59 Manufacture of other chemical products n.e.c. (24)			1		2	
C24.10 Steel						
C24.45 Manufacture of cobalt and cobalt alloys		2			3	
C25.61 Surface treatment of metals	1					
C25.73 Manufacture of tools	3	2			2	5

Sector (n)	Lowest economically feasible OEL for inhalable fraction					
	<=1	>1 - 5	>5 - 10	>10 - 15	>15-20	>20
C27.2 Batteries		1				

Source: Consultation survey. Notes: n = number of responses, n = number of responses

7.2.10.4 Survey - EU Member State Authorities

Questionnaire responses were received from a total of 18 Member State Authorities (MSA). Thirteen MSAs answered all or some of the question *"What would be the impact of the following policy options for combined inhalable and respirable OELs for cobalt and inorganic cobalt compounds?"* The results are shown in Table 7-18. The member States answering all or some of the questions are Belgium, Bulgaria, Cyprus, Finland, Germany, Ireland, Latvia, Lithuania, Poland, Slovakia, Slovenia, Spain, and Sweden. Of these, Slovenia is the only Member State that does not have a national OEL while Bulgaria, Cyprus, Latvia, Lithuania, and Slovakia have national OELs above the highest of the policy options. As in total six Member States do not have a national OEL, Member States without an OEL are under-represented in the survey; whereas Member States with a national OEL above the highest policy option are over-represented.

The number of Member States answering the questions varies by question from 7 to 13. The questionnaire does not indicate whether the assessment of impacts concerns e.g. companies in the Member State represented by the MSA or more general companies in the EU. As the answers to some extent reflects whether national OELs at or below the levels are established, it is considered that the answers in general relate to the Member State concerned.

At the policy option of 20 / 4.2 µg Co/m^3, 90% of the Member States answering the questions think there are no costs for the companies (Cyprus, Finland, Germany, Ireland, Latvia, Poland, Slovenia, Spain, and Sweden) and all think there is no impact on competitiveness. Three Member States think that SME may be moderately or significantly negatively impacted (Cyprus, Latvia and Slovakia).

At the policy option of 10 / 2.5 µg Co/m^3, the majority of Member States answering the question think there will be a moderate (Cyprus, Ireland, Latvia, Slovakia, Slovenia, and Spain) or significant (Poland) negative impact on companies while the answer regarding impact on competitiveness is distibuted between no impact (Finland, Germany, Latvia, Slovakia, and Slovenia), moderate (Cyprus, Ireland, and Spain) and significant negative impact (Poland). Regaring SMEs, the overall trend is higher negative impact at lower policy options and at 10 /2.5 µg Co/m^3 more than half of the Member States answering the question think there will be either a moderate (Ireland, Latvia, Slovakia, and Slovenia) or significant (Cyprus, Poland, and Spain) negative impact to the SMEs.

The overall trend is that an increaseing number of Member States think there will be some negative impacts on business. At 5 /1.25 µg Co/m^3 the majority of Member States answering the question think there will be a moderate (Cyprus, Finland, Latvia, Ireland, Slovakia, and Slovenia) or significant (Poland and Spain) negative impact on companies (Cyprus, Ireland, Latvia Poland, Slovenia, Slovakia, and Spain) while the answer regarding impact on competitiveness is distibuted between no impact (Finland, Latvia, and Slovakia), moderate (Cyprus and Latvia) and significant negative impact (Ireland, Poland and Spain). One Member State (Slovenia) think there will be a significant positive impact. Regaring SMEs more than half of the Member States answering the question think there will be either a moderate (Finland, Latvia, and Slovakia,) or significant (Cyprus, Ireland, Poland, Slovenia, and Spain) negative impact to the SMEs.

At the policy option of 1 / 0.5 µg Co/m³, only one Member State answering the question (Germany) think there will be no costs for companies while half of the Member States think there will be significant negative impact on costs for companies (Ireland, Latvia, Poland, Slovenia, and Spain). The impact on competitiveness is less clear with a split between significant negative impact (Ireland, Poland, and Spain), moderate negative impact (Cyprus, Finland and Lativa), no impact (Germany and Slovakia), and significant positive impact (Slovenia).

As to the impact on occupational health, the overall trend is toward more significant positive impact by lower policy options with a split between no impact and moderate positive impact at the 20 / 4.2 µg Co/m³ policy options whereas 9 out of 12 Member States expect significant positive impact at the 1 / 0.5 µg Co/m³.

As concern costs for public authorities, the overall trend is that less Member States indicated no impact at the lower policy options but there is no marked trend toward increase in answers indicating significant negative impact.

For the impact on environment, the Member States responses are distributed between no impact, moderate positive impact and significant positive impact regardless of the level of the policy option.

Table 7-18 Impact of the policy options for cobalt and inorganic cobalt compounds (n = number of answers). The number of answers varies between 7 and 12 by question and by policy option

Impact (number of answers)	Policy option (µg Co/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Costs for Companies	1 / 0.5 µg Co/m³	5	3	1		
	5 / 1.25 µg Co/m³	2	6	1		
	10 / 2.5 µg Co/m³	1	6	2		
	20 / 4.2 µg Co/m³		1	9		
Costs for public authorities	1 / 0.5 µg Co/m³	2	2	3		1
	5 / 1.25 µg Co/m³	2	2	4		1
	10 / 2.5 µg Co/m³	1	3	5	1	
	20 / 4.2 µg Co/m³		1	8	1	
Competitiveness	1 / 0.5 µg Co/m³	3	3	2		1
	5 / 1.25 µg Co/m³	3	2	3		1
	10 / 2.5 µg Co/m³	3	3	5		
	20 / 4.2 µg Co/m³			9		
SMEs	1 / 0.5 µg Co/m³	5	3	1		
	5 / 1.25 µg Co/m³	5	3	1		
	10 / 2.5 µg Co/m³	3	4	2		
	20 / 4.2 µg Co/m³	1	2	6		
Occupational health	1 / 0.5 µg Co/m³			1	2	9
	5 / 1.25 µg Co/m³			1	5	6
	10 / 2.5 µg Co/m³			2	6	4
	20 / 4.2 µg Co/m³			6	6	1
Environment	1 / 0.5 µg Co/m³			2	3	2
	5 / 1.25 µg Co/m³			2	3	2
	10 / 2.5 µg Co/m³			3	3	2
	20 / 4.2 µg Co/m³			3	4	1

Source: Consultation survey of Member States Authorities.

7.2.10.5 Survey and impact assessment undertaken by the Cobalt Institute and Cobalt REACH Consortium

Eftec (2023) has undertaken an impact assessment of introducing OELs for the Cobalt Institute and Cobalt REACH Consortium. An updated, final report has been submitted for the stakeholder consultation by the Cobalt Institute August 2023. The following binding OELs for the inhalable fraction are assessed: 30, 20, 10, and 1 µg/m^3.

The overall costs/benefit assessment include the following: Costs of compliance to companies, social costs of lost jobs in the EU, and benefits of reduced number of cases of ill health. The focus on the discussion below is the costs estimates, but in order to keep the description of the results together, the estimates of social costs and benefits are also presented here.

The assessment of costs is based on responses with useable information from 59 companies which are extrapolated to total number of companies and sites in the EU27. Of the 59 companies apparently 54 provided information reported on number of employees and potentially exposed workers (indicated as lower bound in survey).

Some background tables with number of companies, number of workers and exposed workers, levels of compliance, etc. by broad use area are shown in Annex D. The tables are divided between consultation responses (survey) and estimated numbers for the whole industry used for the impact assessment.

Costs of compliance to companies

Input parameters. The input parameters for the assessment of costs to companies of compliance include the following parameters:

- **Number of companies in EU 27 with exposure to cobalt**. The number of companies is derived on the basis of previous studies, survey responses and stakeholder workshops. The assessment is divided by broad use areas and the use of the data in relation to the sector-division used in the current study is discussed in section 3.10 on market analysis. The eftec survey does not include some of the down-stream uses covered by this study but overall, a common understanding is shared between the eftec study and the current study for those use areas covered by the eftec study.

- **Share of companies that are SME.** The share of companies that are SMEs has been adjusted compared to a previous version of the report, but as the background data have not been updated, no background for the applied percentage is provided. The updated percentage is not directly indicated but from the presented data it can be back-calculated that an overall percentage of approximately 81% SME has been used for the calculation of aggregated unit costs of RMMs.

- **Percentage of companies that are not in compliance.** The proportion of sites that would not be compliant at the different OEL levels was calculated as the total non-compliant sites reported by all companies, divided by the total number of sites for which compliance data was available.

- **Behavioural response.** The proportion of sites choosing each response (implementing RMMS, using alternatives, discontinuation) was calculated as the total non-compliant sites reported by companies that stated they would choose that response, divided by the total number of non-compliant sites for which behavioural response data was available.

- **Costs of additional RMMs**. For each of the OELs, respondents were asked for the cost of compliance through implementation of RMMs. Respondents were also asked to differentiate costs with and without PPE as part of compliance with each OEL. The unit cost of implementing risk management measures was calculated as the mode of the compliance costs per non-compliant site in the EU-27 as reported by respondents. Respondents were asked for both the one-off and recurrent costs of implementing RMMs. Separate one-of and recurrent costs were calculated for SMEs (less than 250 employees) and large companies (250 employees or more), based on the mode of costs provided by each of these groups. The one-off and recurrent costs used to calculate the final unit cost were an average of the SME and large company one-of and recurrent costs, weighted by the estimated proportion of SMEs and large companies in the industry as a whole. It was assumed that one-off costs are incurred once every 20 years (meaning twice over the course of the 40-year appraisal period) and recurrent costs are incurred annually (40 times over the appraisal period).

- **Costs of implementing biological monitoring.** Respondents were asked for: (i) the actual cost of implementing monitoring programmes at sites that already had them, and (ii) the projected cost of implementing monitoring programmes at sites that do not yet have them. Costs of implementing respiratory fraction monitoring (air monitoring). It was assumed that the respondents' estimates represented the past or future costs of monitoring programmes at all sites that already had/ did not have monitoring programmes implemented. It is in the impact assessment assumed that all companies need to do biomonitoring annually at an average cost of €30,000 per year.

- **Costs of implementing air monitoring.** It is in the impact assessment assumed that all companies need to do air monitoring annually at an average cost of €10,000 per year.

- **Costs of substitution with alternatives**. Respondents were asked if they had previously attempted to substitute cobalt substances they use with any other substances and/or processes instead of being asked to project substitution costs in the future. Spend on substitution was requested as a range, and for the central estimate, an arithmetic mean of the bottom and top of that range was used. For sensitivity analysis, both the bottom and top of the range were used to produce min and max spends. In the sensitivity analysis it is indicated that all substitution costs relate to substitution attempts that companies indicated were only partially successful. There were according to the report no instances of fully successful substitution, which would likely be more expensive.

- **Costs of ceasing production in the EU.** Respondents were asked for the revenue associated with products that used an in-scope substance. The median of the reported revenues is used to calculate the annual profit lost per site (if production ceases in the EU). The median annual revenue was divided by the average number of sites among respondents that provided sales data to calculate an average revenue per site that would be lost if the site ceased to operate. The same process was repeated for SMEs and large companies. The final median revenue used to calculate profit loss was an average of the two, weighted by the estimated proportion of SMEs and large companies in the industry as a whole. This was multiplied by an assumed 10% profit margin to calculate average annual profit loss.

- **Overlap factor.** The assessment applies an 'overlap factor' to estimate a lower and upper bound. The overlap factor is based on the responses to the survey where the lower bound represent the actual number of respondents to the survey and the overlap factor takes into account that some of the companies carry out activities related to more than one use category and have answered for more than one category.

The applied unit costs per site is shown in the table below. The costs represent the costs per site not in compliance at the different OELs levels and for which the cost type is relevant e.g. the costs of additional RMMs for those indicating this response.

The difference between unit costs for additional RMMs varies considerably. The unit costs without use of RPE is for the policy options 30 and 10 µg/m^3 slightly lower than the costs if no RPE is used while it for the 1 µg/m^3 is higher. For 20 µg/m^3 it is significantly higher, but the data seems to be based on outliers. The unit costs are based on respondents not in compliance at the OEL that select RMM as a mean of compliance. The estimates are consequently based on responses from different companies for the different OEL and based on relative few responses. 2022

The estimates of costs of compliance without the use of PPE does not take the existing use of RPE, and the reduction in exposure concentrations obtained, into account - i.e. the estimate include the costs of replacing existing use of RPE with other types of RMMs to reduce the concentrations in the workplace to be in compliance with the new OEL. It is not indicated if the estimates take into account the costs of existing use of RPE and subtract these costs when the RPE is replaced by other RMMs.

Table 7-19 Unit costs 2022-2061 per site, € million

Cost type	Unit costs 2022-2061 per site, € million							
	30 µg/m^3		20 µg/m^3		10 µg/m^3		1 µg/m^3	
	With PPE	Without PPE	With PPE	Without PPE	With PPE	Without PPE	With PPE	Without PPE
RMMs per site, SME	0.7	0.7	1.0	5.0*	1.0	0.3	0.8	0
RMMs per site, large	4.4	5.1	2.2	4.5 *	7.0	11.3	19.4	21
RMMs, unit costs all sites	1.4	1.5	1.2	4.9 *	2.1	2.3	4.1	4.0
Implementing biological monitoring	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Implementing respiratory fraction monitoring	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Substitution with alternatives	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Ceasing production in the EU	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6

*Source: eftec, 2023. * Data indicated in the report, but the costs per SME seems to be too high considering the costs for other options.*

The estimated total costs over 40 years to companies of compliance with the four OEL levels are shown in Table 7-20 and Table 7-21.

At the level of 20 µg/m^3, implementation of air monitoring and biomonitoring takes up 52% of the total costs while implementation of RMMs and ceasing production in the EU account for 16% and 23%, respectively. As the total costs increase from 20 µg/m^3 to 10 µg/m^3, the percentage accounted for by the monitoring decrease to 22% in total and the implementation of RMMs and ceasing production in the EU account at 10 µg/m^3 for 21% and 33%, respectively. At 1 µg/m^3, the major part of the sites would either select substitution or cease production in the EU. As the unit costs applied for substitution are low compared to other measures, and the costs of monitoring decrease due to less companies using cobalt, the total estimated costs at 1 µg/m³ are only about 30% higher than at 10 µg/m³.

If the estimates excluding monitoring are compared with the estimates of the current study (for additional RMMs, alternatives and discontinuation), the total estimated costs are of same magnitude for 1 µg/m³ whereas the estimates for 10 µg/m³ is about ten times higher in eftec (2023). A part of this may be explained by the differences in SME percentage (further described below), where the applied SME percentage in eftec 2023 would result in more than twice the costs compared to the results if the SME percentage of the current study was used. Furthermore, the extrapolation of the percentage of companies in compliance from survey results to the entire industry is here considered to lead to a significant overestimation of the total costs at least for the three policy options above 1 µg/m³ as described further below.

Table 7-20 Estimated total costs 2022-2061 of compliance with a 20 and 30 µg/m³ binding OEL for the inhalable fraction by cost type. The non-compliance percentage indicate the percentage of all companies which would not be in compliance with the OEL. RMM costs without PPE[55].

Cost type	30 µg/m³ (non compliant 16%)				20 µg/m³ (non compliant 22%)			
	Number of sites	Unit costs € million	Total costs € million	% of total	Number of sites	Unit costs € million	Total costs € million	% of total
Implementing RMMs	1,100	1.5	1,650	18%	780	4.9	3,840	32%
Implementing biological monitoring	4,990	1.0	5,150	58%	4,490	1.0	4,640	38%
Implementing respiratory fraction monitoring	3,810	0.5	1,840	21%	3,430	0.5	1,650	14%
Substitution with alternatives	280	0.2	40	0.4%	460	0.2	70	0.6%
Ceasing production in the EU	90	2.6	240	3%	740	2.6	1,950	16%
Total cost lower bound			6,770				9,220	
Total cost upper bound			11,070				15,080	

Tables notes (from eftec (2023):
• Number of sites incurring costs is rounded to the nearest 10. Annualised costs are rounded to the nearest €10 million, unless costs are <€5 million, in which case they have been rounded to the nearest €1 million. Costs across the appraisal period are rounded to the nearest €10 million.
• The total figures are provided for the lower and upper bound. These are calculated using a lower and upper bound estimate of the number of sites using in scope substances across the EU-27. The remaining figures are estimated using an average of the lower and upper bound site estimates for each type of cost.
Source: eftec, 2023.

Table 7-21 Estimated total costs 2022-2061 of compliance with a 10 and 1 µg/m³ binding OEL for the inhalable fraction, by cost type. The non compliant percentage indicate the percentage of all companies which would not be in compliance with the OEL. RMM costs without PPE.

Cost type	10 µg/m³ (non compliant 36%)				1 µg/m³ (non compliant 73%)			
	Number of sites	Unit costs € million	Total costs € million	% of total	Number of sites	Unit costs € million	Total costs € million	% of total
Implementing RMMs	1,160	2.3	2,630	21%	1,130	4.0	4,560	28%

[55] Totals of % distribution might not add to 100% due to runding of number.

Cost type	10 µg/m³ (non compliant 36%)				1 µg/m³ (non compliant 73%)			
	Number of sites	Unit costs € million	Total costs € million	% of total	Number of sites	Unit costs € million	Total costs € million	% of total
Implementing biological monitoring	3,980	1.0	4,110	33%	2,470	1.0	2,550	16%
Implementing respiratory fraction monitoring	3,040	0.5	1,470	12%	1,890	0.5	910	6%
Substitution with alternatives	480	0.1	70	0.6%	2,220	0.1	340	2.1%
Ceasing production in the EU	1,550	3.3	4,100	33%	3,050	3.3	8,070	49%
Total cost lower bound			9,390				12,480	
Total cost upper bound			15,360				20,400	

Tables notes (from eftec (2023): Same as the table above
Source: eftec, 2023.

Costs by sector. The costs by sector are not shown for all broad use categories, but for each policy option, the costs by sector are calculated for these use categories where non-confidential information is available from the survey. According to the sensitivity analysis of the report, however, these use category specific estimates are not considered to be reliable estimates and are thus not used in any further analysis and not included in the sensitivity analysis (eftec, 2023).

Social costs

Social costs are calculated for each OEL from the potential EU jobs lost. The number of jobs at risk for each policy option is estimated using the average number of employees per site multiplied with the number of sites which will potentially need to shut down in response to the OEL. The relevant share of jobs at risk is assumed to be proportional to the share of profits at risk.

For the loss of jobs a unit cost of 0.1 PV € million over the period 2022 - 2061 is applied.

The social costs are for the policy options 10 and 1 µg/m³ estimated to be relatively high compared to the costs to companies as shown in Table 7-23.

Benefits

The current burden of disease is calculated by an approach quite similar to the approach used in the current study. The current burden of disease and the costs of cases of ill health is calculated in a section on ‘cost of inaction’. The assessment includes the following:

- National binding OELs;
- Workplace exposure routes, levels, existing the Risk Management Measures (RMMs) and resulting compliance with each binding OEL assessed in this report;
- Health end points, dose response functions and excess risk at current levels; and,
- Costs of inaction covering the costs due to three health endpoints: lung cancer, respiratory irritation and restrictive lung disease.

The exposure distributions applied is a dataset of exposure data collected as part of the REACH registration process and provided by the REACH Cobalt Consortium. The same data are to a large extent used for the current study and shown in Annex C (CoRC, 2023).

The calculated baseline number of cases over 40 years is shown in the table below. For lung cancer, the numbers are well in accordance with the current study considering that the number of exposed workers included in the current study is about 23% higher than the number in the eftec impact assessment because of the inclusion of more downstream sectors. For non-cancer endpoints, the total number for the two endpoints is higher in the current study, and the distribution is different which may reflect the significant uncertainties in defining the endpoints and derive the DRRs in both studies. The monetised health impact is for the non-cancer endpoints significantly higher in the eftec study as compared with the current study due to estimated higher cost per case.

Table 7-22 Number of cases over and human health impact over 40 years

Health endpoint	Number of cases over 40 years (cases)		Human health impacts over 40 years (PV € million)	
	Lower bound	Upper bound	Lower bound	Upper bound
Cancer	78	130	122	202
Respiratory irritation	2,825	4,669	142	234
Restrictive lung disease	1,012	1,673	203	335
Total			466	771

** note by eftec (2023): 'The estimated numbers of cases have been derived using highly conservative assumptions and are likely overestimated (see Annex A 1.4)'*
Source: eftec (2023)

The total benefits of the different policy options are shown below in Table 7-23. Overall, the benefits are higher than estimated in the current study. The major difference is, however, that the eftec study reach the conclusion that the benefits already at an OEL of 30 µg/m^3 OEL have reduced the baseline health impact by 87%.

Cost/benefit assessment

The costs benefit assessment for the four policy options is summarised in the table below.

Table 7-23 The costs benefit assessment for the four policy options

	Benefits and costs over 40 years, PV € million							
	30 µg/m^3		20 µg/m^3		10 µg/m^3		1 µg/m^3	
	With PPE	No PPE	With PPE	No PPE	With PPE	No PPE	With PPE	No PPE
Benefits- lower - upper bound	406-672		434-718		453-749		466-770	
Costs to companies - lower bound	6,670	6,770	7,040	9,220	9,270	9,390	12,520	12,480
Costs to companies - upper bound	10,900	11,070	11,520	15,080	15,150	15,360	20,470	20,400
Social costs	610		4,910		10,330		20,320	

The estimated total costs and benefits by OEL is shown in the figure below. The costs and benefits are indicated as the average of the lower and upper bound levels. The benefits cannot be read from the figure, but ranges from a mid-point value of 539 € million at 20 µg/m^3 to 618 € million at 1 µg/m^3.

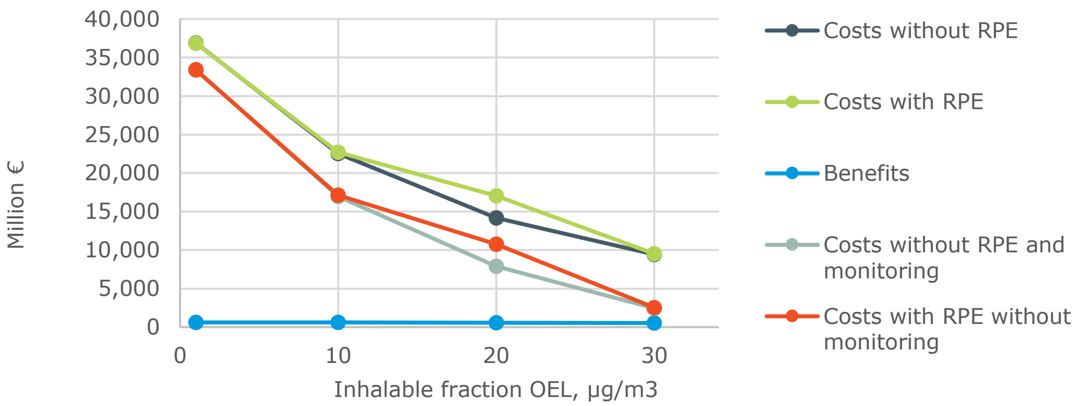


Figure 7-1 *Estimated total costs 2022-2061 and benefits by compliance with four binding OELs for the inhalable fraction*

Comments to the methodology and results

The approach used for the cost assessment is very different from the cost model used for the current study as it is based on extrapolation of data from stakeholder survey. The results are very sensitive to the extrapolation of data from 54 respondent to about 7,000 companies in 24 broad use categories. Furthermore, it is very sensitive to the quality of the responses and the companies' own assessment of compliance level and costs, and sensitive to bias in which companies answer the survey. The respondents are not a random selection of the population, but it could be assumed there is bias towards companies that would have more significant challenges by introduction of an OEL.

Share of SME. As is described above, a main methodology was applied where unit costs for SME and large companies were calculated into an aggregated unit cost weighted by the estimated proportion of SMEs and large companies in the industry as a whole. The used overall weighted average for the industry as a whole is in a detailed table by use category indicated at 44% SME and 56% large companies. These percentages were used for a previous version of the report but has apparently been adjusted for the updated version submitted July 2023. The background for the updated percentage is not described, but it is indicated in the sensitivity analysis of the report that: "*At an EU level it was estimated that the share of SMEs is around 93%, whilst only 34% of the survey respondents were SMEs. Separate costs were calculated for SMEs and large companies, and the total costs were adjusted for the higher SME rate at the EU level*".

In the calculation of the aggregated unit costs used for the cost estimates, however, a SME percentage of about 81% is applied as back-calculated from the presented data. Neither the background for the 93%, indicated in the sensitivity analysis, nor the 81% apparently used for the estimations is described. As the percentage of SME indicated by use category has not been adjusted it is not possible to further analyse the background for the applied SME percentage.

The possible underrepresentation can be illustrated by taking the percentages for large companies. In a previous impact assessment for the Cobalt Institute, RPA (2020) estimated that 3% of the companies were large companies while the revised eftec (2023) impact assessment use a percentage of 19%. For the current study it is estimated that overall 5% are large companies (close to the percentage indicated in the sensitivity analysis of the eftec (2023) report), while the overall share of large companies within the covered sectors in the Eurostat SBS is 0.7% (see section 3.10.4). If an estimate of 5% large companies is applied (as indicated in this study and the sensitivity analysis of the eftec 2023 study), the aggregated unit costs would be approximately 2.2 times lower for the 10 µg/m^3 option and approximately 4.1 times lower for the 1 µg/m^3 policy option.

The unit RMM costs applied for two size groups of companies are quite well in accordance with adjustment costs companies have indicated in the survey of the current study as described in section 7.2.10.2.

Percentage of companies in compliance. The proportion of sites choosing each response was calculated as the total non-compliant sites that stated they would choose that response, divided by the total number of non-compliant sites for which behavioural response data was available. The non-compliance rates were extrapolated to all companies without reflecting the average exposure concentrations of responding use areas and use areas. Two broad use areas 'Professional use in biogas production' and 'Formulation and use in animal feed grade material' represent together nearly 87% of the total number of companies (68-120% of upper and lower boundary, respectively) but only 7% (only production of feed grade material) of respondent companies. Both use areas are characterised by low exposure concentrations which is also shown in the report as 100% of the 4 respondents within the use area 'Formulation and use in animal feed grade material' answered that they would be in compliance with an OEL at 10 µg/m^3. No answers for 'Professional use in biogas production' were obtained. By applying an average rate for non-compliant sites from the survey to these two sectors, which account for close to 87% of the total number of companies, leads to a significant overestimation of the total costs at al OELs above the 1 µg/m^3.

Biomonitoring. Biomonitoring costs account for 58% of the total estimated costs at an OEL at 30 µg/m^3 decreasing to 16% at an OEL at 1 µg/m^3. As RAC has not proposed a BLV and the CMRD does not require that compliance with an OEL is demonstrated by use of biomonitoring, companies' possible costs of biomonitoring cannot be allocated to the introduction of an OEL. The reasoning of including costs of biomonitoring is not discussed in the impact assessment.

Air monitoring. Air monitoring account for 21% of the total estimated costs at an OEL at 30 µg/m^3 decreasing to 6% at an OEL at 1 µg/m^3. It is in the impact assessment assumed that all companies need to do air monitoring annually. As discussed in the section of monitoring of the Methodological Note of this study, costs of annual air monitoring cannot be allocated to the introduction of an OEL.

Together, the costs of biomonitoring and air monitoring over 40 years are estimated at 6.3 € million at 20 µg/m^3 and 5.6 million at 10 µg/m^3 which are far beyond the estimates for costs of air monitoring at these OEL levels in the current study.

Overlap factor. The assessment applies an 'overlap factor' to estimate a lower and upper bound. The overlap factor is based on the responses to the survey where the lower bound represent the actual number of respondents to the survey and the overlap factor takes into account that some of the companies have answered for more than one use category. As the number of companies for most larger use areas are not based on extrapolation of survey responses but based on other sources, the application of the overlap factor for the entire industry is unjustified and upper and lower bound does not indicate an actual uncertainty level.

Definition of compliance. The results are very sensitive to the assumptions regarding use of RPE in the demonstration of compliance. If the reduction in exposure concentration due to current use of RPE, which on average leads to a reduction in the P95 concentration of about a factor of ten, should be obtained by implementation of other types of RMM this certainly leads to high costs - not only to companies which consider themselves not in compliance but also to companies which are currently in compliance with national OELs. For most sectors, certain types of work such as cleaning and maintenance leads to high exposure, for which a reduction without the use of RPE is very costly.

Eftec (2020) has for the Cobalt Institute compared cost estimates for OEL compliance for use areas covered by the five cobalt salts subject to the restriction proposal and for cobalt and cobalt compounds. Three estimates by studies undertaken by the consultants eftec, RPA and EBRC Consulting were compared for introduction of an OEL at 1, 10 or 20 µg/m^3. The estimates are shown in the table below. The EBRC Consulting estimate is based on compliance without taken RPE into account whereas the RPA methodology apply a combination of RPE and other RMMs. Eftec (2019 as cited by eftec, 2020) have made two estimates indicted by the ranges in the table. The low estimates are based on the use of PPE as a first response i.e. if it is possible to comply with an OEL using PPE these will be adopted first rather than the implementation of technical measures like closed systems while the high scenario accounts for following the STOP principle (Substitution, Technical measures, Organizational and Personal protective equipment). The ranges well illustrate the sensitivity of the costs assessments to the assumptions regarding the use of RPE.

Table 7-24 Comparison of estimated costs of compliance with three OEL levels for cobalt and cobalt compounds.

	Total annualised cost of compliance (€ million / year) *		
OEL	**RPA (as cited by eftec, 2020) Best estimate (range) ****	**Eftec (2019 as cited by eftec, 2020) Best estimate (range)**	**EBRC (2020 as cited by eftec, 2020) Best estimate (range)**
20 µg/m^3	44 (35-53)	377 (13 - 740)	283 (238- 327
10 µg/m^3	64 (51-76)	579 (20 - 1,138)	647 (628- 665
1 µg/m^3	384 (307-461)	1,099 (72 - 2,125)	2,774 (2560- 2989)

*Source: eftec 2020. * Please note costs in this table are per year. **According to the RPA assessment (2020), monitoring costs accounted for 99% of total costs at 20 µg/m^3*

7.2.11 Estimated adjustment costs to achieve compliance

The cost model considers companies using each type of RMM and works out which new RMM is required to achieve the policy option. The model calculates the first-year costs (an estimate of the one-off costs, and recurrent costs of the new RMMs. It also calculates the recurrent cost of the old RMMs and the one-off costs of the old RMMs that would have been expected at 20 and 40 years: These are deducted from the costs for the new RMMs as the company was already expecting to pay for these. The model estimates the number of companies that might discontinue. The assessment of discontinuation is based on a combination of technical and economic feasibility. If it is not technical feasible to comply with an OEL, then the model assumes that the company will discontinue. It might be that the RMMs included in the model do not fully cover all possible options for a specific company. It would typically mean that by undertaking very expensive measures a company might technically be able to comply. A generic cost model cannot cover such company specific conditions.

Below the adjustment costs are presented. First, the total adjustment costs including first year costs, discontinuation costs and recurrent costs are presented. The table also indicate for each setr and OEL, whether the costs are based on compliance with the inhalable (I) or respirable (R) fraction.

Table 7-25 Total PV adjustment costs over 40 years for the different policy options by sector, excluding monitoring and administrative costs

Sector		R, I*	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	I, I, I, I	2.8	-	-	-
C19.20	Petrochemical, catalyst	I, I, I, I	38.7	3.9	0.6	-
C20.12	Manufacture of dyes and pigments	I, I, I, R	117.6	34.0	14.3	6.6
C20.13-20.14	Manufacture of basic chemicals	I, I, I, I	92.7	18.4	0.5	-
C20.30	Manufacture of paints and inks	I, I, I, R	16.0	2.8	1.3	0.1
C20.59	Catalysts	I, I, I, I	65.1	10.6	9.0	1.1
C21.20	Pharmaceuticals	I, I, I, I	0.8	-	-	-
C22.11	Production of tyres	I, I, I, I	4.8	0.3	-	-
C23.1	Glass	I, I, I, I	38.4	6.1	0.8	-
C23.4	Ceramics	I, I, I, R	304.3	90.6	38.8	16.4
C23.7	Cutting stone	I, R, R, R	43.2	6.7	2.3	2.3
C24.10	Steel	I, I, I, I	56.4	5.5	2.6	0.1
C24.45	Manufacture of cobalt and cobalt alloys	I, I, I, I	27.8	3.9	1.6	0.4
C25.5	Powder metallurgy	I, I, I, I	76.4	8.7	3.9	0.6
C25.61	Surface treatment of metals	I, I, I, R	343.7	46.4	4.9	4.9
C25.62	Machining	I, I, I, I	2,036.6	616.2	137.0	20.7
C25.73	Manufacture of tools	I, I, I, I	3,478.1	387.6	183.4	15.3
C25.99	Manufacture of other fabricated metal products n.e.c.	I, I, I, I	119.4	29.1	12.7	5.3
C26.1	Production of electronic components and boards	I, I, I, R	479.5	97.5	41.3	19.0
C26.51	Humidity indicator cards	I, I, I, I	0.1	-	-	-
C27.2	Batteries	I, I, I, I	11.5	0.7	-	-
C28.11	Engines and turbines	I, I, I, I	453.9	111.1	22.7	1.2
C29.10-30	Automotive	I, I, I, R	856.5	88.8	1.1	1.1
C30.30	Air and spacecraft	I, I, I, I	199.3	49.3	12.5	0.9
C32.50	Medical and dental devices	I, I, I, I	637.6	180.5	78.4	29.0
E38.32	Metal recovery	I, I, I, I	90.3	6.6	0.6	-
	Biogas	I, I, I, I	-	-	-	-
	Welding	I, R, R, R	51.5	27.3	8.6	3.4
	Grand Total		**9,643**	**1,833**	**579**	**129**

*Source: Study team. * Indicates whether compliance with the OEL for the respirable (R) or the inhalable (I) fraction will be the costliest.*

The total costs presented in Table 7-25 include discontinuation costs. The percentage of discontinuation costs in the total PV40 adjustment costs are estimated below.

First year adjustment costs in Table 7-26 include the first year costs of purchasing/installing alternative RMMs, plus associated operating cost in the first year, minus the first year cost of operating existing RMMs which are being replaced.

Table 7-26 First year PV adjustment costs over 40 years by policy options, sector and company size (excluding the costs of monitoring and associated administrative burden)

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	I, I, I, I	2.7	-	-	-
C19.20	Petrochemical, catalyst	I, I, I, I	11.5	2.5	0.5	-
C20.12	Manufacture of dyes and pigments	I, I, I, R	19.2	9.2	4.6	1.9
C20.13-20.14	Manufacture of basic chemicals	I, I, I, I	7.7	1.4	0.8	-
C20.30	Manufacture of paints and inks	I, I, I, R	2.7	0.7	0.3	0.1
C20.59,1	Catalysts	I, I, I, I	11.2	2.1	1.0	1.1
C21.20	Pharmaceuticals	I, I, I, I	0.8	-	-	-
C22.11	Production of tyres	I, I, I, I	1.2	0.3	-	-
C23.1	Glass	I, I, I, I	14.6	3.6	0.7	-
C23.4	Ceramics	I, I, I, R	120.6	51.9	25.4	10.3
C23.7	Cutting stone	I, R, R, R	23.5	4.3	1.9	1.9
C24.10	Steel	I, I, I, I	2.2	0.5	0.2	0.1
C24.45	Manufacture of cobalt and cobalt alloys	I, I, I, I	8.3	2.2	0.8	0.5
C25.5	Powder metallurgy	I, I, I, I	10.8	2.7	1.1	0.6
C25.61	Surface treatment of metals	I, I, I, R	90.6	21.0	4.1	4.1
C25.62	Machining	I, I, I, I	644.2	366.0	88.0	17.1
C25.73	Manufacture of tools	I, I, I, I	209.0	73.5	27.6	17.4
C25.99	Manufacture of other fabricated metal products n.e.c.	I, I, I, I	22.2	9.6	4.7	1.8
C26.1	Production of electronic components and boards	I, I, I, R	44.1	21.1	10.6	4.1
C26.51	Humidity indicator cards	I, I, I, I	0.1	-	-	-
C27.2	Batteries	I, I, I, I	4.2	0.9	-	-
C28.11	Engines and turbines	I, I, I, I	23.7	11.7	6.0	1.2
C29.10-30	Automotive	I, I, I, R	26.6	7.6	1.7	1.7

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C30.30	Air and space-craft	I, I, I, I	21.0	10.4	5.3	1.1
C32.50	Medical and dental devices	I, I, I, I	137.3	94.6	45.7	20.4
E38.32	Metal recovery	I, I, I, I	12.1	2.9	0.6	-
	Biogas	I, I, I, I	-	-	-	-
	Welding	I, R, R, R	8.6	7.4	5.9	2.4
	Grand Total		**1,481**	**708**	**237**	**88**

*Source: Study team. * Indicates whether compliance with the OEL for the respirable (R) or the inhalable (I) fraction will be the costliest.*

Table 7-27 Discontinuation PV adjustment costs over 40 years by policy options and sector

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	I, I, I, I	-	-	-	-
C19.20	Petrochemical, catalyst	I, I, I, I	-	-	-	-
C20.12	Manufacture of dyes and pig-ments	I, I, I, R	77.1	19.3	7.7	3.9
C20.13-20.14	Manufacture of basic chemicals	I, I, I, I	85.9	17.2	-	-
C20.30	Manufacture of paints and inks	I, I, I, R	12.1	1.9	0.9	-
C20.59	Catalysts	I, I, I, I	47.1	7.2	7.2	-
C21.20	Pharmaceuticals	I, I, I, I	-	-	-	-
C22.11	Production of tyres	I, I, I, I	3.1	-	-	-
C23.1	Glass	I, I, I, I	12.7	1.3	-	-
C23.4	Ceramics	I, I, I, R	46.7	4.5	1.5	0.7
C23.7	Cutting stone	I, R, R, R	-	-	-	-
C24.10	Steel	I, I, I, I	50.9	4.6	2.3	-
C24.45	Manufacture of cobalt and co-balt alloys	I, I, I, I	10.9	1.0	0.5	-
C25.5	Powder metal-lurgy	I, I, I, I	55.5	5.0	2.5	-
C25.61	Surface treat-ment of metals	I, I, I, R	175.9	17.6	-	-
C25.62	Machining	I, I, I, I	87.7	-	-	-
C25.73	Manufacture of tools	I, I, I, I	3,115.9	306.6	153.3	-
C25.99	Manufacture of other fabricated metal products n.e.c.	I, I, I, I	57.1	11.2	4.5	2.2

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C26.1	Production of electronic components and boards	I, I, I, R	392.1	67.2	26.9	13.4
C26.51	Humidity indicator cards	I, I, I, I	-	-	-	-
C27.2	Batteries	I, I, I, I	7.0	-	-	-
C28.11	Engines and turbines	I, I, I, I	407.3	95.9	16.0	-
C29.10-30	Automotive	I, I, I, R	833.1	83.3	-	-
C30.30	Air and spacecraft	I, I, I, I	159.1	37.0	7.4	-
C32.50	Medical and dental devices	I, I, I, I	253.0	-	-	-
E38.32	Metal recovery	I, I, I, I	68.3	3.4	-	-
	Biogas	I, I, I, I	-	-	-	-
	Welding	I, R, R, R	32.9	13.4	-	-
	Grand Total		**5,991.4**	**697.7**	**230.7**	**20.2**

*Source: Study team. * Indicates whether compliance with the OEL for the respirable (R) or the inhalable (I) fraction will be the costliest.*

The next table presents the recurrent costs by policy option and sector.

Table 7-28 Recurrent PV adjustment costs over 40 years by policy options and sector (excluding the costs of monitoring and associated administrative burden)

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	I, I, I, I	0.1	-	-	-
C19.20	Petrochemical, catalyst	I, I, I, I	27.2	1.4	0.1	-
C20.12	Manufacture of dyes and pigments	I, I, I, R	21.3	5.5	1.9	0.9
C20.13-20.14	Manufacture of basic chemicals	I, I, I, I	-0.9	-0.2	-0.3	-
C20.30	Manufacture of paints and inks	I, I, I, R	1.3	0.3	0.1	0.0
C20.59	Catalysts	I, I, I, I	6.8	1.3	0.8	0.0
C21.20	Pharmaceuticals	I, I, I, I	-0.1	-	-	-
C22.11	Production of tyres	I, I, I, I	0.5	0.0	-	-
C23.1	Glass	I, I, I, I	11.1	1.2	0.1	-
C23.4	Ceramics	I, I, I, R	137.0	34.2	11.9	5.5
C23.7	Cutting stone	I, R, R, R	19.7	2.4	0.4	0.4
C24.10	Steel	I, I, I, I	3.3	0.4	0.1	0.0
C24.45	Manufacture of cobalt and cobalt alloys	I, I, I, I	8.6	0.7	0.3	-0.0
C25.5	Powder metallurgy	I, I, I, I	10.1	1.0	0.3	-0.0

Sector		R, I *	Policy options (million €)			
			1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C25.61	Surface treatment of metals	I, I, I, R	77.2	7.8	0.8	0.8
C25.62	Machining	I, I, I, I	1,304.7	250.2	49.0	3.6
C25.73	Manufacture of tools	I, I, I, I	153.2	7.5	2.5	-2.0
C25.99	Manufacture of other fabricated metal products n.e.c.	I, I, I, I	40.1	8.3	3.5	1.2
C26.1	Production of electronic components and boards	I, I, I, R	43.3	9.1	3.8	1.5
C26.51	Humidity indicator cards	I, I, I, I	-0.0	-	-	-
C27.2	Batteries	I, I, I, I	0.3	-0.2	-	-
C28.11	Engines and turbines	I, I, I, I	22.8	3.5	0.7	-0.0
C29.10-30	Automotive	I, I, I, R	-3.3	-2.1	-0.6	-0.6
C30.30	Air and spacecraft	I, I, I, I	19.2	1.9	-0.2	-0.2
C32.50	Medical and dental devices	I, I, I, I	247.3	85.9	32.8	8.6
E38.32	Metal recovery	I, I, I, I	9.8	0.3	-0.0	-
	Biogas	I, I, I, I	-	-	-	-
	Welding	I, R, R, R	10.0	6.5	2.7	1.0
	Grand Total		**2,170.8**	**427.0**	**110.9**	**20.8**

*Source: Study team. * Indicates whether compliance with the OEL for the respirable (R) or the inhalable (I) fraction will be the costliest.*

The discontinuation costs as percentage of the total adjustment costs have been estimate by sector and policy option.

Table 7-29 *PV Discontinuation adjustment costs over 40 years as a percentage of total PV compliance costs, by policy options, sector*

Sector		Aggregated costs, € million			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	0%	0%	0%	1
C19.20	Petrochemical, catalyst	0%	0%	0%	1
C20.12	Manufacture of dyes and pigments	66%	57%	54%	0%
C20.13-20.14	Manufacture of basic chemicals	93%	93%	0%	0%
C20.30	Manufacture of paints and inks	75%	67%	72%	59%
C20.59	Catalysts and formulation	72%	68%	80%	0%
C21.20	Pharmaceuticals	0%	0%	0%	0%
C22.11	Production of tyres	64%	0%	0%	0%
C23.1	Glass	33%	21%	0%	0%
C23.4	Ceramics	15%	5%	4%	0%
C23.7	Cutting stone	0%	0%	0%	0%
C24.10	Steel	90%	84%	87%	4%

Sector		Aggregated costs, € million			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C24.45	Manufacture of cobalt and cobalt alloys	39%	26%	31%	0%
C25.5	Powder metallurgy	73%	58%	64%	0%
C25.61	Surface treatment of metals	51%	38%	0%	0%
C25.62	Machining	4%	0%	0%	0%
C25.73	Manufacture of tools	90%	79%	84%	0%
C25.99	Manufacture of other fabricated metal prod-ucts n.e.c.	48%	39%	35%	0%
C26.1	Production of electronic components and boards	82%	69%	65%	0%
C26.51	Humidity indicator cards	0%	0%	0%	42%
C27.2	Batteries	61%	0%	0%	71%
C28.11	Engines and turbines	90%	86%	70%	0%
C29.10-30	Automotive	97%	94%	0%	0%
C30.30	Air and spacecraft	80%	75%	59%	0%
C32.50	Medical and dental de-vices	40%	0%	0%	0%
E38.32	Metal recovery	76%	52%	0%	0%
	Biogas	0%	0%	0%	0%
	Welding	64%	49%	0%	0%
Total		**62%**	**38%**	**13%**	**16%**

Source: Study team.

The next two tables show the adjustment costs by company size. The first table present the total costs by company size and the second presents the adjustment costs per company by size.

Table 7-30 Total PV adjustment costs over 40 years for the policy options by company size (excluding the costs of monitoring and associated administrative burden)

Size	Policy options, € million			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Small	1,501	407	118	24
Medium	4,738	773	276	50
Large	3,404	652	185	54
Total	**9,643**	**1,833**	**579**	**129**

Source: Study team.

Table 7-31 PV adjustment costs <u>per company</u> over 40 years for the policy options by company size (ex-cluding the costs of monitoring and associated administrative burden)

Size	Policy options, €			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Small	120,300	32,700	9,500	1,900
Medium	2,294,200	374,400	133,500	24,500
Large	4,260,500	815,900	231,900	67,600

Size	Policy options, €			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Total	**628,600**	**119,500**	**37,700**	**8,400**

Source: Study team.

7.2.12 Monitoring costs

Further detail about the assumptions and calculations behind the modelling of air monitoring, are provided in the Methodological Note.

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 general considerations:

- Additional monitoring would not be needed in Member States where the OEL is already at the level of the policy option or lower and with a similar scope.
- Larger companies in general undertake more often monitoring than smaller companies.
- The percentage of companies which would need to monitor increases as the OEL decreases (the larger the difference between the new OEL and current exposure concentrations).
- Not all companies would need additional monitoring - some companies already undertake monitoring and some companies, in particular smaller companies, would install additional RMMs without monitoring.
- Companies that only implement better RPE would not need an additional monitoring campaign to demonstrate efficiency of the RMM.

It is assumed that those companies that monitor would need either one or two monitoring campaigns:

- For all companies that monitor at all, one monitoring campaign before the new RMMs are introduced to establish which RMMs is required.
- For some of the companies, one further monitoring campaign after the introduction of the RMMs to demonstrate compliance if there is uncertainty as to whether the new RMMs will achieve compliance.

Costs of planning, execution, reporting and analysis

The general monitoring model presented in the Methodological Note presents the estimated costs of planning, execution, reporting and analysis programmes for one fraction only.

Based on information from a large international laboratory, the analysis price for cobalt including sample media will typically be the same for both the inhalable and respirable fraction and €200 for each (i.e. €400 for both the inhalable and respirable fraction). It is assumed that the time used for planning, sampling and reporting will be the same for two fractions as for one. The sampling of the two fractions is done simultaneously as the workers are wearing two samplers and even the mounting of samplers may take slightly longer time, the difference is considered marginal. From the stakeholder consultation it has been found that companies would measure both fractions. It is also required by the ISO 15202 standard. The difference between sampling one and two fractions consists of costs of sampling media, analysis and equipment.

The table shows that when the company is much below the OEL (when the median of the measured concentrations is much lower than the OEL (OEL/median >2), then there are less requirements on monitoring and therefore lower costs.

Table 7-32 Costs of planning, execution, reporting by consultant to company and analysis of monitoring campaign per company by size of company, not discounted.

Fractions measured	OEL / median > 2			OEL / median < 2		
	S	M	L	S	M	L
Measuring inhalable fraction only	€ 2,294	€ 6,270	€ 8,729	€ 2,922	€ 9,356	€ 13,646
Measuring both inhalable and respirable fraction	€ 2,914	€ 8,590	€ 12,169	€ 3,902	€ 13,156	€ 19,326
Extra costs of measuring two fractions	€ 620	€ 2,320	€ 3,440	€ 980	€ 3,800	€ 5,680

The estimated costs per sample (inhalable and respirable fraction) range from € 971 for small companies to € 676 for large companies. In comparison it has been reported for the stakeholder consultation that the price per sample for large companies is around € 600.

For comparison eftec (2023) applies a monitoring costs per site (large and medium-sized) for the respiratory fraction at € 10,000 per company per year. The figure is quite well in accordance with the estimates for medium and large companies shown above.

Companies with exposed workers operating above each policy option

As indicated in section 3.1.2, only three Member States have OELs (or comparable limit values) for the respirable fraction: Germany (proposed tolerable and acceptable cancer risk levels), Belgium and Czechia. In all other Member States companies would in addition to what they already measure need to measure the respirable fraction.

In Czechia, no OEL is established for the inhalable fraction. In Belgium a limit value for the inhalable fraction is established for cobalt metal but not for cobalt compounds. However, the highest policy option is for the respirable OEL below the Belgian OEL, and monitoring would consequently be needed. In Germany, a so-called OEL-analogue value ('*AGW analoger Wert*') has been established for the inhalable fraction at 20 µg/m^3. It will consequently be assumed that no additional monitoring would be needed in Germany at the 20 / 4.2 µg Co/m^3 policy level.

Additional costs of monitoring both respirable and inhalable fraction

The costs of monitoring will in general increase by measuring both the respirable and inhalable fraction instead of either the respirable or inhalable fraction. The observed shortage of paired measurements indicates that, apart from Germany, it is not common to measure both fractions. For compliance monitoring some companies may after the initial additional air monitoring campaign choose to measure the fraction which is most critical but as it may differ by work processes it will be assumed that all companies which monitor will measure both fractions.

Not all companies will monitor the air concentrations frequently. If the measured concentrations are well below the OELs many companies would not monitor. This is in particular the situation for small companies. No data are available on the current number of measurements across Europe.

Some indications of number of reported data are available from France and Italy but none of the countries have established binding OELs for cobalt and inorganic cobalt compounds.

It will in accordance with previous OEL studies (e.g. for nickel and di-isocyanate) be assumed that monitoring take place every five years. The additional monitoring campaigns will account for the first two campaigns so in total 7 campaigns are assumed over the 40-years period starting with a campaign after 5 years. In reality many larger companies monitor more often but the five years is taken as an average. It will, furthermore, be assumed that not all companies undertake regular monitoring. As reported in the Methodological Note, only a few small companies do regularly monitoring whereas it is common that the large companies do. Furthermore, companies where exposure to cobalt is prominent and the exposure levels relatively high will typically do monitoring whereas downstream users with relatively low levels and few exposed workers will tend not to do regular monitoring. As an average for all sectors, it will be assumed that 70% of the large companies do regular monitoring, 30% of the medium-sized and 5% of the small-sized.

It will be assumed that the monitoring frequency after 5 years would be independent of the OEL as RMMs would have been applied to bring the exposure concentrations below the OEL.

The extra costs incurred will be estimated as the difference of undertaking monitoring of one fraction only and monitoring of both the inhalable and respirable fraction.

Costs of air monitoring

The total estimated total costs by policy option for up to two additional air monitoring campaigns and costs of the monitoring of one additional fraction each 5 years are summarised in Table 7-33. As there will be an OEL for both fractions, it is assumed that companies to demonstrate compliance would have to monitor both fractions and will have to continue to do so.

The basis for the calculations is the monitoring cost model described in the Methodological Note supplemented with the information above.

The total costs by sector and policy option are shown in Annex I.

Table 7-33 Total estimated costs of up to two additional air monitoring campaigns in € million over 40 years by policy option

Policy option	Total costs € million			
	Small	Medium	Large	Total
1 / 0.5 µg Co/m^3	23.6	52.9	35.6	112.1
5 / 1.25 µg Co/m^3	14.4	44.3	30.2	88.9
10 / 2.5 µg Co/m^3	8.7	27.6	21.0	57.3
20 / 4.2 µg Co/m^3	7.5	19.3	16.2	43.0

Source: Study team

Biomonitoring

Many companies undertake biomonitoring and health surveillance as supplement to air monitoring. Although biomonitoring can be used as an indicator of changes in the exposure situations and thereby contribute to the monitoring of compliance with an OEL, biomonitoring is not directly linked to establishing an OEL. Costs of additional biomonitoring is according to the methodology used only included if a BLV has been proposed by RAC. As the RAC has not proposed a BLV for cobalt, no biomonitoring costs are included in the assessment.

7.2.13 Administrative costs

For enterprises, the cost of planning and executing 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 manage the monitoring undertaken by the third party and this administrative task is included in the company administrative burden.

The administrative burden costs for air monitoring per company by size are shown below, together with the days assumed required by companies by size to set up and manage the monitoring campaigns. As in the previous calculations of cost of the monitoring, the cost of a worker or manager is assumed to be €500/day.

Table 7-34 Costs per company of administrative burden to additional campaigns for air monitoring, by size of enterprise, discounted as appropriate over 40 years

	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.

The total costs of the administrative burden of undertaking the additional air monitoring for companies are shown below, by size of company for each policy option. The costs by sector and policy option are shown in Annex I.

Table 7-35 Total estimated costs of administrative burden of additional air monitoring by size and policy option discounted as appropriate over 40 years

Policy option	Total costs, € million			
	Small	Medium	Large	Total
1 / 0.5 µg Co/m³	3.0	5.6	4.6	13.2
5 / 1.25 µg Co/m³	1.8	4.8	3.9	10.5
10 / 2.5 µg Co/m³	1.2	3.6	3.0	7.8
20 / 4.2 µg Co/m³	1.0	2.3	1.9	5.2

7.2.14 Aggregated costs for companies by sector

The costs of compliance for companies by sector are shown in Table 7-36, by size of company in Table 7-38; and as costs per company by size of company in Table 7-39. The total aggregated costs of risk management measures, monitoring, administrative burden for companies and public authorities are shown in Table 7-44. Data by sector and size of company by policy option are shown in Table 16-17 in Annex I.

These costs exclude the social costs from employment changes which are covered in Section 6.4.

Table 7-36 *Aggregated costs of PV adjustment, monitoring and administrative costs discounted over 40 years, by sector, by policy options)*

Sector		Aggregated costs, € million			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	4	1	1	1
C19.20	Petrochemical, catalyst	42	6	2	1

Sector		Aggregated costs, € million			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C20.12	Manufacture of dyes and pigments	118	35	15	7
C20.13-20.14	Manufacture of basic chemicals	93	19	1	0
C20.30	Manufacture of paints and inks	16	3	1	0
C20.59	Catalysts and formulation	66	12	10	2
C21.20	Pharmaceuticals	1	0	0	0
C22.11	Production of tyres	5	0	0	0
C23.1	Glass	39	7	1	0
C23.4	Ceramics	311	96	42	19
C23.7	Cutting stone	46	9	4	3
C24.10	Steel	57	6	3	0
C24.45	Manufacture of cobalt and cobalt alloys	28	4	2	1
C25.5	Powder metallurgy	77	9	4	1
C25.61	Surface treatment of metals	350	50	8	7
C25.62	Machining	2,090	660	163	41
C25.73	Manufacture of tools	3,492	398	190	20
C25.99	Manufacture of other fabricated metal products n.e.c.	121	30	13	6
C26.1	Production of electronic components and boards	482	100	43	20
C26.51	Humidity indicator cards	0	0	0	0
C27.2	Batteries	12	1	0	0
C28.11	Engines and turbines	455	112	23	2
C29.10-30	Automotive	858	89	2	2
C30.30	Air and spacecraft	200	50	13	1
C32.50	Medical and dental devices	645	187	84	32
E38.32	Metal recovery	91	7	1	0
	Biogas	16	13	10	7
	Welding	52	28	9	4
Total		**9,768**	**1,932**	**644**	**177**

Source: Study team.

Table 7-37 *Aggregated costs of PV adjustment, monitoring and administrative costs for companies discounted over 40 years by policy options*

Cost element	Aggregated costs, € million			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Adjustment costs	9,643	1,833	579	129
Monitoring costs	112	89	57	43
Administration	13	10	8	5
Total	**9,768**	**1,932**	**644**	**177**

Source: Study team.

The aggregated costs of PV adjustment, monitoring and administrative burden discounted over 40 years, by size of enterprise, by sector, by policy options are shown in Annex I and summarised in the tables below.

Table 7-38 PV adjustment, monitoring and administrative burden costs over 40 years for the policy options by company size

Size	Aggregated costs, € million			
	1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Small	1,528	424	128	33
Medium	4,796	822	307	72
Large	3,448	687	209	72
Total	**9,772**	**1,932**	**644**	**177**

Source: Study team.

Table 7-39 PV adjustment, monitoring and administrative burden costs per company over 40 years for the policy options by company size in €

Size	Costs per company, €			
	1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Small	122,400	34,000	10,200	2,600
Medium	2,322,700	398,200	148,600	34,900
Large	4,315,400	859,200	261,800	90,300
Total	**637,000**	**126,000**	**42,000**	**11,500**

Source: Study team.

Table 7-40 Annual adjustment, monitoring and administrative costs for the policy options by company size in € million

Size	Total costs, € million			
	1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Small	38	11	3	1
Medium	120	21	8	2
Large	86	17	5	2
Total	**244**	**48**	**16**	**4**

Source: Study team.

Table 7-41 Annual adjustment, monitoring and administrative costs per company for the policy options by company size

Size	Costs per company, €			
	1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Small	3,060	850	260	70
Medium	58,070	9,960	3,720	870
Large	107,890	21,480	6,550	2,260
Total	**15,930**	**3,150**	**1,050**	**290**

Source: Study team

7.2.15 Regulatory charges

There are no regulatory charges included in any of the considered policy options.

7.2.16 Comparison of costs estimates

The direct adjustment costs calculated above, using the generic adjustment cost model used for the study and the monitoring cost model, differs from the estimated costs of compliance provided by other sources. In the following, the estimated costs using these models are compared to costs per company provided by companies for the stakeholder survey (reported in section 7.2.10.2) and costs estimated by an impact assessment undertaken by the consultancy company eftec for the Cobalt Institute (reported in section 7.2.10.5).

Comparison with estimates provided by companies for the stakeholder survey. Costs per site calculated on the basis of estimates provided by companies for the stakeholder survey and calculated by the use of the cost model for this study, respectively, are shown in Table 7-42. The costs reported for the stakeholder survey represent average costs for companies not in compliance whereas the costs calculated by the costs model represent an average for all companies of which only some companies would have costs of compliance. The costs provided for large companies are of the same size as costs reported by companies to the eftec (2023) study. The costs estimates provided by three small companies for the present stakeholder survey is approximately 1/4 of the costs estimated by the larger companies which is far from the results of the costs model which estimates that the average costs for large companies is about 30 times higher than the average costs for small companies. It is here considered that the costs provided for small companies for the stakeholder survey are far too high. The discussion below will focus on comparisons of estimates for the large companies; quite similar calculations could be done for the medium-sized companies.

The difference between the costs estimated by companies and the costs estimated by use of the cost model is significantly higher for the higher policy options than for the policy option of 1 / 0.5 µg Co/m^3. A remarkable difference between the two set of estimates is that costs estimated by companies is only slightly higher at 1 / 0.5 µg Co/m^3 as compared with the options of 10 / 2.5 µg Co/m^3, whereas the costs estimated by the cost model increase steeply toward the lower policy options.

At the policy option 1 / 0.5 µg Co/m^3, about 95% of the companies would, as estimated by the cost model, have to implement additional RMMs, change to alternatives or cease production. The difference between the estimates provided by companies and calculated by the cost model is a factor of 4, which may reflect that the companies providing estimates for the questionnaire are to a large extent companies in the high end of the supply chain (manufacturers of cobalt and cobalt alloys, producers of cobalt powder and blanks for hardmetal tools, etc.) which may be particularly impacted by introduction of an OEL. These companies would typically have more exposed workers and more SEGs (Similar Exposure Groups) as compared with companies down steam (e.g. companies using the hardmetal blanks for production of tools or companies sharpening tools).

At the policy options 5 / 1.25 µg Co/m^3 and 10 / 2.5 µg Co/m^3, the difference between the estimates by companies and the cost model become significantly larger.

At 10 / 2.5 µg Co/m^3, the average estimates costs provided by companies is for large-sized companies is approximately 60 times the average estimate for the large-sized companies when using the cost model. A part of the difference is that only some of the companies are expected to have costs at this policy level. As mentioned above, the costs reported for the stakeholder survey represent average costs for companies not expecting to be in compliance at the different policy options. At 10 / 2.5 µg Co/m^3, the costs model estimates, the percentage of companies that have to implement additional RMMs at 13% for large sized companies. Taking this into account, still the estimates provided by companies is about 8 times higher than estimates by the cost model. A part of this may reflect that the companies responding to the survey are among the companies which may be particularly affected by the introduction of an OEL. In addition, a part of the difference may reflect that the companies typically assume that the company has to be in fully compliance with the OEL without using RPE for some processes, whereas it for the estimates for the current study is assumed that RPE may be used for some exposure situations where the use of RPE is in general accepted today (e.g. cleaning and maintenance). It is uncertain to what extent the explanations provided above could fully explain the differences, and it cannot be excluded that the difference partly could be due to some underestimations of the actual costs by the cost model, in particular at the higher policy levels. This is further discussed in chapter 13 on limitations and sensitivity analysis.

Table 7-42 Total average adjustment costs per company as indicated by respondents to questionnaire survey and calculated using the cost model for this study, discounted over 40 years, € million

Policy option	Costs per site not in compliance, stakeholder survey, € million			Total costs per company (all companies), calculated by cost model, € million		
	Small (n= 3)	Medium (n=12	Large (n=23)	Small	Medium	Large
1 / 0.5 µg Co/m^3	5.8	20.4	21.9	0.15	2.62	5.01
5 / 1.25 µg Co/m^3	3.9	13.0	16.8	0.04	0.42	0.95
10 / 2.5 µg Co/m^3	7.4	7.8	16.3	0.01	0.15	0.27

Source: Study team on the basis of questionnaire responses.

Comparison with the Cobalt Institute impact assessment.

The impact assessment commissioned by the Cobalt Institute and prepared by the consultancy company eftec (as reported in section 7.2.10.5) as well as data on exposure levels and CSRs (Chemical Safety Reports) provided by the Cobalt Institute have been used as key stakeholder inputs for the current study. The data have been assessed along with data obtained from stakeholder surveys and other available data sources. With regard to exposure levels, exposed workforce, and number and companies with exposed workers - for those sectors covered by the Cobalt Institute impact assessment - the estimates used for the current study are well in accordance with the data provided by the Cobalt Institute.

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

- The overall methodology applied is different between the two impact assessments: The Cobalt Institute impact assessment extrapolates the costs and compliance level from survey responses from 59 companies to a total of 4,962-9,821 companies. The costs of compliance with each policy option are extrapolated from the costs estimated by those companies, which consider they would not be in compliance with the policy option. At an OEL of 20 µg/m³, as an example, 22% of the respondents consider they would not be in compliance, i.e. the total costs for all sectors are extrapolated from responses from about 10 companies representing only some sectors. The current study applies a costs model which use actual exposure levels across sectors and the modelled costs of reducing the exposure levels in order to be in compliance with the different policy options. The cost model has been used for impact assessments of more than 10 substances/substance groups under this and previous OELs assessments. The average costs provided by the companies for the Cobalt Institute impact assessment are for large companies and SMEs well in accordance with the estimates provided by companies for the current study and likely many of the respondents for the two impact assessments are the same. For the current study the costs provided by the companies have been used for informing the study and model estimates but are not considered representative and has not been used for extrapolation.

- The two studies assume different shares of large companies. The Cobalt Institute impact assessment assumes for the extrapolation of costs that 19% of the companies with exposed workers are large companies (the percentage reflects the percentage of responding companies). The current study estimates the share of large companies at 5% based on an assessment of the sector structures. For comparison, the overall share of large companies within the covered sectors in the Eurostat SBS (Structural Business Statistics) is 0.7%. The extrapolation of unit costs of large companies to a high share of all companies results in significant higher costs in the Cobalt Institute impact assessment than estimated in the current study.
- The Cobalt Institute impact assessment is based on the assumption that companies for all processes have to achieve compliance with the OELs without taking RPEs (Respiratory Protection Equipment) into account. The current study provides data on exposure levels by sector both with and without RPE. These data demonstrates that for some processes, the exposure levels without taking the used RPE into account (i.e. the exposure concentration in the workplace) are typically above the highest of the policy option of 20 µg/m³ but is below 20 µg/m³ when the applied RPE is taken into account. For the costs estimates for the current study, in accordance with the methodology used in previous impact assessments, it is assumed that RPE may be used to bring the exposure below the OEL for some exposure situations where the use of RPE is in general accepted today and where the scope for further technical preventive measures for limiting workers' exposure has already been exhausted (e.g. some cleaning and maintenance operations). This result in major differences in costs estimates in particular at the higher OEL levels. It should be noted that the use of RPE is last resort and the CMRD in any case, irrespective of an OEL, stipulates that other RMMs should be applied where possible.
- The Cobalt Institute impact assessment assumes that all companies would need biomonitoring and this account for a significant part of total costs. The costs of biomonitoring are estimated in the Cobalt Institute impact assessment at 33% for an OEL of 10 µg/m³ and around 38% for an OEL of 20 µg/m³. As RAC has not proposed a BLV and the CMRD does not require that compliance with an OEL is demonstrated by use of biomonitoring, it is in the current study considered that companies' possible costs of biomonitoring cannot be allocated to the introduction of an OEL.
- The Cobalt Institute impact assessment assumes that companies need annual air monitoring in order to demonstrate compliance and this account for a significant part of the total costs. The costs of air monitoring are estimated in the Cobal Institute impact assessment at 12% for an OEL of 10 µg/m³ and around 14% for an OEL of 20 µg/m³. The current study applies a model for calculating monitoring costs based on an assessment of actual practice of monitoring and the requirements of the CMRD and the European standard for demonstrating compliance with an OEL (EN 689:2018+AC:2019). The estimated incremental costs are significantly lower than estimated by the Cobalt Institute impact assessment as the compliance costs model takes into account that many companies already undertake monitoring today and that the frequency of compliance monitoring will be lower when companies have implemented the necessary RMMs and demonstrated compliance.

- The current study includes more downstream sectors and thereby include more companies and exposed workers than the Cobalt Institute impact assessment.

7.3 Indirect costs for companies

Indirect costs for companies are covered in Chapter 8 on market effects and in Chapter 11 on the distribution of the impacts.

7.4 Costs for public administrations

7.4.1 Costs of transposition

Member States incur costs transposing the relevant changes into national legislation. In practice, the exact costs depend on the specific changes agreed in the final version of the amendment to the Directive and the regulatory model used in each country to implement the Directive (i.e. the number of departments involved in transposition or implementing the Directive). These costs vary significantly between Member States (for example, some Member States are obliged to carry out an impact assessment on new EU legislation).

Specific data on the costs of transposition of EU legislation by Member States and their relevant departments/ministries are not readily available.

In accordance with the previous OEL studies, this study takes €50,000 per Member State as an approximation of the general order of magnitude of the applicable transposition costs for Member States where there is currently no OEL and €30,000 per Member State where there is some existing OEL.

Total transposition costs for Member State public administrations are summarised in Table 7-43. As none of the Member States have an OEL with exactly the same scope and including both inhalable and respirable fraction, it is assumed that all Member States would have costs of transposition.

If several OELs are implemented at the same time, the transposition costs might be lower.

Table 7-43 Transposition costs for Member State public administrations

Policy option	Member States required to revise the OEL *	Number of MS	Total cost across the EU
1 / 0.5 µg Co/m³	All Member States	27	€ 910,000
5 / 1.25 µg Co/m³	All Member States	27	€ 910,000
10 / 2.5 µg Co/m³	All Member States	27	€ 910,000
20 / 4.2 µg Co/m³	All Member States	27	€ 910,000

** With regard to the level, substances and/or inhalable/respirable fraction covered.*

Member States: Situation	Number of Member States	Transposition cost per Member State, €	Total cost across the EU, € million
1 / 0.5 µg Co/m³			
No OEL: IT, LU, MT, PT, SI	5	€ 50,000	€ 0.25
Has an OEL AU, BE, BG CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE,	22	€ 30,000	€ 0.66

Member States: Situation	Number of Member States	Transposition cost per Member State, €	Total cost across the EU, € million
LV, LT, NL, PL, RO, SE, SK			
Total cost			**€ 0.91**
5 / 1.25 µg Co/m³			
No OEL: IT, LU, MT, PT, SI	5	€ 50,000	€ 0.25
Has an OEL AU, BE, BG CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LV, LT, NL, PL, RO, SE, SK	22	€ 30,000	€ 0.66
Total cost			**€ 0.91**
10 / 2.5 µg Co/m³			
No OEL: IT, LU, MT, PT, SI	5	€ 50,000	€ 0.25
Has an OEL AU, BE, BG CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LV, LT, NL, PL, RO, SE, SK	22	€ 30,000	€ 0.66
Total cost			**€ 0.91**
20 / 4.2 µg Co/m³			
No OEL: IT, LU, MT, PT, SI	5	€ 50,000	€ 0.25
Has an OEL AU, BE, BG CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, LV, LT, NL, PL, RO, SE, SK	22	€ 30,000	€ 0.66
Total cost			**€ 0.91**

Source: Study team.

If limit values for more than one substance/substance group are introduced at the same time, there may be a reduction in cost, but this is impossible to estimate. A Member State may already have a limit value for one substance but not for the other. Furthermore, if the OEL has a phased introduction, there may be an increase in transposition costs as Member States have to alert companies at each stage. The study team does not know which, if any, OELs will actually be introduced and when, and therefore this factor cannot be incorporated into the cost of transposition.

7.4.2 Enforcement costs

The enforcement, monitoring and adjudication costs depend on the number of companies that will be covered by the OEL. In principle, national 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 rules. Such enforcement costs depend on the inspection regime in each Member State, and they are not estimated in this study. Compared to total costs of the measures under consideration these enforcement costs are considered likely to be insignificant.

7.5 Impact of transitional periods on costs

There are two different effects of transitional periods. By transitional periods is here understood the time from adopting on OEL until the actual compliance has to be achieved. The length on the transitional periods could impact on:

- Potentially reduce the adjustment costs;
- Make the financing of the adjustment costs easier and cheaper.

Transitional period might affect the adjustment costs. The longer time companies have to implement compliance measures, the lower are the likely costs. More time means that it is possible to plan investment or that changes motivated by other objectives can be combined with compliance actions. It is not possible to quantify the impact on the adjustment costs.

From the perspective of estimating the net present value over 40 years, and assuming that there would be for example a transitional period of six years, would reduce the discounted costs. If all costs are postponed by six years, the total discounted value would be 16% lower.

Transitional periods will have another effect. That is to make the financing of the investments easier. By spreading the substantial one-off investments over a number of years, it will be easier to finance the investments out of the companies' annual budgets for investments. Again, if the transitional period is six years, then companies would have six years to make savings for the necessary investments. It means when estimating the ratio of one-off costs to annual turnover, the real impact would be only one sixth of the impact without the transitional period of six years.

7.6 Summary of costs of the measures

The aggregated total costs (compliance costs) over 40 years for the policy options (without transitional measures) are summarised in Table 7-40.

The key findings in relation to the costs assessment of the alternative options are discussed below.

The estimated adjustment costs for the lowest OEL are significantly larger than for the other options. This is because it is technically challenging to achieve this OEL. This high cost estimate is based on the assumptions on the existing RMM and the potential for introducing additional RMM measures. This kind of assessment is subject to some uncertainty. The following factors are important:

- The use of closed systems. Closing the processes where the exposure takes place is an effective measure. It might be that potential costs of closed systems deviate from the general assumptions in the cost model. Here, the potential is estimated by sector, but costs are average across all sectors.
- The risk of companies having to discontinue. The cost model estimates the number of companies that might discontinue. It is based on the availability of additional RMM and their costs. If companies already have closed systems, it might not be feasible or be very costly to further improve the system and reduce the workplace concentrations. The costs of discontinuation are very high and for the lowest OEL, the costs of discontinuation comprise a large share of the costs (see the below table). If companies might be able to find RMMs or could shift to alternatives, the costs of the lowest OEL might be significantly lower.

For the three policy options of 5 / 2.15, 10 / 2.5 or 20 / 4.2 µg Co/m³, the costs are of a size where the companies should be able to cover the costs or pass some of them on their customers. This aspect is further analysed in the next section on market effects.

The assessment shows that the one-off adjustment costs for business comprise the largest share of the costs. They account for around 80% of the total PV costs for OEL of 1 / 0.5 µg Co/m³ and around 60% for the OEL of 20 / 4.2 µg Co/m³. The monitoring costs comprise only a small share of the total costs. For the OEL of 20 / 4.2 µg Co/m³ the monitoring and administrative costs for business account for 22%, while for the OEL of 1 / 0.5 µg Co/m³ they comprise only 1%.

It is unlikely that the adjustment costs will lead to significant changes to any consumer product. Hence, the consumers will not be affected.

The further effects of possible discontinuations are very uncertain. Firstly, the number of companies that have to discontinue might be lower than estimated and if there will be companies closing down, this is likely to be offset by increased activity in other companies. Still, there could be the transitional costs associated with companies closing and workers being unemployed for some time. There might also be distributional effects, see Chapter 11. The costs related to one worker being unemployed is estimated as the annual salary in the affected sectors times a factor of 2.7. This factor reflects that the period of unemployment, the costs of job search etc.[56]

The most affected sectors include machining and manufacture of hard metal and diamond tools. For diamond tools and to some extent machining, there are alternatives, and this might reduce the cost impact. These two sectors are related as Machining is using the tools manufactured by the Sector 'Manufacture of tools'. Should the adjustment costs for the manufacture of tools lead to cost increases of the tools, then the sector Machining will be facing increased costs. They might purchase imported tools, but as the market analyses shows, this sector is relatively less impacted.

Table 7-44 Aggregated total costs over 40 years for the policy options, € millions over 40 years (without transition measures)

Description	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Adjustment costs (one-off excluding discontinuation)	Business	1,481	708	237	88
Adjustment costs (recurrent)	Business	2,171	427	111	21
Discontinuation costs	Business	5,991	698	231	20
Monitoring costs	Business	112	89	57	43
Administrative costs	Business	13	10	8	5
Administrative costs	Public administrations	0.9	0.9	0.9	0.9
Single-market	Consumers	No signficant impacts are estimated.			
Total across all sectors /companies /stakeholders		**9,769**	**1,933**	**645**	**178**
Social costs (employment)	Workers & families	1,970	217	83	7

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together). Note that values are rounded and therefore might not add-up exactly.

[56] See the Methodological note, Section 8.2 for details of the estimation of costs of unemployment.

The estimated social costs are subject to large uncertainties. They are not included in the total costs as they are unlikely to be of the estimated level. It is not possible to further assess how large the social costs could be.

8 MARKET EFFECTS

This chapter comprises the following sections:

- Section 8.1: Overall impact
- Section 8.2: Research and innovation
- Section 8.3: Single market
- Section 8.4: Competitiveness of EU businesses
- Section 8.5: Employment.
- Section 9.5: Summary of the market effects

8.1 Overall impact

Overall, market impacts (in terms of the effect on the single market, R&D, competitiveness of EU businesses and employment) are strongly influenced by two key drivers, the extent to which costs are incurred to comply with the OEL and by the feasibility of meeting the required air concentrations. In extreme cases, companies will be forced out of business if they are unable to meet the OEL at a cost that maintains profitability.

The assessment of market effects is based on the calculation of two key indicators, i) the costs in relation to turnover and ii) the costs in relation to operating surplus. The comparison of total costs, where the costs include adjustment costs, monitoring and administrative costs, illustrates the overall impacts on the concerned industries. It shows how much the price of the products manufactured in the concerned industries should increase to cover the additional costs. In cases, where international competition means that additional costs cannot be passed on the consumers, the indicator showing cost compared to annual operation surplus give some indication of the loss of profit that companies would take and whether that will significantly reduce their ability to continue operating.

The starting point is the estimated total costs. In Section 7, the total PV over the 40-year assessment periods has been estimated.

Table 8-1 provides estimates of the adjustment costs that are estimated to be incurred on a per company basis (discounted at 3% over 40 years). The rest of the section provides an analysis of the likely impacts arising from the key drivers of competition in both the EU and overseas markets. Zero values indicate there are no costs for adjustment as enterprises are already achieving the OEL level.

Table 8-1 Total PV compliance costs (RMMs, discontinuations, monitoring and administrative burden) per company discounted over 40 years by policy options and sector) (€ millions)

Sector		Cost of adjustment per company in € millions over 40 years			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91	Manufacture, feeds	0.01	0.00	0.00	0.00
C19.20	Petrochemical, catalyst	0.51	0.07	0.03	0.02
C20.12	Manufacture of dyes and pigments	7.89	2.31	0.98	0.46

Sector		Cost of adjustment per company in € millions over 40 years			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C20.13 -20.14	Manufacture of basic chemicals	3.12	0.63	0.03	0.01
C20.30	Manufacture of paints and inks	1.62	0.29	0.14	0.02
C20.59	Catalysts and formulation	1.35	0.24	0.20	0.03
C21.20	Pharmaceuticals	0.13	0.04	0.03	0.02
C22.11	Production of tyres	1.63	0.12	0.03	0.03
C23.1	Glass	0.77	0.13	0.03	0.01
C23.4	Ceramics	0.62	0.19	0.08	0.04
C23.7	Cutting stone	0.05	0.01	0.00	0.00
C24.10	Steel	8.09	0.81	0.39	0.03
C24.45	Manufacture of cobalt and cobalt alloys	4.69	0.70	0.30	0.09
C25.5	Powder metallurgy	2.49	0.30	0.14	0.03
C25.61	Surface treatment of metals	0.74	0.11	0.02	0.02
C25.62	Machining	0.35	0.11	0.03	0.01
C25.73	Manufacture of tools	1.52	0.17	0.08	0.01
C25.99	Manufacture of other fabricated metal products n.e.c.	0.80	0.20	0.09	0.04
C26.1	Production of electronic compo-nents and boards	1.92	0.40	0.17	0.08
C26.51	Humidity indicator cards	0.02	0.01	0.01	0.00
C27.2	Batteries	0.75	0.07	0.02	0.02
C28.11	Engines and turbines	3.50	0.86	0.18	0.01
C29.10 -30	Automotive	6.60	0.69	0.01	0.01
C30.30	Air and spacecraft	1.54	0.39	0.10	0.01
C32.50	Medical and dental devices	1.29	0.37	0.17	0.06
E38.32	Metal recovery	6.06	0.47	0.06	0.02
	Biogas	0.01	0.00	0.00	0.00
	Welding	1.02	0.54	0.17	0.07
	Total	**0.64**	**0.13**	**0.04**	**0.01**

Source: Study team.

Table 8-2 PV adjustment costs (RMMs) per company to comply with OELs over 40 years, additional to the baseline, by size

Sector	Cost of adjustment per business, by OEL, and by size (in € million)		
	Small	Medium	Large
1 /0.5 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	0.00	0.06	0.19
C19.2 Manufacture of refined petroleum products	-	0.14	0.89
C20.12 Manufacture of dyes and pigments	-	5.33	8.82
C20.13 Manufacture of other inorganic basic chemicals	0.21	4.71	5.59
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.22	3.68	3.82
C20.59 Manufacture of other chemical products n.e.c.	0.17	1.74	1.91
C21.2 Manufacture of pharmaceutical preparations	-	-	0.13
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	1.63
C23.1 Manufacture of glass and glass products	0.06	1.02	2.81
C23.4 Manufacture of other porcelain and ceramic products	0.08	1.07	3.81
C23.7 Cutting, shaping and finishing of stone	0.03	0.31	0.93
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.23	9.78	17.04
C24.45 Other non-ferrous metal production	-	-	4.69
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.18	3.60	4.63
C25.61 Treatment and coating of metals	0.10	1.93	2.86
C25.62 Machining	0.13	0.82	2.47
C25.73 Manufacture of tools	0.28	10.62	10.61
C25.99 Manufacture of other fabricated metal products n.e.c.	0.13	2.50	3.91
C26.1 Manufacture of electronic components and boards	0.28	5.83	10.55
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.00	0.03	0.09
C27.2 Manufacture of batteries and accumulators	-	0.51	0.98
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.86	12.36	19.33
C29.1 Manufacture of motor vehicles	0.19	4.60	86.34
C30.3 Manufacture of air and spacecraft and related machinery	0.25	3.26	19.89
C32.5 Manufacture of medical and dental instruments and supplies	0.13	2.16	5.66
E38.32 Recovery of sorted materials	-	6.10	6.02
R90 Other: Biogas	0.00	0.02	0.04
R90.03 Welding	0.13	3.38	6.49
Total	**0.12**	**2.33**	**4.32**

Sector	Cost of adjustment per business, by OEL, and by size (in € million)		
	Small	Medium	Large
5 /1.25 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	0.001	0.019	0.035
C19.2 Manufacture of refined petroleum products	-	0.025	0.124
C20.12 Manufacture of dyes and pigments	-	1.398	2.639
C20.13 Manufacture of other inorganic basic chemicals	0.042	0.951	1.128
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.039	0.621	0.762
C20.59 Manufacture of other chemical products n.e.c.	0.028	0.289	0.349
C21.2 Manufacture of pharmaceutical preparations	-	-	0.035
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.122
C23.1 Manufacture of glass and glass products	0.010	0.155	0.508
C23.4 Manufacture of other porcelain and ceramic products	0.024	0.284	1.280
C23.7 Cutting, shaping and finishing of stone	0.006	0.063	0.170
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.027	0.957	1.786
C24.45 Other non-ferrous metal production	-	-	0.702
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.023	0.410	0.684
C25.61 Treatment and coating of metals	0.015	0.248	0.467
C25.62 Machining	0.054	0.243	0.600
C25.73 Manufacture of tools	0.035	1.150	1.368
C25.99 Manufacture of other fabricated metal products n.e.c.	0.034	0.593	1.094
C26.1 Manufacture of electronic components and boards	0.064	1.169	2.239
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.001	0.019	0.035
C27.2 Manufacture of batteries and accumulators	-	0.039	0.108
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.211	3.020	4.823
C29.1 Manufacture of motor vehicles	0.027	0.540	8.842
C30.3 Manufacture of air and spacecraft and related machinery	0.068	0.863	4.827
C32.5 Manufacture of medical and dental instruments and supplies	0.053	0.545	1.791
E38.32 Recovery of sorted materials	-	0.383	0.556
R90 Other: Biogas	0.000	0.003	0.010
R90.03 Welding	0.078	1.666	3.645
Total	**0.03**	**0.40**	**0.86**
10 /2.5 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	0.001	0.015	0.029

Sector	Cost of adjustment per business, by OEL, and by size (in € million)		
	Small	Medium	Large
C19.2 Manufacture of refined petroleum products	-	0.015	0.043
C20.12 Manufacture of dyes and pigments	-	0.567	1.126
C20.13 Manufacture of other inorganic basic chemicals	0.003	0.037	0.059
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.019	0.302	0.338
C20.59 Manufacture of other chemical products n.e.c.	0.025	0.268	0.270
C21.2 Manufacture of pharmaceutical preparations	-	-	0.029
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.029
C23.1 Manufacture of glass and glass products	0.002	0.030	0.102
C23.4 Manufacture of other porcelain and ceramic products	0.010	0.121	0.569
C23.7 Cutting, shaping and finishing of stone	0.002	0.031	0.075
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.012	0.468	0.842
C24.45 Other non-ferrous metal production	-	-	0.297
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.010	0.193	0.293
C25.61 Treatment and coating of metals	0.002	0.031	0.091
C25.62 Machining	0.013	0.063	0.144
C25.73 Manufacture of tools	0.016	0.560	0.624
C25.99 Manufacture of other fabricated metal products n.e.c.	0.015	0.256	0.499
C26.1 Manufacture of electronic components and boards	0.028	0.495	0.964
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.001	0.015	0.029
C27.2 Manufacture of batteries and accumulators	-	0.015	0.029
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.043	0.592	1.080
C29.1 Manufacture of motor vehicles	0.003	0.038	0.093
C30.3 Manufacture of air and spacecraft and related machinery	0.021	0.250	1.158
C32.5 Manufacture of medical and dental instruments and supplies	0.024	0.248	0.786
E38.32 Recovery of sorted materials	-	0.029	0.086
R90 Other: Biogas	0.000	0.003	0.010
R90.03 Welding	0.031	0.384	1.439
Total	**0.01**	**0.15**	**0.26**
20 /4.2 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	0.001	0.011	0.024
C19.2 Manufacture of refined petroleum products	-	0.011	0.024
C20.12 Manufacture of dyes and pigments	-	0.279	0.521

Sector	Cost of adjustment per business, by OEL, and by size (in € million)		
	Small	Medium	Large
C20.13 Manufacture of other inorganic basic chemicals	0.001	0.010	0.022
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.003	0.030	0.095
C20.59 Manufacture of other chemical products n.e.c.	0.002	0.021	0.075
C21.2 Manufacture of pharmaceutical preparations	-	-	0.021
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.025
C23.1 Manufacture of glass and glass products	0.001	0.011	0.024
C23.4 Manufacture of other porcelain and ceramic products	0.005	0.057	0.251
C23.7 Cutting, shaping and finishing of stone	0.002	0.026	0.069
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.002	0.025	0.086
C24.45 Other non-ferrous metal production	-	-	0.086
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.002	0.030	0.094
C25.61 Treatment and coating of metals	0.002	0.027	0.085
C25.62 Machining	0.003	0.018	0.039
C25.73 Manufacture of tools	0.003	0.037	0.117
C25.99 Manufacture of other fabricated metal products n.e.c.	0.006	0.117	0.206
C26.1 Manufacture of electronic components and boards	0.013	0.235	0.447
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.000	0.003	0.010
C27.2 Manufacture of batteries and accumulators	-	0.010	0.022
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.003	0.033	0.096
C29.1 Manufacture of motor vehicles	0.003	0.033	0.087
C30.3 Manufacture of air and spacecraft and related machinery	0.003	0.034	0.082
C32.5 Manufacture of medical and dental instruments and supplies	0.009	0.096	0.296
E38.32 Recovery of sorted materials	-	0.011	0.024
R90 Other: Biogas	0.000	0.003	0.010
R90.03 Welding	0.012	0.152	0.592
Total	**0.00**	**0.04**	**0.09**

Source: Study team.

The next two tables present the average annual turnover by sector and company size and the annual operating surplus by sector and company size.

Table 8-3 Average turnover per company based on Eurostat figures, by size and sector (€, millions)

Sector	Small	Medium	Large
C10.91 Manufacture of prepared feeds for farm animals	€ 4.12	€ 74.56	€ 500.14
C19.2 Manufacture of refined petroleum products	€ 2.92	€ 73.54	€ 4,042.99
C20.12 Manufacture of dyes and pigments	€ 1.24	€ 30.71	€ 381.44
C20.13 Manufacture of other inorganic basic chemicals	€ 1.70	€ 41.85	€ 528.70
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	€ 1.73	€ 31.90	€ 209.80
C20.59 Manufacture of other chemical products n.e.c.	€ 2.90	€ 53.51	€ 367.85
C21.2 Manufacture of pharmaceutical preparations	€ 1.61	€ 40.04	€ 758.06
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	€ 1.94	€ 41.02	€ 699.16
C23.1 Manufacture of glass and glass products	€ 0.38	€ 15.71	€ 178.11
C23.4 Manufacture of other porcelain and ceramic products	€ 0.10	€ 9.94	€ 86.40
C23.7 Cutting, shaping and finishing of stone	€ 0.29	€ 14.24	€ 97.38
C24.1 Manufacture of basic iron and steel and of ferro-alloys	€ 0.97	€ 54.79	€ 873.75
C24.45 Other non-ferrous metal production	€ 0.62	€ 20.30	€ 142.22
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	€ 0.76	€ 18.29	€ 145.63
C25.61 Treatment and coating of metals	€ 0.68	€ 18.67	€ 123.09
C25.62 Machining	€ 0.34	€ 9.50	€ 61.66
C25.73 Manufacture of tools	€ 0.54	€ 22.18	€ 217.58
C25.99 Manufacture of other fabricated metal products n.e.c.	€ 0.26	€ 9.16	€ 63.67
C26.1 Manufacture of electronic components and boards	€ 0.83	€ 19.88	€ 351.76
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	€ 0.98	€ 20.01	€ 241.50
C27.2 Manufacture of batteries and accumulators	€ 1.22	€ 26.18	€ 384.03
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	€ 4.02	€ 60.44	€ 883.33
C29.1 Manufacture of motor vehicles	€ 0.60	€ 27.03	€ 5,530.21
C30.3 Manufacture of air and spacecraft and related machinery	€ 1.02	€ 14.23	€ 1,143.18
C32.5 Manufacture of medical and dental instruments and supplies	€ 0.26	€ 14.97	€ 255.66
E38.32 Recovery of sorted materials	€ 1.30	€ 36.66	€ 276.60

Source: Eurostat, Modelling by the study team

Table 8-4 Average gross operating surplus per company based on Eurostat figures, by size and sector (€, millions)

Sector	Small	Medium	Large
C10.91 Manufacture of prepared feeds for farm animals	€ 0.19	€ 3.44	€ 23.04
C19.2 Manufacture of refined petroleum products	€ 0.04	€ 1.06	€ 58.11
C20.12 Manufacture of dyes and pigments	€ 0.09	€ 2.29	€ 28.43
C20.13 Manufacture of other inorganic basic chemicals	€ 0.22	€ 5.42	€ 68.52
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	€ 0.18	€ 3.32	€ 21.86
C20.59 Manufacture of other chemical products n.e.c.	€ 0.28	€ 5.17	€ 35.52
C21.2 Manufacture of pharmaceutical preparations	€ 0.27	€ 6.70	€ 126.88
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	€ 0.21	€ 4.48	€ 76.31
C23.1 Manufacture of glass and glass products	€ 0.04	€ 1.66	€ 18.84
C23.4 Manufacture of other porcelain and ceramic products	€ 0.01	€ 1.16	€ 10.08
C23.7 Cutting, shaping and finishing of stone	€ 0.04	€ 2.15	€ 14.69
C24.1 Manufacture of basic iron and steel and of ferro-alloys	€ 0.01	€ 0.81	€ 12.98
C24.45 Other non-ferrous metal production	€ 0.03	€ 1.03	€ 7.24
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	€ 0.05	€ 1.23	€ 9.76
C25.61 Treatment and coating of metals	€ 0.08	€ 2.29	€ 15.07
C25.62 Machining	€ 0.04	€ 1.15	€ 7.48
C25.73 Manufacture of tools	€ 0.05	€ 2.08	€ 20.44
C25.99 Manufacture of other fabricated metal products n.e.c.	€ 0.03	€ 0.98	€ 6.81
C26.1 Manufacture of electronic components and boards	€ 0.06	€ 1.39	€ 24.65
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	€ 0.09	€ 1.82	€ 21.96
C27.2 Manufacture of batteries and accumulators	€ 0.08	€ 1.76	€ 25.83
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	€ 0.03	€ 0.47	€ 6.84
C29.1 Manufacture of motor vehicles	€ 0.02	€ 1.11	€ 227.19
C30.3 Manufacture of air and spacecraft and related machinery	€ 0.07	€ 0.98	€ 78.60
C32.5 Manufacture of medical and dental instruments and supplies	€ 0.04	€ 2.16	€ 36.89
E38.32 Recovery of sorted materials	€ 0.12	€ 3.27	€ 24.69

Source: Eurostat, Modelling by the study team

The next table showing the total costs per company as a percentage of turnover indicate that at the aggregated level, costs are not very high. It is only for the lowest OEL of 1 /0.5 µg/m³ where there are a few sectors with total costs exceeding one percent of turnover (highlighted in red).

For all the other options, the total costs are low compared to turnover. Only for the smallest companies in a few sectors, the costs could be in range of 0.5% to 1%. Even that level is not high and for most sectors and company sizes, the estimated costs are below 0.1% of turnover. It suggests that impact on the markets could be relative minor. There are reservations to such a conclusion and that is discussed further below in relation to the one-off costs.

Table 8-5 PV adjustment costs RMMs (additional to the baseline) for businesses implementing RMMs as a percentage of turnover (over 40 years, discounted by 3% annually), per company, by size

	PV adjustment costs as a percentage of turnover, per company			Percentage of companies discontinuing
	Small	Medium	Large	
1 /0.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.00%	0.00%	0.00%	0.00%
C19.2 Manufacture of refined petroleum products		0.01%	0.00%	0.00%
C20.12 Manufacture of dyes and pigments		0.73%	0.10%	10.00%
C20.13 Manufacture of other inorganic basic chemicals	0.52%	0.47%	0.04%	2.50%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.55%	0.48%	0.08%	6.50%
C20.59 Manufacture of other chemical products n.e.c.	0.25%	0.14%	0.02%	2.32%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.01%	1.00%
C23.1 Manufacture of glass and glass products	0.63%	0.27%	0.07%	4.90%
C23.4 Manufacture of other porcelain and ceramic products	3.08%	0.45%	0.19%	38.70%
C23.7 Cutting, shaping and finishing of stone	0.47%	0.09%	0.04%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.98%	0.75%	0.08%	11.00%
C24.45 Other non-ferrous metal production			0.14%	10.75%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	1.01%	0.83%	0.13%	10.65%
C25.61 Treatment and coating of metals	0.63%	0.43%	0.10%	5.00%
C25.62 Machining	1.54%	0.36%	0.17%	0.50%
C25.73 Manufacture of tools	2.17%	2.01%	0.20%	30.50%
C25.99 Manufacture of other fabricated metal products n.e.c.	2.10%	1.15%	0.26%	12.42%
C26.1 Manufacture of electronic components and boards	1.43%	1.23%	0.13%	14.44%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.01%	0.01%	0.00%	0.00%
C27.2 Manufacture of batteries and accumulators		0.08%	0.01%	0.94%

	PV adjustment costs as a percentage of turnover, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.90%	0.86%	0.09%	12.75%
C29.1 Manufacture of motor vehicles	1.35%	0.72%	0.07%	10.00%
C30.3 Manufacture of air and spacecraft and related machinery	1.03%	0.96%	0.07%	10.75%
C32.5 Manufacture of medical and dental instruments and supplies	2.04%	0.61%	0.09%	4.75%
E38.32 Recovery of sorted materials		0.70%	0.09%	10.00%
5 /1.25 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.001%	0.00%	0.000%	0.00%
C19.2 Manufacture of refined petroleum products		0.001%	0.000%	0.00%
C20.12 Manufacture of dyes and pigments		0.191%	0.03%	2.50%
C20.13 Manufacture of other inorganic basic chemicals	0.10%	0.10%	0.01%	0.50%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.10%	0.08%	0.02%	1.00%
C20.59 Manufacture of other chemical products n.e.c.	0.04%	0.023%	0.004%	0.36%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.00%	0.00%
C23.1 Manufacture of glass and glass products	0.111%	0.042%	0.012%	0.49%
C23.4 Manufacture of other porcelain and ceramic products	0.99%	0.12%	0.06%	9.86%
C23.7 Cutting, shaping and finishing of stone	0.08%	0.02%	0.01%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.12%	0.07%	0.01%	1.00%
C24.45 Other non-ferrous metal production			0.02%	1.00%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.13%	0.09%	0.020%	0.97%
C25.61 Treatment and coating of metals	0.09%	0.056%	0.0159%	0.50%
C25.62 Machining	0.66%	0.108%	0.0409%	0.00%
C25.73 Manufacture of tools	0.27%	0.22%	0.03%	3.00%
C25.99 Manufacture of other fabricated metal products n.e.c.	0.55%	0.27%	0.072%	2.48%
C26.1 Manufacture of electronic components and boards	0.32%	0.25%	0.03%	2.49%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.005%	0.004%	0.0006%	0.00%

	PV adjustment costs as a percentage of turnover, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C27.2 Manufacture of batteries and accumulators		0.01%	0.00%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.22%	0.21%	0.02%	3.00%
C29.1 Manufacture of motor vehicles	0.19%	0.08%	0.01%	1.00%
C30.3 Manufacture of air and spacecraft and related machinery	0.28%	0.25%	0.02%	2.50%
C32.5 Manufacture of medical and dental instruments and supplies	0.84%	0.15%	0.03%	0.00%
E38.32 Recovery of sorted materials		0.04%	0.01%	0.50%
10 /2.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.001%	0.001%	0.000%	0.00%
C19.2 Manufacture of refined petroleum products		0.001%	0.000%	0.00%
C20.12 Manufacture of dyes and pigments		0.078%	0.012%	1.00%
C20.13 Manufacture of other inorganic basic chemicals	0.007%	0.004%	0.000%	0.00%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.045%	0.040%	0.007%	0.50%
C20.59 Manufacture of other chemical products n.e.c.	0.037%	0.021%	0.003%	0.36%
C21.2 Manufacture of pharmaceutical preparations			0.000%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.000%	0.00%
C23.1 Manufacture of glass and glass products	0.024%	0.008%	0.002%	0.00%
C23.4 Manufacture of other porcelain and ceramic products	0.425%	0.051%	0.028%	3.35%
C23.7 Cutting, shaping and finishing of stone	0.035%	0.009%	0.003%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.052%	0.036%	0.004%	0.50%
C24.45 Other non-ferrous metal production			0.009%	0.50%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.057%	0.044%	0.008%	0.48%
C25.61 Treatment and coating of metals	0.015%	0.007%	0.003%	0.00%
C25.62 Machining	0.160%	0.028%	0.010%	0.00%
C25.73 Manufacture of tools	0.125%	0.106%	0.012%	1.50%
C25.99 Manufacture of other fabricated metal products n.e.c.	0.251%	0.117%	0.033%	0.99%
C26.1 Manufacture of electronic components and boards	0.141%	0.105%	0.012%	1.00%

	PV adjustment costs as a percentage of turnover, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.003%	0.003%	0.001%	0.00%
C27.2 Manufacture of batteries and accumulators		0.002%	0.000%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.045%	0.041%	0.005%	0.50%
C29.1 Manufacture of motor vehicles	0.022%	0.006%	0.000%	0.00%
C30.3 Manufacture of air and spacecraft and related machinery	0.085%	0.074%	0.004%	0.50%
C32.5 Manufacture of medical and dental instruments and supplies	0.379%	0.070%	0.013%	0.00%
E38.32 Recovery of sorted materials		0.003%	0.001%	0.00%
20 /4.2 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.001%	0.001%	0.000%	0.00%
C19.2 Manufacture of refined petroleum products		0.001%	0.000%	0.00%
C20.12 Manufacture of dyes and pigments		0.038%	0.006%	0.50%
C20.13 Manufacture of other inorganic basic chemicals	0.002%	0.001%	0.000%	0.00%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.006%	0.004%	0.002%	0.00%
C20.59 Manufacture of other chemical products n.e.c.	0.004%	0.002%	0.001%	0.00%
C21.2 Manufacture of pharmaceutical preparations			0.000%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.000%	0.00%
C23.1 Manufacture of glass and glass products	0.008%	0.003%	0.001%	0.00%
C23.4 Manufacture of other porcelain and ceramic products	0.200%	0.024%	0.012%	1.53%
C23.7 Cutting, shaping and finishing of stone	0.033%	0.008%	0.003%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.010%	0.002%	0.000%	0.00%
C24.45 Other non-ferrous metal production			0.003%	0.00%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.014%	0.007%	0.003%	0.00%
C25.61 Treatment and coating of metals	0.014%	0.006%	0.003%	0.00%
C25.62 Machining	0.033%	0.008%	0.003%	0.00%
C25.73 Manufacture of tools	0.023%	0.007%	0.002%	0.00%
C25.99 Manufacture of other fabricated metal products n.e.c.	0.104%	0.054%	0.014%	0.50%

	PV adjustment costs as a percentage of turnover, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C26.1 Manufacture of electronic components and boards	0.064%	0.050%	0.005%	0.50%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.001%	0.001%	0.000%	0.00%
C27.2 Manufacture of batteries and accumulators		0.002%	0.000%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.003%	0.002%	0.000%	0.00%
C29.1 Manufacture of motor vehicles	0.021%	0.005%	0.000%	0.00%
C30.3 Manufacture of air and spacecraft and related machinery	0.012%	0.010%	0.000%	0.00%
C32.5 Manufacture of medical and dental instruments and supplies	0.142%	0.027%	0.005%	0.00%
E38.32 Recovery of sorted materials		0.001%	0.000%	0.00%

Source: Study team.

The comparison of total costs to turnover is an indicator of how much the prices of each sectors outputs should increase in order to cover the additional costs. If a company cannot pass on the costs down the supply chain, it will have to cover the costs out of its profit. The following table present the annual operating surplus by sector.

The next table shows the total costs relative to operating surplus. It is a way to compare the adjustment costs with the profit of the affected business. The table shows that also when compared to the operating surplus, it is only for the OEL of 1 / 0.5 µg Co/m³ that there are sectors facing high costs compared to the operating surplus. For this policy options there are several sectors where the costs compared to operating surplus is above 10%. There is no specific benchmark for when the ratio between costs and operating surplus is "too high". At a level of for example 10%, the costs comprise a measurable share of the profits. There are even a few sectors, where costs could be beyond 100% of operating surplus. It means that the company would make a loss if it cannot pass on the costs to its customers.

For all the other policy options, the ratio between total costs and operating surplus does not exceed 10% and for the policy options 10 /2.5 µg/m³ 20 /4.2 µg/m³ the ration does not exceed 5% even for small companies.

Table 8 5 PV adjustment costs RMMs (additional to the baseline) for businesses implementing RMMs as a percentage of gross operating surplus (over 40 years, discounted by 3% annually), per company, by size

Sector and OEL	PV adjustment costs as a percentage of gross operating surplus, per company			Percentage of companies discontinuing
	Small	Medium	Large	
1 /0.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.11%	0.07%	0.04%	0.00%
C19.2 Manufacture of refined petroleum products		0.54%	0.06%	0.00%
C20.12 Manufacture of dyes and pigments		9.77%	1.30%	10.00%
C20.13 Manufacture of other inorganic basic chemicals	4.00%	3.65%	0.34%	2.50%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	5.23%	4.65%	0.73%	6.50%
C20.59 Manufacture of other chemical products n.e.c.	2.58%	1.42%	0.23%	2.32%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.09%	1.00%
C23.1 Manufacture of glass and glass products	5.92%	2.58%	0.63%	4.90%
C23.4 Manufacture of other porcelain and ceramic products	26.42%	3.89%	1.59%	38.70%
C23.7 Cutting, shaping and finishing of stone	3.10%	0.61%	0.27%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	65.85%	50.46%	5.52%	11.00%
C24.45 Other non-ferrous metal production			2.72%	10.75%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	15.01%	12.34%	1.99%	10.65%
C25.61 Treatment and coating of metals	5.17%	3.55%	0.80%	5.00%
C25.62 Machining	12.72%	3.00%	1.39%	0.50%
C25.73 Manufacture of tools	23.12%	21.40%	2.18%	30.50%
C25.99 Manufacture of other fabricated metal products n.e.c.	19.59%	10.74%	2.41%	12.42%
C26.1 Manufacture of electronic components and boards	20.34%	17.59%	1.80%	14.44%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.10%	0.06%	0.02%	0.00%
C27.2 Manufacture of batteries and accumulators		1.22%	0.16%	0.94%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	116.01%	110.86%	11.86%	12.75%
C29.1 Manufacture of motor vehicles	32.91%	17.41%	1.60%	10.00%
C30.3 Manufacture of air and spacecraft and related machinery	15.02%	14.02%	1.06%	10.75%

Sector and OEL	PV adjustment costs as a percentage of gross operating surplus, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C32.5 Manufacture of medical and dental instruments and supplies	14.13%	4.20%	0.64%	4.75%
E38.32 Recovery of sorted materials		7.83%	1.03%	10.00%
5 /1.25 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.02%	0.02%	0.01%	0.00%
C19.2 Manufacture of refined petroleum products		0.10%	0.01%	0.00%
C20.12 Manufacture of dyes and pigments		2.57%	0.39%	2.50%
C20.13 Manufacture of other inorganic basic chemicals	0.80%	0.74%	0.07%	0.50%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.92%	0.78%	0.15%	1.00%
C20.59 Manufacture of other chemical products n.e.c.	0.43%	0.24%	0.04%	0.36%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.01%	0.00%
C23.1 Manufacture of glass and glass products	1.05%	0.39%	0.11%	0.49%
C23.4 Manufacture of other porcelain and ceramic products	8.51%	1.03%	0.53%	9.86%
C23.7 Cutting, shaping and finishing of stone	0.56%	0.12%	0.05%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	7.80%	4.94%	0.58%	1.00%
C24.45 Other non-ferrous metal production			0.41%	1.00%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	1.92%	1.41%	0.29%	0.97%
C25.61 Treatment and coating of metals	0.75%	0.46%	0.130%	0.50%
C25.62 Machining	5.46%	0.89%	0.337%	0.00%
C25.73 Manufacture of tools	2.93%	2.32%	0.28%	3.00%
C25.99 Manufacture of other fabricated metal products n.e.c.	5.14%	2.54%	0.67%	2.48%
C26.1 Manufacture of electronic components and boards	4.61%	3.53%	0.38%	2.49%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.05%	0.043%	0.007%	0.00%
C27.2 Manufacture of batteries and accumulators		0.09%	0.02%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	28.42%	27.09%	2.96%	3.00%
C29.1 Manufacture of motor vehicles	4.59%	2.04%	0.16%	1.00%

Sector and OEL	PV adjustment costs as a percentage of gross operating surplus, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C30.3 Manufacture of air and spacecraft and related machinery	4.04%	3.71%	0.26%	2.50%
C32.5 Manufacture of medical and dental instruments and supplies	5.83%	1.06%	0.20%	0.00%
E38.32 Recovery of sorted materials		0.49%	0.09%	0.50%
10 /2.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.02%	0.02%	0.01%	0.00%
C19.2 Manufacture of refined petroleum products		0.06%	0.00%	0.00%
C20.12 Manufacture of dyes and pigments		1.04%	0.17%	1.00%
C20.13 Manufacture of other inorganic basic chemicals	0.05%	0.03%	0.00%	0.00%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.43%	0.38%	0.06%	0.50%
C20.59 Manufacture of other chemical products n.e.c.	0.38%	0.22%	0.03%	0.36%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.00%	0.00%
C23.1 Manufacture of glass and glass products	0.23%	0.08%	0.02%	0.00%
C23.4 Manufacture of other porcelain and ceramic products	3.65%	0.44%	0.24%	3.35%
C23.7 Cutting, shaping and finishing of stone	0.23%	0.06%	0.02%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	3.49%	2.41%	0.27%	0.50%
C24.45 Other non-ferrous metal production			0.17%	0.50%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.85%	0.66%	0.13%	0.48%
C25.61 Treatment and coating of metals	0.12%	0.06%	0.03%	0.00%
C25.62 Machining	1.32%	0.23%	0.08%	0.00%
C25.73 Manufacture of tools	1.33%	1.13%	0.13%	1.50%
C25.99 Manufacture of other fabricated metal products n.e.c.	2.34%	1.10%	0.31%	0.99%
C26.1 Manufacture of electronic components and boards	2.02%	1.49%	0.16%	1.00%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.04%	0.03%	0.01%	0.00%
C27.2 Manufacture of batteries and accumulators		0.04%	0.00%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	5.83%	5.31%	0.66%	0.50%

Sector and OEL	PV adjustment costs as a percentage of gross operating surplus, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C29.1 Manufacture of motor vehicles	0.54%	0.14%	0.00%	0.00%
C30.3 Manufacture of air and spacecraft and related machinery	1.23%	1.07%	0.06%	0.50%
C32.5 Manufacture of medical and dental instruments and supplies	2.63%	0.48%	0.09%	0.00%
E38.32 Recovery of sorted materials		0.04%	0.01%	0.00%
20 /4.2 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.02%	0.01%	0.00%	0.00%
C19.2 Manufacture of refined petroleum products		0.04%	0.00%	0.00%
C20.12 Manufacture of dyes and pigments		0.51%	0.08%	0.50%
C20.13 Manufacture of other inorganic basic chemicals	0.01%	0.01%	0.00%	0.00%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.06%	0.04%	0.02%	0.00%
C20.59 Manufacture of other chemical products n.e.c.	0.04%	0.02%	0.01%	0.00%
C21.2 Manufacture of pharmaceutical preparations			0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres			0.00%	0.00%
C23.1 Manufacture of glass and glass products	0.08%	0.03%	0.01%	0.00%
C23.4 Manufacture of other porcelain and ceramic products	1.72%	0.21%	0.10%	1.53%
C23.7 Cutting, shaping and finishing of stone	0.22%	0.05%	0.02%	0.00%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.67%	0.13%	0.03%	0.00%
C24.45 Other non-ferrous metal production			0.05%	0.00%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.20%	0.10%	0.04%	0.00%
C25.61 Treatment and coating of metals	0.12%	0.05%	0.02%	0.00%
C25.62 Machining	0.27%	0.06%	0.02%	0.00%
C25.73 Manufacture of tools	0.24%	0.08%	0.02%	0.00%
C25.99 Manufacture of other fabricated metal products n.e.c.	0.98%	0.50%	0.13%	0.50%
C26.1 Manufacture of electronic components and boards	0.91%	0.71%	0.08%	0.50%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.01%	0.01%	0.00%	0.00%
C27.2 Manufacture of batteries and accumulators		0.02%	0.00%	0.00%

Sector and OEL	PV adjustment costs as a percentage of gross operating surplus, per company			Percentage of companies discontinuing
	Small	Medium	Large	
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.39%	0.30%	0.06%	0.00%
C29.1 Manufacture of motor vehicles	0.52%	0.13%	0.00%	0.00%
C30.3 Manufacture of air and spacecraft and related machinery	0.18%	0.14%	0.00%	0.00%
C32.5 Manufacture of medical and dental instruments and supplies	0.98%	0.19%	0.03%	0.00%
E38.32 Recovery of sorted materials		0.01%	0.00%	0.00%

Source: Study team.

First year costs include the initial capital expenditure of installing alternative RMMs as well as one year of alternative operational costs (minus one year of existing RMM operational costs), one year of air monitoring costs, one year of biomonitoring costs, and their associated administrative burden.

Table 8-6 First year compliance costs (RMMs, monitoring and administrative burden), by policy options, sector and company size (minus discontinuations)

Sector and OEL	First year PV compliance costs in € million			
	Small	Medium	Large	Total
1 /0.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	1.03	1.34	0.94	3.31
C19.2 Manufacture of refined petroleum products	-	2.72	10.30	13.02
C20.12 Manufacture of dyes and pigments	-	1.33	18.19	19.52
C20.13 Manufacture of other inorganic basic chemicals	0.26	2.45	5.27	7.98
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.21	1.08	1.47	2.76
C20.59 Manufacture of other chemical products n.e.c.	0.28	2.27	9.08	11.63
C21.2 Manufacture of pharmaceutical preparations	-	-	0.97	0.97
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	1.26	1.26
C23.1 Manufacture of glass and glass products	0.77	4.03	10.24	15.05
C23.4 Manufacture of other porcelain and ceramic products	4.74	40.10	78.46	123.31
C23.7 Cutting, shaping and finishing of stone	15.83	3.25	5.98	25.06
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.07	0.99	1.21	2.28
C24.45 Other non-ferrous metal production	-	-	8.42	8.42
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.40	6.12	4.60	11.13

Sector and OEL	First year PV compliance costs in € million			
	Small	Medium	Large	Total
C25.61 Treatment and coating of metals	9.86	26.33	57.19	93.38
C25.62 Machining	221.20	214.32	233.82	669.33
C25.73 Manufacture of tools	63.23	84.12	67.47	214.82
C25.99 Manufacture of other fabricated metal products n.e.c.	4.30	8.64	9.95	22.90
C26.1 Manufacture of electronic components and boards	7.19	18.79	19.26	45.25
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.01	0.02	0.06	0.09
C27.2 Manufacture of batteries and accumulators	-	0.84	3.60	4.44
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	4.35	7.86	12.02	24.23
C29.1 Manufacture of motor vehicles	4.64	5.31	17.17	27.12
C30.3 Manufacture of air and spacecraft and related machinery	5.09	4.43	11.87	21.39
C32.5 Manufacture of medical and dental instruments and supplies	14.55	64.61	61.78	140.93
E38.32 Recovery of sorted materials	-	2.17	10.25	12.42
5 /1.25 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.14	0.27	0.08	0.49
C19.2 Manufacture of refined petroleum products	-	0.75	2.63	3.39
C20.12 Manufacture of dyes and pigments	-	0.66	8.81	9.47
C20.13 Manufacture of other inorganic basic chemicals	0.05	0.54	1.05	1.64
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.05	0.28	0.37	0.70
C20.59 Manufacture of other chemical products n.e.c.	0.06	0.55	1.84	2.46
C21.2 Manufacture of pharmaceutical preparations	-	-	0.11	0.11
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.30	0.30
C23.1 Manufacture of glass and glass products	0.20	1.08	2.57	3.84
C23.4 Manufacture of other porcelain and ceramic products	3.49	16.66	34.26	54.41
C23.7 Cutting, shaping and finishing of stone	3.16	0.72	1.20	5.08
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.02	0.27	0.29	0.57
C24.45 Other non-ferrous metal production	-	-	2.31	2.31
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.10	1.69	1.19	2.98
C25.61 Treatment and coating of metals	2.38	6.67	13.66	22.71

Sector and OEL	First year PV compliance costs in € million			
	Small	Medium	Large	Total
C25.62 Machining	170.71	118.02	98.35	387.08
C25.73 Manufacture of tools	20.85	31.37	26.51	78.73
C25.99 Manufacture of other fabricated metal products n.e.c.	1.83	4.05	4.32	10.20
C26.1 Manufacture of electronic components and boards	3.35	9.03	9.78	22.16
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.00	0.01	0.01	0.02
C27.2 Manufacture of batteries and accumulators	-	0.24	0.89	1.13
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	2.22	4.20	5.72	12.14
C29.1 Manufacture of motor vehicles	1.29	1.54	5.10	7.93
C30.3 Manufacture of air and spacecraft and related machinery	2.61	2.32	5.77	10.70
C32.5 Manufacture of medical and dental instruments and supplies	11.12	47.24	39.41	97.77
E38.32 Recovery of sorted materials	-	0.59	2.53	3.11
10 /2.5 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.09	0.21	0.06	0.37
C19.2 Manufacture of refined petroleum products	-	0.36	0.85	1.21
C20.12 Manufacture of dyes and pigments	-	0.33	4.45	4.78
C20.13 Manufacture of other inorganic basic chemicals	0.03	0.33	0.61	0.96
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.02	0.12	0.15	0.29
C20.59 Manufacture of other chemical products n.e.c.	0.03	0.29	0.95	1.27
C21.2 Manufacture of pharmaceutical preparations	-	-	0.08	0.08
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.03	0.03
C23.1 Manufacture of glass and glass products	0.05	0.29	0.59	0.92
C23.4 Manufacture of other porcelain and ceramic products	1.98	7.83	16.97	26.78
C23.7 Cutting, shaping and finishing of stone	1.51	0.39	0.58	2.48
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.01	0.11	0.11	0.23
C24.45 Other non-ferrous metal production	-	-	0.89	0.89
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.04	0.69	0.48	1.21
C25.61 Treatment and coating of metals	0.54	1.81	3.04	5.39
C25.62 Machining	43.45	31.40	24.31	99.16
C25.73 Manufacture of tools	8.13	12.30	9.94	30.38

Sector and OEL	First year PV compliance costs in € million			
	Small	Medium	Large	Total
C25.99 Manufacture of other fabricated metal products n.e.c.	0.90	2.02	2.11	5.02
C26.1 Manufacture of electronic components and boards	1.65	4.47	4.98	11.11
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.00	0.01	0.01	0.02
C27.2 Manufacture of batteries and accumulators	-	0.06	0.08	0.14
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1.14	2.19	2.90	6.23
C29.1 Manufacture of motor vehicles	0.30	0.39	1.21	1.90
C30.3 Manufacture of air and spacecraft and related machinery	1.32	1.18	2.96	5.46
C32.5 Manufacture of medical and dental instruments and supplies	5.38	23.78	18.95	48.11
E38.32 Recovery of sorted materials	-	0.15	0.56	0.70
20 /4.2 µg/m3				
C10.91 Manufacture of prepared feeds for farm animals	0.08	0.16	0.05	0.30
C19.2 Manufacture of refined petroleum products	-	0.22	0.33	0.55
C20.12 Manufacture of dyes and pigments	-	0.14	1.82	1.95
C20.13 Manufacture of other inorganic basic chemicals	0.00	0.05	0.05	0.11
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.01	0.07	0.08	0.16
C20.59 Manufacture of other chemical products n.e.c.	0.03	0.28	0.99	1.30
C21.2 Manufacture of pharmaceutical preparations	-	-	0.05	0.05
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	0.03	0.03
C23.1 Manufacture of glass and glass products	0.01	0.08	0.07	0.16
C23.4 Manufacture of other porcelain and ceramic products	0.82	3.49	7.05	11.36
C23.7 Cutting, shaping and finishing of stone	1.48	0.36	0.55	2.38
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0.00	0.06	0.06	0.12
C24.45 Other non-ferrous metal production	-	-	0.47	0.47
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.02	0.40	0.25	0.67
C25.61 Treatment and coating of metals	0.53	1.64	2.91	5.08
C25.62 Machining	10.11	9.27	6.16	25.54
C25.73 Manufacture of tools	5.01	7.73	6.53	19.27
C25.99 Manufacture of other fabricated metal products n.e.c.	0.37	0.88	0.87	2.12

Sector and OEL	First year PV compliance costs in € million			
	Small	Medium	Large	Total
C26.1 Manufacture of electronic components and boards	0.67	1.84	1.95	4.46
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	-	-	-	-
C27.2 Manufacture of batteries and accumulators	-	0.04	0.06	0.09
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.25	0.51	0.63	1.39
C29.1 Manufacture of motor vehicles	0.30	0.37	1.18	1.85
C30.3 Manufacture of air and spacecraft and related machinery	0.29	0.27	0.64	1.20
C32.5 Manufacture of medical and dental instruments and supplies	2.46	10.85	8.27	21.58
E38.32 Recovery of sorted materials	-	0.04	0.07	0.11

Source: Study team.

In addition to comparing the total compliance costs to the total turnover for the 40-year period, a comparison of the first-year costs to the annual turnover could provide indications of whether the initial investments could be preventive and force companies to cease their activities.

Having the above reservations in mind, the table indicate that for the OELs of 20 / 4.2 µg Co/m³ and 10 / 2.5 µg Co/m³, the initial investments are below one percentage of annual turnover for the majority of sectors. Only for a few, the investments might be more significant. It includes the sectors "Machining" (C25.62), "Manufacturing of tools" (C25.73), "Porcelain and ceramic products" (C23.4), "Other fabricated metal products" (C25.99) and "Electronic components" (C.26.1). For these sectors in the small companies where the ratios are above one percentage. For the OEL of 5 / 1.25 µg Co/m³, there are more sectors potentially facing more significant first year investments. For the OEL of 1 / 0.5 µg Co/m³ a few of the sectors would potentially face investments above 10% of turnover.

The further analysis also taken the possible to changing to non-cobalt alternatives might change the results and indicate that more companies are likely to continue operation.

Table 8-7 First year costs compliance costs (RMMs, monitoring and administrative burden) minus discontinuation as percentage of annual turnover, by policy options, sector and company size, and the proportion of companies expected to continue operations

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
1 /0.5 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.09%	0.06%	0.03%	0.05%	100%
C19.20 Manufacture of refined petroleum products	0.00%	0.09%	0.01%	0.01%	100%
C20.12 Manufacture of dyes and pigments	0.00%	1.21%	0.48%	0.50%	90%
C20.13-20.14 Manufacture of other inorganic basic chemicals	1.30%	0.55%	0.15%	0.20%	98%

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	2.21%	1.21%	0.75%	0.93%	94%
C20.59 Manufacture of other chemical products n.e.c.	0.70%	0.24%	0.15%	0.16%	98%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.02%	0.02%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.06%	0.06%	99%
C23.1 Manufacture of glass and glass products	7.60%	1.80%	0.75%	0.95%	95%
C23.4 Manufacture of other porcelain and ceramic products	29.03%	3.90%	2.05%	2.53%	61%
C23.7 Cutting, shaping and finishing of stone	5.71%	1.14%	0.61%	1.63%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	3.93%	0.51%	0.16%	0.23%	89%
C24.45 Other non-ferrous metal production	0.00%	0.00%	1.11%	1.11%	89%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	5.28%	2.21%	1.18%	1.65%	89%
C25.61 Treatment and coating of metals	4.65%	1.58%	1.04%	1.27%	95%
C25.62 Machining	13.43%	2.52%	1.27%	2.34%	100%
C25.73 Manufacture of tools	8.38%	2.37%	0.97%	1.91%	70%
C25.99 Manufacture of other fabricated metal products n.e.c.	16.79%	3.59%	2.21%	3.20%	88%
C26.1 Manufacture of electronic components and boards	5.37%	2.21%	0.49%	0.92%	86%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.18%	0.10%	0.03%	0.03%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.40%	0.12%	0.14%	99%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1.18%	0.88%	0.19%	0.33%	87%
C29.10-30 Manufacture of motor vehicles	8.02%	1.68%	0.04%	0.06%	90%
C30.30 Manufacture of air and spacecraft and related machinery	4.95%	3.51%	0.16%	0.29%	89%
C32.50 Manufacture of medical and dental instruments and supplies	19.35%	3.02%	0.51%	0.98%	95%
E38.32 Recovery of sorted materials	0.00%	0.94%	0.51%	0.56%	90%
5 /1.25 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.01%	0.01%	0.00%	0.01%	100%

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C19.20 Manufacture of refined petroleum products	0.00%	0.03%	0.00%	0.00%	100%
C20.12 Manufacture of dyes and pigments	0.00%	0.55%	0.22%	0.24%	98%
C20.13-20.14 Manufacture of other inorganic basic chemicals	0.26%	0.12%	0.03%	0.04%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.52%	0.30%	0.18%	0.24%	99%
C20.59 Manufacture of other chemical products n.e.c.	0.15%	0.06%	0.03%	0.03%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.00%	0.00%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.01%	0.01%	100%
C23.1 Manufacture of glass and glass products	1.85%	0.46%	0.18%	0.24%	100%
C23.4 Manufacture of other porcelain and ceramic products	11.30%	1.60%	0.88%	1.12%	90%
C23.7 Cutting, shaping and finishing of stone	1.14%	0.25%	0.12%	0.33%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	0.84%	0.12%	0.03%	0.06%	99%
C24.45 Other non-ferrous metal production	0.00%	0.00%	0.27%	0.30%	99%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	1.22%	0.55%	0.28%	0.44%	99%
C25.61 Treatment and coating of metals	1.07%	0.38%	0.24%	0.31%	100%
C25.62 Machining	10.31%	1.38%	0.53%	1.36%	100%
C25.73 Manufacture of tools	1.98%	0.63%	0.27%	0.70%	97%
C25.99 Manufacture of other fabricated metal products n.e.c.	6.41%	1.51%	0.87%	1.43%	98%
C26.1 Manufacture of electronic components and boards	2.19%	0.93%	0.22%	0.45%	98%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.05%	0.05%	0.01%	0.01%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.11%	0.03%	0.03%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.54%	0.42%	0.08%	0.16%	97%
C29.10-30 Manufacture of motor vehicles	2.03%	0.44%	0.01%	0.02%	99%
C30.30 Manufacture of air and spacecraft and related machinery	2.32%	1.68%	0.07%	0.14%	98%
C32.50 Manufacture of medical and dental instruments and supplies	14.10%	2.10%	0.31%	0.68%	100%
E38.32 Recovery of sorted materials	0.00%	0.23%	0.11%	0.14%	100%

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
10 /2.5 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.01%	0.01%	0.00%	0.01%	100%
C19.20 Manufacture of refined petroleum products	0.00%	0.01%	0.00%	0.00%	100%
C20.12 Manufacture of dyes and pigments	0.00%	0.27%	0.11%	0.12%	99%
C20.13-20.14 Manufacture of other inorganic basic chemicals	0.15%	0.07%	0.02%	0.02%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.21%	0.13%	0.073%	0.10%	100%
C20.59 Manufacture of other chemical products n.e.c.	0.07%	0.03%	0.015%	0.02%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.00%	0.00%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.00%	0.00%	100%
C23.1 Manufacture of glass and glass products	0.42%	0.12%	0.04%	0.06%	100%
C23.4 Manufacture of other porcelain and ceramic products	5.77%	0.75%	0.44%	0.55%	97%
C23.7 Cutting, shaping and finishing of stone	0.54%	0.14%	0.06%	0.16%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	0.33%	0.05%	0.013%	0.02%	100%
C24.45 Other non-ferrous metal production	0.00%	0.00%	0.10%	0.12%	100%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.48%	0.22%	0.11%	0.18%	100%
C25.61 Treatment and coating of metals	0.24%	0.10%	0.05%	0.07%	100%
C25.62 Machining	2.63%	0.37%	0.13%	0.35%	100%
C25.73 Manufacture of tools	0.76%	0.24%	0.10%	0.27%	99%
C25.99 Manufacture of other fabricated metal products n.e.c.	3.10%	0.74%	0.42%	0.70%	99%
C26.1 Manufacture of electronic components and boards	1.07%	0.45%	0.11%	0.23%	99%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.03%	0.04%	0.00%	0.01%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.03%	0.00%	0.00%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.27%	0.21%	0.04%	0.08%	100%
C29.10-30 Manufacture of motor vehicles	0.47%	0.11%	0.00%	0.00%	100%
C30.30 Manufacture of air and spacecraft and related machinery	1.15%	0.84%	0.04%	0.07%	100%
C32.50 Manufacture of medical and dental instruments and supplies	6.82%	1.06%	0.15%	0.33%	100%
E38.32 Recovery of sorted materials	0.00%	0.06%	0.03%	0.03%	100%

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
20 /4.2 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.01%	0.01%	0.00%	0.00%	100%
C19.20 Manufacture of refined petroleum products	0.00%	0.01%	0.00%	0.00%	100%
C20.12 Manufacture of dyes and pigments	0.00%	0.11%	0.04%	0.05%	100%
C20.13-20.14 Manufacture of other inorganic basic chemicals	0.02%	0.01%	0.00%	0.00%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0.11%	0.07%	0.04%	0.05%	100%
C20.59 Manufacture of other chemical products n.e.c.	0.07%	0.03%	0.02%	0.02%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.00%	0.00%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.00%	0.00%	100%
C23.1 Manufacture of glass and glass products	0.08%	0.03%	0.00%	0.01%	100%
C23.4 Manufacture of other porcelain and ceramic products	2.34%	0.33%	0.18%	0.23%	98%
C23.7 Cutting, shaping and finishing of stone	0.53%	0.13%	0.06%	0.16%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	0.17%	0.03%	0.01%	0.01%	100%
C24.45 Other non-ferrous metal production	0.00%	0.00%	0.06%	0.06%	100%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0.26%	0.13%	0.06%	0.10%	100%
C25.61 Treatment and coating of metals	0.24%	0.09%	0.05%	0.07%	100%
C25.62 Machining	0.61%	0.11%	0.03%	0.09%	100%
C25.73 Manufacture of tools	0.46%	0.15%	0.07%	0.17%	100%
C25.99 Manufacture of other fabricated metal products n.e.c.	1.28%	0.32%	0.17%	0.30%	100%
C26.1 Manufacture of electronic components and boards	0.43%	0.19%	0.04%	0.09%	100%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.00%	0.00%	0.00%	0.00%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.02%	0.00%	0.00%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	0.06%	0.05%	0.01%	0.02%	100%
C29.10-30 Manufacture of motor vehicles	0.46%	0.11%	0.00%	0.00%	100%
C30.30 Manufacture of air and spacecraft and related machinery	0.25%	0.19%	0.01%	0.02%	100%
C32.50 Manufacture of medical and dental instruments and supplies	3.12%	0.48%	0.06%	0.15%	100%

Sector	% of turnover				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
E38.32 Recovery of sorted materials	0.00%	0.02%	0.00%	0.00%	100%

Table 8-8 First year compliance costs (RMMs, monitoring and administrative burden) minus discontinuation) as a percentage of annual gross operating surplus, by policy options, sector and company size, and the proportion of companies expected to continue operations

Sector	% of gross operation surplus				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
1 /0.5 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	2.06%	1.30%	0.68%	1.14%	100%
C19.20 Manufacture of refined petroleum products	0.00%	6.27%	0.43%	0.54%	100%
C20.12 Manufacture of dyes and pigments	0.00%	16.18%	6.46%	6.74%	90%
C20.13-20.14 Manufacture of other inorganic basic chemicals	10.00%	4.22%	1.13%	1.51%	98%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	21.16%	11.60%	7.17%	8.97%	94%
C20.59 Manufacture of other chemical products n.e.c.	7.30%	2.49%	1.53%	1.69%	98%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.10%	0.10%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.56%	0.56%	99%
C23.1 Manufacture of glass and glass products	71.85%	17.04%	7.13%	8.93%	95%
C23.4 Manufacture of other porcelain and ceramic products	248.87%	33.45%	17.56%	21.69%	61%
C23.7 Cutting, shaping and finishing of stone	37.83%	7.58%	4.07%	10.82%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	264.45%	34.31%	10.51%	15.73%	89%
C24.45 Other non-ferrous metal production	0.00%	0.00%	21.70%	21.70%	89%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	78.84%	32.92%	17.67%	24.64%	89%
C25.61 Treatment and coating of metals	37.96%	12.90%	8.50%	10.34%	95%
C25.62 Machining	110.79%	20.78%	10.48%	19.33%	100%
C25.73 Manufacture of tools	89.15%	25.25%	10.32%	20.31%	70%
C25.99 Manufacture of other fabricated metal products n.e.c.	156.90%	33.58%	20.69%	29.89%	88%
C26.1 Manufacture of electronic components and boards	76.58%	31.56%	6.98%	13.12%	86%

Sector	% of gross operation surplus				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	2.01%	1.07%	0.29%	0.37%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	6.02%	1.76%	2.03%	99%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	152.58%	113.07%	25.08%	41.97%	87%
C29.10-30 Manufacture of motor vehicles	195.13%	40.86%	0.93%	1.46%	90%
C30.30 Manufacture of air and spacecraft and related machinery	0.00%	0.00%	0.00%	0.00%	89%
C32.50 Manufacture of medical and dental instruments and supplies	0.00%	0.00%	0.00%	0.00%	95%
E38.32 Recovery of sorted materials	0.00%	0.00%	0.00%	0.00%	90%
5 /1.25 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.27%	0.26%	0.06%	0.17%	100%
C19.20 Manufacture of refined petroleum products	0.00%	1.74%	0.11%	0.14%	100%
C20.12 Manufacture of dyes and pigments	0.00%	7.36%	2.89%	3.27%	98%
C20.13-20.14 Manufacture of other inorganic basic chemicals	2.01%	0.91%	0.22%	0.31%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	5.04%	2.88%	1.69%	2.29%	99%
C20.59 Manufacture of other chemical products n.e.c.	1.52%	0.60%	0.31%	0.36%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.01%	0.01%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.13%	0.13%	100%
C23.1 Manufacture of glass and glass products	17.48%	4.34%	1.71%	2.28%	100%
C23.4 Manufacture of other porcelain and ceramic products	96.89%	13.69%	7.55%	9.57%	90%
C23.7 Cutting, shaping and finishing of stone	7.55%	1.68%	0.82%	2.19%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	56.24%	8.29%	2.22%	3.93%	99%
C24.45 Other non-ferrous metal production	0.00%	0.00%	5.38%	5.96%	99%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	18.17%	8.18%	4.11%	6.60%	99%
C25.61 Treatment and coating of metals	8.74%	3.12%	1.94%	2.51%	100%
C25.62 Machining	85.07%	11.38%	4.39%	11.18%	100%
C25.73 Manufacture of tools	21.06%	6.75%	2.91%	7.44%	97%

Sector	% of gross operation surplus				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C25.99 Manufacture of other fabricated metal products n.e.c.	59.85%	14.13%	8.12%	13.32%	98%
C26.1 Manufacture of electronic components and boards	31.28%	13.29%	3.13%	6.43%	98%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.57%	0.50%	0.06%	0.10%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	1.68%	0.43%	0.51%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	70.13%	54.40%	10.76%	21.03%	97%
C29.10-30 Manufacture of motor vehicles	49.36%	10.77%	0.25%	0.43%	99%
C30.30 Manufacture of air and spacecraft and related machinery	0.00%	0.00%	0.00%	0.00%	98%
C32.50 Manufacture of medical and dental instruments and supplies	0.00%	0.00%	0.00%	0.00%	100%
E38.32 Recovery of sorted materials	0.00%	0.00%	0.00%	0.00%	100%
10 /2.5 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.18%	0.21%	0.05%	0.13%	100%
C19.20 Manufacture of refined petroleum products	0.00%	0.84%	0.04%	0.05%	100%
C20.12 Manufacture of dyes and pigments	0.00%	3.59%	1.44%	1.65%	99%
C20.13-20.14 Manufacture of other inorganic basic chemicals	1.12%	0.55%	0.13%	0.18%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	2.02%	1.20%	0.70%	0.95%	100%
C20.59 Manufacture of other chemical products n.e.c.	0.71%	0.32%	0.16%	0.19%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.01%	0.01%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.01%	0.01%	100%
C23.1 Manufacture of glass and glass products	4.01%	1.17%	0.39%	0.55%	100%
C23.4 Manufacture of other porcelain and ceramic products	49.48%	6.44%	3.74%	4.71%	97%
C23.7 Cutting, shaping and finishing of stone	3.61%	0.91%	0.40%	1.07%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	22.01%	3.42%	0.87%	1.59%	100%
C24.45 Other non-ferrous metal production	0.00%	0.00%	2.06%	2.29%	100%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	7.17%	3.35%	1.64%	2.69%	100%
C25.61 Treatment and coating of metals	1.99%	0.84%	0.43%	0.60%	100%
C25.62 Machining	21.65%	3.03%	1.08%	2.86%	100%

Sector	% of gross operation surplus				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C25.73 Manufacture of tools	8.09%	2.61%	1.07%	2.87%	99%
C25.99 Manufacture of other fabricated metal products n.e.c.	29.00%	6.93%	3.90%	6.56%	99%
C26.1 Manufacture of electronic components and boards	15.21%	6.49%	1.57%	3.22%	99%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.38%	0.39%	0.05%	0.08%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.40%	0.04%	0.06%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	35.02%	27.66%	5.33%	10.80%	100%
C29.10-30 Manufacture of motor vehicles	11.39%	2.70%	0.06%	0.10%	100%
C30.30 Manufacture of air and spacecraft and related machinery	0.00%	0.00%	0.00%	0.00%	100%
C32.50 Manufacture of medical and dental instruments and supplies	0.00%	0.00%	0.00%	0.00%	100%
E38.32 Recovery of sorted materials	0.00%	0.00%	0.00%	0.00%	100%
20 /4.2 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	0.16%	0.16%	0.04%	0.10%	100%
C19.20 Manufacture of refined petroleum products	0.00%	0.51%	0.01%	0.02%	100%
C20.12 Manufacture of dyes and pigments	0.00%	1.48%	0.58%	0.67%	100%
C20.13-20.14 Manufacture of other inorganic basic chemicals	0.12%	0.09%	0.01%	0.02%	100%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	1.10%	0.68%	0.37%	0.52%	100%
C20.59 Manufacture of other chemical products n.e.c.	0.76%	0.30%	0.16%	0.19%	100%
C21.20 Manufacture of pharmaceutical preparations	0.00%	0.00%	0.01%	0.01%	100%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.00%	0.00%	0.01%	0.01%	100%
C23.1 Manufacture of glass and glass products	0.76%	0.33%	0.04%	0.09%	100%
C23.4 Manufacture of other porcelain and ceramic products	20.02%	2.87%	1.55%	2.00%	98%
C23.7 Cutting, shaping and finishing of stone	3.53%	0.83%	0.37%	1.03%	100%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	11.42%	1.86%	0.44%	0.84%	100%
C24.45 Other non-ferrous metal production	0.00%	0.00%	1.08%	1.21%	100%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	3.92%	1.90%	0.87%	1.49%	100%
C25.61 Treatment and coating of metals	1.94%	0.76%	0.41%	0.56%	100%

Sector	% of gross operation surplus				Incurred by (% of companies continuing)
	Small	Medium	Large	Total	
C25.62 Machining	5.04%	0.89%	0.27%	0.74%	100%
C25.73 Manufacture of tools	4.90%	1.61%	0.69%	1.82%	100%
C25.99 Manufacture of other fabricated metal products n.e.c.	11.94%	3.01%	1.60%	2.77%	100%
C26.1 Manufacture of electronic components and boards	6.09%	2.65%	0.61%	1.29%	100%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.00%	0.00%	0.00%	0.00%	100%
C27.2 Manufacture of batteries and accumulators	0.00%	0.26%	0.03%	0.04%	100%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	7.70%	6.40%	1.15%	2.40%	100%
C29.10-30 Manufacture of motor vehicles	11.19%	2.60%	0.06%	0.10%	100%
C30.30 Manufacture of air and spacecraft and related machinery	0.00%	0.00%	0.00%	0.00%	100%
C32.50 Manufacture of medical and dental instruments and supplies	0.00%	0.00%	0.00%	0.00%	100%
E38.32 Recovery of sorted materials	0.00%	0.00%	0.00%	0.00%	100%

The comparison shows that it is mainly for the lowest policy option there could be significant impacts. For the policy option of 5 / 1.25 µg Co/m³, there are a few sectors where the one-off costs are above 1% of annual turnover and with some sectors facing one-off costs above 2%. For policy options 10 / 2.5 µg Co/m³ there are only two sectors around or above a ratio of 1%. How significant companies in these and other sectors are affected depends on the extent to which the companies would be able to spread the investment over a few years. If that is the case, for example if there is a transitional period, then it should be financially feasible to implement the necessary RMMs. With no transitional period, companies where the first year costs are above 10% of turnover might face difficulties on implementation of the necessary RMMs. There is risk that it could mean that they might close their activity. This risk is included in the assessment of the possible number of companies discontinuing their activity.

It means that overall, the assessment of the costs burden suggests that for the lowest two policy options 1 / 0.5 µg Co/m³ and 5 / 1.25 µg Co/m³ costs impacts could be significant. For the two hight policy options 10 / 2.5 or 20 / 4.2 µg Co/m³, overall, the estimated adjustment costs should not lead to significant market impacts.

8.2 Research and innovation

The impact on R&I would come through the following channels:

- Resources used for the complying with the OEL are not available for R&I activities leading to less R&I
- Providing an incentive to R&I in cobalt free alternatives

These two types of effects would generate different impacts.

Taking the issue of companies' financial resources being focused on compliance could lead to overall less R&I activities in the sectors. Given the size of the estimated adjustment costs, it is only for the lowest policy option and for a few sectors where any significant impact can be expected.

Considering the alternative options of an OEL at 5 / 1.25, 10 / 2.5 or 20 / 4.2 µg Co/m³, the one-off costs would be in the order of 1-2% of the annual production costs. Assuming that the companies can finance the investment over 2-3 years, the costs will be well below one percent of turnover. It means that if they increase the price by one percent, they will cover the adjustment costs. Or if they have to cover it by a lower profit, that would also be feasible.

Table 8-9 provides estimates of average R&I expenditures for small, medium and large companies in the sectors with workers exposed to cobalt and inorganic cobalt compounds, based on Eurostat data. Clearly significant investment is being made in large enterprises across the different sectors.

Table 8-9 Average annual R&D expenditure per company, by company size, by sector (€ million)

Sector		Average annual R&D expenditure per company (€ million)		
		Small	Medium	Large
C10.91	Manufacture, feeds	0.07	1.30	8.74
C19.20	Petrochemical, catalyst	0.05	1.29	70.65
C20.12	Manufacture of dyes and pigments	0.02	0.54	6.67
C20.13-20.14	Manufacture of basic chemicals	0.03	0.73	9.24
C20.30	Manufacture of paints and inks	0.03	0.56	3.67
C20.59,1	Catalysts	0.05	0.94	6.43
C21.20	Pharmaceuticals	0.03	0.70	13.25
C22.11	Production of tyres	0.03	0.72	12.22
C23.1	Glass	0.01	0.27	3.10
C23.4	Ceramics	0.00	0.17	1.51
C23.7	Cutting stone	0.00	0.25	1.70
C24.10	Steel	0.02	0.96	15.27
C24.45	Manufacture of cobalt and cobalt alloys	0.01	0.23	1.61
C25.5	Powder metallurgy	0.01	0.32	2.53
C25.61	Surface treatment of metals	0.01	0.33	2.15
C25.62	Machining	0.01	0.17	1.08
C25.73	Manufacture of tools	0.01	0.39	3.80
C25.99	Manufacture of other fabricated metal products n.e.c.	0.00	0.16	1.11
C26.1	Production of electronic components and boards	0.01	0.31	5.44
C26.51	Humidity indicator cards	0.02	0.35	4.22
C27.2	Batteries	0.02	0.33	4.77
C28.11	Engines and turbines	0.07	1.06	15.44
C29.10-30	Automotive	0.01	0.47	96.37
C30.30	Air and spacecraft	0.02	0.25	19.98
C32.50	Medical and dental devices	0.00	0.21	3.59
E38.32	Metal recovery	0.01	0.29	2.16

Source: Eurostat (2018)

Note: 1. In most cases, R&D expenditure is not available at the level of the specific subsector in Eurostat. In these cases, the next level where data was available has been taken as a proxy for the sub-sector using cobalt, and so may be under- or over-estimated.
2. Data gaps exist for some Member States. In these cases, the most recent data was used.
3. Data in Eurostat is not presented by company size. It is assumed that share of R&D expenditure between different sized companies is the same as the share for turnover (based on 2018 data)

The next table presents the adjustment costs compared to the R&D expenditure. It should be noted that since the adjustment costs include also potential discontinuation costs, the comparison should be understood so that estimated discontinuation costs represent high adjustment costs.

Table 8-10 PV adjustment costs (additional to the baseline) for businesses implementing RMMs as a percentage of R&D expenditure (over 40 years, discounted by 3% annually), per company

Sector	PV adjustment costs as a percentage of R&D expenditure, per company			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C10.91 Manufacture of prepared feeds for farm animals	0.11%	0.00%	0.00%	0.00%
C19.2 Manufacture of refined petroleum products	0.06%	0.01%	0.00%	0.00%
C20.12 Manufacture of dyes and pigments	6.76%	1.96%	0.82%	0.38%
C20.13 Manufacture of other inorganic basic chemicals	5.49%	1.09%	0.03%	0.00%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	12.58%	2.17%	1.00%	0.11%
C20.59 Manufacture of other chemical products n.e.c.	2.23%	0.36%	0.31%	0.04%
C21.2 Manufacture of pharmaceutical preparations	0.03%	0.00%	0.00%	0.00%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	0.57%	0.03%	0.00%	0.00%
C23.1 Manufacture of glass and glass products	5.76%	0.91%	0.13%	0.00%
C23.4 Manufacture of other porcelain and ceramic products	15.22%	4.54%	1.95%	0.82%
C23.7 Cutting, shaping and finishing of stone	6.99%	1.09%	0.38%	0.37%
C24.1 Manufacture of basic iron and steel and of ferro-alloys	12.77%	1.25%	0.60%	0.03%
C24.45 Other non-ferrous metal production	12.47%	1.77%	0.72%	0.20%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	25.18%	2.87%	1.29%	0.18%
C25.61 Treatment and coating of metals	11.00%	1.49%	0.16%	0.16%
C25.62 Machining	17.60%	5.32%	1.18%	0.18%
C25.73 Manufacture of tools	53.17%	5.93%	2.80%	0.23%
C25.99 Manufacture of other fabricated metal products n.e.c.	36.48%	8.89%	3.87%	1.61%
C26.1 Manufacture of electronic components and boards	23.46%	4.77%	2.02%	0.93%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	0.05%	0.00%	0.00%	0.00%
C27.2 Manufacture of batteries and accumulators	1.22%	0.08%	0.00%	0.00%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	13.20%	3.23%	0.66%	0.04%

Sector	PV adjustment costs as a percentage of R&D expenditure, per company			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C29.1 Manufacture of motor vehicles	4.24%	0.44%	0.01%	0.01%
C30.3 Manufacture of air and spacecraft and related machinery	5.98%	1.48%	0.38%	0.03%
C32.5 Manufacture of medical and dental instruments and supplies	13.02%	3.69%	1.61%	0.59%
E38.32 Recovery of sorted materials	20.29%	1.48%	0.13%	0.00%

Source: Eurostat, Modelling by the study team

The assessment indicates the adjustment costs for several costs are high compared to the R&D costs. It is a similar pattern as when comparing one-off costs to annual turnover.

Introduction of an OEL will provide additional incentive to develop cobalt free alternatives. As discussed in Section 3.11 on alternatives, there are ongoing R&I activities developing such alternatives. As cobalt is a critical raw material, there are many reasons for wanting to substitute away from cobalt.

The key sectors where high costs have been estimated include machining and manufacture of tools.

Manufacture of tools: This is one the more affected sectors both in terms of total costs and when costs are compared to turnover. It is also the one sector the cost model assessment indicate that a number of companies might discontinue (see Section 7.67.6). It is important to note that it is only for the lowest and most demanding policy option this could happen.

Whether it will happen is subject to some uncertainty. While it is clear the lowest OEL will require substantial adjustment costs, it might be that many companies in this sector will be able to switch to an alternative.

Overall, there might be a temporarily reduction in some R&D activities as companies invest in compliance with an OEL. Then, the introduction of an OEL might lead to an increase in the efforts of developing and introducing cobalt free alternatives.

8.3 Single market

8.3.1 Competition

Table 8-11 below includes the screening of impacts on competition in order to focus the analysis on those impacts likely to be the most significant. The most significant impacts are further explored in the following paragraphs.

The answers in the table concern the overall assessment and are followed by more sector specific considerations.

Table 8-11 Screening of competition impacts

Impacts	Key questions	Yes/No
Existing firms	Additional costs?	Yes
	Scale of costs significant?	No – only for a few sectors and the lowest OELs.
	Old firms affected more than new?	No
	Location influences?	No
	Some firms will exit the market?	It might be for the most affected sectors and for the lowest policy option.
	Are competitors limited in growth potential?	No
	Increased collusion likely?	No
New entrants	Restrict entry?	No
Prices	Increased prices for consumers	No
Non-price impacts	Product quality/variety affected?	No
	Impact on innovation	The on-off costs might reduce the financing resources for innovation. On the other hand, there might be increased incentives to develop alternatives to the use of cobalt.
Upstream and downstream market	Will OELs affect vertically integrated companies more or less than non-integrated ones?	No
	Will OELs encourage greater integration and market barriers?	No
	Will OELs affect bargaining power of buyers or suppliers?	No

Source: Study team.

The introduction of an OEL will not affect the level of competition at the EU internal market. While there are sectors where some companies might face hight adjustment costs and potentially leave the market, it will not affect the overall level of competition at these specific sectors. It is only a small share that might close or discontinue. Introducing an OEL is unlikely to prevent new entrants. They will by design of their new production facilities be able to comply at low costs or they might start operating with a cobalt free alternative.

8.3.1.1 Existing firms

The impacts on existing firms are described above under the overall impacts. The issue of possible discontinuation is discussed in the next section.

8.3.1.2 Firms leaving the market (discontinuations)

Based on the cost model assessment, the number of companies that might discontinue has been estimated. It can be noted that it is assumed that for large companies, it is only a part of the company (10% of its activity) that is closing. Then, it should be mentioned as discussed above, that the estimation of discontinuations is subject to uncertainty. Still, taking the cost model assessment at face value, it is mainly for the two lowest policy options there could be companies that would discontinue. For the two highest policy options, the estimated number of potential closures is low and here it is likely that no company will actually close.

Table 8-12 Estimates of companies or business units that will discontinue operation under different policy options by sector and size of enterprise

Sector	1 / 0.5 µg Co/m³			5 / 1.25 µg Co/m³			10 / 2.5 µg Co/m³			20 / 4.2 µg Co/m³		
	S	M	L	S	M	L	S	M	L	S	M	L
Total	947	109	30	128	11	3	51	5	1	9	0	0

Source: Study team.

The next table shows the estimated number of companies potentially discontinuing by sector and by policy option.

Table 8-13 Companies discontinuing at different policy options by sector

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
1 / 0.5 µg/m³					
C10.91 Manufacture of prepared feeds for farm animals	3,786	300	0	0.0%	0.0%
C19.20 Manufacture of refined petroleum products	821	82	0	0.0%	0.0%
C20.12 Manufacture of dyes and pigments	485	15	2	0.3%	10.0%
C20.13-20.14 Manufacture of other inorganic basic chemicals	858	30	1	0.1%	2.5%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,247	10	1	0.0%	6.5%
C20.59 Manufacture of other chemical products n.e.c.	4,076	49	1	0.0%	2.3%
C21.20 Manufacture of pharmaceutical preparations	3,158	8	0	0.0%	0.0%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1,460	3	0	0.0%	1.0%
C23.1 Manufacture of glass and glass products	13,813	51	3	0.0%	4.9%
C23.4 Manufacture of other porcelain and ceramic products	14,029	500	194	1.4%	38.7%
C23.7 Cutting, shaping and finishing of stone	33,363	1,000	0	0.0%	0.0%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	2,769	7	1	0.0%	11.0%
C24.45 Other non-ferrous metal production	522	6	1	0.1%	10.8%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	13,732	31	3	0.0%	10.6%
C25.61 Treatment and coating of metals	26,393	470	24	0.1%	5.0%
C25.62 Machining	126,791	6,000	30	0.0%	0.5%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
C25.73 Manufacture of tools	15,892	2,300	702	4.4%	30.5%
C25.99 Manufacture of other fabricated metal products n.e.c.	48,846	151	19	0.0%	12.4%
C26.1 Manufacture of electronic components and boards	10,236	251	36	0.4%	14.4%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	9,073	5	0	0.0%	0.0%
C27.2 Manufacture of batteries and accumulators	551	16	0	0.0%	0.9%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,300	130	17	1.3%	12.8%
C29.10-30 Manufacture of motor vehicles	2,067	130	13	0.6%	10.0%
C30.30 Manufacture of air and spacecraft and related machinery	1,417	130	14	1.0%	10.8%
C32.50 Manufacture of medical and dental instruments and supplies	64,571	500	24	0.0%	4.8%
E38.32 Recovery of sorted materials	16,900	15	2	0.0%	10.0%
5 /1.25 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	3,786	300	0	0.0%	0.0%
C19.20 Manufacture of refined petroleum products	821	82	0	0.0%	0.0%
C20.12 Manufacture of dyes and pigments	485	15	0	0.1%	2.5%
C20.13-20.14 Manufacture of other inorganic basic chemicals	858	30	0	0.0%	0.5%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,247	10	0	0.0%	1.0%
C20.59 Manufacture of other chemical products n.e.c.	4,076	49	0	0.0%	0.4%
C21.20 Manufacture of pharmaceutical preparations	3,158	8	0	0.0%	0.0%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1,460	3	0	0.0%	0.0%
C23.1 Manufacture of glass and glass products	13,813	51	0	0.0%	0.5%
C23.4 Manufacture of other porcelain and ceramic products	14,029	500	49	0.4%	9.9%
C23.7 Cutting, shaping and finishing of stone	33,363	1,000	0	0.0%	0.0%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
C24.10 Manufacture of basic iron and steel and of ferro-alloys	2,769	7	0	0.0%	1.0%
C24.45 Other non-ferrous metal production	522	6	0	0.0%	1.0%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	13,732	31	0	0.0%	1.0%
C25.61 Treatment and coating of metals	26,393	470	2	0.0%	0.5%
C25.62 Machining	126,791	6,000	-	0.0%	0.0%
C25.73 Manufacture of tools	15,892	2,300	69	0.4%	3.0%
C25.99 Manufacture of other fabricated metal products n.e.c.	48,846	151	4	0.0%	2.5%
C26.1 Manufacture of electronic components and boards	10,236	251	6	0.1%	2.5%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	9,073	5	0	0.0%	0.0%
C27.2 Manufacture of batteries and accumulators	551	16	0	0.0%	0.0%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,300	130	4	0.3%	3.0%
C29.10-30 Manufacture of motor vehicles	2,067	130	1	0.1%	1.0%
C30.30 Manufacture of air and spacecraft and related machinery	1,417	130	3	0.2%	2.5%
C32.50 Manufacture of medical and dental instruments and supplies	64,571	500	0	0.0%	0.0%
E38.32 Recovery of sorted materials	16,900	15	0	0.0%	0.5%
10 /2.5 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	3,786	300	0	0.0%	0.0%
C19.20 Manufacture of refined petroleum products	821	82	0	0.0%	0.0%
C20.12 Manufacture of dyes and pigments	485	15	0	0.0%	1.0%
C20.13-20.14 Manufacture of other inorganic basic chemicals	858	30	0	0.0%	0.0%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,247	10	0	0.0%	0.5%
C20.59 Manufacture of other chemical products n.e.c.	4,076	49	0	0.0%	0.4%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
C21.20 Manufacture of pharmaceutical preparations	3,158	8	0	0.0%	0.0%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1,460	3	0	0.0%	0.0%
C23.1 Manufacture of glass and glass products	13,813	51	0	0.0%	0.0%
C23.4 Manufacture of other porcelain and ceramic products	14,029	500	17	0.1%	3.4%
C23.7 Cutting, shaping and finishing of stone	33,363	1,000	0	0.0%	0.0%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	2,769	7	0	0.0%	0.5%
C24.45 Other non-ferrous metal production	522	6	0	0.0%	0.5%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	13,732	31	0	0.0%	0.5%
C25.61 Treatment and coating of metals	26,393	470	0	0.0%	0.0%
C25.62 Machining	126,791	6,000	0	0.0%	0.0%
C25.73 Manufacture of tools	15,892	2,300	35	0.2%	1.5%
C25.99 Manufacture of other fabricated metal products n.e.c.	48,846	151	2	0.0%	1.0%
C26.1 Manufacture of electronic components and boards	10,236	251	3	0.0%	1.0%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	9,073	5	0	0.0%	0.0%
C27.2 Manufacture of batteries and accumulators	551	16	0	0.0%	0.0%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,300	130	1	0.1%	0.5%
C29.10-30 Manufacture of motor vehicles	2,067	130	0	0.0%	0.0%
C30.30 Manufacture of air and spacecraft and related machinery	1,417	130	1	0.0%	0.5%
C32.50 Manufacture of medical and dental instruments and supplies	64,571	500	0	0.0%	0.0%
E38.32 Recovery of sorted materials	16,900	15	0	0.0%	0.0%
20 /4.2 µg/m3					
C10.91 Manufacture of prepared feeds for farm animals	3,786	300	0	0.0%	0.0%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
C19.20 Manufacture of refined petroleum products	821	82	0	0.0%	0.0%
C20.12 Manufacture of dyes and pigments	485	15	0	0.0%	0.5%
C20.13-20.14 Manufacture of other inorganic basic chemicals	858	30	0	0.0%	0.0%
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,247	10	0	0.0%	0.0%
C20.59 Manufacture of other chemical products n.e.c.	4,076	49	0	0.0%	0.0%
C21.20 Manufacture of pharmaceutical preparations	3,158	8	0	0.0%	0.0%
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	1,460	3	0	0.0%	0.0%
C23.1 Manufacture of glass and glass products	13,813	51	0	0.0%	0.0%
C23.4 Manufacture of other porcelain and ceramic products	14,029	500	8	0.1%	1.5%
C23.7 Cutting, shaping and finishing of stone	33,363	1,000	0	0.0%	0.0%
C24.10 Manufacture of basic iron and steel and of ferro-alloys	2,769	7	0	0.0%	0.0%
C24.45 Other non-ferrous metal production	522	6	0	0.0%	0.0%
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	13,732	31	0	0.0%	0.0%
C25.61 Treatment and coating of metals	26,393	470	0	0.0%	0.0%
C25.62 Machining	126,791	6,000	0	0.0%	0.0%
C25.73 Manufacture of tools	15,892	2,300	0	0.0%	0.0%
C25.99 Manufacture of other fabricated metal products n.e.c.	48,846	151	1	0.0%	0.5%
C26.1 Manufacture of electronic components and boards	10,236	251	1	0.0%	0.5%
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	9,073	5	0	0.0%	0.0%
C27.2 Manufacture of batteries and accumulators	551	16	0	0.0%	0.0%
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1,300	130	0	0.0%	0.0%
C29.10-30 Manufacture of motor vehicles	2,067	130	0	0.0%	0.0%

Sector	Number of enterprises in EU (Eurostat)	Estimated enterprise with exposed workers in EU	No. of discontinuations	Discontinuations as % of enterprises	Discontinuations as % of enterprises with exposed workers
C30.30 Manufacture of air and spacecraft and related machinery	1,417	130	0	0.0%	0.0%
C32.50 Manufacture of medical and dental instruments and supplies	64,571	500	0	0.0%	0.0%
E38.32 Recovery of sorted materials	16,900	15	0	0.0%	0.0%

Source: Study team.

The sectors where the cost model-based assessment has indicated the hight risks of companies having to discontinue are the sector "Manufacture of tool" (C25.73) followed by sector "Manufacture of other porcelain and ceramic products" (C23.4). Manufacture of tools is the overall most affected sectors in terms of number companies and workers exposed. The assessment of the current situation for example the current use of closed systems means that there might be companies where it will be very expensive or not feasible to further reduce the exposure. This can be compared to the Sector "Machining" which is also facing high total costs due to many companies and exposed workers. The assumptions on the use of existing RMMs (see Table 7-3) suggests that in this sector there are less use of closed systems. This means that the model-based assessment will estimate use of this RMM and therefore fewer companies facing the risk of discontinuation.

8.3.1.3 New entrants

There is no barrier for new entrants. An OEL will not prevent new entrants. They will by design of their production facilities be able to comply at low costs or they might start operating with a cobalt free alternative.

Significant capital expenditures are often incurred by new start-ups when entering the market. When entering the market companies are required to monitor exposure and so costs of running monitoring campaigns for start-ups cannot be attributed to the introduction of OELs. However, as limit values become lower more precise and more expensive monitoring techniques are required, potentially increasing the costs of the monitoring campaign and making entry to the market more challenging. Still, incumbent companies also face the increased monitoring costs so overall, there is not specific barrier for new entrants.

8.3.2 Consumers

The overall impacts are of a size where it is very unlikely that any consumer product will be affected. Over the 40-year period, the adjustment costs are below 1% of turnover for all sectors and in most cases below 0.1%. It means that the price of consumer products will not increase significantly in response to introduction of an OEL.

8.3.3 Internal market

No Member States have exactly the OELs that are analysed here. There are several Member States that apply an OEL of 20 µg Co/m³, but not with the same scope. Then there 6 Member States that have no OEL (or similar limit value) for cobalt. Introducting an OEL at EU level, means that the competition with be more equal across EU. It will therefore ensure a level playing fields. This impact cannot be further quantified.

Table 8-14 Simplification/level playing field

Policy option	Number of Member States currently at or above the policy option or with different scope
1 / 0.5 µg Co/m³	27
5 / 1.25 µg Co/m³	27
10 / 2.5 µg Co/m³	27
20 / 4.2 µg Co/m³	27

Source: Study team

8.4 Competitiveness of EU businesses

The introduction of a harmonised OEL will have an impact on companies' cost competitiveness but will be more significant for the lower policy options. As indicated previously, the increase in costs due to having to implement more or better RMMs represents the burden of compliance on companies. This would make those companies incurring these costs less competitive where they are competing with companies not using cobalt and inorganic cobalt compounds and with any companies already compliant at this level.

8.4.1 Sectors affected

The section above on the overall impact presents the sectors where the relative cost impact will be most significant. The share of one-off costs compared with the annual turnover provides a good indicator for the relative cost impact and how much industries' competitiveness could be affected.

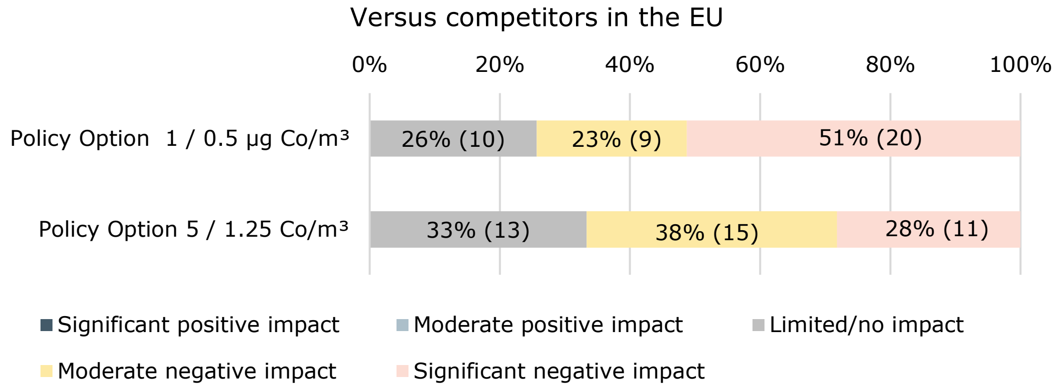
This is shown in Table 8-7 it is only for the lowest OEL that there could be an issue. For all the other OELs, the shares of one-off costs are at the most only a couple of percentage out of turnover. It means that sectors are likely to be able to cover the necessary adjustment costs out of annual budgets. In most cases, they can finance the investments over a few years.

Manufacture of tools are significantly more affected compared to other sectors. As discussed, it might be that some companies can shift to alternatives and thereby reducing the cost impacts. If not, there might be companies that will close down. The further indirect effects could be either i) existing companies that are able to comply at lower costs increase their market share or ii) there will be an increased import of tools.

8.4.2 Stakeholder survey

The stakeholder survey included for the two policy options with the lowest OELs a question whether the policy options would affect the competitiveness of the company. The distribution of answers for those respondents answering the question is shown in the figure below. None of the respondents answered that the introduction of an OEL could have a positive impact i.e. companies in Member States with OELs in the low end of the range of national OELs, did not expect that introduction of a common OEL at EU level would have a positive impact on competitiveness.

The majority of respondents indicated that they expected a significant negative impact versus competitors outside the EU for both policy options.



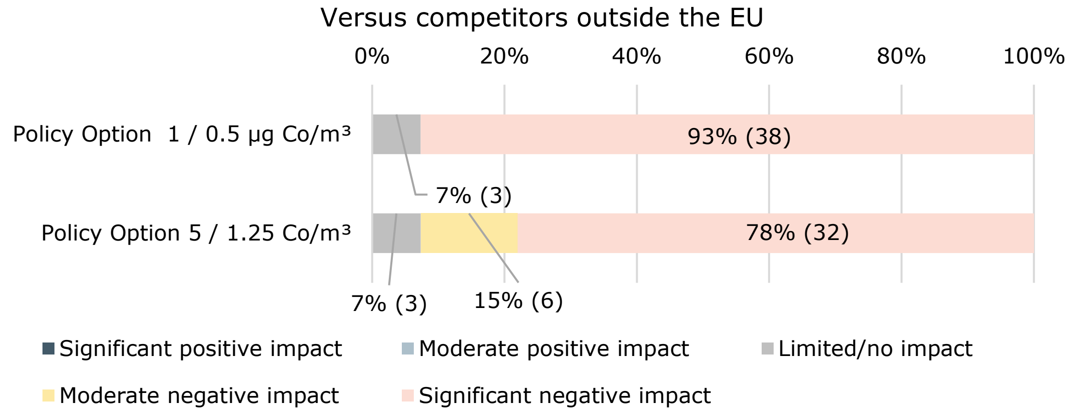


Table 8-15 *Respondents' answers to the questions whether the policy options would affect the competitiveness of the company (for those answering the question). Number of respondents in brackets. Source: Stakeholder survey.*

The results of the Member States Authorities survey as regards competitiveness and SMEs are shown in Table 8-16. The overall result of the survey is described in section 7.2.10.4.

Table 8-16 *Impact of the policy options for cobalt and inorganic cobalt compounds on competitiveness and SMEs (n = number of answers).*

Impact (number of answers)	Policy option (µg Co/m³)	Significant negative impact	Moderate negative impact	No impact	Moderate positive impact	Significant positive impact
Competitiveness	1 / 0.5 µg Co/m³	3	3	2		1
	5 / 1.25 µg Co/m³	3	2	3		1
	10 / 2.5 µg Co/m³	3	3	5		
	20 / 4.2 µg Co/m³			9		
SMEs	1 / 0.5 µg Co/m³	5	3	1		
	5 / 1.25 µg Co/m³	5	3	1		
	10 / 2.5 µg Co/m³	3	4	2		
	20 / 4.2 µg Co/m³	1	2	6		

Source: Consultation survey of Member States authorities.

8.4.3 SME competitiveness

The estimated adjustment costs compared to for example turnover indicate that SME are more affected. The above table (see Table 8-7) shows that for SMEs, the lowest policy options will pose significant cost burdens on SMEs in several sectors. It means that SMEs under the two lowest policy options might face a risk of not being able to finance the additional RMMs needed for compliance. That could increase the number of SMEs that will close down.

Some of the sectors that are most effected are described below. The table present the 5 sectors where the first-year costs comprise the largest share of turnover for small companies.

Table 8-17 Share of first year costs (additional to the baseline) for small companies implementing RMMs as a percentage of annual turnover (for the five sectors with the highest shares)

	Share of 1st year costs compared to turnover for small companies			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
C23.4 Manufacture of other porcelain and ceramic products	29.03%	11.30%	5.77%	2.34%
C32.50 Manufacture of medical and dental instruments and supplies	19.35%	14.10%	6.82%	3.12%
C25.99 Manufacture of other fabricated metal products n.e.c.	16.79%	6.41%	3.10%	1.28%
C25.62 Machining	13.43%	10.31%	2.63%	0.61%
C25.73 Manufacture of tools	8.38%	1.98%	0.76%	0.46%

Source: Study team

These sectors might face challenges. The high share of 1st year costs might be difficult to finance. Therefore, there is risk that companies might discontinue. The key factors are:

- Finance the 1st year costs over a period of time
- The financial status of the individual company
- The possibility to find alternatives

The first two factors are related. If a company is a solid financial status, it might be able to loan fiancé investments. There are not feasible to assess individual companies, but as the estimated number of companies potentially discontinuing indicate, these sectors will be challenged.

The sector on *manufacture of other porcelain and ceramic products* has a relatively low turnover and therefore, the compliance cost comprise a relatively high share. It might be that some companies might find alternatives to cobalt. As discussed in Section 3.10.11, there might be alternative pigments though they may not provide the exact same colour. Whether companies in this sector might find alternative products where cobalt is not needed has not investigated. Overall, there could be some companies that will close and the production of specific products where cobalt is used, will relocate to outside EU.

For *manufacture of medical and dental instruments*, there are alternative available but at higher costs and with lower quality. It means that companies might be able to find alternatives. It might also that the additional costs can be passed on given medical products are generally less price sensitive. Whether larger companies in the sector might take over the production is another outcome. It would still mean that some SMEs might close, but with less overall follow-on impacts, for example on employment.

The sector on *other fabricated metal products* comprises diverse types of production. There is limited knowledge of the sector. The results are therefore subject to some uncertainty also with regards to number of companies and number of exposed workers. It is not possible to further assess specific on this sector.

Machining is one of large sectors in terms of number of exposed workers. The exposure is related to the use of hard metal tools in particular sharpening of the tools. As described above, see section 3.10.3.17, there is diversity type of products where this takes place. It means that the impacts depend on the specific supply chain. Given that sharpening of tools is a minor component of all processes in the affected supply chain it is more likely that the additional costs can be passed on down the supply chain. The cost model assessment also indicates a relatively low share of companies closing. If the sharpening of hardmetal tools is provided by small specialist companies, this service is unlikely to be relocated outside of the EU. So overall, for this sector it is expected that SMEs will be able to pass on the costs.

Manufacturer of hardmetal and diamond tools is a sector where the cost model assessment indicates the large number of SMEs that might discontinue. Though, the assessment is uncertain it points to this sector as one of the most challenged sectors. There might be alternative for diamond tools, but to what extent the companies can switch to the alternatives is unclear. It is also not possible to assess whether the production by small companies that may discontinue will be taken over by larger companies or relocate outside of the EU.

The model estimation of the number of discontinuations also indicate that it is SMEs that comprise the largest share of the companies potentially closing down.

Table 8-18 SME share of companies discontinuing

Policy option	Total estimated number of companies closing	SME share of closures
1 / 0.5 µg Co/m^3	886	97%
5 / 1.25 µg Co/m^3	120	98%
10 / 2.5 µg Co/m^3	47	98%
20 / 4.2 µg Co/m^3	9	100%

Source: Study team
Note: For large companies, it only 10% of the company that is assumed to close.

Again, it is for the two lowest policy option where the impacts on SMEs are significant. As discussed above for the most affected sectors, there is risk of SMEs discontinuing and the production being taken over by imported products. It is not possible to further quantify these impacts.

For the highest two policy options, the overall level of adjustment costs means that in most sectors, there will be no significant impacts.

8.4.4 Cost competitiveness

This is discussed as part of the overall assessment. Increased adjustment costs will be a challenge but in all but a few sectors, the impacts are not significant.

For the key affected sectors, 'Machining' and 'Manufacture of tools', see the above discussions in Section 7.6 and Section 8.1.

8.4.5 *Capacity to innovate*

As discussed above in the section on research and innovation, there could be a temporarily decrease in the R&D activities, but no long-term impacts are likely to occur.

8.4.6 *International competitiveness*

In the event that EU companies are required to comply with stricter OELs than those in effect in third countries, EU companies will be at a disadvantage when compared to their competitors who will be able to operate without incurring the capital and operating costs of compliance with a lower OEL. In certain cases, in particular where they have existing plants in third countries, EU companies working with cobalt and inorganic cobalt compounds might have the incentive to shift EU operations away from the EU. Large and medium-sized companies are more likely to operate on an international scale and have greater opportunity to transfer operations to existing plants outside the EU.

A number of competitor countries have OELs for the inhalable fraction or total dust comparable to the current mode of OELs in EU Member States of 20 µg/m^3: Canada (Québec, binding), Japan, (MHLW, binding), Norway (indicative), South Korea, and USA (ACGIH, indicative). Australia (binding), China, Japan (JOSH, indicative), Switzerland (binding) and USA (NIOSH, indicative) have a value for the inhalable fraction or total dust of 50 µg/m^3, whereas the United Kingdom (binding) and USA (OSHA, binding) have a value of 100 µg/m^3. For none of the countries it is specifically indicated that the OELs concern the respirable fraction. Countries often have different compliance rules and methods to define exposure and it is also not possible to determine whether the sampling is of the inhalable, total dust or respirable fraction for several countries: This makes comparison difficult.

However, lower OELs in competitor countries may provide an incentive for EU based companies to re-locate their operations, particularly if they already have facilities in these countries and perceive that the costs of adapting existing operations within the EU to comply with the OELs will have excessive negative impacts on their profitability. One large company has for the stakeholder consultation indicated that they may relocate the dustiest processes with the highest exposure concentrations to countries outside the EU.

Again, however, the costs that adaptation measures represent are not considered particularly significant based on the calculations modelled in this study, and the cost of relocation may exceed that of taking the necessary measures to comply with whatever OEL is introduced, particularly at levels of 5 µg/m^3 and above.

Table 8-19 below draws on information provided in Table 3-2 in section 3.1.

Table 8-19 OELs in selected non-EU countries

Country	OEL, µg Co/m^3	Specification of OEL
Australia	50 (D, F) **	- S
Brazil	-	
Canada, Ontario	-	
Canada, Québec	20 **	- Carc, S
China	50	
India	-	

Country	OEL, µg Co/m³	Specification of OEL
Japan, MHLW	20 **	
Japan, JOSH	50 ^^^	- Carc, Srd
Norway	20 (T) ^^	- Cobalt and its inorganic compounds, except Co(II)
Russia	4 1	- Cobalt, acceptable risk under daily exposure (at least 24), Sk - Cobalt, acceptable risk under chronic exposure (at least 1 year), Sk
South Korea	20	
Switzerland	50 (I) *	- Cobalt and its compounds, Carc, Repro, S, Sk
Turkey	-	
United Kingdom	100 *	- Cobalt and its compounds, Carc (only for cobalt dichloride and sulphate), S
USA, ACGIH	20 (I) ^	- Carc, Srd
USA, NIOSH	50 (D, F) ^	- Cobalt
USA, OSHA	100 (D, F) *	- Cobalt

Source: Information on sources is presented in Table 3-1 in section 3.1.
** Binding value according to country-specific source*
*** Binding value according to the Final report for OEL/STEL deriving systems from 2018*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018
(I) = inhalable fraction/aerosol
(V) = vapour
(D) = dust
(F) = fume
(T) Total dust
S = notation for sensitisation assigned
Srd = respiratory and skin/dermal sensitisation
Sk = skin notation assigned or danger of skin absorption
Carc = notation for carcinogenicity
Repro = notation for reproductive toxicity assigned
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health

8.5 Employment

The number of companies that might discontinue is subject to large uncertainty. For the most affected sector, manufacture of tools, there are for some types of tools potentially alternatives. Should there be discontinuation as estimated by the cost model, it is a question whether this will lead to more than very temporary unemployment. Within the affected sectors, there are companies that are likely to comply with of OELs except for the lowest, and they might increase their market share to compensate for those closing their activities. It means that these complying companies might increase their level of employment. Hence, at the overall EU level this reduces the risks that there will be any major unemployment effect. There could be local and regional distributional effects. It is also worth noting the unemployment rates are currently generally decreasing within the EU. This increases the likelihood that any worker losing their job due to discontinuation, might find another job.

The table shows the potential number of workers affected by discontinuation. As discussed above, the main impact is in the sector 'Manufacturing of tools'. If the production is taken over by other companies in this industry there might not be an aggreged impact on employment. There could be a distributional effect, where the closing and expanding companies might be located in the different Member States. In the below table, the number of discontinuances, number of workers and social costs are displayed for the two lowest OELs. It is not likely that there will be any discontinuations for the other OELs.

Table 8-20 Social cost (in € million) due to unemployment resulting from discontinuances

Sector	Discontinuances	Number of workers	Total social cost in € million
OEL = 1 / 0.5 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	-	-	-
C19.2 Manufacture of refined petroleum products	-	-	-
C20.12 Manufacture of dyes and pigments	2	136	17
C20.13 Manufacture of other inorganic basic chemicals	1	58	10
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	1	30	3
C20.59 Manufacture of other chemical products n.e.c.	1	63	6
C21.2 Manufacture of pharmaceutical preparations	-	-	-
C22.11 Manufacture of rubber tyres and tubes; re-treading and rebuilding of rubber tyres	0	6	0
C23.1 Manufacture of glass and glass products	3	117	4
C23.4 Manufacture of other porcelain and ceramic products	194	600	18
C23.7 Cutting, shaping and finishing of stone	-	-	-
C24.1 Manufacture of basic iron and steel and of ferro-alloys	1	76	8
C24.45 Other non-ferrous metal production	1	24	-
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	3	219	20
C25.61 Treatment and coating of metals	24	974	62
C25.62 Machining	30	522	42
C25.73 Manufacture of tools	702	17,977	1,247
C25.99 Manufacture of other fabricated metal products n.e.c.	19	355	20
C26.1 Manufacture of electronic components and boards	36	1,178	127
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	-	-	-
C27.2 Manufacture of batteries and accumulators	0	15	2

Sector	Discontinuances	Number of workers	Total social cost in € million
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	17	930	104
C29.1 Manufacture of motor vehicles	13	951	142
C30.3 Manufacture of air and spacecraft and related machinery	14	429	40
C32.5 Manufacture of medical and dental instruments and supplies	24	1,017	85
E38.32 Recovery of sorted materials	2	174	10
Total	**1,086**	**25,849**	**1,970**
5 /1.25 µg/m3			
C10.91 Manufacture of prepared feeds for farm animals	-	-	-
C19.2 Manufacture of refined petroleum products	-	-	-
C20.12 Manufacture of dyes and pigments	0	34	4
C20.13 Manufacture of other inorganic basic chemicals	0	12	2
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0	5	1
C20.59 Manufacture of other chemical products n.e.c.	0	10	1
C21.2 Manufacture of pharmaceutical preparations	-	-	-
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	-
C23.1 Manufacture of glass and glass products	0	12	0
C23.4 Manufacture of other porcelain and ceramic products	49	99	3
C23.7 Cutting, shaping and finishing of stone	-	-	-
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0	7	1
C24.45 Other non-ferrous metal production	0	2	-
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0	20	2
C25.61 Treatment and coating of metals	2	97	6
C25.62 Machining	-	-	-
C25.73 Manufacture of tools	69	1,768	123
C25.99 Manufacture of other fabricated metal products n.e.c.	4	71	4
C26.1 Manufacture of electronic components and boards	6	203	22
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	-	-	-

Sector	Discontinuances	Number of workers	Total social cost in € million
C27.2 Manufacture of batteries and accumulators	-	-	-
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	4	219	24
C29.1 Manufacture of motor vehicles	1	95	14
C30.3 Manufacture of air and spacecraft and related machinery	3	100	9
C32.5 Manufacture of medical and dental instruments and supplies	-	-	-
E38.32 Recovery of sorted materials	0	9	0
Total	**142**	**2,761**	**217**
10 /4.5 µg/m3			
C10.91 Manufacture of prepared feeds for farm animals	-	-	-
C19.2 Manufacture of refined petroleum products	-	-	-
C20.12 Manufacture of dyes and pigments	0	14	2
C20.13 Manufacture of other inorganic basic chemicals	-	-	-
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	0	2	0
C20.59 Manufacture of other chemical products n.e.c.	0	10	1
C21.2 Manufacture of pharmaceutical preparations	-	-	-
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	-
C23.1 Manufacture of glass and glass products	-	-	-
C23.4 Manufacture of other porcelain and ceramic products	17	34	1
C23.7 Cutting, shaping and finishing of stone	-	-	-
C24.1 Manufacture of basic iron and steel and of ferro-alloys	0	3	0
C24.45 Other non-ferrous metal production	0	1	-
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	0	10	1
C25.61 Treatment and coating of metals	-	-	-
C25.62 Machining	-	-	-
C25.73 Manufacture of tools	35	884	61
C25.99 Manufacture of other fabricated metal products n.e.c.	2	28	2
C26.1 Manufacture of electronic components and boards	3	81	9

Sector	Discontinuances	Number of workers	Total social cost in € million
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	-	-	-
C27.2 Manufacture of batteries and accumulators	-	-	-
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	1	36	4
C29.1 Manufacture of motor vehicles	-	-	-
C30.3 Manufacture of air and spacecraft and related machinery	1	20	2
C32.5 Manufacture of medical and dental instruments and supplies	-	-	-
E38.32 Recovery of sorted materials	-	-	-
Total	**57**	**1,124**	**83**
20 /4.2 µg/m³			
C10.91 Manufacture of prepared feeds for farm animals	-	-	-
C19.2 Manufacture of refined petroleum products	-	-	-
C20.12 Manufacture of dyes and pigments	0	7	1
C20.13 Manufacture of other inorganic basic chemicals	-	-	-
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	-	-	-
C20.59 Manufacture of other chemical products n.e.c.	-	-	-
C21.2 Manufacture of pharmaceutical preparations	-	-	-
C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres	-	-	-
C23.1 Manufacture of glass and glass products	-	-	-
C23.4 Manufacture of other porcelain and ceramic products	8	15	0
C23.7 Cutting, shaping and finishing of stone	-	-	-
C24.1 Manufacture of basic iron and steel and of ferro-alloys	-	-	-
C24.45 Other non-ferrous metal production	-	-	-
C25.5 Forging, pressing, stamping and roll-forming of metal; powder metallurgy	-	-	-
C25.61 Treatment and coating of metals	-	-	-
C25.62 Machining	-	-	-
C25.73 Manufacture of tools	-	-	-
C25.99 Manufacture of other fabricated metal products n.e.c.	1	14	1

Sector	Discontinuances	Number of workers	Total social cost in € million
C26.1 Manufacture of electronic components and boards	1	41	4
C26.51 Manufacture of instruments and appliances for measuring, testing and navigation	-	-	-
C27.2 Manufacture of batteries and accumulators	-	-	-
C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines	-	-	-
C29.1 Manufacture of motor vehicles	-	-	-
C30.3 Manufacture of air and spacecraft and related machinery	-	-	-
C32.5 Manufacture of medical and dental instruments and supplies	-	-	-
E38.32 Recovery of sorted materials	-	-	-
Total	**10**	**77**	**7**

Source: Study team

8.6 Summary of market effects

The assessment based on the estimated costs and the comparison of costs to turn over and profits indicates that overall, the market impacts are not expected to be large but in a few sectors.

The market effects can be summarised in the following points:

- The estimated adjustment costs comprise for the majority of sectors less than 1% of turnover, in factor for most sectors it is below 0.1% of turnover. It means that all follow-on effects on the markets will be very small or marginal.
- Only for the manufacture of tools, and here mainly for the lowest OEL, there might be more significant impacts. In this sector, there is a risk of companies closing down because of high adjustment costs. This might lead to a potential higher import of tools instead of EU production. It is difficult to assess the extent to which existing EU companies with lower adjustment costs might increase their market share in compensation for the closing companies/production sites. If that happens, there will be only minor aggregated effects also for this sector.
- It is not likely that there will be impacts on consumer products and therefore consumers are not expected to be affected by introduction of EU OEL for cobalt.

9 ENVIRONMENTAL IMPACTS

This chapter comprises the following sections:

- Section 9.1: Potential environmental impacts
- Section 9.2: Environmental exposure to the substance
- Section 9.3: Direct impact on the environment
- Section 9.4: Indirect impacts on the environment and environmental legislation
- Section 9.5: Summary of environmental impacts

9.1 Potential environmental impacts

The overall approach to the assessment of the environmental impacts, based on the Better Regulation (BR) Toolbox for environmental impacts (BR Tool #36) is described in the Methodological Note. Initially, the key questions listed in section 3.3. of the BR Tool #36 have been screened in order to identify which questions is relevant for the introduction of an OEL and should be answered in the impact assessment (see the Methodological Note).

For cobalt and inorganic cobalt compounds the following potential environmental impacts are included in the assessment:

- Impact on environmental exposure to the substances. The introduction of an OEL for cobalt and inorganic cobalt compounds may lead to changes in the releases of the substances due to introduction of risk management measures. This may potentially impact organisms in the environment and human exposure via the environment.
- Impact on the extraction of cobalt and the environmental effects of the extraction. The introduction of an OEL may lead to reduced use of cobalt and inorganic cobalt compounds as the introduction of the OEL may lead to further use of alternatives.
- Impact on waste handling and recycling. The introduction of an OEL may increase the costs of recovery of cobalt from waste products and lead to reduced recycling of the substance.
- Impact on climate change. The introduction of an OEL may increase the costs of components used for the green transmission such as batteries and magnets. In addition, introduction of RMMs may potentially lead to higher energy consumption.

Furthermore, in accordance with the BR Toolbox, this chapter includes an assessment of impact on implementation and enforcement of existing environmental legislation; more specifically the EU Green Deal and Climate Neutrality Objectives.

9.2 Environmental exposure to the substance

9.2.1 Persistent, bioaccumulative, and toxic (PBT) screening

According to Annex XIII of REACH (regulation (EC) 1907/2006), a PBT (persistent, bioaccumulative, and toxic) and vPvB (very Persistent and very Bioaccumulative) assessment shall not be conducted for inorganic substances, thus a PBT and vPvB assessment is not included in the REACH Registration. The criteria for identification of substances as PBT and vPvB as defined in Annex XIII to REACH apply only to organic substances, including organo-metals. The following screening for PBT properties should consequently be considered informative.

Cobalt is an element (a metal) and can therefore not undergo degradation under environmental conditions. Hence, it may be regarded as persistent (P) in the environment.

According to the registrations dossier for cobalt (ECHA, 2023), cobalt is an essential element for plants and animals and as such homeostatic mechanisms maintain cobalt concentrations in tissues and body fluids within ideal levels by actively accumulating or depurating cobalt depending on metabolic requirements. According to an assessment from the International Programme on Chemical Safety (IPCS, 2006) cobalt is taken up by unicellular algae with reported bioconcentration factors (BCF) (dry weight) of 40,000 for Scenedesmus *obliquus* and 18,000 for Selenastrum *capricornutum*. Freshwater molluscs have concentration factors of 100–14,000 (~1–300 in soft tissue). Much of the cobalt taken up by molluscs and crustaceans from water or sediment is adsorbed to the shell or exoskeleton; very little cobalt is generally accumulated in the edible parts. In studies with starfish, accumulation of cobalt was found to be predominately from seawater rather than from food. Bio-accumulation factors for marine fish and freshwater fish are 100–4,000 and <10–1,000, respectively. However, accumulation is mostly in the viscera and skin of the fish, not the edible parts of the fish) (IPCS, 2006). According to REACH, a substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2,000, but as mentioned these criteria apply only to organic substances, including organo-metals. According to IARC (2023) biomagnification of cobalt up the food chain does not occur.

There is a harmonised classification for cobalt under the CLP Regulation (Regulation 1272/2008). Based on this, cobalt is assessed to fulfil the PBT-criteria with regard to toxicity (T) as the metal is classified carcinogenic category 1B and reprotoxic category 1B. However, with regard to environmental toxicity, cobalt does not meet the toxicity criterion (classified Aquatic Chronic 4).

In conclusion, cobalt would in principle fulfil the criteria as PBT (persistent, bioaccumulative and toxic), but for an essential element as cobalt, the bioaccumulation criteria are of limited relevance for a risk assessment and the criteria for identification of a substance as PBT under REACH does not apply to cobalt. Of importance for an environmental exposure assessment is that cobalt does not biomagnify in the food chains.

9.2.2 Current environmental exposure

9.2.2.1 Sources

As summarised by the Toxicological Profile for Cobalt from the US Agency for Toxic Substances and Disease Registry (ATSDR, 2023), the sources of cobalt in the atmosphere are both natural and anthropogenic. Natural sources include wind-blown continental dust, seawater spray, volcanoes, forest fires, and continental and marine biogenic emissions. The worldwide emission of cobalt from natural sources has been estimated to range from 5,900 to 6,800 tonnes/year (Lantzy and Mackenzie 1979; Nriagu 1989 as cited by ATSDR, 2023). The global atmospheric emission of cobalt from anthropogenic sources is estimated at 4,400 tones/year. Therefore, natural sources contribute slightly more to cobalt emissions to the atmosphere than anthropogenic sources. The primary anthropogenic sources of cobalt to the atmosphere are the burning of fossil fuels and sewage sludge, phosphate fertilizers, mining and smelting of cobalt-containing ores, processing of cobalt-containing alloys, and industries that use or process cobalt compounds (ATSDR, 2023).

Cobalt is not included in the European Pollutant Release and Transfer Register (E-PRTR) nor in the reporting of emissions data under the UNECE (United Nations Economic Commission for Europe) Convention on Long-range Transboundary Air Pollution (LRTAP) and no overview of anthropogenic sources to cobalt releases in the EU has been identified. In Canada, the main sources of the total releases to the atmosphere of 8.2 tonnes/year reported to the Canadian Pollutant Release and Transfer Register was metal smelters/refineries (46% of total), mines and mills (20%), transport (16%), other manufacturing (10%) and chemicals 2(%) (Government of Canada, 2017). 'Other manufacturing' is not further described. The Canadian data are not readily comparable with the EU as mining and smelters likely account for a larger part of the total releases.

The anthropogenic releases of cobalt to water are small compared to anthropogenic releases to the air and the reported anthropogenic releases to water in the USA is about 1/10 of the emissions to air (IPCS, 2006). Releases from industrial processes to water is not considered potentially affected by introduction of an OEL.

For the assessment of possible impact of an OEL on environmental levels, the main question is to what extent production and use of cobalt may lead to elevated levels in the vicinity of sites where the substances are produced or used. According to ATSDR (2023), exposure to cobalt in communities near mining and smelting facilities or metal shops where cobalt is used in grinding tools is a public health concern, especially for infants and children. Dissipation of cobalt from mining and smelting facilities would typically not be impacted by additional use of RMMs in order to reduce occupational exposure. Releases to the vicinity of metal shops where cobalt is used in grinding tools are not further documented in ATSDR (2023) and no other documentation for significant releases to the surroundings from these activities have been identified.

Furthermore, according to ATSDR (2023), in communities near industrial and hazardous waste sites, cobalt may have been tracked in from outdoors and contaminate carpeting. A study of metal concentrations in air conducted in four communities near metal recyclers in the USA demonstrated elevated levels in the air in the neighbourhood.

9.2.2.2 Background exposure

Cobalt is a naturally occurring metallic element (element no. 27), which is ubiquitously present in the biosphere. It is an essential element as it is involved in various biological processes e.g. the normal growth of many species of microorganisms, plants and also several species of vertebrates.

The background concentrations of cobalt vary across Europe and reflect the geological and local physicochemical conditions. As summarised by ECHA (2022), cobalt is usually found in the environment combined with other elements such as oxygen, sulphur, and arsenic. Cobalt occurs in nature in a widespread but dispersed form in many rocks and soils. The cobalt concentration in the earth's crust is about 20 mg/kg. Small amounts of cobalt compounds can be found in plants and animals. Cobalt is found in water in dissolved or ionic form, typically in small amounts.

A biochemically important cobalt compound is vitamin B12 (cobalamin). Vitamin B12 is essential for good health in animals and humans (ATSDR, 2004). A dietary reference value for cobalamin (vitamin B12) (Adequate Intake (AI)) is 4 µg/day for adults based on data on different biomarkers of cobalamin status and in consideration of observed mean intakes, which range between 4.2 and 8.6 µg/day in adults in several EU countries (EFSA, 2015).

9.2.2.3 Environmental levels in relation to hazard data

According to the summary from IPCS (2006), a comparison of the guidance values for the marine environment with environmental concentrations would suggest that effects are likely only in the vicinity of major anthropogenic releases. There is some evidence that under freshwater conditions of extremely low divalent calcium concentration there is less competition for cobalt at fish gill binding sites and therefore greater uptake of cobalt. Therefore, the greatest risk to aquatic organisms might be in very soft water areas close to sources of anthropogenic release (IPCS, 2006).

Data regarding the toxicity of cobalt to soil microorganisms are limited. There is little evidence of cobalt toxicity to plants due to elevated concentrations in soil. Cobalt tolerance, along with tolerance to other metals, has been found in plant populations growing on soils high in particular metals. Exclusion of the metal has been demonstrated in the cobalt tolerance of some species, whereas others growing on cobalt-rich copper clearings are hyperaccumulators of cobalt. Adverse effects on earthworm growth and springtail reproduction have been reported at 300–400 mg/kg dry weight. In the terrestrial environment, adverse effects of cobalt on birds and wild mammals would appear unlikely, with cobalt deficiency in ruminants more likely than cobalt toxicosis (IPCS, 2006).

9.2.3 Summary of potential impact on environmental exposure

Releases to the environment from anthropogenic sources would primarily be from thermal processes (e.g. burning of fossil fuels or and smelting of cobalt-containing ores) and from outdoor dusty activities (e.g. mining). Available information indicates that some processes such as use of diamond tools may also lead to some releases to the vicinity of the sites where the processes take place, but no quantitative data has been identified. The absence of quantitative data may be taken as an indication for these releases would be of limited importance for the environmental exposure and/or exposure of the population around the facilities.

9.3 Direct impact on the environment

To what extent further use of RMMs in order to reduce occupational exposure to cobalt may lead to higher or lower releases depends on the RMMs, and even for the same RMMs, the possible impact may go in both directions. Further use of general ventilation system is not considered an efficient way to reduce the occupational exposure and further use of general ventilation is not selected as RMM by the cost model used for the current study. Further use of local exhaust ventilation (LEV) and closed systems may to the extent the ventilation system is not equipped with filter lead to higher releases via the ventilation system. However the LEV and exhaust from closed systems would usually be equipped with a filter and further use of LEV and closed systems may rather reduce the releases from the general ventilation system and diffuse releases though doors and windows than increase the releases.

Through the analysis of consultation results, literature review and cost-benefit modelling, the study team has identified five primary technical RMM's currently used in operations containing cobalt and cobalt compounds. These are:

- Partially closed systems
- Open hoods over equipment or local extraction ventilation
- Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)
- Half and full facemasks (negative pressure respirators)
- General dilution ventilation

Table 9-1 outlines how alternative RMM processes are likely to change for each OELs option, together with the broad environmental impact of each change. The environmental impact of all RMMs is outlined in the Methodological Note.

The use of alternative technical RMMs to meet new OELs are not anticipated to contribute to significant environmental impacts and should generally lead to no change or possibly even lower environmental impacts. It is unlikely that the alternative RMMs will result in rogue emissions or increased waste by-products as they arrive at the same endpoint. For example, where general dilution ventilation may be replaced by an open hood system (local exhaust ventilation), the same endpoint (filters or waste containment sack) will typically occur.

Table 9-1 Primary and alternative RMMs for each policy option, together with the broad impact on environmental exposure

Primary RMM	Alternative primary RMM for each policy option				Impact on environmental exposure
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³	
Partially closed systems	Closed system Discontinuation	Closed system Discontinuation	Closed system	Partially closed systems	Reduced
Open hoods over equipment or local extraction ventilation	Closed system Discontinuation	Closed system Discontinuation	Closed system	Open hoods	Reduced
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	Self-contained breathing apparatus	Self-contained breathing apparatus	Self-contained breathing apparatus	Self-contained breathing apparatus	No impact
Half and full facemasks (negative pressure respirators)	Self-contained breathing apparatus	Self-contained breathing apparatus	Half and full facemasks	Half and full facemasks	No impact
General dilution ventilation	Closed system Discontinuation	Closed system	Open hoods over equipment	Open hoods over equipment	Reduced

9.4 Indirect impacts on the environment and environmental legislation

9.4.1 EU Green Deal

In 2019, the European Commission announced the European Green Deal to encourage future policies to be developed in line with minimal adverse impacts on the environment and to support efforts to move to sustainable practices (European Commission, 2019). This section screens the implementation of OELs for cobalt and inorganic cobalt substances in the context of the key elements of the green deal. This is also in line with the approach described in chapter 36 of the better regulation toolbox.

Table 9-2 outlines the key elements put forward in the EU Green Deal and contains a short overview of the expected impact (positive or negative) of introducing OELs for cobalt and inorganic cobalt substances on the progress towards each of these elements. A short explanation is given to indicate the justification for the expected impact. The table presents the expected types of impacts. The magnitude of the impact will vary across the policy options. The lower the OEL, the more significant the impact will be. This is the case for all the elements of the EU Green Deal described in the table. It means that the impacts will be most significant for the OEL of 1 / 0.5

µg Co/m³, and the least significant impacts will be for the OEL of 20 / 4.2 µg Co/m³.

Table 9-2 Potential for OELs to impact benefits of the EU Green Deal

Elements of the EU Green Deal	OELs impact (Yes/No)	Comment
Increasing the EU's climate ambition for 2030 and 2050	No	
Supplying clean affordable and secure energy	Yes	An OEL for cobalt and inorganic cobalt compounds may increase costs of renewable energy sources (e.g. increased costs of magnets) and energy storage systems (e.g. increased costs of batteries) In the longer term, the introduction of an OEL may be a driver for development of alternatives and reduce the demand for critical raw materials (cobalt), and thereby have a positive impact on the supply of clean affordable and secure energy.
Mobilising industry for a clean and circular economy	Yes	An OEL for cobalt and inorganic cobalt compounds may increase the costs of recycling of cobalt and thereby have a negative impact on the circular economy efforts
Building and renovating in an energy and resource efficient way	No	
Accelerating the shift to sustainable and smart mobility	Yes	An OEL for cobalt and inorganic cobalt compounds may in the short term increase the costs of batteries for vehicles and thereby have a negative impact on the shift to sustainable and smart mobility. In the longer term, the introduction of an OEL may be a driver for development of alternatives and reduced the demand for critical raw materials (cobalt), and thereby have a positive impact on the shift to sustainable and smart mobility.
Designing a fair, healthy and environmentally-friendly food system	No	
Preserving and restoring ecosystems and biodiversity	No	
Zero pollution ambition for a toxic-free environment	Yes	An OEL for cobalt and inorganic cobalt compounds may reduce releases of cobalt to the surroundings of facilities where the substances are used

Source: Study team

9.4.2 European Climate Law

The European climate law was introduced in 2021 and sets out legally binding targets for emissions reductions proposed by the EU Green Deal. The main target proposed is to ensure that the European economy and society become climate neutral by 2050, with an intermediate goal to reduce greenhouse gas emissions by 55% in 2030, compared to 1990 levels (Regulation (EU) 2021/1119)[57]. The implementation of OELs for cobalt and inorganic cobalt compounds is not considered to contradict the objectives set out in this legislation.

An introduction of an OEL may have an impact on climate change by the following mechanisms:

[57] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law')

- The introduction of further ventilation may increase the electricity consumption for running the ventilation and increase the overall energy consumption for heating or cooling by replacement of indoor air with outdoor air.
- Further use of alternatives may lead to either higher or lower GHG (greenhouse gases) emissions depending on the actual alternatives (as described in section 9.4.4).
- Reduction in recycling rates may lead to increased GHG emissions as the GHG emissions from recycling of cobalt is in general lower that manufacture from virgin materials (as described in section 9.4.4)

Whereas it is well documented that introduction of general ventilation would increase energy consumption (mainly documented for office buildings and residential buildings), no quantification of increased energy consumption by introduction of LEV and closed systems with exhaust in industry has been identified. According to the website of a major international supplier of ventilation systems, industrial air filtration systems can account for as much as 30% of a plant's total energy consumption[58]. In general, installation of more LEV would lead to increased energy consumption, and it cannot be excluded that introduction of an OEL could have some negative impacts on climate change due to increased energy consumption.

Overall, it is assessed that introduction of an OEL may have some negative climate impact on climate change due to increased energy consumption for ventilation and through reduced recycling of cobalt (further discussed in next section).

9.4.3 Waste management and disposal

Occupational exposure by waste management has only been quantified for recovery activities. Apart from recovery of cobalt and cobalt compounds, addressed below, the introduction of new OELs is not considered to significantly change the waste management and disposal of cobalt-containing waste.

Introduction of an OEL may potentially reduce recycling of cobalt and inorganic cobalt compounds by increasing the costs of recovery of cobalt from metal scrap and other waste. The assessment of the adjustment costs indicates that for the lowest policy option, the adjustment costs could lead to a price increase of up to 1% if all the adjustment costs are passed on. While this might have impact on the recovery of cobalt and inorganic cobalt compounds, such an impact is unlikely for the higher policy options. For the second highest policy options, the potential increase of the price of cobalt recovery would be in the order of 0.03% or less. This is unlikely to have any impacts on the amount of recovery. For the highest policy option, there will be no impacts.

Cobalt is today recovered by various processes as described in section 3.2.5. As of 2021, about 22% of cobalt substances used in Europe were recycled from batteries, catalysts, superalloys, and hard metals (eftec 2023). The recovery efficiency, i.e. the percentage of cobalt disposed of as waste, which was recovered, is indicated at 32% which includes recycling that occurs outside the EU-27 (eftec 2023).

Eftec (2023) suggest that at a stringent OEL may discourage further investment and development in recycling. Eftec (2023) suggest that at an OEL of 1 µg/m^3 or below, for the catalysts, tires, and diamond tool/hard metal industries, recycling of the material may become too complicated and for

[58] https://www.nederman.com/en/knowledge-center/faq

the oil production (catalysts) and chemical manufacturing industries, recycling of cobalt would likely cease. The current study estimates that one large company (of a total of 15 companies off all sizes) in the metal recovery sector may discontinue at an OEL of 1 µg/m^3, but do not assess to what extent the recovery of cobalt would decrease at the different policy options.

For batteries, which in the future is expected to take up the largest share of the cobalt disposed of for recovery, the minimum recycling rates are determined by legislation. The target of the new Regulation on Batteries and waste batteries [59] is that 65% of a lithium-ion battery weight is recycled in 2025, increasing to 70% by 2030. For Ni-CD and Ni-MH batteries the target is 50% recycling. For cobalt, a recovery rate of 90% of the recycled material is targeted by 2026. By 2030, the target raises to 95%.

Another driver for the recycling of cobalt is the new mandated targets of the Regulation on Batteries and waste batteries for recycled lithium, nickel, and cobalt contained in batteries sold in the EU. For cobalt it will start at 16% recycled material in 2031 (if the legislation is passed this year) and the recycled percentage will increase to 26% for cobalt 13 years after the legislation is passed. According to the European Battery Alliance (EBA, 2022), since the majority of the materials at the end of the recycling process can be fed back into battery production, and due to the scarcity of these raw materials, the conditions for a closed-loop business model will be ripe. Furthermore, the organisation believes that raw material prices and pure scarcity, supported by regulation, will make battery recycling in Europe truly work at scale.

The Proposal for a regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials[60] (referred to as the European Critical Raw Materials Act) sets benchmarks for domestic capacities along the strategic raw material supply chain and to diversify EU supply by 2030. Among the benchmarks, Union recycling capacity, including for all intermediate recycling steps, should be able to produce at least 15% of the Union's annual consumption of strategic raw materials. Whereas the benchmark does not apply to each critical raw material, but the total critical raw materials, any impacts on the recycling of cobalt due to increased costs of recycling may be contrary to the intentions of the European Critical Raw Materials Act.

Whereas it is uncertain to what extent introduction of an OEL will reduce recycling rates, available studies indicate that the environmental impact of recycling is smaller than the impact of production of virgin material.

Rinne *et al.* (2021) performed a comparative life cycle assessment for hydrometallurgical recycling of mixed LIB (lithium-ion batteries) and Ni-MH (nickel metalhydride) waste and production of virgin materials. The recycling process resulted in 38% less greenhouse gas (GHG) emissions than virgin production and for all analysed environmental impact categories except for ozone depletion a "*significant potential reductions in climate change, acidification, freshwater eutrophication, and human toxicity were also achievable when compared to the life cycle impacts of the primary production of battery metals, mainly due to the high environmental footprint of primary nickel and cobalt sulphate production.* " (Rinne *et al.*, 2021). Rinne *et al.* (2021) compared the results with the results of previous studies of Amarakoon *et al.* (2013, as cited by Rinne *et al.*, 2021) which

[59] https://data.consilium.europa.eu/doc/document/PE-2-2023-INIT/en/pdf

[60] Proposal for a regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/102

modeled hydrometallurgical, pyro-metallurgical, and direct physical recycling methods and presented the environmental mitigation as an average of the three processes; the GHG savings obtained by recycling were only 3.6% on average compared to primary production, depending on the battery chemistry. The results calculated by Gaines (2018 as cited by Rinne *et al.*, 2021), on the other hand, would suggest that increasing the amount of recycled material in battery cells decreases the overall energy consumption significantly, especially when aluminum is also recovered.

Golroudbary *et al.* (2002) found in a study of environmental benefits of circular economy approach to use of cobalt that, compared to the primary production of cobalt, recycling might lead to a reduction of energy consumption by 46% associated with the global cobalt supply chain and the corresponding fall in the use of water by 40%. Furthermore, recycling of cobalt was estimated to mitigate around 59% of the total emissions of greenhouse gases and 98% of the total emissions of sulphur oxides.

Furberg *et al.* (2019) concludes in a LCA (Life Cycle Assessment) study of hardmetals (cemented carbide) that recycling greatly reduce life cycle environmental impacts of hardmetals.

Besides the reduction in environmental impacts, the recycling also leads to reduced extraction of cobalt which is considered a critical raw material.

9.4.4 Resource consumption and circular economy

9.4.4.1 Extraction of cobalt and impact of further use of alternatives

The possible further use of alternatives in response to introduction of an OEL at EU level may lead to less demand for cobalt. Cobalt is included in the EU list of Critical Raw Materials and replacement with less critical raw materials may be considered a positive impact and further described in Chapter 10. This section focuses on the possible environmental impacts of changes in raw materials.

The two application areas where introduction of an OEL is considered most likely to contribute to a change to alternatives are diamond tools and batteries where alternatives are already widely used. Especially at the lowest policy option alternatives may also be relevant for other application areas. The impacts will depend on which alternatives substitute for cobalt.

No comparative Life Cycle Assessments (LCAs) have been identified for diamond tools.

In a study for the European Federation for Transport and Environment, Pell and Lindsay (2022) have undertaken a LCA of solid state batteries (with cobalt) with conventional Li-ion batteries with cobalt (type NMC-211, type of lithium-nickel-manganese-cobalt-oxide battery) and two types of lithium batteries without cobalt: LFP (lithium-iron-phosphate) batteries and LFMP (lithium-iron-manganese-phosphate) batteries. For the assessed impact category 'Global Warming Potential' (similar to 'greenhouse gas' emission), the kg CO_2 eq. per kWh was 76.7 for the cobalt-containing Li-ion battery and 77.9 and 66 for the LFP and LFMP batteries, respectively. Compared to the most common alternative, the LFP battery, no significant differences in CO_2 eq. pr kWh is indicated. The energy density of the LFP battery is lower than the density of the cobalt-containing Li-ion battery which means that the overall material consumption per kWh is higher.

In a report from the International Energy Agency, greenhouse gas intensity and other environmental parameters of various commodities used in the production of batteries are compared, but the report does not provide a comparative assessment for the entire batteries. As shown in the figure below, the average GHG impacts of cobalt sulphate per tonne of material is relatively high compared with other commodities; first of all from the processing step.

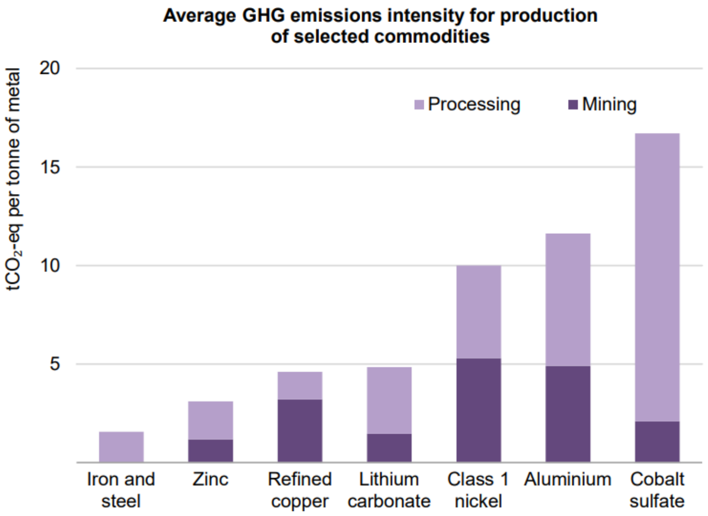


Figure 9-1 *Average greenhouse gas (GHG) emissions intensity in CO_2 equivalents for production of selected commodities. Source: IEA, 2021.*

Ricardo (2023) in a study requested by the European Parliament's Committee on Transport and Tourism concludes "*In the longer term, achieving a rapid reduction in cobalt content per unit of LIB storage capacity appears to be the most promising strategy (Li, Lee, & Manthiram, 2020), up to its complete displacement in favour of completely cobalt-free chemistries (see Section 3.8.2.a). Given the comparatively high carbon intensity of cobalt supply, the latter strategies may also be expected to result in reduced GHG impacts from BEV*[61] *manufacturing as a whole*." The authors further conclude: "*However, these options typically have lower energy density (so require more materials per kWh capacity) than current NMC/NCA*[62] *chemistries, which may offset some of the gains elsewhere in terms of energy density and GHG impact (discussed also in the next section)"*

A comparative LCA by Yang *et al.* (2020) found that the LFP battery had a lower global warming potential (GWP) and acidification potential than the cobalt-containing NCM battery whereas the NCM battery had a lower potential as regards abiotic depletion (fossil) and human toxicity potential. Quan *et al.* (2022) concluded that comparative LCA results suggested that the cobalt-containing NCM battery had better overall environmental performance than the LFP battery, but shorter service life.

The available LCAs for batteries do not reach common conclusions regarding the cobalt-containing batteries versus alternatives which may reflect that LCAs are very sensitive to the assumptions regarding energy sources and disposal pathways for end-of-life articles.

For the diamond tools, and likely also other applications, it will be essential to include the possible higher material consumption as consequence of lower technical quality of alternatives in the

[61] BEV: Battery Electric Vehicle (fully electric)

[62] *NMC/NCA:* Lithium-nickel-manganese-cobalt oxide / Lithium-nickel-cobalt-aluminium oxide

assessment and without detailed LCAs, which takes this into account, it is not possible to assess the potential impact of further use of alternatives.

9.4.5 Global impacts

The implementation of OELs for cobalt and inorganic cobalt compounds may especially at the lowest policy option cause industry to relocate outside of Europe. Compared to the current situation, this is assessed not to result in significant changes in environmental pollution/removal of hazardous substances. Cobalt and raw materials for cobalt refining in the EU is in any case imported into the EU as the domestic extraction of cobalt in the EU is insignificant. Introduction of OELs for cobalt and inorganic cobalt compounds is not considered significantly to increase product carbon footprint due to increased shipping of goods.

To the extent introduction of OELs leads to reduced use of cobalt e.g. by further use of alternatives, there will be a reduction in the environmental effects of cobalt extraction which mainly take place in developing counties, first of all in the Democratic Republic of Congo.

9.4.6 Green initiatives

As described elsewhere in this report, the implementation of an OEL may lead to switch to alternatives and result in the removal of harmful chemicals (the substances concerned) from industry.

9.5 Summary of environmental impacts

This section has evaluated the potential environmental impacts of introducing an OEL for cobalt and inorganic cobalt compounds, including direct and indirect effects, and how these relate to EU environmental policies such as the EU Green Deal.

The direct impacts are the changes to emissions at all facilities using cobalt and inorganic cobalt compounds. The use of alternative RMMs to meet new OELs are not anticipated to lead to any significant changes in environmental exposure and exposure of humans via the environment but may lead to slightly lower releases to the surroundings around facilities using cobalt and inorganic cobalt compounds and thereby lead to a small decrease in environmental exposure. However, it is assessed that introduction of an OEL may add to the companies' contribution to climate change due to increased energy consumption for ventilation. This impact will however decrease over time as the electricity production becomes carbon neutral.

The indirect impacts include the following three main issues:

Recycling: The introduction of new OELs may lead to lower recycling rates for cobalt. This impact would be most likely for the lowest OEL value. It is also possible for the second lowest OEL, while for the two highest OELs, (10 / 2.5 µg Co/m³ and 20 / 4.2 µg Co/m³), the additional costs are so marginal that it is unlikely to lead to any negative impacts on recycling. If there would be an impact that reduces the level of recovery and recycling, then that might again lead to different effects. It could increase the extraction and refining of virgin cobalt and lead to an increase in price of cobalt as the supply for recycling cobalt would decrease. As the environmental impacts of extraction of virgin materials is higher than the impacts of recovery, the introduction of the OEL may lead to overall larger environmental impacts.

Green energy transition: Any increase in the costs of using cobalt (directly in sectors that have to apply more RMMs or indirectly (as discussed above for recycling) could increase the costs of renewable energy sources (e.g. increased costs of magnets) and energy storage systems (e.g. increased costs of batteries). Increased costs would negatively impact on the green transition of the energy and mobility systems. This impact might be mitigated through the development of cobalt free alternatives.

Alternatives: The introduction of new OELs might give an increased incentive to develop alternatives to cobalt and inorganic cobalt compounds. The follow-on effects of a shift to alternatives could lead to both positive and negative environmental impacts. It depends on the specific alternatives being used. For example, Life Cycle Assessments (LCAs) comparing cobalt-containing batteries with alternative materials have reached different conclusions. Although cobalt has a relatively high greenhouse gas emission intensity per tonne compared with other raw materials used as lithium battery raw materials this may to some extent be counterbalanced with the higher consumption of other raw materials due to lower energy density of batteries with low or no cobalt content. The same may be the situation for diamond tools where the lower quality of alternatives may lead to higher overall raw materials consumption.

The possible indirect impacts are very complex to analyse. There are different factors that affects both the supply and demand for cobalt. In short, the introduction of an OELs might decrease the supply of recycled cobalt which would increase the price of cobalt. Then, the increased costs of using cobalt would tent to reduce the demand. The net effect of this is difficult to predict. For the two highest OELs (10 / 2.5 µg Co/m³ and 20 / 4.2 µg Co/m³) the relative increases in costs are for all sectors so small that only very limited impacts can be expected. For the two lowest OELs, there might be somewhat higher impacts.

In conclusion, the introduction of an OEL for cobalt and inorganic cobalt compounds presents a complex picture with potential positive and negative impacts on the environment. The impacts will vary depending on the level of OEL established and how industry adapts to comply with an OEL.

10 OTHER IMPACTS

This chapter comprises the following sections:

- Section 10.1: Impact on EU Strategic Goals
- Section 10.2: Impacts on fundamental rights, including equality
- Section 10.3: Impacts on digitalisation
- Section 10.4: Contributions to the UN sustainable development goals;
- Section 10.5: Summary of other impacts

10.1 Impact on EU Strategic Goals

At its meeting in Brussels on 20 June 2019, the European Council agreed 'A new strategic agenda 2019-2024' which sets out the priority areas that will steer the work of the European Council and provide guidance for the work programmes of other EU institutions (European Council, 2019).

The strategic agenda focuses on four main priorities:

- Protecting citizens and freedoms.
- Developing a strong and vibrant economic base.
- Building a climate-neutral, green, fair and social Europe.
- Promoting European interests and values on the global stage.

Based on a screening of the specific goals listed for each of the four main priorities, the following goals are assessed to be those where introduction of an OEL may potentially have an impact [63]:

- Ensuring fair competition within the EU and on the global stage.
- Accelerating the transition to renewables and increasing energy efficiency.
- Reducing dependence on outside sources, diversifying supplies and investing in solutions for the mobility of the future.

10.1.1 Stakeholder input

An assessment of a possible impacts of an OEL on cobalt compounds on EU Strategic Goals has been submitted by the Cobalt Institute on 20 April 2023 (RPA, 2023). The main conclusion of the study is summarised in this section, while the results are further discussed in section 10.1.2 and 10.2. The four potential OELs investigated by the study were 20, 10, 1 and 0.1 µg Co/m^3 (inhalable fraction). The study combines interviews with seven members of the Cobalt Institute and 15 companies, and a previous impacts assessment undertaken by RPA (2020).

[63] Bullets refer to the summary provided at: https://www.consilium.europa.eu/en/eu-strategic-agenda-2019-2024/

A summary of the study's assessment of the sectors' interrelationship with selected goals (Y or N) and the sectors' ability to comply with potential OEL is provided in Table 10-1. The colour coding indicates the point at which achieving the potential OEL becomes difficult.

The assessment of the sectors' ability to comply with potential OEL is based on the 22 respondents and for many sectors the assessment is based on one or two responses only. Only for one sector, manufacture of pigments, the respondents assessed that it would be difficult to achieve compliance with an OEL of 10 µg Co/m^3. For nine sectors, respondents found it difficult to achieve compliance with an OEL of at 1 µg Co/m^3.

According to the study, three sectors/sector clusters stand out as having a particularly significant impact on the EU's strategic economic and environmental goals:

- C27.2 batteries;
- Several interrelated sectors such as the following: C24.1 alloys, C24.2 steel, C24.4 non-ferrous metals, C25.61 metal surface treatment, C25.62 machining and C25.73 diamond tools / hard metals; and
- E38.3 materials recovery.

For these sectors/sector clusters, the respondents to the study assessed that it would be difficult to achieve compliance with an OEL of 1 µg Co/m^3, but do not indicate difficulties in achieving compliance with an OEL of 10 µg Co/m^3 (Table 10-1).

According to the study, the battery industry is currently undergoing significant investment across the EU based upon existing OELs, which are already not easily achieved. Respondents are concerned that new or relatively new facilities might require further substantial investment to achieve the OELs, making them uncompetitive and reducing future investment in innovative research and development in this fast developing industry. On the other hand, the assessment indicates that "*Battery cell manufacturing is often done in a clean room environment, making achieving given levels relatively easier*."

Furthermore, it is assessed by RPA (2023) "*that the interrelationship between the alloys, steel, non-ferrous metals, surface treatment, machining and tools industries is complex, but the industries themselves are very large and they supply many other key industries. One of Europe's industrial strengths is the nimbleness and innovation of these industries and those that they supply: this allows the development of highly engineered, high value added products. Economically, achieving the potential OELs will increase costs, potentially reducing both competitiveness and investment in future innovative research and development. These industries also include a high proportion of SMEs. From an environmental perspective, any reduction in innovation is likely to impact the development of renewables and mobility of the future, as well as other technologies that are required to tackle climate change".*

According recycling it is noted in the study: "*Whilst there are little data about exposure levels in recycling, nearly every respondent mentioned concerns about recycling, with an expectation that the lowest potential OELs are likely to be lower than the existing exposure levels in the recycling processes*."

The study, furthermore, point at potential impacts on the goal of protecting citizens and freedoms which is discussed in section 10.2.

Table 10-1 Summary of the study's assessment of the sectors' interrelationship with selected goals (Y or N) and the sectors' ability of comply with potential OEL

Table 0-1: Summary of EU's economic strategic goals and sectors' ability to achieve potential OELs							
Sector	**Competitiveness**	**Innovation**	**SMEs or regions**	**Climate change**	**Circular economy**	**Renewables**	**Mobility of the future**
C10 Animal feed	Y	N	N	Y	N	N	N
C19.2 Oil refineries	Y	Y	Y	Y	Y	N	N
C20.12 Pigments	Y	Y	Y	N	N	N	N
C20.3 Paints and coatings	Y	N	Y	N	N	N	N
C20.59 Catalysts for oil refining	Y	N	Y	Y	Y	N	N
C20.59 Catalysts for new fuel markets	Y	N	Y	Y	Y	N	Y
C22.11 Tyres	Y	Y	N	N	Y	N	N
C22.19 Conveyor belts*	Y	Y	Y	Y	Y	N	N
C24.1 Alloys	Y	Y	Y	Y	Y	N	Y
C24.2 - C24.3 Stainless steel	Y	N	N	N	Y	N	N
C24.4 Non-ferrous metals	Y	N	Y	N	N	N	N
C25.61 Metal surface treatment	Y	Y	Y	Y	N	Y	Y
C25.62 Machining	Y	Y	Y	Y	Y	N	N
C25.73 Diamond tools / hard metals	Y	Y	Y	Y	Y	Y	Y
C27.2 Batteries**	Y	Y	N	Y	Y	Y	Y
C28.11 Wind and gas turbines	Y	Y	N	N	N	Y	N
C32.5 Medical devices	Y	Y	Y	N	Y	N	N
E38.3 Materials recovery	Y	Y	N	N	Y	N	Y
E38.3 Materials recovery (batteries)	Y	Y	Y	Y	Y	Y	Y

*Source: RPA (2023). Notes from source: Colour coding indicates the point at which achieving the potential OEL becomes difficult: red – difficult at 10 µg Co/m^3, orange - difficult at 1 µg Co/m^3, yellow – difficult at 0.1 µg Co/m^3, green – probably achievable at 0.1 µg Co/m^3, white – unknown. * Based upon comments from suppliers to this sector. ** Dry processes using powder generally have higher exposure levels and will find achieving any given level more difficult. Battery cell manufacturing is often done in a clean room environment, making achieving given levels relatively easier.*

Other documents related to EU strategic goals include the Strategic Foresight Reports. In the 2022 report[64], there is brief mentioning of cobalt in relation to batteries for electric vehicles. The report mentions the development of cobalt free alternatives, but with not quantification of the impacts. See also the discussion below on the development of cobalt free alternatives.

Eurometaux, Europe's metals association, has commission a report on the future of metals[65] which include considerations on the future supply and demand for cobalt. Also, here focus is on the demand for cobalt in batteries for electric vehicles. Despite the technological development is project an increased demand.

10.1.2 Assessment of impact

Based on a screening of the specific goals listed for each of the four main priorities, the following goals are assessed to be those where introduction of an OEL may potentially have an impact

Ensuring fair competition within the EU and on the global stage. The OEL will contribute to a level playing field for companies in the EU. As described in section 8.3.1 in total 19% of 57 companies responding to the question regarding benefits of an OEL indicated level playing field as a benefit of establishing an OEL. However, establishing additional RMMs in order to comply with a new OEL may be more challenging for SME than for large companies. This is addressed in section 8.4 on competitiveness of EU businesses, where also the possible impact of the competition between companies within the EU and outside the EU is discussed.

[64] COM(2022) 289 final 2022 Strategic Foresight Report eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022DC0289
[65] metals-for-clean-energy.pdf (eurometaux.eu)

Accelerating the transition to renewables and increasing energy efficiency. According to RPA (2023), cobalt is a key component of the alloys required for the tools needed to produce renewable sources of energy, particularly wind turbines and introduction of the lower OELs (0.1 and 1 µg/m^3 in that study) might reduce the commercial interest in developing new methods for the renewables industries which could have a detrimental effect on future improvements in those industries.

According to the Foresight Study on Critical Raw Materials for Strategic Technologies and Sectors in the EU, the additional material consumption for stationary batteries in renewables (excl. vehicles), fuel cells, and wind turbines, 2050 compared to current EU consumption of the material in all applications, is projected to be 2.2 times and 4.7 times for the low and high scenario, respectively (Bobba *et al.*, 2020). Key applications of cobalt for these areas are magnets in wind turbines, cathodes in stationary batteries, and catalysts in fuel cells. For other applications, cobalt is not particularly used in the renewables sector e.g. cobalt alloys is to a higher degree used in gas turbines and not wind turbines and hard metal tools and surface treatment is as well used in the conventional energy sector. It cannot be excluded that introduction of al OEL at the lowest policy level might reduce the commercial interest in developing new methods for the renewables industries, but the effect may quite well be increased research in cobalt-free alternatives which might lead to less dependence on outside sources of critical raw materials.

As described in section 4.5, according to a report from the Joint Research Centre, the global trends in battery R&I show general shift to low cobalt chemistries and cheap LFP (cobalt free) batteries. Also new cobalt-free chemistries, like solid state, LNP or iron trifluoride may play an important role in the future for batteries (Bielewski *et al.*, 2022). The report describes several companies involved in the development of cobalt free cathodes, among these Umicore, a big European cathode material supplier. According to Bielewski *et al.* (2022) the company's roadmap shows that materials with more than 80% nickel are already in the qualification and industrialization stage. On the horizon are manganese-rich electrodes with nearly zero cobalt, high-voltage spinels, and nickel- and cobalt free cathodes.

An example of the R&D cooperative projects at EU level is the European Horizon 2020 supported CoFBAT (Cobalt-free batteries) project with key players in the European battery and catalyst industry developing the next generation cobalt free lithium-ion batteries for different stationary storage applications[66]. As indicated at the project website "*The expected results will strengthen EU competitiveness in advanced materials and nanotechnologies and the related battery storage value chain".* Another example is the EIT RawMaterials funded project COFREE with key manufacturers of hardmetal tools with the aim to develop cobalt-free mining and manufacturing tools.[67]

It should be noted that the Horizon Europe Work Programme 2023-2024 on 'Climate, Energy and Mobility' does not specifically address development of cobalt-free batteries or other articles [68].

Reducing dependence on outside sources, diversifying supplies and investing in solutions for the mobility of the future. The specific goal of the strategic agenda on reducing dependence on outside sources and diversifying supplies is indicated in a paragraph that address an

[66] https://cicenergigune.com/en/blog/cofbat-cobalt-free-batteries-stationary-storage-applications
[67] https://eit.europa.eu/news-events/news/eit-rawmaterials-cobalt-free-solutions-cemented-carbide-tools-and-their-production
[68] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-8-climate-energy-and-mobility_horizon-2023-2024_en.pdf

integrated, interconnected and properly functioning European energy market that provides sustainable, secure and affordable energy. Introduction of an OEL (in particular at the lowest policy options) may potentially make the price of magnets for wind turbines higher but for the total price of wind turbines the impact is considered insignificant. It is assessed that possible future supply shortage for cobalt is more critical for the development of wind turbine capacity and the energy market and in this context, it is more likely that increased prices could be a driver for development of batteries with lower or no cobalt content and have a positive impact.

As described in section 4.5 the consumption of cobalt for electrical vehicle batteries has been projected to increase significantly in the next years but cobalt-fee batteries have entered the market within the last few years and take up an increasing share of the market. The technological development is moving fast and there are no updated projections of the future share of cobalt free batteries. The impact of an OEL on the price of batteries is assessed to be very small and for the development of solutions for the future mobility and it is assessed that possible future supply shortage for cobalt is more critical. It is assessed to be more likely that increased prices (if any) could be a further driver for development of batteries with lower or no cobalt content and thereby have a positive impact**.** The current trend is that many R&D projects aim at reducing the cobalt content of the batteries and thereby reduce Europe's dependency of critical raw materials. Examples of research projects are the Horizon 2020 supported COBRA (CObalt-free Batteries for FutuRe Automotive Applications) project[69] with 18 partners and the 3Believe project[70] with 21 partners with the aim of developing automotive battery cells that are highly performant and free of critical raw materials such as cobalt and natural graphite*.* Overall, the demand for cobalt for batteries is very difficult to project. The introduction on an OEL is not assessed to significantly affect the further demand.

The policy options might impact the recycling of cobalt. Increased recycling is one source for meeting the demand and it is an important element of reducing the dependency of imported cobalt. The estimated impact on the recycling sector is low. The estimated compliance costs comprise less than 1% of turnover for all the policy options, for example comparing the first-year costs to annual turnover. For the two highest policy options (10 /2.5 µg/m³ and 20 /4.2 µg/m³), the first-year costs comprise less than 0.06% of annual turnover. It means that the policy options are unlikely to affect the recycling.

Additionally, consideration has been given to the EU Commission priority areas for 2019-2024. These are assessed in table 10-1 below.

Table 10-1 Potential for OELs to impact benefits of the EU Green Deal

EU Commission Priority Areas 2019-2024	OELs impact (Yes/No)	Comment
A European Green Deal		See section 9.4.1
A Europe Fit for the Digital Age		See section 10.3
An Economy that Works for People		See sections 8.3 and 8.4

[69] https://projectcobra.eu/#cobra
[70] https://www.3believe.eu/

EU Commission Priority Areas 2019-2024	OELs impact (Yes/No)	Comment
A Stronger Europe in the World	Yes	The introduction of OELs will help to affirm the EU's reputation of delivering safe workplaces and respecting the fundamental rights of EU workforce. If OELs are set at a disproportionately low level however this could compromise the attractiveness of EU to international business and so to meet this priority area a balance should be found.
Promoting our European Way of Life	Yes	The introduction of EU Binding OELs will mean all member states are subject to the same regulation of hazardous substances set out in the CMRD. EU OELs therefore support an equal approach to chemical risk management and a united Europe when dealing with external markets.
A New Push for European Democracy	No	The introduction of OELs for cobalt and inorganic cobalt compounds does not impact the push for a maintained and renewed European democracy.

Source: Study team

10.2 Impacts on fundamental rights, including equality

Article 31.1 of the Charter of Fundamental Rights of the European Union[71] states that "*Every worker has the right to working conditions which respect his or her health, safety and dignity.*" All of the policy options lead to an improvement in air quality for at least some European workers that are currently exposed to cobalt and inorganic cobalt compounds.

Article 21.1 of the Charter prohibits discrimination on the grounds of sex. The OELs would be equal protective independent on gender and ethnicity. No specific OELs or BLVs for e.g. women of childbearing age are proposed by RAC. The introduction of the OEL would not lead to exclusion of women or ethnic groups from workplaces with exposure to cobalt and inorganic cobalt compounds.

RPA (2023) assess as described in the previous section that introduction of an OEL may lead to a negative impact of the potential OELs for cobalt on the EU's strategic goal on protecting citizens and freedoms, as two sectors could make the EU more dependent upon third countries, and particularly China, for key products relating to food and energy security: Animal feed additives and batteries. The rationale for the feed sector is that introduction of an OEL may lead to higher dependency upon third countries, and the subsequent security of food supplies, which may then have an impact on protecting citizens and freedoms. A similar rational is used for batteries. These potential effects of dependency upon third countries are not included in the specific goals listed in the EU Strategic Agenda under the main priority area 'protecting citizens and freedoms'. As mentioned in the previous section, the EU is in any case highly dependent on third countries for the supply of cobalt and the high dependency on third countries (whether the cobalt is imported in mixtures and articles or not) is of concern and addressed by various EU strategies in order to make the EU less dependent on third countries for cobalt and other strategic raw materials. As the introduction of an OEL may lead to substitution of cobalt for certain applications (e.g. batteries and diamond tools), the introduction of an OEL may rather lead to less dependency on third countries as compared to

[71] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:C2012/326/02

the current situation. The suggested negative impact on fundamental rights is therefore assessed rather to be a potential positive impact, but more likely to be insignificant.

10.3 Impacts on digitalisation

The Commission has in its 2030 Digital Compass Communication[72] set out a vision, targets and avenues for a successful digital transformation of Europe by 2030. To support this process, the Commission committed to assess how the options under consideration reflect the 'digital by default' principle and contribute to the digital transformation.

Introduction of an OEL for cobalt and inorganic cobalt compounds is not considered to have any impact on digitalisation as cobalt is not a key element for development of IT systems.

10.4 Contributions to the UN sustainable development goals

The introduction of an OEL for cobalt and inorganic cobalt compounds is considered to contribute to the following UN sustainable development goals[73]:

- Goal 3, Good health and wellbeing - improved worker and family health;
- Goal 8, Decent work & economic growth; and
- Goal 12, Responsible consumption and production.

For goal 8 on decent work & economic growth, the introduction of an OEL for cobalt and inorganic cobalt compounds would contribute towards the targets for:

- (8.2) Achieving higher levels of economic productivity through diversification, technological upgrading and innovation, including through a focus on high-value added and labour-intensive sectors.
- (8.8) Protecting labour rights and promoting safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment.

For goal 12 on responsible consumption and production, it is of importance to what extent introduction of an OEL would reduce investments in capacity for further recycling of cobalt from various types of waste. As mentioned above, at the lowest policy option, stakeholders indicate that introduction of an OEL may negatively impact the recycling intensity and thereby have a negative contribution to Goal 12, 'Responsible consumption and production'.

10.5 Summary of other impacts

A summary of other impacts is provided in the table below.

Table 10-2 Summary of other impacts

Other impacts	Impacts
EU Strategic goals	

[72] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en

[73] https://www.undp.org/sustainable-development-goals

Other impacts	**Impacts**
- Ensuring fair competition within the EU and on the global stage	Positive - generate level playing field within the EU Negative - introduction of an OEL may be more challenging for SME.
- Accelerating the transition to renewables and increasing energy efficiency	Positive - may be a driver for development cobalt free alternatives (e.g. for batteries) reducing the demand for this critical raw material. Negative - may result in higher prices of cobalt containing parts for renewable energy systems e.g. wind turbines and energy storage.
- Reducing dependence on outside sources, diversifying supplies and investing in solutions for the mobility of the future.	Positive - may be a driver for development cobalt free alternatives (e.g. for batteries) reducing the demand for this critical raw material. Negative - may reduce recovery of cobalt from waste within the EU.
Fundamental rights	Positive impact on health and safety.
Digitalisation	No impacts.
UN Sustainable Development Goals –Goal 3, Good health and wellbeing	Positive.
UN Sustainable Development Goals – Goal 12, Responsible consumption and production	Potentially negative impact on recovery of cobalt from waste.

11 DISTRIBUTION OF THE IMPACTS

This chapter comprises the following sections:

- Section 11.1: Businesses
- Section 11.2: SMEs
- Section 11.3: Workers
- Section 11.4: Consumers
- Section 11.5: Taxpayers/public authorities
- Section 11.6: Specific Member States/regions
- Section 11.7: Summary of distribution of the impacts

11.1 Businesses

The costs and benefits for businesses (relative to the baseline) are summarised in Table 11-1 for the different policy options. Benefits are shown as negative costs.

Table 11-1 Costs and benefits to EMPLOYERS (PV over 40 years, policy options relative to the baseline)

	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Total benefits for employers (avoided disruption)	€ 1,582,000	€ 1,508,000	€ 958,000	€ 356,000
Total RMM compliance, Monitoring, and administrative costs	€ 9,768,230,000	€ 1,931,900,000	€ 643,909,000	€ 176,789,000
Number of companies minus those discontinuing	14,250	15,200	15,280	15,330
Benefits (avoided disruption) per enterprise	€ 111	€ 99	€ 63	€ 23
Compliance, monitoring and admin costs per enterprise	€ 685,000	€ 127,000	€ 42,000	€ 12,000

Source: Study Team

For business, the main impact is the total adjustment costs. The benefits are relatively small compared to the costs. Considering the total adjustment costs per company of a 40-year period, they are relatively small. As discussed elsewhere, the main point is the one-off costs and how much they comprise. For the two lowest policy options, the one-off costs might be significant. For the two highest policy options, they comprise only a limited share of the annual turnover or operating surplus. It means that most companies can finance the additional costs for example out of annual profits over one to three years.

11.2 SMEs

The assessment of the impact on SMEs are done following the principles of the SME test; see BR Tool #23. The SME test includes the following steps:

- Identification of affected business
- Consultation of SME stakeholders
- Assessment the impacts on SMEs

- Minimising the negative impacts on SMEs

The result of the SME test is summarised in the below table.

Table 11-2 Summary of the SME test

SME test	Summary assessment
Identification of affected businesses	
	81% of the affected companies are small companies and 13% are medium sized companies.
	The share of SMEs is similar across all the most affected sectors (the sectors with highest number of exposed workers).
Consultation with SME stakeholders	
	SMEs have been consulted as part of stakeholder consultation. The share of SME respondents is 37% in the stakeholder survey conducted for this study. While this share is lower than the share of SMEs in affected companies, SMEs are still well represented.
	SME stakeholders express concern that the two lowest OEL options, 1/0.5 µg/m³ and 5/1.25 µg/m³ will negatively affect their competitiveness.
Assessing the impacts on SMEs	
	One indicator for assessing the impacts on SMEs is the share of first year costs in annual turnover. While there is no specific agreed benchmark for what significant impacts are, when the indicator is above 5%, then it will be considered significant in this study. The table presents how many sectors where the indicator is above 5% for small and medium companies. This indicates that it is only small companies that face more significant challenges for the lower OELs.

OEL	Share of sectors where first year costs exceed 5% of annual turnover	
	Small sized companies	**Medium sized companies**
1 / 0.5 µg Co/m³	37%	0%
5 / 1.25 µg Co/m³	15%	0%
10 / 2.5 µg Co/m³	7%	0%
20 / 4.2 µg Co/m³	0%	0%

SME test	Summary assessment
Minimising the negative impacts on SMEs	
	The option proposed by the ACSH with a transitional period of 6 years before the option of the OEL 10 / 2.5 µg Co/m³ will be introduced allows companies to plan and finance their investments in RMMs over the six-year period. The is will be particular important for SMEs. It means that in all sectors, the SMEs will have to invest less than 1 % of turnover in RMMs each year of the transitional period.

SME test	Summary assessment
	This is likely to mitigate the possible negative impacts on the SMEs.

The numbers of small, medium and large enterprises likely to have workers exposed to cobalt and inorganic cobalt compounds in the EU are estimated in Table 3-97 in Section 3.10.

In additional to the discussion of the indicator: first year costs in annual turnover in the above summary table, further assessments and comparison across company size on total compliance costs, costs per company and the cost per company as percentage of turnover by size of company are summarised in the table below.

Table 11-3 Costs for EMPLOYERS by size of company (PV over 40 years, constant discount rate, policy options relative to the baseline) and number of discontinuations

Sector	Small	Medium	Large
Number of companies	12,477	2,065	799
1 /0.5 µg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden in millions	€ 1,528	€ 4,796	€ 3,448
Average cost per company	€ 0.1224476	€ 2.323	€ 4.315
Average cost per company as a percentage of average turnover per company	1.16%	0.646%	0.0431%
Discontinuations	947	109	30
5 /1.25 µg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden in millions	€ 420.97	€ 817.86	€ 683.38
Average cost per company	€ 0.03	€ 0.40	€ 0.86
Average cost per company as a percentage of average turnover per company	0.319%	0.110%	0.009%
Discontinuations	128	11	3
10 /2.5 µg/m³			
Total RMM adjustment costs, monitoring costs, and administrative burden in millions	€ 126.10	€ 303.45	€ 206.81
Average cost per company	€ 0.010	€ 0.147	€ 0.259
Average cost per company as a percentage of average turnover per company	0.095%	0.041%	0.0026%
Discontinuations	51	5	1
20 /4.2 µg/m³			

Sector	Small	Medium	Large
Total RMM adjustment costs, monitoring costs, and administrative burden in millions	€ 31.17	€ 70.00	€ 70.67
Average cost per company	€ 0.002	€ 0.034	€ 0.088
Average cost per company as a percentage of average turnover per company	0.02%	0.009%	0.0009%
Discontinuations	9	0	0

Source: Study Team

The costs comprise a higher share for the smallest companies. It is usually the case that SMEs are relatively more affected as compared to larger companies. With the overall level that has been estimated here, it is only for the lowest OEL and for certain sectors that the impacts might be more than marginal.

11.3 Workers

The costs and benefits for workers and their families (relative to the baseline) are summarised below for the different policy options. The benefits are the avoided costs of ill health.

Table 11-4 Comparison of the costs and benefits to WORKERS & THEIR FAMILIES (PV over 40 years, policy options, relative to the baseline)

Method	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Number of workers	112,739	112,739	112,739	112,739
Benefits (avoided ill health) (M1) in € million	156	135	81	31
Benefits (avoided ill health) (M2) in € million	145	130	80	29
Costs (unemployment distress) in € million	€ 1,970	€ 217	€ 83	€ 7
Benefits (avoided ill health) per worker (M1) in €	1,380	1,195	717	277
Benefits (avoided ill health) per worker (M2) in €	1,280	1,152	707	253
Costs (unemployment distress) per worker	€ 17,470	€ 1,927	€ 735	€ 58

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table.
Source: Study Team

The social costs related to possible unemployment are presented in italics. They are very uncertain in the sense that there might not be that many job losses. The estimate of social costs is therefore a 'worst' case estimate. It is likely to be lower.

11.4 Consumers

No significant impacts on consumers have been identified. In case of significant impacts on EU-based companies, it is expected that the consumer market would be able to source the relevant products from outside the EU. The estimated adjustment costs would be very small. For the lowest policy option, the price increase could be up to 1% for certain products and only when produced by SMEs. Overall, this would only very marginally affect consumers. For any of the higher policy options, there would be no impacts.

11.5 Taxpayers/public authorities

The benefits for taxpayers and public authorities are based upon the reduced cost of healthcare and loss of tax revenue due to morbidity or mortality.

The costs and benefits for the public sector (relative to the baseline) are summarised in Table 11-5 for the different policy options.

The benefits are relatively modest and much smaller than those for workers and their families. There are no direct costs to the taxpayers and public authorities, but indirectly there is a cost due to lower tax revenues if company's profitability is reduced or they employ fewer staff.

Table 11-5 Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 40 years, policy options relative to the baseline) € million

Cost elements	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Benefits				
Avoided costs of healthcare and avoided loss of tax revenue	8.00	7.73	6.69	4.24
Avoided costs of implementing OELs	0.50	0.50	0.50	0.50
Costs				
Transposition costs	0.91	0.91	0.91	0.91

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table.
Source: Study Team

11.6 Specific Member States/regions

As described in section 3.1, none of the Member States have a set of OELs with exactly the same scope as the policy options and all Member States, consequently, would need to introduce or alter legislation when the amendment to the Directive is transposed into the national legislation.

Table 11-6 Member States with OELs for cobalt and inorganic cobalt compounds higher than the envisaged policy options or with different scope

OEL (ppm)	MSs who would need to introduce or alter legislation	% of MSs who would need to introduce or alter legislation	No of MSs required to introduce or alter legislation
1 / 0.5 µg Co/m³	All Member States	100%	27
5 / 1.25 µg Co/m³	All Member States	100%	27
10 / 2.5 µg Co/m³	All Member States	100%	27
20 / 4.2 µg Co/m³	All Member States	100%	27

Source: Study Team

No detailed analysis of direct impacts on member states can be derived from this assessment. This is because the distribution of companies using cobalt across EU member states has been modelled based on Eurostat data and so may have a level of uncertainty relating to the true distribution. Still, some indications can be provided using the Eurostat based distribution of companies by Member State, see also Section 3.10.6.

The Member States with the highest share of companies comprise Czechia, France, Germany, Italy and Poland. It can therefore be expected that industries in these Member States will face the largest compliance costs. These five Member States accounts for about 60% of the companies and therefore, they will also face around 60% of impacts. It means both costs and benefits. The mentioned Member States are also for the most the larger Member States. If compared to the total size of the industry, there is overrepresentation of companies in Czechia, Italy, Poland and Slovakia. This is a reflection of large metal industries in these Member States. So also considering that the larges costs by sector include Machining and Manufacture of metal tools, these Member States are likely to be most affected.

11.7 Summary of distribution of the impacts

The majority of the costs are incurred by the companies while the majority of the benefits are health and safety benefits for workers.

Table 11-7 Distribution of costs and benefits by stakeholder (PV over 40 years, policy options relative to the baseline) in %

Cost elements	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Benefits				
Workers	94%	94%	93%	93%
Business	1%	1%	1%	1%
Public authorities	5%	5%	6%	6%
Costs				
Business	99.99%	99.95%	99.85%	99.48%
Public authorities	0.01%	0.05%	0.15%	0.52%

Source: Study Team

12 SUMMARY OF ECONOMIC, SOCIAL AND ENVIRONMENTAL IMPACTS

This chapter comprises the following sections:

- Section 12.1: Economic impacts
- Section 12.2: Social impacts
- Section 12.3: Environmental impacts

12.1 Economic impacts

The economic impacts relate to the direct and indirect costs that fall on companies that need to comply with the policy options are shown in Table 12-1. The benefit in terms of improved health and safety is included under the social impacts. Hence, the below table is not presenting the cost-benefit ratio, only the costs and benefits directly for the business.

Table 12-1 Aggregated PV costs and benefits for companies discounted over 40 years by policy options, € millions

Cost or benefit	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Cost	9,773	1,933	645	178
Benefit (avoided cost)	1.6	1.5	0.9	0.3

Source: Study team

The comparison of the estimated adjustment costs to turnover and operating surplus indicates that for all but the lowest OEL, the costs comprise so low shares that indirect market impacts are not likely. Only for the lowest OEL and for certain sectors such as 'Manufacturing of tools', significant market impacts could happen.

For the 'Manufacturing of tools', the relatively high adjustment costs could lead to companies having to discontinue some or all of their activities. The are different factors affecting what will happen in this sector. Availability of alternatives for diamond tools might reduce the adjustment costs and thereby reduce the risks of companies having to discontinue some or all of their activities. There could also be effects where the companies with highest current workplace concentrations will close, but those with lower workplace concentrations continue and take over the market share from those closing.

There are currently variations in the existing national OELs across EU. It means that introducing one common OEL will make competition more even.

For the lowest OEL, there might be some impact on innovation as resources otherwise used for R&D activities might be allocated to cover adjustment investments. It is difficult to quantify this impact any further. It should be mentioned that introduction of an OEL might increase the already existing incentives to develop cobalt free alternatives.

In terms of international competitiveness, the policy options considered in this study are all, but the highest OEL (20/4.2 µg Co/m³) lower than what is required in competing countries. Hence, there could be a potential disadvantage for EU companies in the affected sectors. The level of the estimated adjustment costs are relatively low and therefore only limited impacts could be expected.

12.2 Social impacts

The social impacts relate to the health benefits and costs that fall on workers and public administrations, are shown in Table 12-2.

Table 12-2 Aggregated PV costs and benefits for workers and public administrations discounted over 40 years by policy options, € millions

Cost or benefit	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Workers				
Cost	?	?	?	?
Benefit (avoided cost) M1	146	126	72	23
Benefit (avoided cost) M2	135	121	72	21
Public administrations				
Cost	0.9	0.9	0.9	0.9
Cost to public enterprises	0	0	0	0
Benefit avoided cost	8	7	4	1
Benefit indirect	0	0	0	0

Source: Study team
Notes: M1= Method 1, a methodology that relies on 'willingness to pay' values
M2= Method 2, a methodology that relies on monetised Disability Adjusted Life Years

As discussed above, it is very uncertain how much the social costs related to unemployment will be. The risk of discontinuation exists but mainly in the sector 'Manufacturing of tools'. If companies will close some or all of their activities, there might be workers that will be unemployed. The number is very difficult to estimate. Below, a worst-case scenario is presented. It is based on the number of companies that could close (for large companies, it is assumed that only 10% of companies' activities will be closed).

Table 12-3 Overview of possible employment impacts, in numbers of workers, companies and € millions

Policy options	1 /0.5 µg/m³	5 /1.25 µg/m³	10 /2.5 µg/m³	20 /4.2 µg/m³
Total number of employees made redundant	25,849	2,761	1,124	77
Total number of enterprises discontinuing	1,086	142	57	10
Percentage of enterprises in sector discontinuing	7.1%	0.9%	0.4%	0.1%
Percentage of employees in sector made redundant	2.90%	0.30%	0.10%	0.00%
Social cost of unemployment (million €)	€ 1,970	€ 217	€ 83	€ 7
Number of enterprises continuing operations	14,255	15,199	15,284	15,331
Number of employees retained	813,751	835,763	837,329	838,317

Source: Study team

12.3 Environmental impacts

The use of alternative RMMs to meet new OELs are not anticipated to lead to any significant changes in environmental exposure and exposure of humans via the environment but may lead to slightly lower releases to the surroundings around facilities using cobalt and inorganic cobalt compounds and thereby lead to a small decrease in environmental exposure. This effect will be largest for the lowest policy option and less for the higher policy options. The impact on the direct environmental exposure of cobalt and inorganic cobalt compounds will in any case be very limited.

The introduction of new OELs may for some applications (e.g. use in diamond tools and batteries) lead to reduced use of cobalt by introduction of alternatives. This may lead to reduced environmental exposure to cobalt and to reduced environmental impacts from the extraction of cobalt. Life Cycle Assessments (LCAs) comparing cobalt-containing batteries with alternative materials have reached different conclusions. Although cobalt has a relatively high greenhouse gas emission intensity per tonne compared with other raw materials use for lithium battery raw materials this may to some extent be counterbalanced with the higher consumption of other raw materials due to lower energy density of batteries with low or no cobalt content. The same may be the situation for diamond tools where the lower quality of alternatives may lead to higher overall raw materials consumption. The incentive to substitute cobalt will be higher for the lower policy options. For the two highest policy options, the incentive will be very limited.

The introduction of new OELs may lead to lower recycling rate for cobalt. As the environmental impacts of extraction of virgin materials is higher than the impacts of recovery, the introduction of the OEL may lead to overall larger environmental impacts of extraction of cobalt. Furthermore, it is assessed that introduction of an OEL may have some negative impact on climate change due to increased energy consumption for ventilation. This impact will however decrease over time as the electricity production becomes carbon neutral. Also, for recycling, it only for the lowest policy option where there could be a small impact. For the highest policy options, there will be no impacts.

Overall, there will only negligible environmental impacts under the two highest policy options. Even for the lowest policy option, the environmental impacts will be minor.

13 LIMITATIONS & SENSITIVITY ANALYSIS

This chapter comprises the following sections:

- Section 13.1: Overview of limitations and uncertainties
- Section 12.2: Key limitations and uncertainties

13.1 Overview of limitations and uncertainties

This section sets out the key limitations and uncertainties and considers their potential impact on the conclusions. These are summarised below and their significance for the results of this study are assessed. A more detailed assessment of some of these limitations and uncertainties is provided in the next sections.

Table 13-1 Overview of the key limitations/uncertainties and their significance

Limitation or uncertainty	Explanation	Estimates in this study are likely U (underestimates) or O (overestimates)	
		Costs	Benefits
Cost assessment	The cost assessment is uncertain. There are factors that could mean both over and underestimation of the adjustment costs.	U/O	
Exposed workforce	The uncertainty about the exposed workforce will not change the cost-benefit ratio.		
Workforce turnover	It is not having a major impact if the workforce turnover is either higher or lower.		
Additional health endpoints	The assessment of the health impacts are subject to uncertainty. There could be more health endpoints.		U
Slope of ERRs/DRRs	The ERR and DDRs are the best estimates,		U/O
The latency period for cancer	A shorter latency would increase the number of cases.		U
Future trends	There are future trends that could mean both higher or lower values of costs and benefits. The assessment has not identified trends that would substantially change the cost-benefit ratios.		
Discount rate	A lower discount rate would relatively increase the estimated benefits more than the costs.		U
'Positive bias' in reported data	The reported cost data could be assumed to come from companies facing higher the average costs of achieving the different OELs. This has been considered when comparing the different	O	
RMMs in place	The availability and specific costs of the RMM is subject to uncertainty.	O/V	
Assessment period	The length of the assessment period is not critical for the assessment.		

13.2 Key limitations and uncertainties

13.2.1 Cost estimates and sensitivity scenarios

There is discrepancy between the cost model results and the costs estimated reported by stakeholders. The stakeholder reported costs are higher than the cost estimated in the cost model. It means that potentially, the adjustment costs for companies could be higher. The estimates are in particular sensitive to the assumptions regarding existing use of RPE and the influence on the exposure distributions used for both the benefits and costs model. Whereas these assumptions would not influence the cost/benefit ratio they may influence both costs and benefits which may be underestimated by the applied method.

The possibility of using alternatives could reduce the estimated costs. The cost model has estimated that a number of companies might have to discontinue some or all of their activities. The costs of the discontinuation as share of the total adjustment costs over the 40-year period is shown below.

Table 13-2 Overview of impacts on costs of discontinuations

Policy options	1 /0.5 µg/m³	5 /1.25 µg/m³	10 /2.5 µg/m³	20 /4.2 µg/m³
Costs of discontinuation as % of total adjustment costs	62%	38%	13%	16%
Total number of enterprises discontinuing	1,086	142	57	10
Percentage of enterprises with exposed workforce in sectors which discontinue	7.1%	0.9%	0.4%	0.1%

The data from eftec (2023) indicates that unit costs of switching to an alternative is significantly lower than discontinuation for uses where alternatives are available. In particular for the sector 'Manufacturing of tools', this might reduce the total costs. The availability of an alternative will reduce the number of discontinuations and thereby reduce the estimated adjustment costs.

These two factors point to the costs being either too low or too high. Overall, the estimate is therefore considered as the best estimate.

13.2.2 Benefit assessment and sensitivity scenarios

A sensitivity analysis has been performed on the benefits of avoided ill health for the two non-cancer endpoints. The assessment of intangible cost is uncertain and in the base case, low disability wights have been selected. It means that the low-end value of the range of disability weighs for a disease with similar symptoms were used. For the sensitivity assessment, the high-end values are applied. They are three times higher than the base case for the restrictive lung disease and twice the value for the upper airway irritation. The results are presented in the next table.

Table 13-3 Sensitivity analysis of valuation of non-cancer endpoints (€ millions)

Sensitivity scenario	Policy option			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Standard discount rate (3% discounted annually over 40 years for costs and benefits)				
Benefits M1	156	135	81	31
Benefits M2	145	130	80	29
Costs	9,773	1,933	645	178
CBR M1	63	14	8	6
CBR M2	68	15	8	6
Higher disability weights for the non-cancer endpoints (3% discounted annually over 40 years)				
Benefits M1	400	380	230	80
Benefits M2	364	346	228	78
Costs	9,773	1,933	645	178
CBR M1	24	5	3	2
CBR M2	27	6	3	2

Source: Study team.

13.2.3 Discount rate

Given the current global economic climate, the standard discount rates of 3% may no longer reflect reality. Therefore, the study team has provided an alternative discount rate scenario. In Table 13-4, 'Standard discount rate' refers to the general costs and benefits unaffected by any sensitivity changes (discounted by a static 3% annually over 40 years). 'Differential rate' refers to costs modelling performed at a static 3% annually over 40 years, and benefit modelling performed at a static 1.5% annually over 40 years.

Table 13-4 Sensitivity analysis of discount rates (€ millions)

Sensitivity scenario	Policy option			
	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Standard discount rate (3% discounted annually over 40 years for costs and benefits)				
Benefits M1	156	135	81	31
Benefits M2	145	130	80	29
Costs	9,773	1,933	645	178
CBR M1	63	14	8	6
CBR M2	68	15	8	6
Differential rate (costs discounted at 3% and benefits at 1.5% annually over 40 years				
Benefits M1	260	220	132	52
Benefits M2	237	200	131	51
Costs	9,773	1,933	645	178
CBR M1	38	9	5	3
CBR M2	41	10	5	3

Source: Study team.

This sensitivity assessments indicates that if the benefits that occur in the future are discounted at lower rate, benefits increase. Using a discount rate of 1.5% instead of 3% leads to a more of less doubling of the benefits. Hence, the cost benefit ratio changes accordingly to a level half the standard scenario.

14 OVERVIEW OF THE IMPACTS

This chapter comprises the following sections:

- Section 14.1: Cost-benefit assessment (CBA)
- Section 14.2: Multi-criteria analysis (MCA)
- Section 14.3: Practical implications of establishing an OEL
- Section 14.4: Compliance with the subsidiarity and proportionality principles
- Section 14.5: Highlighted issues
- Section 14.6: Summary for the option suggested by the ACSH

This chapter summarises the estimates presented in the previous chapters by means of a Cost-benefit assessment (CBA), a Multi-criteria (MCA) analyses and analyses of effectiveness, efficiency and coherence of the policy options. All the costs and benefits presented in this chapter are Present value (PV) over 40 years and additional to the baseline scenario.

14.1 Cost-benefit assessment (CBA)

14.1.1 Overview of the benefits for the policy options

The benefits (relative to the baseline) estimated in this report for the different policy options are summarised in the tables below. The benefits include the direct, the indirect and the intangible benefits.

The main benefits are the reduced number of cases of ill health. The assessed health endpoints include lung cancer, restrictive lung disease and upper airway irritation.

Table 14-1 Overview of the benefits (PV cost savings due to reduced ill health and avoided costs) per policy option € million

Impact	Stakeholders affected	Policy options			
		1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	20 / 4.2 µg Co/m³
Direct benefits – improved well-being - health					
Reduced cases of ill health (Lung Cancer)	Workers & families	71	51	27	15
Reduced cases of ill health (Restrictive Lung disease)	Workers & families	4,370	4,370	2,840	1,000
Reduced cases of ill health (Upper airway Irritation)	Workers & families	14,150	12,270	7,360	2,140
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€150 - €140	€130 - €120	€75 - €74	€29 - €27
Avoided costs	Companies	€ 1.6	€ 1.5	€ 1.0	€ 0.4
Avoided costs	Public sector	€ 8.0	€ 7.0	€ 4.0	€ 1.5
EU policy agenda	All	Increasing the protection of workers health is main social benefit.			
Direct benefits – improved well-being – environmental					
Environmental releases	All	Limited reduction of environmental release of cobalt. Uncertain whether changes towards cobalt free alternatives will have positive or negative overall environmental impacts.			
Direct benefits – market efficiency					
Level playing field	Companies	Positive effects though not of significant importance.			
Indirect benefits					
Administrative simplification	Companies	Positive minor impact.			
Synergy	Companies	Positive minor impact.			
Corporate Social Responsibility	Companies	Positive minor impact.			
Avoided cost of setting OEL[74]	Public sector	€ 0.5	€ 0.5	€ 0.5	€ 0.5

Source: Study team
Note: May not sum to total due to rounding

[74] This element of avoided cost might be an under estimation of the total avoided costs. It could be that some Member States with an existing OEL would want to revise it during the assessment period to increase worker protection. It is however not certain how many Member States would do that. This possible underestimation would be insignificant compared with the other benefits.

14.1.2 Overview of the costs for the policy options

The estimated direct and indirect costs are presented in Table 14-2.

Table 14-2 Overview of the costs (incremental to the baseline, PV in € million over 40 years)

Impact	**Stakeholders affected**	**Policy options**			
		1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Direct costs – adjustment					
Risk management measures (first year and recurrent) and discontinuation costs	Companies	€ 9,600	€ 1,800	€ 580	€ 130
Monitoring (sampling and analysis)	Companies	€ 110	€ 90	€ 60	€ 40
Direct costs - administrative burdens					
Administrative burden	Companies	€ 13	€ 10	€ 8	€ 5
Direct compliance costs - total					
Adjustment, monitoring and administrative burden	Companies	**€ 9,800**	**€ 1,900**	**€ 640**	**€ 180**
Direct costs - enforcement costs					
Transposition costs	Public sector	€ 0.9	€ 0.9	€ 0.9	€ 0.9
Enforcement costs	Public sector	No major changes. A small increase – same for all options, but insignificant compared to other costs			
Monitoring costs	Public sector	No major changes. A small increase – same for all options, but insignificant compared to other costs			
Adjudication costs	Public sector	No change compared to baseline.			
Indirect costs - other					
Firms (or departments of large companies)) exiting the market - No. of company (departments) closures	Companies	1,090	140	60	10
Employment – Jobs lost	Workers & families	25,850	2,760	1,120	80
Employment – Social cost	Workers & families	€ 2,000	€ 220	€ 80	€ 7

Impact	**Stakeholders affected**	**Policy options**			
		1 / 0.5 µg Co/m³	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
International competitiveness	Companies	Adjustment costs could lead to weakened competitiveness	The size of the adjustment costs compared to turnover suggests no or very limited impacts.		
Consumers	Consumers	No change compared to baseline.			
Internal market Lowest to highest OEL	Companies	Positive effects though not of significant large importance.			
Specific MSs/regions - MSs that would have to change OELs	Public sector	27 Member States	27 Member States	27 Member States	27 Member States
Regulation	Companies	No change compared to baseline.			

Source: Study team
Note: May not sum to total due to rounding

14.1.3 Impact of different timescales for costs and benefits

The majority of the estimated costs will be incurred by the affected stakeholders at time of introducing the OEL, while some of the benefits will only occur with a long-time lag. Therefore, the results are subject to the choice of discount rate. Using a lower discount rate will change the cost-benefit ratio in favour of the benefits. Still, the monetised costs will exceed the benefits for all the policy options.

14.1.4 CBA for the policy options

The overall costs and benefits of the policy options are shown in Table 14-3.

Table 14-3 Summary of monetised costs and benefits (static discount rate 3%, additional to the baseline)

Policy option	**1 / 0.5 µg Co/m³**	**5 / 1.25 µg Co/m³**	**10 / 2.5 µg Co/m³**	**20 / 4.2 µg Co/m³**
Total benefits M1 in € million	€ 160	€ 140	€ 81	€ 31
Total benefits M² in € million	€ 150	€ 130	€ 80	€ 29
Total costs in € million	€ 9,800	€ 1,900	€ 640	€ 180
Cost benefit ratio M1	63	14	8	6
Cost benefit ratio M2	68	15	8	6

*Notes: *Values relate to method 1 - method 2;* May not sum to total due to rounding; *Cost benefit ratios calculated from figures without rounding.*
Source: Study team

14.2 Multi-criteria analysis (MCA)

Table 14-4 below summarises both the monetised and qualitative impacts.

The MCA includes the monetised health benefits and the quantified compliance costs. Other impacts including market effects are described only qualitatively.

The sensitivity assessment presented in the previous section indicates the uncertainty related to the monetised and quantified values. The sensitivity assessment points to the fact that benefits and costs could be of the same order of magnitude, the number presented below suggests that costs exceed benefits.

The MCA table includes the option proposed by the ACSH. The option proposed by the ACSH includes a transitional period so that initially, the OEL will be 20 / 4.2 µg Co/m³ and then after 6 years, the OEL will be 10 / 2.5 µg Co/m³. For more details on this option, see Section 14.6.

Table 14-4 Multi-criteria analysis (all impacts over 40 years and additional to the baseline) by policy option, € million

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Direct costs - adjustment						
Risk management measures - first year	Companies	€ 1,500	€ 710	€ 240	Cannot be monetised	€ 90
Risk management measures - recurrent	Companies	€ 2,200	€ 430	€ 110	Cannot be monetised	€ 20
Risk management measures - discontinuations	Companies	€ 6,000	€ 700	€ 230	Cannot be monetised	€ 20
Risk management measures -total	Companies	€ 9,600	€ 1,800	€ 580	€ 530	€ 130
Risk management measures - total per company (in '000 €)	Companies	€ 630	€ 120	€ 38	€ 35	€ 8
Risk management measures excluding discontinuation costs -total per continuing company (in '000 €)	Companies	€ 260	€ 80	€ 24	Cannot be monetised	€ 8
Monitoring (sampling and analysis)	Companies	€ 110	€ 90	€ 60	€ 50	€ 40
Direct costs - administrative						
Company cost of administration burden	Companies	€ 13	€ 9	€ 7	€ 6	€ 4
Direct compliance costs – total						
Adjustment, monitoring and administration burden costs	Companies	€ 9,800	€ 1,900	€ 640	€ 590	€ 180
Adjustment, monitoring and administration burden costs per company (in '000 €)	Companies	€ 640	€ 130	€ 42	€ 38	€ 12
Direct costs - enforcement costs						
Transposition costs	Public sector	€ 0.9	€ 0.9	€ 0.9	€ 0.9	€ 0.9

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Enforcement costs	Public sector	Enforcement costs may arise as a result of ensuring compliance with new OELs however these costs are not estimated as they are specific to Member States individual inspection regime.				
Indirect costs - other						
Firms exiting the market - No. of company closures	Companies	1,090	140	60	Cannot be quantified	10
Firms discontinuing at least a part of their business - %	Companies	7.1%	0.9%	0.4%	Cannot be quantified	0.1%
Total compliance costs as % of turnover over 40 years (including discontinuations)	Companies	Up to 3% (small companies)	Up to 1% (small companies)	Up to 0.4% (small companies)	Cannot be quantified	Up to 0.2% (small companies)
First year compliance costs as % of turnover over 40 years (excluding discontinuations)	Companies	Up to 29% (small companies), but up to 4% (medium companies)	Up to 10% (small companies), but up to 1.5% (medium companies)	Up to 5.8% (small companies), but up to 0.75% (medium companies)	Cannot be quantified	Up to 2.3% (small companies), but up to 0.3% (medium companies)
Employment – Jobs lost	Workers & families	25,850	2,760	1,120	Cannot be quantified	80
Employment – Social cost	Workers & families	€ 2,000	€ 220	€ 80	Cannot be monetised	€ 7
International competitiveness	Companies	Negative impacts	No significant impacts	No significant impacts	No significant impacts	No significant impacts
Consumers	Consumers	Negative impact in some sectors	No impact	No impact	No impact	No impact
Internal market	Companies	Positive effects though not of significant importance.				
Innovation	Companies	Negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	Limited negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	No or limited negative impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	No or limited impact (reduce R&I, but incentive to R&I in cobalt free alternatives)	No or very limited negative impact
Specific MSs/regions - MSs that would have to change OELs	Public sector	All	All	All	All	All
Regulation	Companies	€ 0	€ 0	€ 0	€ 0	€ 0
Direct benefits – improved well-being - health						

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Reduced cases of ill health – lung cancer	Workers & families	71	51	23	23	12
Reduced cases of ill health – restrictive lung disease	Workers & families	4,370	4,370	2,840	2,840	1,000
Reduced cases of ill health – upper airway irritation	Workers & families	14,150	12,270	7,360	7,360	2,140
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€ 150 - 140 million	€ 130 - 120 million	€ 75 - 74 million	€ 69 - 68 million	€ 29 - 27 million
Direct benefits – improved well-being – safety						
Avoided costs	Companies	€ 2	€ 2	€ 1	€ 1	€ 0
Avoided costs	Public sector	€ 8	€ 7	€ 4	€ 4	€ 1
EU policy agenda	All		Contribution to the EU Green Deal: Chemical Strategy towards a toxic-free environment			
Direct benefits – improved well-being - environmental						
Environmental releases	All	Limited reduction of environmental release of cobalt. Changes to cobalt free alternatives will have positive impact whereas increased costs of some articles may have a negative. Increased costs of recycling may have a negative impact.				
Direct benefits – market efficiency						
Level playing field	Companies	A harmonised OEL at EU level would help to ensure a level playing field between companies operating in different EU Member States.				
Indirect benefits						
Administrative simplification	Companies	Should all Member States have a harmonised OEL this would reduce the administrative burden for companies with operations across multiple Member States.				
Synergy	Companies	Positive minor impact.				
Corporate Social Responsibility	Companies	Positive minor impact.				
Avoided cost of setting OEL[75]	Public sector	€ 0.5	€ 0.5	€ 0.5	€ 0.5	€ 0.5

[75] This element of avoided cost might be an under estimation of the total avoided costs. It could be that some Member States with an existing OEL would want to revise it during the assessment period to increase worker protection. It is however not certain how many Member States would do that. This possible underestimation would be insignificant compared with the other benefits.

Impact	Stakeholders affected	1 / 0.5 µg Co/m³	5 / 1.25 µg Co/m³	10 / 2.5 µg Co/m³	Transitional option	20 / 4.2 µg Co/m³
Other impacts						
Recycling – loss of business	Recycling companies	Negative impacts due to compliance costs.	Negative impacts due to compliance costs.	Minor negative impacts.	Minor negative impacts.	Minor negative impacts.
Impacts on fundamental rights	All	Compulsory monitoring of cobalt levels will help to ensure that the fundamental right of workers to workplace environments which respect human health is reliably enforced.				
Impacts on digitalisation	Companies	No impacts on digitalisation are expected.				
Contributions to the UN sustainable development goals	All	In relation to the third sustainable development goal – "*good health and wellbeing - improved worker and family health"* – the above comment for impacts on fundamental rights also applies.				

Source: Study team.
** For large companies it is only 10% of the company activities that are assumed to close down. The share of large companies in the number of discontinuations is less than 3%.*
Note: May not sum to total due to rounding

14.3 Practical implications of establishing an OEL

The practical implications of establishing an OEL for cobalt and inorganic cobalt compounds are summarised in the table below.

Table 14-5 Practical implications of establishing an OEL for cobalt and inorganic cobalt compounds

Citizens/Consumers	Businesses	Administrations
Some of the quantified costs to business may be passed on to the citizens/consumers as increased prices. However, the impact should be very limited. Workers have the duty to comply with the dispositions provided by the employers as regards the use of preventive and protective measures necessary to comply with OSH legislation incl. the newly established OELs under the CMRD.	Employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - Implementation of the necessary risk management measures (RMMs) (e.g. closed systems, local exhaust ventilation, reduction of number of workers exposed, personal protection equipment) in order to comply with the new OEL; - Implementation of a sampling strategy and air concentrations measurement programme for the chemical agents with a new OEL, as part of the risk assessment process and effectiveness check of the existing RMMs; - Ensure that cobalt and inorganic cobalt compounds are managed in line with the provisions of the carcinogens mutagens and reprotoxic substances national legislation; - Ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OEL, collection of records, information to competent authorities, etc.).	Member States must transpose the amended Directive into national legislation which may involve: - Assessment of the national situation and potential impact on business; - Tripartite consultation of the new OELs under the CMRD (workers, employers, authorities); Furthermore, Member States Authorities may facilitate implementation of the national legislation e.g. by providing technical guidance to employers.

Source: Study team

14.4 Compliance with the subsidiarity and proportionality principles

Article 5.3 of the Treaty of Europe says, "*Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.*" [76]

[76] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0013:0045:en:PDF

Whilst Member States can and do set their own limit values, the analysis and decision making are more efficient and effective if the process of setting limit values is undertaken at the Union level. The introduction of limit values at Union level also ensures that there is not divergence of risk within industry operating across the Union. For these reasons the introduction of EU wide limit values can be seen as compliant with the principle of subsidiary.

For control of exposure to CMR substances it has been established that the inclusion in the CMRD and the subsequent introduction of limit values is an appropriate method of controlling exposure.

For cobalt and cobalt compounds, the analysis shows that the existing OELs established by Member States varies considerably (from 20 to 500 µg/m^3 for the inhalable fraction) and, furthermore, OELs for these substances have not been established by a number of Member States. The ex-post evaluation of the European Union Occupational Safety and Health Directives (REFIT evaluation)[77] emphasizes that chemicals classified as carcinogens and mutagens continue to be manufactured across the EU and workers in manufacturing and downstream uses continue to be exposed to the substances. Following concerns raised by different stakeholders' groups in the REFIT evaluation process and in the National Implementation Reports, the need to adopt limit values for more substances should according to the evaluation be considered. The ACSH has in its opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation from 2021 listed cobalt and inorganic cobalt compounds as a priority carcinogen under the CMRD (immediate priorities) (ACHS, 2021). Furthermore, the Committee for Risk Assessment (RAC) under ECHA has in its opinion on the scientific evaluation of occupational exposure limits for cobalt and inorganic cobalt compounds suggested to establish an OEL for cobalt and inorganic cobalt compounds under the CMRD. An OEL for cobalt and inorganic cobalt compounds at EU level would lead to a better chemical risk management in the future.

Article 5.3 of the Treaty of Europe says, "*Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties."* [78]. It is often described as "not using a sledgehammer to crack a nut". In the Better Regulation context, the assessment of proportionality is often related to the question whether the costs are commensurate with the objectives of the intervention.

Cobalt and inorganic cobalt compounds are already covered by the CMRD, and the employers have the obligation to reduce the exposure to the substances as much as feasible. Member States are obliged under the CMRD to continually work to reduce the exposure to cobalt and inorganic cobalt compounds. Establishing an OEL is a common way to define what would be feasible and acceptable and establish a level playing field for businesses in the EU. The employers should as a minimum comply with the OEL, but the employers would still be required to minimise the occupational exposure as much as possible in accordance with the general provisions of the CMRD. The assessment of the costs of the alternative policy options indicates that for the lowest policy option, the estimated costs could be significant. It is political decision to what extent the potentially high costs are proportional or not.

Member States have already agreed that setting limit values through the process managed by the Advisory Committee for Safety and Health at Work (ACSH), the Working Party on Chemicals (WPC) and DG EMPL is the appropriate and proportionate manner to reduce the exposure to carcinogenic, mutagenic and reprotoxic substances. This study assists the WPC, ACSH and DG EMPL in

[77] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017SC0010

[78] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0013:0045:en:PDF

specifying acceptable limit values. Given the structure and previous establishment of the above process, the introduction of EU wide limit values can be seen as compliant with the principle of proportionality.

14.5 Highlighted issues

Other issues to be considered in the decision-making process include:

- **Inhalable vs. respirable fraction**. The policy options consist of pairs of OELs which are set independently based on the different health effects of the inhalable and the respirable fraction, respectively. Furthermore, for the inhalable fraction the highest policy option is set based on the mode of nationals OEL in those Member States where an OEL is established. The ratio between the OEL for the respirable and the inhalable fraction differs between the policy option with a respirable to inhalable fraction ratio (R:1) of 1:2 for the 1 / 0.5 µg/m^3 policy option and 1:4.7 for the 20 / 4.2 µg/m^3. Based on data on respirable to inhalable fraction ratios for the different sectors, it is assessed that at the 1 / 0.5 µg/m^3 policy option compliance with the inhalable fraction will be the most challenging for all sectors except for welding and similar high-temperature activities. At the 20 / 4.2 µg/m^3 policy option, for some sectors using cobalt compounds, the OEL for the respirable fraction will be the most challenging whereas for sectors using cobalt metal it will be the inhalable fraction which is the most challenging. If a policy option with other sets of OELs is proposed, it may be possible to roughly estimate the overall costs and benefits by interpolation from the assessed policy option, but new model estimations would be needed in order to analyse the sector-specific impacts.

- **Costs of monitoring**. Setting OELs for both the inhalable and the respirable fraction would increase the monitoring costs for the companies as companies today (except for Germany) typically monitor one fraction only. The total additional monitoring costs of measuring two parameters instead of one is estimated at € 13.7 million over a 40 year period. A major part of the total monitoring costs are assumed to be due to one to two additional monitoring campaigns after the introduction of the new OELs. The additional costs of measuring one extra parameter are estimated to account for 33% of the total additional monitoring costs at the 20 / 4.2 µg/m^3 policy option with the percentage gradually decreasing to 13% of total additional monitoring costs at the 1 / 0.5 µg/m^3 policy option. In percentage of total adjustment costs to companies, the additional monitoring costs of measuring two parameters is 10%, 2.2%, 0.7% and 0.1% for the four policy options, respectively with the highest percentage at the 20 / 4.2 µg/m^3 policy option.

- **Level of adjustment costs.** The output data of the cost model should be interpreted with caution as the calculation is based on a number of assumptions and simplifications as outlined in section 6.3 and the Methodological Note. Nonetheless, the data give an indication of magnitude. Compared to companies' turnover, the adjustment costs are small for the majority of sectors and for all but the lowest OEL. The levels of adjustment costs estimated by companies for the stakeholder consultation is significantly higher than calculated by the cost model except for the 1 / 0.5 µg/m^3 policy option. The main difference is assessed to depend on the differences in taking existing use of RPE into account.

- **Recycling**. The introduction of an OEL may, at least at the two lowest policy options, decrease the percentage of cobalt in waste recovered within the EU because of the extra adjustment costs. A part of the cobalt in the waste may either be disposed of without recovery or be exported for recovery outside the EU. Increased recovery of cobalt within the EU is in accordance with the intentions and benchmarks of the European Critical Raw Materials Act even the

Regulation proposal do not set up specific benchmarks for cobalt recovery. For batteries recovery targets are set in the new Regulation on batteries and waste batteries but for other waste categories it may be relevant to investigate how it is ensured that the introduction of an OEL does not make recovery of the cobalt within the EU unprofitable.

- **Critical raw material and green transition.** Cobalt is a critical raw material and is used for some of the key technologies in the green transition such as batteries for vehicles and storage and magnets in wild turbines. The adjustment costs for implementing the OELs may be passed on to the articles which may lead to higher costs of key technologies in the green transition. On the other hand, the introduction of an OEL may among other drivers push to the development of cobalt-free alternatives e.g. for some tools and batteries where alternatives already are on the market and make the EU less dependent on raw materials imported from a few countries outside the EU.

- **Impacts on SME**. The cost of compliance consisting of risk management measures, monitoring and administrative burden are relatively high for small and medium sized companies at all policy options. For the majority of sectors, however, the additional cost burden is not assessed to significantly affect the operation of SMEs in these sectors.

- **Discontinuation and dislocation**. An OEL for cobalt and inorganic cobalt compounds is unlikely to be the only cause for companies to discontinue, which in reality, for many medium and large companies, may be relocating outside the EU whereas it for small companies may be discontinuation of the activities. EU's competitor countries have OELs for cobalt and inorganic cobalt compounds that are at the same level or higher than the highest policy option of 20 / 4.2 µg/m^3. None of the competitor countries have OELs for both the inhalable and the respirable fraction. From the stakeholder consultation at least one international company has indicated that they may relocate the activities with the highest exposure concentrations to facilities outside the EU.

- **Time needed to achieve compliance.** The costs of adjustments will depend on the time provided for the adjustments. For some OELs, additional transition periods have been set for specific sectors or activities e.g. an additional transition period for copper smelters for the OEL on arsenic acid and its salts and an additional transition period for welding for the OEL on chromium VI. The current assessment has not identified any sectors or activities where implementation of the needed measures indicates the need for sector specific additional transition period. The main exposure situations in many sectors are more or less the same such as handling of raw materials and other dusty materials, cleaning and maintenance, and sampling for material quality control.

14.6 Summary for the option proposed by the ACSH

The ACSH opinion on OEL value for cobalt and inorganic cobalt compounds was adopted on 22 September 2023. The opinion notes that cobalt and inorganic cobalt compounds to workers should be controlled by the intervention at the EU level. In the discussions, it was agreed that there should be an OEL for both the inhalable and the respirable fractions. The OEL should be set at the value of 20 µg Co/m^3 for the inhalable fraction and 4.2 µg Co/m^3 for the respirable fraction. After 6 years, the limit values should be set at of 10 µg Co/m^3 for the inhalable fraction and 2.5 µg Co/m^3 for the respirable fraction.

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; and
- Or, if possible, avoiding closure by focussing on other areas of business that do not use cobalt and inorganic cobalt compounds: this may lead to costs for retraining, retooling and redundancy payments.

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 monetised impact on the costs and benefits is only due to the discount factor for the transitional period, which is shown in the Methodological Note section 8.4 to lead to a reduction in costs and benefits of approximately 8% for the sectors with a transitional period.

As both the costs and benefits reduce by 8%, the cost benefit ratios are unchanged.

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 are thus expected to delay and reduce the impacts for the following impact categories as shown in Table 14-6.

Table 14-6 Summary of the impact of a transitional period compared with no transitional period and an OEL of 10 /2.5 µg Co/m³

Other impacts	Impacts
Social impacts	
Impact on workers (ill health cases and monetised health benefits including direct, indirect and intangible costs, and in particular healthcare costs.)	The benefits in terms of the reduced number of cases of ill-health be the same. The monetary value will decrease by around 8% as the benefits will be postponed by on average three years.
Impact on employment (job losses)	There may be fewer job losses if some companies can use the transitional period to avoid discontinuation
Economic impacts	
Impact on businesses, including SMEs (adjustment costs (one off and recurrent), number of discontinuations, air monitoring costs (one-off and recurrent), administrative burden (one-off and recurrent), cost savings from reduced ill health.	The total estimated costs will reduce by approximately 8% for all sizes of company. The costs of discontinuation are likely to be reduced, while the costs of RMMs might increase when companies are able to finance the investments in RMM instead of closing down. The possibility to plan and finance investments RMMs over the transition period will in particular be important for SMEs. It is therefore likely that it will reduce the number of discontinuations amount SMEs. It might also be that the costs of RMMs will be reduced if companies can plan and do investments as part of investment in new production facilities and equipment.

Other impacts	Impacts
Impact on competitiveness (cost and price competitiveness (incl. consumers), international competitiveness and capacity to innovate).	The transitional period will reduce some of the negative impact of the costs upon competitiveness as it allows companies to better the plan and finance the necessary investments.
Impact on the single market (in particular better level playing field due to more harmonised legislations)	The transitional period will not affect the impacts on the single market. Introduction of the EU wide OEL for cobalt and inorganic cobalt compounds will lead to more level playing field across EU.
Impact on Member States (which MS are more expected to be impacted)	The expected fewer discontinuations as a result of the transitional period will benefit the Member States where the largest impacts are expected. These Member States are Czechia, France, Germany, Italy and Poland. They will see fewer discontinuations and therefore fewer negative impacts on SMS and employment.
Impact on public authorities (transposition costs, avoided healthcare treatment costs, benefit)	There are not significant changes to the estimated impacts on public authorities.
Impact on EU Strategic autonomy (where relevant)	The transitional period might decrease any negative impacts on EU strategic autonomy. The OEL might lead to more cobalt free products (e.g. batteries), but also potentially increase the costs of cobalt recovery. The transitional period is likely to lead to overall more positive impacts on the EU Strategic autonomy.
Impact on digitalisation	There are no impacts on digitalisation.
Environmental impacts	
Direct impacts on environment (releases of substances in the air)	The transitional period is not expected to change the direct environmental impacts.
Indirect impacts on environment (EU Green Deal)	The transitional period is not expected to change the indirect direct environmental impacts.

As indicated in section 7.5, the transitional period can result in a reduction in the adjustment costs or facilitate the financing of adjustment costs by making it easier and cheaper to implement. The study team has not investigated with stakeholders what is the most likely scenario due to the confidentiality status of the transitional period at the time of writing the report.

The most recent survey and report from the Cobalt Institute covers the impacts of the specific OELs proposed by the ACSH, which include the transitional period. The report indicates that the share of companies responding that they might have close is significantly lower when the transitional period is taken into account. This finding supports that assessment presented above, the introduction of the transportational period will allow companies to better plan and invest in RMMs to comply with the OEL.

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16 ANNEXES

16.1 Annex A - Summary of Consultation

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').

16.1.1 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[79];
- 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[80] 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) conducted the interviews with stakeholders. 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 can 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 objectives of

[79] 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.

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

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 work, 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 16-1 Consultation tools and strategies

Stakeholder type	Interests represented	Main consultation tools	Strategy
EU Associations and REACH Consortia	Industry	Online interviews Email requests	Our previous work demonstrated that EU Associations are the best instrument for reaching out to manufacturers/users. Upon our 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 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 been also 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 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 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.

Key summary information of the consultation so far for cobalt and inorganic cobalt compounds are provided below.

Sector	Number of responses to questionnaire
C19.20 Manufacture of refined petroleum products	1
C20.12 Manufacture of dyes and pigments	3
C20.13 Manufacture of other inorganic basic chemicals	6
C20.14 Manufacture of other organic basic chemicals	1
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3
C20.59 Manufacture of other chemical products n.e.c.	6
C21.20 Manufacture of pharmaceutical preparations	1
C23.19 Manufacture and processing of other glass, including technical glass-ware	1
C23.4 Manufacture of other porcelain and ceramic products	7
C24.10 Manufacture of basic iron and steel and of ferro-alloys	2
C24.45 Other non-ferrous metal production	7
C25.61 Treatment and coating of metals	2
C25.73 Manufacture of tools	12
C26.1 Manufacture of electronic components and boards	1
C27.2 Manufacture of batteries and accumulators	3
C29.30 Manufacture of parts and accessories for motor vehicles	1
C32.50 Manufacture of medical and dental instruments and supplies	1
F42 Civil engineering*	1
Grand Total	**59**

** The answer is considered a mistake whereas all substances except PAH is selected instead of selecting PAH.*

Number of interviews of companies, associations and HSE experts (Several of the interviews include participants from different organisations)	17
Site visits	4 Manufacture of basic chemicals Catalysts Manufacture of cobalt and cobalt alloys Manufacture of tools All in Western Europe

16.2 Annex B - Results of stakeholder survey

Data on exposure concentrations are presented in Annex C

Data on current use of RMMs and respondents' expected RMMs to be implemented to comply with the policy options are presented in the table below for key RMMs which are included in the cost model. Summaries for some further RMMs are provided in section 7.2.10.1.

Table 16-2 Percentage breakdown of primary RMMs currently used by enterprises by sector and expected RMMs to be further implemented (or improved) by the four policy options. The numbers represent work processes included in responses.

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
Current situation												
C19.20 Manufacture of refined petroleum products (1)			100% (1)							100% (1)		
C20.12 Manufacture of dyes and pigments (6)		33% (2)	33% (2)	50% (3)					33% (2)	67% (4)		33% (2)
C20.13 Manufacture of other inorganic basic chemicals (20)		35% (7)	60% (12)	60% (12)		15% (3)		50% (10)	35% (7)	45% (9)		60% (12)
C20.14 Manufacture of other organic basic chemicals (4)		25% (1)						50% (2)	50% (2)			100% (4)
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)			14% (1)	43% (3)				29% (2)		100% (7)	29% (2)	
C20.59 Manufacture of other chemical products n.e.c. (24)		33% (8)	50% (12)	67% (16)	29% (7)			46% (11)	71% (17)	13% (3)	33% (8)	67% (16)
C21.20 Manufacture of pharmaceutical preparations (1)		100% (1)		100% (1)		100% (1)		100% (1)		100% (1)		100% (1)
C23.19 Manufacture and processing of other glass, including technical glassware (1)		100% (1)		100% (1)						100% (1)	100% (1)	
C23.4 Manufacture of other porcelain and ceramic products (15)		47% (7)		53% (8)						33% (5)	100% (15)	100% (15)
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)			75% (3)	100% (4)				75% (3)				100% (4)
C24.45 Other non-ferrous metal production (16)		25% (4)	56% (9)	75% (12)	13% (2)	56% (9)	25% (4)	50% (8)	19% (3)	31% (5)		81% (13)
C25.61 Treatment and coating of metals (4)			50% (2)	25% (1)			25% (1)		75% (3)	50% (2)	100% (4)	

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
C25.73 Manufacture of tools (40)		38% (15)	60% (24)	88% (35)	5% (2)	5% (2)		55% (22)	20% (8)	70% (28)	20% (8)	78% (31)
C26.1 Manufacture of electronic components (2)				50% (1)				50% (1)		50% (1)		50% (1)
C27.2 Manufacture of batteries and accumulators (10)		30% (3)	40% (4)	10% (1)	20% (2)			10% (1)	10% (1)	30% (3)		70% (7)
C29.30 Manufacture of parts and accessories for motor vehicles (0)												
C32.50 Manufacture of medical and dental instruments and supplies (4)		100% (4)								100% (4)		
F42 Civil engineering (4)		75% (3)	50% (2)	100% (4)	50% (2)	25% (1)	75% (3)			25% (1)	100% (4)	100% (4)
Grand Total (163)		34% (56)	44% (72)	63% (102)	9% (15)	10% (16)	5% (8)	37% (61)	26% (43)	46% (75)	26% (42)	67% (110)
Policy option 20 / 4.2 µg/m³												
C19.20 Manufacture of refined petroleum products (1)	100% (1)											
C20.12 Manufacture of dyes and pigments (6)	83% (5)											
C20.13 Manufacture of other inorganic basic chemicals (20)	5% (1)	30% (6)	25% (5)	25% (5)	10% (2)	15% (3)		60% (12)	20% (4)	25% (5)		20% (4)
C20.14 Manufacture of other organic basic chemicals (4)	25% (1)	25% (1)	75% (3)	75% (3)				50% (2)				
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	100% (7)		14% (1)	14% (1)		14% (1)		14% (1)		43% (3)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	50% (12)	13% (3)	8% (2)	4% (1)								4% (1)
C21.20 Manufacture of pharmaceutical preparations (1)												

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
C23.19 Manufacture and processing of other glass, including technical glassware (1)	100% (1)				100% (1)							
C23.4 Manufacture of other porcelain and ceramic products (15)	100% (15)											
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)	75% (3)											25% (1)
C24.45 Other non-ferrous metal production (16)	50% (8)	44% (7)	13% (2)		6% (1)			25% (4)	13% (2)	13% (2)		
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)	15% (6)	60% (24)	28% (11)	18% (7)	8% (3)		5% (2)	25% (10)	3% (1)	23% (9)		15% (6)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	90% (9)							20% (2)	20% (2)			
C32.50 Manufacture of medical and dental instruments and supplies (4)		25% (1)					25% (1)	50% (2)	25% (1)			
F42 Civil engineering (4)		25% (1)										
Grand Total (163)	43% (70)	26% (43)	15% (24)	10% (17)	4% (7)	2% (4)	2% (3)	20% (33)	7% (11)	12% (19)	1% (2)	8% (13)
Policy option 10 / 2.5 µg/m³												
C19.20 Manufacture of refined petroleum products (1)			100% (1)	100% (1)								
C20.12 Manufacture of dyes and pigments (6)		50% (3)		83% (5)								
C20.13 Manufacture of other inorganic basic chemicals (20)	20% (4)	30% (6)	15% (3)	15% (3)	20% (4)	25% (5)		40% (8)		20% (4)		20% (4)

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
C20.14 Manufacture of other organic basic chemicals (4)												
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	71% (5)		14% (1)	14% (1)		14% (1)		14% (1)		43% (3)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	38% (9)	17% (4)	4% (1)	4% (1)				8% (2)			13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)					100% (1)							
C23.4 Manufacture of other porcelain and ceramic products (15)	100% (15)											
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	25% (4)	44% (7)	31% (5)	19% (3)	13% (2)	13% (2)		25% (4)	13% (2)	13% (2)		13% (2)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)	13% (5)	33% (13)	13% (5)	13% (5)	5% (2)		5% (2)	15% (6)	5% (2)	20% (8)	3% (1)	15% (6)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	80% (8)	10% (1)	10% (1)				10% (1)	30% (3)	10% (1)			
C32.50 Manufacture of medical and dental instruments and supplies (4)												
F42 Civil engineering (4)												

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
Grand Total (163)	31% (51)	21% (34)	10% (17)	12% (19)	6% (9)	5% (8)	2% (3)	15% (24)	4% (6)	10% (17)	4% (6)	8% (13)
Policy option 5 / 1.5 µg/m³												
C19.20 Manufacture of refined petroleum products (1)			100% (1)	100% (1)				100% (1)				
C20.12 Manufacture of dyes and pigments (6)			33% (2)									
C20.13 Manufacture of other inorganic basic chemicals (20)	5% (1)	35% (7)	10% (2)	20% (4)	10% (2)			20% (4)			15% (3)	
C20.14 Manufacture of other organic basic chemicals (4)												
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)	14% (1)		14% (1)			14% (1)				29% (2)	29% (2)	14% (1)
C20.59 Manufacture of other chemical products n.e.c. (24)	21% (5)	8% (2)	4% (1)	8% (2)				13% (3)			13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)					100% (1)							
C23.4 Manufacture of other porcelain and ceramic products (15)			53% (8)	40% (6)						87% (13)		
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	19% (3)	50% (8)	38% (6)	19% (3)	25% (4)	6% (1)	25% (4)	13% (2)	6% (1)	13% (2)		6% (1)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
C25.73 Manufacture of tools (40)	10% (4)	33% (13)	5% (2)	3% (1)			13% (5)	3% (1)	3% (1)	3% (1)	3% (1)	3% (1)
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	60% (6)	20% (2)	20% (2)	10% (1)			10% (1)	10% (1)	10% (1)			
C32.50 Manufacture of medical and dental instruments and supplies (4)												
F42 Civil engineering (4)												
Grand Total (163)	13% (21)	20% (32)	15% (25)	11% (18)	4% (7)	1% (2)	6% (10)	7% (12)	2% (4)	11% (18)	6% (9)	2% (3)
Policy option 1 / 0.5 µg/m³												
C19.20 Manufacture of refined petroleum products (1)		100% (1)	100% (1)	100% (1)			100% (1)	100% (1)				
C20.12 Manufacture of dyes and pigments (6)		50% (3)		50% (3)					50% (3)			
C20.13 Manufacture of other inorganic basic chemicals (20)		35% (7)		20% (4)	20% (4)			20% (4)			15% (3)	
C20.14 Manufacture of other organic basic chemicals (4)												
C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics (7)		29% (2)								29% (2)		
C20.59 Manufacture of other chemical products n.e.c. (24)		21% (5)		8% (2)		8% (2)		17% (4)	17% (4)		13% (3)	
C21.20 Manufacture of pharmaceutical preparations (1)												
C23.19 Manufacture and processing of other glass, including technical glassware (1)												

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
C23.4 Manufacture of other porcelain and ceramic products (15)		93% (14)							100% (15)			
C24.10 Manufacture of basic iron and steel and of ferro-alloys (4)												
C24.45 Other non-ferrous metal production (16)	25% (4)	75% (12)	38% (6)	44% (7)	38% (6)	13% (2)	38% (6)	25% (4)	13% (2)	25% (4)	38% (6)	13% (2)
C25.61 Treatment and coating of metals (4)	25% (1)								25% (1)			
C25.73 Manufacture of tools (40)		40% (16)	3% (1)	3% (1)			18% (7)		3% (1)	3% (1)	5% (2)	
C26.1 Manufacture of electronic components (2)												
C27.2 Manufacture of batteries and accumulators (10)	50% (5)	40% (4)	60% (6)	10% (1)			30% (3)	50% (5)	40% (4)			
C32.50 Manufacture of medical and dental instruments and supplies (4)												
F42 Civil engineering (4)												
Grand Total (163)	6% (10)	39% (64)	9% (14)	12% (19)	6% (10)	2% (4)	10% (17)	11% (18)	18% (30)	4% (7)	9% (14)	1% (2)

Source: Study team

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
Current situation (163)		34% (56)	44% (72)	63% (102)	9% (15)	10% (16)	5% (8)	37% (61)	26% (43)	46% (75)	26% (42)	67% (110)
Policy option 20 / 4.2 µg/m^3 (163)	43% (70)	26% (43)	15% (24)	10% (17)	4% (7)	2% (4)	2% (3)	20% (33)	7% (11)	12% (19)	1% (2)	8% (13)

Policy option 10 / 2.5 µg/m^3 (163)	31% (51)	21% (34)	10% (17)	12% (19)	6% (9)	5% (8)	2% (3)	15% (24)	4% (6)	10% (17)	4% (6)	8% (13)
Policy option 5 / 1.5 µg/m^3 (163)	13% (21)	20% (32)	15% (25)	11% (18)	4% (7)	1% (2)	6% (10)	7% (12)	2% (4)	11% (18)	6% (9)	2% (3)
Policy option 1 / 0.5 µg/m^3 (163)	6% (10)	39% (64)	9% (14)	12% (19)	6% (10)	2% (4)	10% (17)	11% (18)	18% (30)	4% (7)	9% (14)	1% (2)

Sector (number of work processes)	No action required	Full enclosure	Partial enclosure	Open hood	Pressurised or sealed cabin	Simple enclosed cabin	Self-cont. Breathing apparatus	Powered air-purifying resp.	HEPA filter	Simple mask	Reduce amount of substance	General dilution ventilation
Current situation (163)		34% (56)	44% (72)	63% (102)	9% (15)	10% (16)	5% (8)	37% (61)	26% (43)	46% (75)	26% (42)	67% (110)
Policy option 20 / 4.2 µg/m^3 (163)	43% (70)	26% (43)	15% (24)	10% (17)	4% (7)	2% (4)	2% (3)	20% (33)	7% (11)	12% (19)	1% (2)	8% (13)
Policy option 10 / 2.5 µg/m^3 (163)	31% (51)	21% (34)	10% (17)	12% (19)	6% (9)	5% (8)	2% (3)	15% (24)	4% (6)	10% (17)	4% (6)	8% (13)
Policy option 5 / 1.5 µg/m^3 (163)	13% (21)	20% (32)	15% (25)	11% (18)	4% (7)	1% (2)	6% (10)	7% (12)	2% (4)	11% (18)	6% (9)	2% (3)
Policy option 1 / 0.5 µg/m^3 (163)	6% (10)	39% (64)	9% (14)	12% (19)	6% (10)	2% (4)	10% (17)	11% (18)	18% (30)	4% (7)	9% (14)	1% (2)

16.3 Annex C - Summary of exposure data by sector and activity

In the following Annex, available exposure data are reported in three tables covering:

- Exposure data obtained from the Cobalt REACH Consortium. The dataset includes only inhalable data. EBRC consultant working for the Cobalt REACH Consortium consider the respirable data to be less representative and more uncertain and has not submitted these.
- Exposure data from stakeholder survey
- Exposure data from the literature

The exposure data are presented by sector in section 3.3.

Exposure data obtained from the Cobalt REACH Consortium

Table 16-3 Statistical summary of personal air monitoring measurements not adjusted for use of RPE obtained from the Cobalt REACH Consortium. All values in µg Co/m³ and considered to represent 8-h TWA. Raw data without adjustment for RPE and duration

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
C10.91	Manufacture, feeds	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	45
		Handling of low and/or medium dusty materials	162	60.0	17.0	17.0	58.0	162.4	231.8	2007 - 2022	10	20
		Raw material handling	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	20
		Raw material handling	27	89.5	68.0	68.0	125.0	178.0	234.0	2012 - 2019	10	20
C20.12	Manufacture of dyes and pigments	(Raw material) Handling of solutions	10	3.6	2.4	2.4	3.2	8.7	9.8	2013 - 2017	1	480
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	364
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Hot (metallurgical) process	64	136.7	62.5	62.5	137.3	307.0	634.0	2007 - 2022	10	480
		Preparation of raw material	171	19.2	7.0	7.0	13.5	32.0	52.5	2007 - 2022	1	480
		Raw material handling	100	56.0	12.5	12.5	45.0	149.6	282.5	2007 - 2022	10	480
		Raw material handling	13	6.2	5.0	5.0	9.0	11.4	15.2	2013 - 2017	1	480
		Raw material handling	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	480
		Wet process	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
		Reaction	133	5.7	3.0	3.0	6.0	9.8	24.0	2006 - 2018	1	480
C20.13-20.14	Manufacture of basic chemicals	(Raw material) Handling of solutions	10	3.6	2.4	2.4	3.2	8.7	9.8	2013 - 2017	1	20
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	60
		Drying	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	480
		Further processing in the manufacture of another substance	83	80.8	38.0	38.0	79.0	214.8	277.1	2007 - 2022	10	295
		Handling of low and/or medium dusty materials	162	60.0	17.0	17.0	58.0	162.4	231.8	2007 - 2022	10	480
		Handling of powders with high dustiness potential	99	309.1	64.0	64.0	342.9	976.0	1210.2	2009 - 2022	40	139
		Hot (metallurgical) process	64	136.7	62.5	62.5	137.3	307.0	634.0	2007 - 2022	10	53
		Packaging of high dusty materials	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	60
		Packaging of low and/or medium dusty materials	27	89.5	68.0	68.0	125.0	178.0	234.0	2012 - 2019	10	172
		Packaging of very low dusty materials	38	0.1	0.0	0.0	0.0	0.1	0.4	2018	1	480
		Preparation of raw material	171	19.2	7.0	7.0	13.5	32.0	52.5	2007 - 2022	1	148

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Raw material handling	32	59.2	25.5	25.5	80.1	120.9	298.6	2004 - 2022	10	180
		Raw material handling	100	56.0	12.5	12.5	45.0	149.6	282.5	2007 - 2022	10	93
		Reaction	133	5.7	3.0	3.0	6.0	9.8	24.0	2006 - 2018	1	220
		Wet process	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	120
C20.59	Catalysts	Calcination and/or drying of catalysts	2	2.4	2.4	2.4	3.1	3.5	3.7	2013 - 2014	1	480
		Cleaning and maintenance	33	29.4	12.0	12.0	22.3	108.9	132.2	2003 - 2019*	10	120
		Closed catalysts manufacture	141	6.7	1.7	1.7	7.0	16.2	21.7	2005 - 2019	20	480
		Closed screening of catalysts	8	12.1	11.7	11.7	17.0	20.9	21.3	2006 - 2009	1	480
		Delivery and storage of raw material	27	1.7	1.1	1.1	1.8	2.9	4.5	2008 - 2015	1	148
		Dissolution	6	1.9	0.6	0.6	1.9	4.5	5.7	2005 - 2008	1	45
		Filtration and drying	4	8.0	9.7	9.7	10.4	10.4	10.4	2008 - 2009	1	155
		Impregnation and drying of catalysts	4	8.0	9.7	9.7	10.4	10.4	10.4	2008 - 2009	1	25
		Reduction of precipitate	8	12.1	11.7	11.7	17.0	20.9	21.3	2006 - 2009	1	60
C20.59	Formulation other chemicals	(Raw material) Handling of solutions	10	3.6	2.4	2.4	3.2	8.7	9.8	2013 - 2017	1	52
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	24
		Cleaning and maintenance	9	5.9	3.9	3.9	6.1	13.6	16.8	2004 - 2019	1	24
		Cleaning and maintenance	99	309.1	64.0	64.0	342.9	976.0	1210.2	2009 - 2022	40	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Formulation of solid materials	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	480
		Formulation of solutions	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
		Formulation of solutions	133	5.7	3.0	3.0	6.0	9.8	24.0	2006 - 2018	1	480
		Handling and re-packaging of the solid substance	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	480
		Handling of low and/or medium dusty materials	162	60.0	17.0	17.0	58.0	162.4	231.8	2007 - 2022	10	480
		Handling of solutions	6	0.5	0.5	0.5	0.5	0.5	0.5	2017	1	403
		Raw material handling (low dusty input materials)	1	0.1	0.1		0.1	0.1	0.1	2013	1	15
		Raw material handling (solid input materials)	4	4.2	2.0	2.0	4.3	8.3	9.7	2013 - 2019	1	15
C20.30	Manufacture of paints and inks	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Formulation/Pre-formulation	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
		Handling of low and/or medium dusty materials	162	60.0	17.0	17.0	58.0	162.4	231.8	2007 - 2022	10	480
		Raw material handling	16	74.4	17.1	17.1	28.3	232.5	442.8	2003 - 2022	20	480
C21.20	Pharmaceuticals	Handling of liquid raw material	2	1.0	1.0	1.0	1.1	1.2	1.2	2013 - 2017	1	18
C22.11; C22.19	Rubber adhesion	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Finishing and shipping	4	0.1	0.1	0.1	0.1	0.1	0.1	2018	1	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Kneading (mixing) in a closed process	36	0.6	0.1	0.1	0.2	2.3	4.2	2016 - 2018	1	480
		Kneading (mixing) of very low dusty materials	38	0.1	0.0	0.0	0.0	0.1	0.4	2018	1	480
		Raw material handling	33	0.9	0.1	0.1	1.0	2.0	5.0	2016 - 2018	1	480
		Raw material handling (very low dusty input materials)	38	0.1	0.0	0.0	0.0	0.1	0.4	2018	1	480
C23.1	Glass	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Further processing (under closed conditions)	36	0.6	0.1	0.1	0.2	2.3	4.2	2016 - 2018	1	480
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
C24.45	Manufacture of cobalt and cobalt alloys, manufacture	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Leaching unit	133	5.7	3.0	3.0	6.0	9.8	24.0	2006 - 2018	1	480
		Packaging of metal chips	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Powder production and milling	184	77.6	28.0	28.0	75.3	180.0	388.0	2007 - 2021	10	480
		Raw material handling (high dusty input materials)	74	44.8	7.5	7.5	26.0	102.8	179.3	2005 - 2021	10	480
		Screening and packaging	232	207.1	91.5	91.5	248.8	530.0	694.7	2007 - 2022	20	480
		Shearhouse (cutting)	32	5.2	1.0	1.0	7.2	17.3	20.4	2005 - 2022	1	480
		Solvent extraction unit	27	3.3	1.0	1.0	2.0	4.8	6.7	2006 - 2018	10	480
		Supervision	61	9.2	7.6	7.6	11.2	17.0	24.0	2010 - 2022	1	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Tankhouse (electrowinning)	41	26.6	19.0	19.0	32.0	52.0	65.0	2007 - 2009	10	480
C24.45	Manufacture of cobalt and cobalt alloys	(Mechanical) Finishing/Processing of massive objects	32	5.2	1.0	1.0	7.2	17.3	20.4	2005 - 2022	1	480
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Handling of powders	20	357.8	198.5	198.5	479.3	1079.3	1210.0	2009 - 2022	40	480
		Handling of very low/massive dusty materials	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Raw material handling	232	207.1	91.5	91.5	248.8	530.0	694.7	2007 - 2022	20	480
		Sintering, melting and casting	7	1.2	1.0	1.0	1.0	1.4	1.8	2007 - 2008	1	480
C25.61	Surface treatment of metals	(Mechanical) Finishing/Processing of massive objects	32	5.2	1.0	1.0	7.2	17.3	20.4	2005 - 2022	1	480
		(Raw material) Handling of solutions	10	3.6	2.4	2.4	3.2	8.7	9.8	2013 - 2017	1	30
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Cleaning and maintenance	9	5.9	3.9	3.9	6.1	13.6	16.8	2004 - 2019	1	240
		Handling of dusty materials	232	207.1	91.5	91.5	248.8	530.0	694.7	2007 - 2022	20	480
		Handling of low and/or medium dusty materials	162	60.0	17.0	17.0	58.0	162.4	231.8	2007 - 2022	10	480
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Handling/Finishing of (surface-treated) articles	6	1.9	1.9	1.9	2.1	2.8	3.2	2007 - 2013	1	480
		Plating	60	5.3	2.8	2.8	5.6	12.2	14.2	2004 - 2017	1	240

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Raw material handling (low dusty input materials)	1	0.1	0.1		0.1	0.1	0.1	2013	1	10
		Raw material handling (solid input materials)	4	4.2	2.0	2.0	4.3	8.3	9.7	2013 - 2019	1	10
		Wet process	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
C25.62	Machining	Handling and mechanical treatment (low kinetic energy) of tools, metals and/or alloys	26	10.0	10.0	10.0	10.0	20.0	20.0	1998 - 2021	1	480
		Manual tasks using cobalt-containing tools	30	23.8	6.0	6.0	20.0	31.0	117.0	1995 - 2022	10	480
		Handling and use of hard-metal articles	1	340.0	340.0		340.0	340.0	340.0	2003 - 2019*	20	480
C25.73	Manufacture of tools	(Mechanical) Finishing/Processing of massive objects	32	5.2	1.0	1.0	7.2	17.3	20.4	2005 - 2022	1	480
		Brazing or welding	1	0.6	0.6		0.6	0.6	0.6	2022	1	480
		Classifying of powder	9	64.8	80.0	80.0	90.0	94.0	102.0	2019 - 2021	10	480
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Cleaning and maintenance	54	24.4	15.0	15.0	27.1	54.0	90.6	2019 - 2022	20	480
		Cleaning and maintenance	16	3.4	1.8	1.8	4.4	8.4	9.2	2019 - 2022	1	480
		Drying	9	64.8	80.0	80.0	90.0	94.0	102.0	2019 - 2021	10	480
		Grinding and/or turning	12	6.7	0.6	0.6	15.1	17.7	19.4	2018 - 2022	1	480
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Hot (metallurgical) process	64	136.7	62.5	62.5	137.3	307.0	634.0	2007 - 2022	10	480
		Marking	1	0.6	0.6		0.6	0.6	0.6	2022	1	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Milling	5	12.3	10.0	10.0	19.0	19.6	19.8	2019 - 2022	10	480
		Mixing	3	324.0	20.0	20.0	485.0	764.0	857.0	2016 - 2021	200	480
		Press charging and pressing	82	5.9	2.5	2.5	4.1	12.0	19.9	2013 - 2022	10	480
		Raw material handling	232	207.1	91.5	91.5	248.8	530.0	694.7	2007 - 2022	20	480
		Shaping	24	10.5	1.1	1.1	4.0	38.5	40.0	2014 - 2022	1	480
		Sieving	9	64.8	80.0	80.0	90.0	94.0	102.0	2019 - 2021	10	480
		Sintering	9	40.8	20.0	20.0	86.0	110.0	110.0	2014 - 2022	10	480
		Transfer operation	2	236.0	236.0	236.0	353.0	423.2	446.6	2016 - 2021	40	480
		Weighing Powders & Filling the Mill	41	66.0	40.0	40.0	83.0	190.0	190.0	2019 - 2022	20	480
C25.99	Manufacture of other fabricated metal products n.e.c.	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Hot (metallurgical) process	64	136.7	62.5	62.5	137.3	307.0	634.0	2007 - 2022	10	480
		Preparation of pre-sintered materials	11	50.0	62.4	62.4	66.4	96.0	109.6	2003 - 2019*	10	480
		Preparation of raw material	171	19.2	7.0	7.0	13.5	32.0	52.5	2007 - 2022	1	480
		Raw material handling	100	56.0	12.5	12.5	45.0	149.6	282.5	2007 - 2022	10	480
		Wet process	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
C26.1	Production of electronic components	Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	480

NACE	Sector	Worker contributing scenario	n	AM	SD	P50	P75	P90	P95	Period	APF	Duration
		Handling of massive objects/articles	11	3.3	1.0	1.0	5.5	8.0	8.5	2005 - 2021	1	480
		Hot (metallurgical) process	64	136.7	62.5	62.5	137.3	307.0	634.0	2007 - 2022	10	480
		Preparation of pre-sintered materials	11	50.0	62.4	62.4	66.4	96.0	109.6	2003 - 2019*	10	480
		Preparation of raw material	171	19.2	7.0	7.0	13.5	32.0	52.5	2007 - 2022	1	480
		Raw material handling	100	56.0	12.5	12.5	45.0	149.6	282.5	2007 - 2022	10	480
		Wet process	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	480
C27.2	Batteries	(Mechanical) Finishing/Processing of massive objects	32	5.2	1.0	1.0	7.2	17.3	20.4	2005 - 2022	1	480
		Cleaning and maintenance	99	309.1	64.0	64.0	342.9	976.0	1210.2	2009 - 2022	40	30
		Cleaning and maintenance	229	50.5	13.0	13.0	40.0	100.2	187.7	2010 - 2022	10	30
		Mix preparation	159	13.9	5.0	5.0	11.0	36.0	70.1	2007 - 2022	10	83
		Raw material handling	100	56.0	12.5	12.5	45.0	149.6	282.5	2007 - 2022	10	18
E38.32	Metal recovery	Chemical recycling	6	1.5	1.0	1.0	1.0	2.5	3.3	2020 - 2022	10	480
	Biogas	Industrial use of mixtures in biogas production, handling of solutions	6	0.5	0.5	0.5	0.5	0.5	0.5	2017	1	15
		Industrial use of mixtures in biogas production, handling of solid material	6	0.5	0.5	0.5	0.5	0.5	0.5	2017	1	15
		Professional use in biogas production	6	0.5	0.5	0.5	0.5	0.5	0.5	2017	1	15
F	Welding, etc,	Furnace brazing	7	1.2	1.0	1.0	1.0	1.4	1.8	2007 - 2008	1	480

Source: Cobalt REACH Consortium, 2023

Exposure data from stakeholder survey

Table 16-4 Statistical summary of exposure data from stakeholder survey not adjusted for use of RPE. All values in µg Co/m³ and considered to represent 8-h TWA. See explanatory notes in the sector description in section 3.3. [min, GV and LEV to be added, RPE Yes to be replaced by indicated APF]

Sector		Site	Activity	I,R	n W*	Min	AM	P50	P95	Max	n	Year	RPE, APF	GV	LEV
C20.12	Manufacture of dyes and pigments	1	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	I	30		3.6	0.61	10.2	40.3	19	2011-2022	Yes		
			PROC 5 Mixing or blending in batch processes **	I	30		1.3	0.13	2.3	15.9	16		Yes		
			PROC 8b Transfer of substance or mixture **	I	30	30	16	5.9	5	14.8	16		Yes		
		2	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	I	12	12	15	6	6	15	15	2022	Yes		
			PROC 9 Transfer of substance or mixture into small containers **	I	3	3	3	3	3.5	5	3		Yes		
C20.13 -20.14	Manufacture of basic chemicals	1	PROC 3 Manufacture or formulation in the chemical industry in closed batch processes	I	30		828	60	3,174	3,861	8	2022	Yes		
			PROC 8b Transfer of substance or mixture	I	10		19.3	19	38.9	39	4		Yes		
			PROC 27a Production of metal powders (hot processes)	I	10		619	350	1,820	2,200	20		Yes		
			PROC 2 Chemical production or refinery in closed continuous process	I	25		27.6	8.5	111	150	8		Yes		

Sector		Site	Activity	I,R	n W*	Min	AM	P50	P95	Max	n	Year	RPE, APF	GV	LEV
C20.59	Catalysts	1	Manufacture of process chemicals for petrochemicals industry	I	20		3.6	0.61	10.2	40.3	20	2016-2022	10		
				R	20		1.3	0.13	2.3	15.9	20		10		
C24.45	Manufacture of cobalt and cobalt alloys	1	PROC 23 Open processing and transfer operations	I	10		40.5	-	-	59	2	2022	Yes		
			PROC 27b Production of metal powders (wet processes)	I	30		9.3			27	10	2022	Yes		
			PROC 27a Production of metal powders (hot processes)	I	40		5.6			32	19	2022	Yes		
			PROC 28 Manual maintenance (cleaning and repair) of machinery	I	10		19			230	20	2022	Yes		
		2	PROC 2 Chemical production or refinery in closed continuous process	I	4		9.4	9.4	10.6	10.7	2	2023	Yes		
				I	6		1.6	1.6	2.8	3.1	20	2022	Yes		
				I	20		0.5	0.0	1.7	1.7	8	2023	No		
C25.73	Manufacture of tools	*1*	Production of hardmetal powder, aggregated	I			12	7.5	39	64	33	2022	Yes		
		2	Production of sintered hardmetal articles, aggregated	I			2	1.0	4.4	5.8	85	2022	No		
		3	Production of hardmetal tools aggregated	I	24		71	50	190	193	47	2019-2022	Yes		
				R	84		9	5.4	20.9	30	47		Yes		
		4		I			91	-	-	260	8	2021	Yes		

Sector		Site	Activity	I,R	n W*	Min	AM	P50	P95	Max	n	Year	RPE, APF	GV	LEV
			Mixing and Preparation of Ready to press powder (tungsten carbide+Cobalt)	R			3			6	8	2021	Yes		
			PROC 28 Manual maintenance (cleaning and repair) of machinery	I			535			3,100	8	2022	Yes		
				R			25			130	8	2022	Yes		
			Pressing, Filling of Press forms	I			120			130	2	2021	Yes		
				R			6			6.3	2	2021	Yes		
			Machining of green bodies	I			21			47	7	2022	No		
				R			10			62	7	2022	No		
		5	Production of powder for hardmetal tools, aggregated, PROC 5, 9, and 17	I	30		96	47	297	320	24	2006-2021	Yes		
			Production of hardmetal tools, PROC 8b	I	193		30	8	14	40	118		No		
		6	Production of hardmetal tools, aggregated	I			46	42	59	62	4	2019	Yes		
C27.2	Batteries	1	Preparation of nickel hydroxide	I	NA			0.03		0.1	3	2022	No		
			Manufacture of active of positive active material	I	NA			1.1		1.5	3		No		
			Manufacture of Plates	I	NA			0.4		5.3	164		No		
			Maintenance	I	NA		-	0.7		1.1	4		Yes		
		2	PROC 5 Mixing or blending in batch processes	I	27		2	2		4	9	2022	Yes		
			PROC 9 Transfer of substance or mixture into small containers	I	20		1.2	1		4	6		No		
			Slitting, calendering, coated electrode spiraling	I	40		0.5	0.1		2	15		Yes		

Source: Stakeholder survey. n W = number of workers.*

Exposure data from the literature

Table 16-5 Statistical summary of personal air monitoring measurements from the literature not adjusted for use of RPE. All values in µg Co/m³ and considered to represent 8-h TWA.

Sector/activity this study		Activity, as reported	R, I **	n	AM	GM	P50	P75	P90	P95	Max	Year	Source
C20.12	Manufacture, dyes and pigments	Manufacture of cobalt pigments	R	7			11					1999	Blome, 2006
C20.13-20.14	Manufacture, basic chemicals	Manufacture of cobalt compounds	R	22	78	63		98	137	153		1997-2000	Blome, 2006
C24.45	Manufacture, cobalt and cobalt alloys	Manufacture of cobalt and cobalt compounds (refinery)	I	248			15	53			108	2007	Lantin *et al.*, 2013
C25.73	Manufacture of tools	Production of hardmetals - all processes	R	91	78	22	21	70	250	315		1996-2002	Blome, 2006
		- Powder processing	R	39	104	43		155	310	324			Same
		- Shaping	R	23	66	32		65	126	238			
		Hardmetal processing incl. sintering	R	28	12	6		20	23	35			
		Production of hardmetals - all processes	I	71	3.3	2.0	2.2				2017-2018		Wahlquist *et al.*, 2020
		- Forming/prototype	I	5	2	1.7	1.7				3.4		
		- Laboratory	I	5	0.6	0.5	0.4				1.3		
		- Maintenance	I	7	1.0	0.9	0.9				1.8		
		- Powder department	I	15	7.1	6	5.7				19		
		- Pressing department	I	39	2.8	1.8	2.3				10		

Sector/activity this study		Activity, as reported	R, I **	n	AM	GM	P50	P75	P90	P95	Max	Year	Source
NA	NA	Change of catalyst	R	37	36	15	-	50	98	131		1992-2002	Blome, 2006
C25.61	Surface treatment of metals	Plasma spraying	I	54	2.3						390	1996	Chadwick *et al.*, 1997
C32.50	Medical and dental devices	Dental laboratories	R	16			0.09			0.47	-	2012-2018	BG ETEM, 2020
		Dental laboratory, work with CoCr alloys	I	8	41	8.4	7.1				155	2013-2014	Kettelarij *et al.*, 2018
		Orthopaedic implants	I	10	4.4	1.8	1.4				25	2013	Beaucham *et al.*, 2015
		Detonation gun spraying	I	29	2.7						80		
		Plasma spraying - Workshop control	I	35	1						20		
		Plasma spraying - Control	I	20	2					2			
E38.32	Metal recovery	E-waste recycling	I	40		0.04	0.04				0.3	2017-2018	Gerding *et al.*, 2021
			R	40		0.02	0.02				0.02		
		E-waste recycling	I	77		0.07					3.3	2007-2009	Julander *et al.*, 2014
		E-waste recycling, office workers	I	3		0.004					0.005		
A2	Thermal spraying	Plasma spraying	I	54	23						390	1996	Chadwick *et al.*, 1997
		Detonation gun spraying	I	29	27						80		
		Plasma spraying - Workshop background level	I	35	1						20		

Sector/activity this study		Activity, as reported	R, I **	n	AM	GM	P50	P75	P90	P95	Max	Year	Source
A4	Service life of hardmetal tools	Sharpening of hardmetal tools	I	19		0.3	0.27				4.5	2019	Paganelli *et al.,* 2020
A5	Service life of diamond tools	Use of cobalt-based diamond disk tools	I	7	20	15	14			44	45	1989	Oever *et al.,* 1990

*** Respirable (R); Inhalable (I). NA - A sector cannot be allocated on the basis of the description in data source.*

16.4 Annex D - Data from the eftec (2023) impact assessment for the Cobalt Institute

This Annex includes selected data from the revised eftec (2023) impact assessment for the Cobalt Institute received August 2023 which are used for various sections in the current study. In addition to data presented here, some data and information from the impact assessment is quoted and discussed directly in the various sections.

The information in the tables is discussed in the sections where the results are considered.

The Annex contain the following tables:

- A summary of data from respondent to the eftec (2023) survey regarding number of FTE (Full time equivalent) workers and number of FTE workers potentially exposed, number of respondents and the SME percentage of these (the impact assessment aggregate small and medium-sixed companied). For broad uses where the number of responses were less than three, data are for confidentiality reason not shown and they are indicated with Insufficient respondent data'). The dataset includes data for cobalt substances out of scope. The total survey included 54 responses, and some responses concerned more sectors and data are added twice. This is reflected in the indication of total for upper bound (without taking into account that data are included twice and lower bound which reflect the actual number of responding companies).

- A summary of the impact assessment's estimated total number of companies, sites, employed FTE workers, and FTE workers potentially exposed and share of SME. The data are in this report mainly used and discussed in section 3.4 on exposed workforce and section 3.10 on market analysis. The data are organised into broad uses and the organisation of the data into the sectors used in the current study is discussed in the said sections. The impact assessment does not include a number of downstream uses of the cobalt compounds included in the current study such as service life of hardmetal tools and diamond tool, as well as downstream uses in the ceramics and glass sectors. The broad use category 'use in metallurgical alloys' is in the current study divided into a number of downstream sectors such as medical and dental sector, aviation sector, etc. As for the survey responses, totals are indicated for upper bound (without taking into account that data are included twice and lower bound which reflect the actual number of responding companies).

- Answers to the eftec (2023) survey regarding the companies' own assessment of compliance with each OEL i.e. would the company be in compliance if an OEL at indicated level came into force? The level of compliance is not indicated i.e. it could be one process where the company would not be in compliance or it could be more or all processes where the concentrations are too high. It is not indicated whether the companies take the current use of RPE into account in the assessment of compliance.

- Responses to the eftec (2023) survey regarding the companies' assessment of technical and economic feasibility of compliance. The answers concern only <u>those companies which have answered that they are not currently in compliance</u> i.e. the number of respondents increases toward the lower policy options. The original table include columns indicating unknown feasibility which is typically at a level of 50% of the answers for not technically or economically feasible.

Table 16-6 Eftec (2023) survey responses, number of companies sites and employees

Broad use	Number of companies	Number of sites	% of total companies	SME%	Number of FTE workers employed		Number of FTE workers potentially exposed		% exposed
					Male	Female	Male	Female	
Manufacture of cobalt and/or cobalt substances	15	27	16%	13%	23,620	4,380	2,240	260	9%
Recycling of materials containing cobalt substances	7	9	8%	14%	4,030	800	900	110	21%
Manufacture of other chemicals	5	8	5%	60%	390	120	200	10	41%
Manufacture of precursor chemicals for batteries	Insufficient respondent data								
Manufacture of catalysts	3	3	3%	0%	800	130	140	20	17%
Manufacture of pigments and dyes	6	11	7%	17%	2,350	670	720	110	27%
Manufacture of driers / paints	No respondent data								
Use as catalysts - used as a catalyst or catalyst precursor	3	3	3%	0%	800	130	140	20	17%
Use as catalysts - used as oxidation catalyst/for PTA and IPA	No respondent data								
Use in surface treatment - Formulation of surface treatment	4	6	4%	75%	1,210	330	140	10	10%
Use in surface treatment - Passivation or anti-corrosion treatment processes	5	9	5%	60%	9,110	3,730	300	50	3%
Use in surface treatment - Metal or metal alloy plating	5	14	5%	60%	3,700	890	1,340	190	33%
Use in biotechnology – Formulation and industrial use of mixtures in biogas production	No respondent data								
Use in biotechnology – Professional use in biogas production	No respondent data								
Use in biotechnology – Use in fermentation, fertilizers, biotech, scientific research and standard analysis	No respondent data								
Use in biotechnology – Formulation and use in animal feed grade material	4	4	4%	100%	160	90	70	0	28%

Broad use	Number of companies	Number of sites	% of total companies	SME%	Number of FTE workers employed		Number of FTE workers potentially exposed		% ex-posed
					Male	Female	Male	Female	
Bespoke uses – Use in humidity indicators cards, plugs and/or bags with printed spots	Insufficient respondent data								
Bespoke uses – Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	Insufficient respondent data								
Bespoke uses – Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	No respondent data								
Adhesion (inc. rubber adhesion agent)	5	22	5%	0%	36,010	4,740	6,730	520	18%
Use in electronics	No respondent data								
Use in magnetic alloys	Insufficient respondent data								
Use in metallurgical alloys	12	28	13%	33%	7,430	2,240	2,290	580	30%
Use in cemented carbide/diamond tools	17	36	19%	47%	8,400	2,440	3,430	670	38%
Total (of data provided above) *	91	180		35%	98,010	20,690	18,640	2,550	18%
Upper bound (with overlap)	96	195			128,189		22,758		
Lower bound (without overlap), summed across questionnaire respondents	54	111			81,470		13,769		

Source: eftec, 2023. * Total of reported data added here; Upper and lower bound include broad uses with insufficient respondent data to present in the report.

Table 16-7 Eftec (2023) estimated number of companies, sites, total workers employed and potentially exposed, and total workers and exposed workers per company.

Broad use	Number of companies	Number of sites	Share of SME	Number of FTE workers employed	Number of FTE workers potentially exposed	% potentially exposed relative to total employment	% of workers exposed directly or indirectly in scope (based on respondent data)	FTE workers pr. company *	Exposed FTE workers pr company
Manufacture of cobalt and/or cobalt substances	45-80	85-145	38%	56,900-89,600	4,800-8,000	8-9%	89%	1,120-1,264	55-56
Recycling of materials containing cobalt substances	25-45	35-65	33%	22,200-34,000	4,400-7,300	20-21%	100%	776-888	112-126
Manufacture of other chemicals	30	50	67%	5,200	2,200	42%	88%	173	44
Manufacture of precursor chemicals for batteries	20	70	0%	7,400	2,000	27%	100%	370	29
Manufacture of catalysts	15	15	0%	3,600	600	17%	100%	240	40
Manufacture of pigments and dyes	15	30	33%	8,700	2,400	28%	91%	580	80
Manufacture of driers / paints	100	100	35%	3,600	600	17%	100%	36	6
Use as catalysts - used as a catalyst or catalyst precursor	80	80	0%	3,000	500	17%	100%	38	6
Use as catalysts - used as oxidation catalyst/for PTA and IPA	40	40	0%	1,200	200	17%	100%	30	5
Use in surface treatment - Formulation of surface treatment	10	15	90%	2,100	200	9%	100%	210	13
Use in surface treatment - Passivation or anti-corrosion treatment processes	750	1,350	89%	221,500	5,900	3%	100%	295	4
Use in surface treatment - Metal or metal alloy plating	190	530	89%	13,500	4,500	33%	100%	71	8
Use in biotechnology – Formulation and industrial use of mixtures in biogas production	310	310	34%	3,000	500	17%	100%	10	2
Use in biotechnology – Professional use in biogas production	2,790	2,790	34%	29,000	4,900	17%	100%	10	2

Broad use	Number of companies	Number of sites	Share of SME	Number of FTE workers employed	Number of FTE workers potentially exposed	% potentially exposed relative to total employment	% of workers exposed directly or indirectly in scope (based on respondent data)	FTE workers pr. company *	Exposed FTE workers pr company
Use in biotechnology – Use in fermentation, fertilizers, biotech, scientific research and standard analysis	100	100	35%	5,300	900	17%	100%	53	9
Use in biotechnology – Formulation and use in animal feed grade material	3,300	4,000	34%	50,000	2,500	5%	100%	15	1
Bespoke uses – Use in humidity indicators cards, plugs and/or bags with printed spots	5	5	40%	40,000	100	0%	100%	8,000	20
Bespoke uses – Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	5	30	40%	5,300	1,500	28%	100%	1,060	50
Bespoke uses – Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	5	5	40%	600	100	17%	100%	120	20
Adhesion (inc. rubber adhesion agent)	20	100	35%	150,000	11,300	8%	27%	7,500	113
Use in electronics	200	200	35%	7,700	1,300	17%	100%	39	7
Use in magnetic alloys	30	30	40%	3,500	1,800	52%	100%	117	60
Use in metallurgical alloys	170	395	35%	69,300	20,600	30%	100%	408	52
Use in cemented carbide/diamond tools	630	720	95%	25,600	9,700	38%	100%	41	13
Total (upper bound)	8,921	11,175	44%	783,600	89,600	11%	88%		
Total (lower bound)	4,962	6,360	44%	498,000	54,200	11%	88%		

Source: eftec, 2023. * The lower bound is calculated as part of the present study by adding the lower estimate in the range for manufacture of cobalt and recycling (upper two rows) to the lower bound indicated by eftec for the downstream uses.

Table 16-8 Answers to the eftec (2023) survey regarding the companies' assessment of compliance with each OEL. Broad uses with no or insufficient respondent data are excluded from the table.

Broad use	Percentage non-compliance sites			
	1 µg/m³	10 µg/m³	20 µg/m³	30 µg/m³
All	73%	36%	22%	16%
Manufacture of cobalt and/or cobalt substances	97%	36%	26%	14%
Recycling of materials containing cobalt substances	100%	36%	32%	14%
Manufacture of other chemicals	100%	100%	0%	0%
Manufacture of precursor chemicals for batteries	100%	71%	50%	25%
Manufacture of catalysts	100%	33%	17%	0%
Manufacture of pigments and dyes	91%	64%	36%	18%
Use as catalysts - used as a catalyst or catalyst precursor	100%	33%	17%	0%
Use in surface treatment - Formulation of surface treatment	67%	67%	0%	0%
Use in surface treatment - Passivation or anti-corrosion treatment processes	44%	44%	0%	0%
Use in surface treatment - Metal or metal alloy plating	87%	71%	60%	47%
Use in biotechnology – Formulation and use in animal feed grade material	33%	0%	0%	0%
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	100%	71%	57%	29%
Adhesion (inc. rubber adhesion agent)	42%	0%	0%	0%
Use in metallurgical alloys	97%	48%	23%	13%
Use in cemented carbide/diamond tools	98%	54%	40%	32%

Table 16-9 Answers to the eftec (2023) regarding the companies' assessment of technical and economic feasibility of compliance. The answers concern only those sites for which companies have answered that they are not currently in compliance (as shown the table above) i.e. the number of answers increase toward the lower policy options. Broad uses with no or insufficient respondent data are excluded from the table. The original table include a table with unknown feasibility which is typically at a level of 50% of the answers for not technically or economically feasible.

	% of companies (not in compliance) considering the OEL not technically feasibility				**% of companies (not in compliance) considering the OEL not economically feasibility**			
	30 µg/m3	**20 µg/m3**	**10 µg/m3**	**1 µg/m3**	**30 µg/m3**	**20 µg/m3**	**10 µg/m3**	**1 µg/m3**
Manufacture of cobalt and/or cobalt substances	0%	13%	20%	93%	25%	27%	20%	39%
Manufacture of catalysts				33%				33%
Manufacture of pigments and dyes			0%	100%			14%	90%
Use as catalysts - used as a catalyst or catalyst precursor				33%				33%
Use in surface treatment - Metal or metal alloy plating				100%				92%
Use in metallurgical alloys	41%	38%	20%	77%	21%	36%	39%	93%
Use in cemented carbide/diamond tools	8%	47%	45%	79%	0%	53%	50%	87%
Recycling of materials containing cobalt substances		13%	11%	96%		36%	32%	91%
Total	25%	51%	41%	79%	25%	56%	53%	63%

16.5 Annex E - Who is affected and how?

Table 16-10 Overview of benefits (total for all provisions) – preferred option 10 / 2.5 µg Co/m³ in €millions

Description	Amount €millions
Direct benefits	
Workers & families - Reduced cases of ill health (lung cancer)	27
Workers & families - Reduced cases of ill health (Restrictive lung disease)	2,842
Workers & families - Reduced cases of ill health (Upper airway irritation)	7,363
Workers & families - Ill health avoided, incl. intangible costs (M1 to M2)	€75.45 - €74.28
Companies - Avoided costs	€ 0.96
Public sector - Avoided costs	€ 4.45
Indirect benefits	
Public sector - Avoided cost of setting an OEL	0.5

Source: Study team

Notes: Benefits are PV discounted over 40 years

Table 16-11 and Table 16-12 give an overview of costs and apply the "one in, one out" approach for the preferred option. The costs are presented as present value costs discounted over 40 years and are not split between one-off and recurrent costs. In the study, adjustment costs are presented as first year and recurrent costs. First year costs include recurrent costs incurred in the first year: this also applies to first year compliance (adjustment plus monitoring and administrative burden) costs.

Table 16-11 Overview of costs – Preferred option 10 / 2.5 µg Co/m³

	Companies	Public Administrations
Direct adjustment costs	€ 579	€ 0.91
Direct administrative costs	€ 7	NA
Direct regulatory fees and charges	NA	NA
Direct enforcement costs	NA	Not estimated

	Companies	Public Administrations
Indirect costs	Not quantified	0

Source: Study team

Notes: Costs are PV discounted over 40 years

Enforcement costs are not estimated as they are specific to Member States individual inspection regime.

Table 16-12 Application of the 'one in, one out' approach – Preferred option 10 / 2.5 µg Co/m³ €millions

	Total
Businesses	
New administrative burdens (INs)	€ 7
Removed administrative burdens (OUTs)	0
Net administrative burdens	€ 7
Adjustment costs	0
Total administrative burdens	€ 7

Source: Study team

Notes: recurrent costs are PV discounted over 40 years

Table 16-13 Overview of relevant Sustainable Development Goals – Preferred Option 8.5 mg/m³

Relevant SDG	Expected progress towards the Goal
SDG 8 Decent work & economic growth	Based on the preferred policy option the introduction of OELs will help to ensure labour rights for the provision of safe and secure workplaces are protected.
SDG 3 Good health and wellbeing	Requirements of the preferred policy option to monitor isoprene in workplaces will help to prove that worker environments will remain safe from hazardous chemical exposure.

Source: Study team

16.6 Annex F - Overview of limit values in member States

Current OEL and STEL values for cobalt and its inorganic compounds are shown in the table below.

As part of the stakeholder consultation, Member States' authorities have been asked a question regarding the binding/indicative status of the national OELs and similar limit values. Information regarding the binding vs. indicative status of the OEL has been provided by 13 Member States (Belgium, Bulgaria, Cyprus, Denmark, Finland, Germany, Latvia, Lithuania, Netherlands, Poland, Slovakia, Spain, and Sweden). For the remaining Member States, this information has been collected from the OELs 3 report on OEL and STEL deriving systems from 2018 (Kalberlah and BierWisch, 2018) and the GESTIS database[81]. It has not been investigated whether the OELs have changed status in some Member States in recent years.

Table 16-14 Current OELs and STELs in EU Member States and selected non-EU countries for cobalt and inorganic cobalt compounds

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
EU countries				
Austria [1,2,3]	100 (I) *	Cobalt and cobalt alloys, cobalt oxide, cobalt sulphate and cobalt sulphide - TRK value[#], Carc, Srd, Sk A value of 0.5 for certain processes	400 (I) *	- TRK value[#], Carc, Srd, Sk
Belgium [1,2,4]	20 (I, V) **	Cobalt metal (dust and fume) - Carc	-	
Belgium [4]	5 (R) **	Hardmetal of cobalt and tungsten carbide, as Co	-	
Bulgaria [5]	100 **	Cobalt and inorganic compounds	-	
Croatia [6]	100 **	Cobalt and its compounds - Srd	-	
Cyprus [7]	100 **	Metal dust and fumes, total dust	-	
Czechia [8]	50 (R) *	Cobalt and its compounds - Carc, Repro, S	0.1 (R) *	- Carc, Repro, S
Denmark [1,2,9]	10 **	Cobalt, powder, dust, smoke, and inorganic compounds Carc	20 **	- powder, dust, and smoke, Carc
Estonia [10]	50 *	Cobalt and its inorganics compounds - S	-	
Finland [1,2,11]	20 (I) ^^	Cobalt and its inorganics compounds	-	
France [2,12]	2.5 ^	Cobalt compounds, excluding hardmetals Recommendation derived by ANSES	12.5 ^	- recommendation derived by ANSES

[81] https://www.dguv.de/ifa/gestis/index-2.jsp

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
Germany [1,2,13]	4 (R) § * 0.2 (R) $	Cobalt and cobalt compounds classified as Carc 1A and 1B	40 (R) § *	- Cobalt compounds classified as Carc 1A and 1B, 15 min average value
Greece [14]	100 *	Cobalt and its compounds	-	
Hungary [1,2,15]	20 15 *	Cobalt and its inorganic compounds, S [15] A value of 0.1 mg/m³ applies for cobalt and its compounds [1,2]	400 *	- Cobalt and its compounds [1,2]
Ireland [1,2,16]	20 ^	Cobalt and its compounds, S	-	
Italy [17]	-		-	
Latvia [1,2,18]	500 **	- Cobalt, cobalt (II) and (III) oxide	-	
Lithuania [19]	50 **	Cobalt and its inorganic compounds - Carc, S	-	
Luxembourg [20]	-		-	
Malta [21]	-		-	
Netherlands [1,2,22]	20 (D, F) **	Cobalt (dust and smoke)	-	
Poland [1,2,23]	20 **	Cobalt and its inorganic compounds	-	
Portugal [24]	-		-	
Romania [1,2,25]	50 *	Cobalt, cobalt oxide,	100 *	- Cobalt, 15 min average value
Slovakia [26]	50 **	Cobalt and its compounds, total dust - S	-	
Slovenia [27]	-		-	
Spain [1,2,28]	20 (I) ^^	Cobalt and inorganic cobalt compounds - S, Carc (cobalt and specific compounds)	-	
Sweden [1,2,29]	20 (I) **	Cobalt and its inorganic compounds - Carc, S, Sk	-	
European Union	-		-	
RAC [2]	1 (I) 0.5 (R)	Cobalt and its inorganic compounds - Srd	-	
Candidate countries				
Albania [45]	-		-	
Bosnia and Herzegovina [46]	-		-	
Georgia [47]	-	- S	-	
Moldova [48] [49]	50 *	Cobalt (oxide of cobalt) - Carc, S (Cobalt in urine 15 µg/l Sampling time: at the end of the work shift or work week)	100*	- S
Montenegro [50]	-		-	

Country	OEL (µg/m³)	Specification of OEL	STEL (µg/m³)	Specification of STEL
North Macedonia [51]	500 (I) 100 (I)	Cobalt (metal, cobalt oxide and cobalt sulfide) - obtaining powder from coal catalysts, carbide substrates and and powder, compaction and mechanical treatment of magnets (prep unsintered pieces) - Others	-	
Serbia [52]	-		-	
Turkey [40]	-		-	
Ukraine [53]	-		-	
Other countries				
Australia [1,30]	50 (D, F) ***	- S	-	
Brazil [31]	-		-	
Canada, Ontario [32]	-		-	
Canada, Québec[1,33]	20 ***	- Carc, S	-	
China [1]	50%		100%	- 15 min average value
India [34]	-		-	
Japan, MHLW [1,35]	20 ***		-	
Japan, JOSH [1,36]	50 ^^^	- Carc, Srd	-	
Norway [1,2, 37]	20 (T)& ^^	- Cobalt and its inorganic compounds, except Co(II)	-	
Russia [38]	4% 1%	- Cobalt, acceptable risk under daily exposure (at least 24), Sk - Cobalt, acceptable risk under chronic exposure (at least 1 year), Sk	-	
South Korea [1]	20%		-	
Switzerland [1,2, 39]	50 (I) *	- Cobalt and its compounds, Carc, Repro, S, Sk	-	
United Kingdom [1,2,41]	100 *	- Cobalt and its compounds, Carc (only for cobalt dichloride and sulphate), S	-	
USA, ACGIH [42]	20 (I) ^	- Carc, Srd	-	
USA, NIOSH [1,43,$$]	50 (D, F) ^	- Cobalt	-	
USA, OSHA [1,2,44]	100 (D, F) *	- Cobalt	-	

Notes:
** Binding value according to country-specific source*
*** Binding value according to reply of member state authority on questionnaire*
**** Binding value according to the Final report for OEL/STEL deriving systems from 2018 (Available at: https://bit.ly/3PKDhbS, accessed on 05.07.2023). Status was not checked since 2018.*
^ Indicative value according to country-specific source
^^ Indicative value according to reply of member state authority on questionnaire
^^^ Indicative value according to the Final report for OEL/STEL deriving systems from 2018

(Available at: https://bit.ly/3PKDhbS , accessed on 05.07.2023). Status was not checked since 2018.
% According to (country-specific) source unclear if value is binding or indicative
& Information according to reply of member state authority on questionnaire

(T) Total dust
ANSES = French Agency for Food, Environmental and Occupational Health & Safety
RAC = Committee for Risk Assessment
MHLW = Ministry of Health, Labour and Welfare
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
TRK value= Technical Guidance Concentrations ('Technische Richtkonzentrationen') in Austria
(I) = inhalable fraction/aerosol
(R) = respirable fraction/aerosol
(V) = vapour
(D) = dust
(F) = fume
Carc = notation for carcinogenicity. Where a more detailed notation for carcinogenicity was given, the following notations were reported:
Repro = notation for reproductive toxicity assigned
S = notation for sensitisation assigned. Where a more detailed notation for sensitisation was given, the following notation was reported:
Srd = respiratory and skin/dermal sensitisation
Sk = skin notation assigned or danger of skin absorption
- no value available
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk
$$ For NIOSH recommended exposure limits (RELs), 'TWA' indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.'; Online: https://www.cdc.gov/niosh/npg/pgintrod.html, assessed December 2022
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16.7 Annex G - Consistency and synergies of establishing OELs under CMRD

Cobalt and a number of inorganic cobalt compounds are today within the scope of the CMRD, although no OEL has been established, as they meet the criteria for classification as category 1A or 1B carcinogen, mutagen or reproductive toxicant.

The substances within the scope of the study are subject to the requirements for registrations under REACH (Regulation (EC) No 1272/2008). For some intermediate uses, the use is further described in section 3.9.

Restrictions. None of the substances within the scope of this study are subject to restrictions under REACH. For five cobalt salts, a restriction proposal was prepared by ECHA (European Chemicals Agency) in 2018 (ECHA 2018a), but the proposal has been withdrawn by Commission Decision of 8th April 2022 on the termination of the restrictions process on cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) under REACH (C(2022) 2137 final).

A number of arsenic, cadmium, nickel, lead, and inorganic ammonium substances subject to restrictions contain cobalt, but none of the substances are registered and consequently out of the scope of this study. The relevant entries in REACH Annex XVII are as follows: Arsenic compounds (entry 19), cadmium and its compounds (entry 23), nickel and its compounds (entry 27), lead and its compounds (entry 63), and inorganic ammonium salts (entry 65).

Authorisation. None of the substances within the scope of this study are subject to authorisation under of REACH.

Chemical Safety Reports (CSRs). As part of the registration processes for the substances within the scope of the study, companies have prepared CSRs which among others include an exposure assessment and risk characterisation that address all the identified hazards of the substance. The CSRs include for all Worker Contributing Scenarios (WCS) a description of the operational conditions and the risk management measures. This CSRs provide key information for the risk assessments to be undertaken in accordance with the requirements of the CMRD.

Classification and Labelling Inventory (C&L Inventory). This database contains classification and labelling information on notified and registered substances received from manufacturers and importers (self-classification) as well as harmonised classifications as listed in the CLP. Companies have provided this information in their C&L notifications or registration dossiers. Where there is a difference in the classification and labelling of the substance between potential registrants, the obligatory Substance Information Exchange Forums (SIEF) shall agree on the classification and labelling. For substances without harmonised classification, the self-classifications are used as basis for the human health hazard assessment undertaken as part of the REACH registration process. Self-classifications of substances within the scope of the study are listed in Table 1-3.

Risk management option analysis. A risk management option analysis (RMOA) for five cobalt salts from 2017[82] concluded that follow-up regulatory action at EU level was needed and that a restriction would be the most appropriate for the five substances. The restriction process

[82] Accessed Dec. 2022 at https://www.echa.europa.eu/documents/10162/60163f64-8961-9f0a-c8b4-e2f3837d8398

has later been terminated as described above and replaced by the policy option of establishing an OEL. For cobalt metal and other inorganic cobalt compounds no RMOA has been developed.

16.8 Annex H – Selection procedure of relevant compounds in substance groups

Inorganic cobalt substances[83] within the scope of this study are cobalt and inorganic cobalt compounds within the scope of the CMRD and registered under REACH.

Substances within the scope of the directive are substances that meet the criteria for classification as category 1A or 1B carcinogen, mutagen or reproductive toxicant as set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (the CLP). Substances that meet the criteria may either have a harmonised classification and listed in Annex VI to the CLP or they may have been classified by the manufacturers' or importers' self-classification.

Harmonised classification

Harmonised classification under the CLP has been established for cobalt and 7 inorganic cobalt compounds. Cobalt and five of the compounds are classified carcinogenic (Carc. 1B or 1A); of these, cobalt and four cobalt compounds are further classified reprotoxic (Repr. 1B). Of the substances within the scope, the production/import of cobalt lithium nickel oxide (EC number 442-750-5) has ceased as described in section 3.2.1.

Two of the substances with harmonised classification (cobalt oxide and cobalt sulphide) are not classified carcinogen, mutagen and/or reprotoxic substance according to the harmonised classification, but for cobalt oxide, the self-classifications in the C&L Inventory classify the substances as Carc. 1B and Repr. 1B (see Table 1-3).

According to the ECHA Scientific Report (now Annex 1 to the RAC opinion), Annex VI to the CLP lists eight entries for the classification of cobalt and its inorganic compounds for registered substances. Of these, six substances are classified carcinogenic.

Please note that the organic compound cobalt di(acetate) with a harmonised classification as carcinogenic and included in the restriction proposal for five cobalt salts (ECHA, 2018) is not within the scope of the current study.

Table 16-15 Harmonised classification of cobalt and inorganic cobalt compounds according to Annex VI to the CLP

EC No	Chemical name	CAS No	Hazard class and category	Hazard statement code
208-169-4	Cobalt carbonate	513-79-1	**Carc. 1B** Muta. 2 **Repr. 1B** Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F *** H334 H317 H400 H41
215-154-6	Cobalt oxide	1307-96-6	Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410
215-273-3	Cobalt sulphide	1317-42-6	Skin Sens. 1 Aquatic Acute 1	H317 H400

[83] In this study, the term 'substances' is used in accordance with the use of the term under REACH. Cobalt substances includes both cobalt metal, cobalt compounds and complex reaction masses, matte, residues, etc. containing cobalt. Cobalt compounds are a subset of cobalt substances.

EC No	Chemical name	CAS No	Hazard class and category	Hazard statement code
			Aquatic Chronic 1	H410
231-158-0	Cobalt	7440-48-4	**Carc. 1B** Muta. 2 **Repr. 1B** Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4	H350 H341 H360F H334 H317 H413
231-589-4	Cobalt dichloride	7646-79-9	**Carc. 1B** Muta. 2 **Repr. 1B** Acute Tox. 4 * Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F *** H302 H334 H317 H400 H410
233-334-2	Cobalt sulphate	10124-43-3	**Carc. 1B** Muta. 2 **Repr. 1B** Acute Tox. 4 * Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic	H350i H341 H360F *** H302 H334 H317 H400 H41
233-402-1	Cobalt dinitrate	10141-05-6	**Carc. 1B** Muta. 2 **Repr. 1B** Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360F *** H334 H317 H400 H410
442-750-5	Cobalt lithium nickel oxide	-	**Carc. 1A** Acute Tox. 2 * STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H330 H372 ** H317 H400 H410

** The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard statement not specifying the route of exposure as the necessary information is not available. *** For fertility and developmental effects under Directive 67/548/EEC, the classifications have been translated only for those effects classified under the Directive. These hazard statements are indicated by the reference in Table 3 of Annex VI to the CLP.

Self-classification

A substance or mixture which meets the criteria for classification as a carcinogen, mutagen and/or reprotoxic substance (category 1A or 1B) according to the criteria described in Annex 1 to CLP Regulation does not necessarily have a harmonised classification.

Self-classified substances that meet the criteria would also be within the scope of the CMRD. The table below lists six registered substances classified Carc. 1B, Repr. 1B or both as indicated in the manufacturers' or importers' self-classification in the C&L inventory at ECHA's website. In addition, the Cobalt REACH Consortium self-classify cobalt monoxide as Carc. 1B and Repr. 1B, but this self-classification does not appear from the C&L inventory as the substances have a harmonised classification (see the table above) and for substances with a harmonised classification only this classification is listed in the C&L inventory.

In total, cobalt and 15 inorganic cobalt compounds have a classification that makes the substances within the scope of the CMRD.

For one of the substances, cobalt titanite green spinel (269-047-4), the Inorganic Pigment (IP) Consortium notes in its response to the stakeholder consultation to the ECHA (2022) Scientific Report that for this substance, several classifications notified to the C&L inventory include a classification as Carcinogen 1A, affected by impurities. This classification is exclusively due to the presence, in certain compositions of this substance, of nickel titanium trioxide as impurity and is not related to the content of cobalt in this substance. For the current study it will be assumed that inorganic cobalt compound classified carcinogenic will be within the scope of the OEL irrespective of the reason for the classification as carcinogenic.

Table 16-16 Self-classification of cobalt and inorganic cobalt compounds according to the C&L inventory for Hazard class and category of relevance for the CMRD

EC No	Substance	CAS No	Hazard class and category of relevance for the CMRD
215-154-6	Cobalt oxide *	1307-96-6	Carc. 1B Repr. 1B
235-362-0	Cobalt lithium dioxide	12190-79-3	Repr. 1B
237-358-4	Cobalt molybdate	13762-14-6	Carc. 1B Repr. 1B
244-166-4	Cobalt dihydroxide	21041-93-0	Carc. 1B Repr. 1B
269-047-4	Cobalt titanite green spinel	68186-85-6	Carc 1A **
269-093-5	Olivine, cobalt silicate blue	68187-40-6	Repr. 1B
480-390-0	Cobalt lithium manganese nickel oxide	NA	Carc. 1A Repr. 1B
700-042-6	Aluminium cobalt lithium nickel oxide	177997-13-6	Carc. 1A Repr. 1B
701-439-7	Reaction mass of cobalt olivine and crystalline silicon dioxide	68187-40-6	Repr. 1B

* As indicated by the Cobalt REACH Consortium's self-classification. The C&L inventory lists the harmonised classification only.
** Classification according to more than 50% of companies with joint entries in the C&L inventory. For all entries, about 10% classify the substance Carc 1A.

16.9 Annex I - Costs by sector, size and policy option

This Annex includes tables with costs by sector, size and policy options as supplement to the costs estimates in Chapter 7. The costs are calculated for the 40-years assessment period.

Table 16-17 Aggregated costs of PV adjustment, monitoring and administrative burden discounted over 40 years, by size of enterprise, by sector, by policy options

Sector		Total compliance costs , € million			
		Small	Medium	Large	Total
1 / 0.5 µg Co/m³					
C10.91	Manufacture, feeds	1.3	1.7	1.2	4.1
C19.20	Petrochemical, catalyst	-	5.6	36.5	42.1
C20.12	Manufacture of dyes and pigments	-	21.3	97.1	118.4
C20.13-14	Manufacture of basic chemicals	2.5	51.8	39.1	93.5
C20.30	Manufacture of paints and inks	1.3	11.0	3.8	16.2
C20.59	Catalysts + Formulation	2.4	31.3	32.4	66.2
C21.20	Pharmaceuticals	-	-	1.1	1.1
C22.11	Production of tyres	-	-	4.9	4.9
C23.1	Glass	1.6	15.3	22.5	39.4
C23.4	Ceramics	26.4	112.7	171.5	310.6
C23.7	Cutting stone	30.9	6.2	9.3	46.5
C24.10	Steel	0.5	39.1	17.0	56.6
C24.45	Manufacture of cobalt and cobalt alloys	-	-	28.1	28.1
C25.5	Powder metallurgy	2.0	61.2	13.9	77.1
C25.61	Surface treatment of metals	33.7	181.7	134.4	349.8
C25.62	Machining	607.9	741.3	740.9	2,090.1
C25.73	Manufacture of tools	561.7	2,442.3	487.9	3,491.9
C25.99	Manufacture of other fabricated metal products n.e.c.	14.6	75.1	31.3	121.0
C26.1	Production of electronic components and boards	53.2	291.7	137.2	482.1
C26.51	Humidity indicator cards	0.0	0.0	0.1	0.1
C27.2	Batteries	-	4.1	7.9	12.0
C28.11	Engines and turbines	90.3	210.1	154.6	455.0
C29.10-30	Automotive, parts	20.7	59.8	777.0	857.6
C30.30	Air and spacecraft	28.4	32.6	139.2	200.2
C32.50	Medical and dental devices	38.3	324.1	283.0	645.4
E38.32	Metal recovery	-	42.7	48.2	90.9
Biogas		4.8	6.0	4.9	15.7

Sector		Total compliance costs , € million			
		Small	Medium	Large	Total
Welding		5.3	27.1	19.5	51.8
	Total	**1,527.8**	**4,796.3**	**3,448.0**	**9,772.1**
5 / 1.25 µg Co/m³					
C10.91	Manufacture, feeds	0.3	0.6	0.2	1.1
C19.20	Petrochemical, catalyst	-	1.0	5.1	6.1
C20.12	Manufacture of dyes and pigments	-	5.6	29.0	34.6
C20.13	Manufacture of basic inorganic chemicals	0.5	10.5	7.9	18.9
C20.30	Manufacture of paints and inks	0.2	1.9	0.8	2.9
C20.59	Catalysts + Formulation	0.4	5.2	5.9	11.5
C21.20	Pharmaceuticals	-	-	0.3	0.3
C22.11	Production of tyres	-	-	0.4	0.4
C23.1	Glass	0.3	2.3	4.1	6.7
C23.4	Ceramics	8.5	29.8	57.6	95.9
C23.7	Cutting stone	5.6	1.3	1.7	8.5
C24.10	Steel	0.1	3.8	1.8	5.7
C24.45	Manufacture of cobalt and cobalt alloys	-	-	4.2	4.2
C25.5	Powder metallurgy	0.3	7.0	2.1	9.3
C25.61	Surface treatment of metals	4.9	23.3	21.9	50.2
C25.62	Machining	261.1	219.0	180.0	660.1
C25.73	Manufacture of tools	71.1	264.5	62.9	398.5
C25.99	Manufacture of other fabricated metal products n.e.c.	3.8	17.8	8.7	30.4
C26.1	Production of electronic components and boards	12.0	58.5	29.1	99.6
C26.51	Humidity indicator cards	0.0	0.0	0.0	0.1
C27.2	Batteries	-	0.3	0.9	1.2
C28.11	Engines and turbines	22.1	51.3	38.6	112.1
C29.10-30	Automotive	2.9	7.0	79.6	89.5
C30.30	Air and spacecraft	7.6	8.6	33.8	50.1
C32.50	Medical and dental devices	15.8	81.7	89.6	187.1
E38.32	Metal recovery	-	2.7	4.4	7.1
	Biogas	3.0	5.2	4.4	12.6
	Welding	3.2	13.5	11.0	27.6
	Total	**423.7**	**822.3**	**686.5**	**1,932.5**
10 / 2.5 µg Co/m³					

Sector		Total compliance costs , € million			
		Small	Medium	Large	Total
C10.91	Manufacture, feeds	0.2	0.4	0.2	0.8
C19.20	Petrochemical, catalyst	-	0.6	1.8	2.4
C20.12	Manufacture of dyes and pigments	-	2.3	12.4	14.7
C20.13	Manufacture of basic inorganic chemicals	0.0	0.4	0.4	0.9
C20.30	Manufacture of paints and inks	0.1	0.9	0.3	1.4
C20.59	Catalysts + Formulation	0.4	4.8	4.6	9.8
C21.20	Pharmaceuticals	-	-	0.2	0.2
C22.11	Production of tyres	-	-	0.1	0.1
C23.1	Glass	0.1	0.4	0.8	1.3
C23.4	Ceramics	3.6	12.7	25.6	41.9
C23.7	Cutting stone	2.3	0.6	0.8	3.7
C24.10	Steel	0.0	1.9	0.8	2.7
C24.45	Manufacture of cobalt and cobalt alloys	-	-	1.8	1.8
C25.5	Powder metallurgy	0.1	3.3	0.9	4.3
C25.61	Surface treatment of metals	0.8	2.9	4.3	8.0
C25.62	Machining	63.2	56.6	43.1	162.9
C25.73	Manufacture of tools	32.3	128.7	28.7	189.7
C25.99	Manufacture of other fabricated metal products n.e.c.	1.7	7.7	4.0	13.4
C26.1	Production of electronic components and boards	5.3	24.7	12.5	42.5
C26.51	Humidity indicator cards	0.0	0.0	0.0	0.0
C27.2	Batteries	-	0.1	0.2	0.4
C28.11	Engines and turbines	4.5	10.1	8.6	23.2
C29.10-30	Automotive	0.3	0.5	0.8	1.7
C30.30	Air and spacecraft	2.3	2.5	8.1	12.9
C32.50	Medical and dental devices	7.1	37.2	39.3	83.6
E38.32	Metal recovery	-	0.2	0.7	0.9
	Biogas	2.1	4.1	3.6	9.9
	Welding	1.3	3.2	4.4	8.8
	Total	**127.9**	**306.8**	**209.2**	**643.9**
20 / 4.2 µg Co/m³					
C10.91	Manufacture, feeds	0.2	0.3	0.1	0.7
C19.20	Petrochemical, catalyst	-	0.4	1.0	1.4

Sector		Total compliance costs , € million			
		Small	Medium	Large	Total
C20.12	Manufacture of dyes and pigments	-	1.1	5.7	6.8
C20.13	Manufacture of basic inorganic chemicals	0.0	0.1	0.2	0.3
C20.30	Manufacture of paints and inks	0.0	0.1	0.1	0.2
C20.59	Catalysts + Formulation	0.0	0.4	1.3	1.7
C21.20	Pharmaceuticals	-	-	0.2	0.2
C22.11	Production of tyres	-	-	0.1	0.1
C23.1	Glass	0.0	0.2	0.2	0.4
C23.4	Ceramics	1.7	6.0	11.3	19.0
C23.7	Cutting stone	2.2	0.5	0.7	3.4
C24.10	Steel	0.0	0.1	0.1	0.2
C24.45	Manufacture of cobalt and cobalt alloys	-	-	0.5	0.5
C25.5	Powder metallurgy	0.0	0.5	0.3	0.8
C25.61	Surface treatment of metals	0.8	2.5	4.0	7.3
C25.62	Machining	12.8	15.9	11.8	40.5
C25.73	Manufacture of tools	5.8	8.6	5.4	19.8
C25.99	Manufacture of other fabricated metal products n.e.c.	0.7	3.5	1.6	5.9
C26.1	Production of electronic components and boards	2.4	11.7	5.8	19.9
C26.51	Humidity indicator cards	0.0	0.0	0.0	0.0
C27.2	Batteries	-	0.1	0.2	0.3
C28.11	Engines and turbines	0.3	0.6	0.8	1.6
C29.10-30	Automotive	0.3	0.4	0.8	1.5
C30.30	Air and spacecraft	0.3	0.3	0.6	1.2
C32.50	Medical and dental devices	2.7	14.4	14.8	31.9
E38.32	Metal recovery	-	0.1	0.2	0.3
	Biogas	1.8	2.8	2.8	7.3
	Welding	0.5	1.3	1.8	3.6
	Total	**32.6**	**72.0**	**72.2**	**176.8**

The next table presents the total additional costs of monitoring. It is following by a table presenting the total administrative costs. Please note that costs are here in € 1000 and not € million.

Table 16-18 Estimated costs by sector, by size and policy option of additional air monitoring in € 1000 over 40 years

Sector		Total costs of additional monitoring, € 1000			
		Small	Medium	Large	Total
1 / 0.5 µg Co/m³					
C10.91	Manufacture, feeds	404	561	203	1,168
C19.20	Petrochemical, catalyst	-	1,108	1,947	3,055
C20.12	Manufacture of dyes and pigments	-	108	522	631
C20.13-14	Manufacture of basic chemicals	24	297	332	654
C20.30	Manufacture of paints and inks	12	81	47	141
C20.59	Catalysts + Formulation	21	337	574	932
C21.20	Pharmaceuticals	-	-	270	270
C22.11	Production of tyres	-	-	101	101
C23.1	Glass	56	405	380	841
C23.4	Ceramics	701	2,837	2,137	5,676
C23.7	Cutting stone	1,943	540	475	2,958
C24.10	Steel	4	108	47	160
C24.45	Manufacture of cobalt and cobalt alloys	-	-	285	285
C25.5	Powder metallurgy	22	459	142	624
C25.61	Surface treatment of metals	659	2,540	2,232	5,431
C25.62	Machining	9,615	24,320	14,248	48,183
C25.73	Manufacture of tools	4,054	6,215	2,185	12,454
C25.99	Manufacture of other fabricated metal products n.e.c.	226	811	380	1,417
C26.1	Production of electronic components and boards	377	1,351	617	2,345
C26.51	Humidity indicator cards	5	19	34	57
C27.2	Batteries	-	150	270	420
C28.11	Engines and turbines	210	459	380	1,050
C29.10-30	Automotive, parts	216	351	427	995
C30.30	Air and spacecraft	226	270	332	829
C32.50	Medical and dental devices	601	4,053	2,375	7,029
E38.32	Metal recovery	-	189	380	569
Biogas		4,127	5,216	4,190	13,533
Welding		61	150	101	312
	Total	**23,565**	**52,936**	**35,618**	**112,119**
5 / 1.25 µg Co/m³					
C10.91	Manufacture, feeds	257	488	182	927

Sector		Total costs of additional monitoring, € 1000			
		Small	Medium	Large	Total
C19.20	Petrochemical, catalyst	-	667	1,244	1,911
C20.12	Manufacture of dyes and pigments	-	93	462	555
C20.13	Manufacture of basic inorganic chemicals	12	179	212	403
C20.30	Manufacture of paints and inks	6	49	30	85
C20.59	Catalysts + Formulation	14	293	516	822
C21.20	Pharmaceuticals	-	-	243	243
C22.11	Production of tyres	-	-	91	91
C23.1	Glass	27	244	243	514
C23.4	Ceramics	440	2,446	1,891	4,777
C23.7	Cutting stone	943	325	303	1,572
C24.10	Steel	3	93	42	138
C24.45	Manufacture of cobalt and cobalt alloys	-	-	252	252
C25.5	Powder metallurgy	14	396	126	536
C25.61	Surface treatment of metals	320	1,529	1,426	3,275
C25.62	Machining	6,028	20,969	12,608	39,604
C25.73	Manufacture of tools	2,542	5,359	1,933	9,834
C25.99	Manufacture of other fabricated metal products n.e.c.	142	699	336	1,177
C26.1	Production of electronic components and boards	236	1,165	546	1,947
C26.51	Humidity indicator cards	3	16	30	50
C27.2	Batteries	-	130	243	373
C28.11	Engines and turbines	132	396	336	864
C29.10-30	Automotive	105	211	273	590
C30.30	Air and spacecraft	142	233	294	669
C32.50	Medical and dental devices	377	3,495	2,101	5,973
E38.32	Metal recovery	-	163	336	499
	Biogas	2,622	4,538	3,763	10,922
	Welding	39	130	91	260
	Total	**14,401**	**44,305**	**30,156**	**88,862**
10 / 2.5 µg Co/m³					
C10.91	Manufacture, feeds	183	389	154	726
C19.20	Petrochemical, catalyst	-	532	1,053	1,585

Sector		Total costs of additional monitoring, € 1000			
		Small	Medium	Large	Total
C20.12	Manufacture of dyes and pigments	-	52	283	334
C20.13	Manufacture of basic inorganic chemicals	8	143	180	331
C20.30	Manufacture of paints and inks	4	39	26	69
C20.59	Catalysts + Formu-lation	10	234	437	680
C21.20	Pharmaceuticals	-	-	205	205
C22.11	Production of tyres	-	-	77	77
C23.1	Glass	19	195	205	419
C23.4	Ceramics	243	1,362	1,156	2,761
C23.7	Cutting stone	672	259	257	1,189
C24.10	Steel	1	52	26	79
C24.45	Manufacture of co-balt and cobalt al-loys	-	-	154	154
C25.5	Powder metallurgy	8	221	77	305
C25.61	Surface treatment of metals	228	1,220	1,207	2,655
C25.62	Machining	3,327	11,676	7,705	22,708
C25.73	Manufacture of tools	1,403	2,984	1,181	5,568
C25.99	Manufacture of other fabricated metal products n.e.c.	78	389	205	673
C26.1	Production of elec-tronic components and boards	130	649	334	1,113
C26.51	Humidity indicator cards	2	13	26	41
C27.2	Batteries	-	104	205	309
C28.11	Engines and tur-bines	73	221	205	499
C29.10-30	Automotive	75	169	231	475
C30.30	Air and spacecraft	78	130	180	388
C32.50	Medical and dental devices	265	2,739	1,731	4,735
E38.32	Metal recovery	-	91	205	296
	Biogas	1,869	3,620	3,185	8,674
	Welding	28	104	77	209
	Total	**8,704**	**27,584**	**20,968**	**57,256**
20 / 4.2 µg Co/m³					
C10.91	Manufacture, feeds	169	295	127	591
C19.20	Petrochemical, cat-alyst	-	399	860	1,258
C20.12	Manufacture of dyes and pigments	-	36	217	253

Sector		Total costs of additional monitoring, € 1000			
		Small	Medium	Large	Total
C20.13	Manufacture of basic inorganic chemicals	7	99	139	244
C20.30	Manufacture of paints and inks	4	28	20	52
C20.59	Catalysts + Formu-lation	8	163	338	509
C21.20	Pharmaceuticals	-	-	151	151
C22.11	Production of tyres	-	-	67	67
C23.1	Glass	18	147	168	333
C23.4	Ceramics	229	1,053	965	2,248
C23.7	Cutting stone	588	187	204	980
C24.10	Steel	1	37	20	59
C24.45	Manufacture of co-balt and cobalt al-loys	-	-	81	81
C25.5	Powder metallurgy	7	166	63	235
C25.61	Surface treatment of metals	204	899	973	2,077
C25.62	Machining	2,948	8,532	6,173	17,652
C25.73	Manufacture of tools	1,126	2,001	890	4,017
C25.99	Manufacture of other fabricated metal products n.e.c.	74	301	172	547
C26.1	Production of elec-tronic components and boards	107	443	255	805
C26.51	Humidity indicator cards	0	3	10	14
C27.2	Batteries	-	70	156	227
C28.11	Engines and tur-bines	64	160	164	388
C29.10-30	Automotive	66	122	184	373
C30.30	Air and spacecraft	67	92	140	299
C32.50	Medical and dental devices	177	1,371	1,002	2,551
E38.32	Metal recovery	-	69	170	239
	Biogas	1,568	2,522	2,466	6,557
	Welding	23	72	60	155
	Total	**7,455**	**19,269**	**16,236**	**42,961**

Table 16-19 Total estimated costs of administrative burden to companies of additional air monitoring by sector, by size and policy option in € 1,000 over 40 years

Sector		Administrative burden to companies, € 1,000			
		Small	Medium	Large	Total
1 / 0.5 µg Co/m³					
C10.91	Manufacture, feeds	63	82	34	180

Sector		Administrative burden to companies, € 1,000			
		Small	Medium	Large	Total
C19.20	Petrochemical, catalyst	-	112	236	348
C20.12	Manufacture of dyes and pigments	-	11	63	74
C20.13	Manufacture of basic inorganic chemicals	3	30	40	73
C20.30	Manufacture of paints and inks	1	8	6	15
C20.59	Catalysts + Formulation	3	49	98	150
C21.20	Pharmaceuticals	-	-	46	46
C22.11	Production of tyres	-	-	17	17
C23.1	Glass	7	41	46	94
C23.4	Ceramics	84	287	259	630
C23.7	Cutting stone	232	55	57	344
C24.10	Steel	0	11	6	17
C24.45	Manufacture of cobalt and cobalt alloys	-	-	34	34
C25.5	Powder metallurgy	3	47	17	66
C25.61	Surface treatment of metals	79	257	270	606
C25.62	Machining	1,149	2,462	1,724	5,335
C25.73	Manufacture of tools	485	629	264	1,378
C25.99	Manufacture of other fabricated metal products n.e.c.	27	82	46	155
C26.1	Production of electronic components and boards	45	137	75	256
C26.51	Humidity indicator cards	1	3	6	9
C27.2	Batteries	-	22	46	68
C28.11	Engines and turbines	25	47	46	118
C29.10-30	Automotive	26	36	52	113
C30.30	Air and spacecraft	27	27	40	95
C32.50	Medical and dental devices	72	410	287	769
E38.32	Metal recovery	-	19	46	65
	Biogas	646	763	712	2,121
	Welding	10	22	17	49
	Total	**2,987**	**5,649**	**4,591**	**13,226**
5 / 1.25 µg Co/m³					
C10.91	Manufacture, feeds	38	69	29	137
C19.20	Petrochemical, catalyst	-	95	201	295

Sector		Administrative burden to companies, € 1,000			
		Small	Medium	Large	Total
C20.12	Manufacture of dyes and pigments	-	9	54	63
C20.13	Manufacture of basic inorganic chemicals	2	25	34	61
C20.30	Manufacture of paints and inks	1	7	5	13
C20.59	Catalysts + Formu-lation	2	42	83	127
C21.20	Pharmaceuticals	-	-	39	39
C22.11	Production of tyres	-	-	15	15
C23.1	Glass	4	35	39	78
C23.4	Ceramics	50	243	220	513
C23.7	Cutting stone	139	46	49	235
C24.10	Steel	0	9	5	14
C24.45	Manufacture of co-balt and cobalt al-loys	-	-	29	29
C25.5	Powder metallurgy	2	39	15	56
C25.61	Surface treatment of metals	47	217	230	495
C25.62	Machining	689	2,080	1,469	4,238
C25.73	Manufacture of tools	291	532	225	1,047
C25.99	Manufacture of other fabricated metal products n.e.c.	16	69	39	125
C26.1	Production of elec-tronic components and boards	27	116	64	206
C26.51	Humidity indicator cards	0	2	5	8
C27.2	Batteries	-	18	39	58
C28.11	Engines and tur-bines	15	39	39	94
C29.10-30	Automotive	16	30	44	90
C30.30	Air and spacecraft	16	23	34	74
C32.50	Medical and dental devices	43	347	245	635
E38.32	Metal recovery	-	16	39	55
	Biogas	387	645	607	1,639
	Welding	6	18	15	39
	Total	**1,792**	**4,772**	**3,912**	**10,476**
10 / 2.5 µg Co/m³					
C10.91	Manufacture, feeds	25	52	22	100
C19.20	Petrochemical, cat-alyst	-	71	154	225
C20.12	Manufacture of dyes and pigments	-	7	41	48

Sector		Administrative burden to companies, € 1,000			
		Small	Medium	Large	Total
C20.13	Manufacture of basic inorganic chemicals	1	19	26	46
C20.30	Manufacture of paints and inks	1	5	4	10
C20.59	Catalysts + Formulation	1	31	64	96
C21.20	Pharmaceuticals	-	-	30	30
C22.11	Production of tyres	-	-	11	11
C23.1	Glass	3	26	30	59
C23.4	Ceramics	34	182	169	384
C23.7	Cutting stone	93	35	37	165
C24.10	Steel	0	7	4	11
C24.45	Manufacture of cobalt and cobalt alloys	-	-	22	22
C25.5	Powder metallurgy	1	30	11	42
C25.61	Surface treatment of metals	32	163	176	371
C25.62	Machining	460	1,563	1,124	3,147
C25.73	Manufacture of tools	194	399	172	766
C25.99	Manufacture of other fabricated metal products n.e.c.	11	52	30	93
C26.1	Production of electronic components and boards	18	87	49	154
C26.51	Humidity indicator cards	0	2	4	6
C27.2	Batteries	-	14	30	44
C28.11	Engines and turbines	10	30	30	70
C29.10-30	Automotive	10	23	34	67
C30.30	Air and spacecraft	11	17	26	54
C32.50	Medical and dental devices	29	260	187	477
E38.32	Metal recovery	-	12	30	42
	Biogas	258	484	465	1,207
	Welding	4	14	11	29
	Total	**1,195**	**3,586**	**2,994**	**7,774**
20 / 4.2 µg Co/m³					
C10.91	Manufacture, feeds	23	36	16	74
C19.20	Petrochemical, catalyst	-	48	106	154
C20.12	Manufacture of dyes and pigments	-	4	25	29
C20.13	Manufacture of basic inorganic chemicals	1	11	16	28

Sector		Administrative burden to companies, € 1,000			
		Small	Medium	Large	Total
C20.30	Manufacture of paints and inks	0	3	2	6
C20.59	Catalysts + Formu-lation	1	19	39	59
C21.20	Pharmaceuticals	-	-	17	17
C22.11	Production of tyres	-	-	9	9
C23.1	Glass	2	18	21	41
C23.4	Ceramics	31	128	122	281
C23.7	Cutting stone	78	22	24	125
C24.10	Steel	0	4	2	7
C24.45	Manufacture of co-balt and cobalt al-loys	-	-	4	4
C25.5	Powder metallurgy	1	20	8	29
C25.61	Surface treatment of metals	27	107	118	253
C25.62	Machining	395	1,014	746	2,155
C25.73	Manufacture of tools	146	228	101	475
C25.99	Manufacture of other fabricated metal products n.e.c.	10	37	22	69
C26.1	Production of elec-tronic components and boards	14	51	29	94
C26.51	Humidity indicator cards	-	-	-	-
C27.2	Batteries	-	8	18	26
C28.11	Engines and tur-bines	9	19	20	47
C29.10-30	Automotive	9	15	22	45
C30.30	Air and spacecraft	9	11	17	36
C32.50	Medical and dental devices	23	160	118	301
E38.32	Metal recovery	-	8	21	30
	Biogas	207	293	287	787
	Welding	3	8	7	18
	Total	**990**	**2,272**	**1,938**	**5,200**

16.10 Annex J - Specifically on tyres

Adhesion agents used in tyres and some other rubber products are organic cobalt compounds and consequently outside the scope of the current assessment. The European Tyre & Rubber Manufacturers Association (ETRMA), and a number of companies participating in a teleconference with the industry, have expressed concern that the sector may anyhow be impacted from the implementation of the OELs in the Member States. The rubber sector is included in the current assessment only for the companies that might use substances within the scope for in-house manufacture of the organic compounds; an activity assumed to take place based on reports provided by the Cobalt Institute.

The impact assessment prepared by eftec (2023) includes the sector in the broad use category 'Adhesion (inc. rubber adhesion agent)' but notes that most of the companies use only compounds outside the scope of the OEL. It was agreed with the sector that the present report should include an annex based on eftec (2023) to illustrate to what extent a possible inclusion of the sector would have significant impact on the overall assessment.

According to eftec (2023), the sector represents 1.3% of the baseline number of cases of ill health. The report does not indicate the contribution of the sector (or any other sector) to the total costs using the general assessment approach, but the sector is included in tables with costs by broad use derived from sector-specific inputs to the assessment. It is noted by eftec (2023) that the results of these sector-specific assessments are quite uncertain compared to the overall assessments. However in the absence of other data, the sector-specific cost estimates for the broad use category 'Adhesion (inc. rubber adhesion agent), which mainly consists of production of tyres, are shown in the table below together with the percentage of the total costs for all broad use areas. The contribution of the broad use area Adhesion (inc. rubber adhesion agent) ranges from 0.1 to 0.3%. The data clearly illustrate that a possible inclusion of production of tyres and other use of cobalt-containing rubber adhesion agents would not have a significant influence on the current impact assessment.

Table 16-20 Estimated costs for the broad use area 'Adhesion (inc. rubber adhesion agent)' and the costs for this broad use area as percentage of total costs for all use areas.

	Costs, PV € million Without PPE *	Percentage of total costs, average Without PPE **
30 µg/m^3	20-30	0.3%
20 µg/m^3	20-30	0.2%
10 µg/m^3	20-30	0.2%
1 µg/m^3	10-20	0.1%

** Data derived from tables with costs by broad use. The numbers are the same with RPE. **Data derived by comparing to data from table with totals for all broad uses (average of upper and lower bound).*
Source: eftec 2023, percentage calculated by the study team.

16.11 Annex K - Questionnaire

Questionnaire for companies: cobalt and inorganic cobalt compounds

Fields marked with * are mandatory.

Questionnaire for Companies: cobalt and inorganic cobalt compounds

This survey is part of a study 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**). Specifically, the study assesses the impacts of establishing new limit values for some substances or introducing a substance into Annex I.

The substances being considered are:

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

New OELs are proposed for the first 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. 'Skin sensitisation' and 'respiratory sensitisation' notations are also proposed for cobalt and inorganic cobalt compounds, and 'skin' notations are proposed for isoprene, PAHs and 1,4-dioxane.

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

This questionnaire is intended for all companies where exposure to **cobalt and inorganic cobalt compounds** takes place.

The study is being undertaken by 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) under a contract for the European Commission's Directorate-General for Employment, Social Affairs and Inclusion.

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 a **single facility.** If workers are exposed at multiple facilities, please complete the questionnaire several times or contact the study team.

It will take approximately 15–45 minutes to answer the questionnaire depending on data availability and detail.

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

This questionnaire is available in English, French, German, Italian, Polish and Spanish. However, you are welcome to answer the questions in an official language of the European Union of your choice. If you prefer to be interviewed in your language or if you have questions about the survey, please contact: OELs6@rpaltd.co.uk

Abbreviations used in the questionnaire:

8-hour TWA: 8-hour Time-Weighted Average, measured in parts per million (ppm) or milligrams per cubic metre (mg/m³). 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/m³) 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).*

CMRD: Carcinogens, Mutagens or Reprotoxic substances Directive

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).

PPE: Personal protective equipment

RMM: Risk management measure

RPE: Respiratory protective equipment

Registered cobalt substances within the scope of the CMRD are shown in the table below, along with their registered quantities.

In processes where both substances within the scope of the CMRD and other inorganic or organic cobalt compounds are used, it is assumed that the total concentration, measured as cobalt (Co), should be in compliance with the OEL.

Substance	EC number	CAS number	Registered quantities, full registration
Cobalt carbonate	208-169-4	513-79-1	1,000–10,000
Cobalt oxide	215-154-6	1307-96-6	1,000–10,000
Cobalt	231-158-0	7440-48-4	10,000–100,000
Cobalt dichloride	231-589-4	7646-79-9	1,000–10,000
Cobalt sulphate	233-334-2	10124-43-3	>100,000
Cobalt dinitrate	233-402-1	10141-05-6	1,000–10,000
Cobalt lithium dioxide	235-362-0	12190-79-3	10–1000
Cobalt molybdate	237-358-4	13762-14-6	10–1000
Cobalt dihydroxide	244-166-4	21041-93-0	>100,000
Cobalt titanite green spinel	269-047-4	68186-85-6	10–1000
Olivine, cobalt silicate blue	269-093-5	68187-40-6	1,000–10,000
Cobalt lithium nickel oxide	442-750-5	-	-
Aluminium cobalt lithium nickel oxide	700-042-6	177997-13-6	1,000–10,000
Reaction mass of cobalt olivine and crystalline silicon dioxide	701-439-7	68187-40-6	100–1,000
Cobalt lithium manganese nickel oxide	480-390-0	-	-

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A) About your company

A1) Please provide the following details about your company

* **Name of contact person**

* **Company**

* **Email address of contact person**

Telephone number of contact person

* **Country of facility**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovak Republic
- Slovenia
- Spain
- Sweden
- Other

If other, please specify

A2) Please define the sector in which your company is active (if possible, using a NACE code)

- C10.91 Manufacture of prepared feeds for farm animals
- C19.20 Manufacture of refined petroleum products
- C20.12 Manufacture of dyes and pigments

- C20.13 Manufacture of other inorganic basic chemicals
- C20.14 Manufacture of other organic basic chemicals
- C20.15 Manufacture of fertilisers and nitrogen compounds
- C20.16 Manufacture of plastics in primary forms
- C20.30 Manufacture of paints, varnishes and similar coatings, printing ink and mastics
- C20.59 Manufacture of other chemical products n.e.c.
- C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations
- C21.20 Manufacture of pharmaceutical preparations
- C22.11 Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres
- C22.19 Manufacture of other rubber products
- C23.19 Manufacture and processing of other glass, including technical glassware
- C23.4 Manufacture of other porcelain and ceramic products
- C24.10 Manufacture of basic iron and steel and of ferro-alloys
- C24.45 Other non-ferrous metal production
- C25.61 Treatment and coating of metals
- C25.62 Machining
- C25.73 Manufacture of tools
- C25.9 Manufacture of other fabricated metal products
- C25.99 Manufacture of other fabricated metal products n.e.c
- C26.11 Manufacture of electronic components
- C26.51 Manufacture of instruments and appliances for measuring, testing and navigation
- C27.2 Manufacture of batteries and accumulators
- C28.11 Manufacture of engines and turbines, except aircraft, vehicle and cycle engines
- C29.10 Manufacture of motor vehicles
- C29.30 Manufacture of parts and accessories for motor vehicles
- C30.30 Manufacture of air and spacecraft and related machinery
- C32.12 Manufacture of jewellery and related articles
- C32.50 Manufacture of medical and dental instruments and supplies
- E37.00 Sewerage
- E38.21 Treatment and disposal of non-hazardous waste
- E38.22 Treatment and disposal of hazardous waste
- E38.32 Recovery of sorted materials
- F41 Construction of building
- F42 Civil engineering
- F43.34 Painting and glazing
- M71.20 Technical testing and analysis
- Other

If other, please specify

A3) Please define the overall application in the company of cobalt and inorganic cobalt compounds within the scope of the study

A4) How many workers are employed in your company at the facility for which you are filling out this questionnaire?

A5) How many workers are exposed to cobalt and inorganic cobalt compounds within the scope of the study in your company at the facility for which you are filling out this questionnaire?

A6) Have you any experience of workers having health issues resulting from occupational exposure to cobalt and inorganic cobalt compounds?

A7) Have any workers left the company due to health issues associated with exposure to cobalt and inorganic cobalt compounds?

A8) What is the annual turnover in EUR at the facility for which you are filling out this questionnaire?

- < €2 million
- €2–10 million
- €10–50 million
- €50–100 million
- > €100 million

Please complete a separate questionnaire for each facility

A9) Please give the name and address (incl. country) of the facility for which you are completing this questionnaire

A10) If your workers are exposed to cobalt and inorganic cobalt compounds within the scope of the CMRD, please specify the compounds that they are exposed to (e.g. cobalt, cobalt carbonate, etc.). See a list of examples for relevant compounds at the beginning of the questionnaire.

B) Information about current exposure at your facility

B1) Please specify the most important processes during which exposure to the relevant substance can occur. You can specify a maximum of four processes.

Process 1

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12 Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
- PROC 21 Low energy manipulation of substances bound in materials and/or articles
- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process.

Process 2

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12 Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
- PROC 21 Low energy manipulation of substances bound in materials and/or articles
- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process.

Process 3

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
-

PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12 Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
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- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process.

Process 4

- PROC 1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
- PROC 2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
- PROC 3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
- PROC 4 Chemical production where opportunity for exposure arises
- PROC 5 Mixing or blending in batch processes
- PROC 6 Calendering operations
- PROC 7 Industrial spraying
- PROC 8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

- PROC 8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
- PROC 9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- PROC 10 Roller application or brushing
- PROC 11 Non-industrial spraying
- PROC 12 Use of blowing agents in manufacture of foam
- PROC 13 Treatment of articles by dipping and pouring
- PROC 14 Tabletting, compression, extrusion, pelletisation, granulation
- PROC 15 Use as laboratory reagent
- PROC 16 Use of fuels
- PROC 17 Lubrication at high energy conditions in metal working operations
- PROC 18 General greasing/lubrication at high kinetic energy conditions
- PROC 19 Manual activities involving hand contact
- PROC 20 Use of functional fluids in small devices
- PROC 21 Low energy manipulation of substances bound in materials and/or articles
- PROC 22 Manufacturing and processing of minerals and/or metals at substantially elevated temperature
- PROC 23 Open processing and transfer operations with minerals/metals at elevated temperature
- PROC 24 High (mechanical) energy work-up of substances bound in materials and/or articles
- PROC 25 Other hot work operations with metals
- PROC 26 Handling of solid inorganic substances at ambient temperature
- PROC 27a Production of metal powders (hot processes)
- PROC 27b Production of metal powders (wet processes)
- PROC 28 Manual maintenance (cleaning and repair) of machinery
- Other

Please specify the process.

B2) Please provide the number of workers exposed at all exposure levels during a typical working day, for each process.

	Number of workers exposed
Process 1	
Process 2	
Process 3	
Process 4	

B3) Please provide your most recent airborne concentration data (inhalable fraction) taken in accordance with an OEL (8-hour Time Weighted Averages) in µg Co/m³.

	Process 1	Process 2	Process 3	Process 4
Lowest exposure level (value)				
Highest exposure level (value)				
Arithmetic mean exposure level (value)				
Median exposure level (value)				
95th percentile level (value)				
Number of samples (n)				
Year of monitoring				
B4) Please select the sampling method followed	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE
B5) Are the workers wearing respiratory protective equipment (RPE) during the activity?	○ Yes ○ No	○ Yes ○ No	○ Yes ○ No	○ Yes ○ No
	○ BGI 505–15E	○ BGI 505–15E	○ BGI 505–15E	○ BGI 505–15E

B6) Please indicate the standard/analytical method followed	DFG (E) IFA 7808 IRSST Analytical Method 362 ISO 15202 ISO 30011 MDHS 30/2 MDHS 91/2 MTA/MA – 065/A16 NIOSH 7300 and 7301 NIOSH 7302 NIOSH 7306 OSHA-ID 1006 Other	DFG (E) IFA 7808 IRSST Analytical Method 362 ISO 15202 ISO 30011 MDHS 30/2 MDHS 91/2 MTA/MA – 065/A16 NIOSH 7300 and 7301 NIOSH 7302 NIOSH 7306 OSHA-ID 1006 Other	DFG (E) IFA 7808 IRSST Analytical Method 362 ISO 15202 ISO 30011 MDHS 30/2 MDHS 91/2 MTA/MA – 065/A16 NIOSH 7300 and 7301 NIOSH 7302 NIOSH 7306 OSHA-ID 1006 Other	DFG (E) IFA 7808 IRSST Analytical Method 362 ISO 15202 ISO 30011 MDHS 30/2 MDHS 91/2 MTA/MA – 065/A16 NIOSH 7300 and 7301 NIOSH 7302 NIOSH 7306 OSHA-ID 1006 Other
B7) If you answered 'other' to question B6, please specify the standard(s)/analytical method(s) followed				

B8) If you have indicated below limit of quantification (LoQ) and/or limit of detection (LoD) in the responses above, what was the LOQ or LOD for the inhalable fraction?

	Value	Unit
Limit of quantification for inhalable fraction		
Limit of detection for inhalable fraction		

B9) Please provide your most recent airborne concentration data (respirable fraction) taken in accordance with an OEL (8-hour Time Weighted Averages) in µg Co/m³.

	Process 1	Process 2	Process 3	Process 4
Lowest exposure level (value)				
Highest exposure level (value)				
Arithmetic mean exposure level (value)				
Median exposure level (value)				
95th percentile level (value)				
Number of samples (n)				
Year of monitoring				
B10) Please select the sampling method followed	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE	○ Stationary sampling ○ Personal sampling ○ Personal sampling of inhalation air inside the RPE
B11) Are the workers wearing respiratory protective equipment (RPE) during the activity?	○ Yes ○ No	○ Yes ○ No	○ Yes ○ No	○ Yes ○ No
	○ BGI 505–15E	○ BGI 505–15E	○ BGI 505–15E	○ BGI 505–15E

B12) Please indicate the standard/analytical method followed	◯ DFG (E) ◯ IFA 7808 ◯ IRSST Analytical Method 362 ◯ ISO 15202 ◯ ISO 30011 ◯ MDHS 30/2 MDHS 91/2 ◯ MTA/MA – 065/A16 ◯ NIOSH 7300 and 7301 ◯ NIOSH 7302 ◯ NIOSH 7306 ◯ OSHA-ID 1006 ◯ Other	◯ DFG (E) ◯ IFA 7808 ◯ IRSST Analytical Method 362 ◯ ISO 15202 ◯ ISO 30011 ◯ MDHS 30/2 MDHS 91/2 ◯ MTA/MA – 065/A16 ◯ NIOSH 7300 and 7301 ◯ NIOSH 7302 ◯ NIOSH 7306 ◯ OSHA-ID 1006 ◯ Other	◯ DFG (E) ◯ IFA 7808 ◯ IRSST Analytical Method 362 ◯ ISO 15202 ◯ ISO 30011 ◯ MDHS 30/2 MDHS 91/2 ◯ MTA/MA – 065/A16 ◯ NIOSH 7300 and 7301 ◯ NIOSH 7302 ◯ NIOSH 7306 ◯ OSHA-ID 1006 ◯ Other	◯ DFG (E) ◯ IFA 7808 ◯ IRSST Analytical Method 362 ◯ ISO 15202 ◯ ISO 30011 ◯ MDHS 30/2 MDHS 91/2 ◯ MTA/MA – 065/A16 ◯ NIOSH 7300 and 7301 ◯ NIOSH 7302 ◯ NIOSH 7306 ◯ OSHA-ID 1006 ◯ Other
B13) If you answered 'other' to question B12, please specify the standard(s)/analytical method(s) followed				

B14) If you have indicated below limit of quantification (LoQ) and/or limit of detection (LoD) in the responses above, what was the LOQ or LOD for the respirable fraction?

	Value	Unit
Limit of quantification for respirable fraction		
Limit of detection for respirable fraction		

B15) Could actions related to covid-19 have artificially altered exposure levels? For example, greater use of PPE.

- Yes, reduced exposure
- Yes, increased exposure
- No change
- Don't know

B16) Please provide a short explanation for your answer to B15

B17) Do you have any other information on exposure to cobalt and inorganic cobalt compounds at your facility?

If you are happy to provide more detailed information about numbers of workers exposed, exposure levels and/or further processes, please email this to Carsten Lassen, crl@cowi.com, directly.

B18) Which Risk Management Measures are in place to control exposure of cobalt and inorganic cobalt compounds in the different processes at this facility? Please tick all that you use. If PPE is essential regardless of the OEL (e.g. for maintenance processes), please indicate this.

Restructuring operations/processes

	Process 1	Process 2	Process 3	Process 4
Reduced amount of substance used	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction

	Process 1	Process 2	Process 3	Process 4
Closed systems	☐	☐	☐	☐
Enclosure with extraction	☐	☐	☐	☐
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)

	Process 1	Process 2	Process 3	Process 4
PPE is essential regardless of the OEL	☐	☐	☐	☐
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, faceshields, 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

	Process 1	Process 2	Process 3	Process 4
Training and education	☐	☐	☐	☐
Cleaning	☐	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐

Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

B19) Could there be co-exposure from both cobalt and inorganic cobalt compounds AND any of the following substances or processes at this facility? Please tick all that apply.

- ☐ Polycyclic aromatic hydrocarbons (PAH)
- ☐ Isoprene
- ☐ 1,4-dioxane
- ☐ Perform welding

B20) Is your company making any investments not directly related to exposure to cobalt and inorganic cobalt compounds that are likely to lead to a reduction in exposure to cobalt and inorganic cobalt compounds?

- ○ Investments are being made that will significantly reduce exposure to cobalt and inorganic cobalt compounds
- ○ Investments are being made that may reduce exposure to cobalt and inorganic cobalt compounds
- ○ No investments are planned that will reduce exposure to cobalt and inorganic cobalt compounds
- ○ Don't know

B21) If any investments are being made in question B20, what are the investments for? Please tick all that apply.

	Select
Compliance with other OELs (please specify which)	☐
Improved risk management measures being implemented alongside other improvements to production facilities	☐
New or improved production facilities that will remove from or reduce exposure to worker	☐
Other	☐

If you responded 'compliance with other OEls', please specify the OELs here.

If you responded 'other,' please specify

B22) When will the reduction in worker exposure take effect?

at most 1 answered row(s)

	Select

By the end of 2024	☐
By the end of 2029	☐
By the end of 2034	☐

C) What are the lowest exposure levels that you could achieve?

.

	Value	Unit
C1) What do you think is the lowest *technically* possible 8 hour TWA air concentration that can be achieved in this facility for the inhalable fraction?		☐ µg/m³ ☐ mg/m³
C2) What do you think is the lowest *technically* possible 8 hour TWA air concentration that can be achieved in this facility for the respirable fraction?		☐ µg/m³ ☐ mg/m³
C3) What do you think is the lowest *economically* feasible 8 hour TWA air concentration that can be achieved in this facility for the inhalable fraction?		☐ µg/m³ ☐ mg/m³
C4) What do you think is the lowest *economically* feasible 8 hour TWA air concentration that can be achieved in this facility for the respirable fraction?		☐ µg/m³ ☐ mg/m³

C5) Any comments on above answers?

C6) Do you have to comply with the European Workplace exposure standard EN 689?

- ○ Yes
- ○ No
- ○ Don't know

D) Compliance with a new OEL/BLV and risk management measures

This section considers the additional Risk Management Measures (RMMs) that would have to be put in place to comply with a new OEL under the Carcinogens, Mutagens or Reprotoxic substances Directive. The OELs would be accompanied by the following notations: “Skin sensitisation” and “Respiratory sensitisation".

The following limit values and air concentrations given below are used as policy options for this questionnaire.

Policy option	Cobalt and inorganic cobalt compounds
Policy option 1 OELs (For the inhalable fraction, currently the OEL used in most EU Member States)	Inhalable fraction: 20 µg Co/m³ Respirable fraction: 4.2 µg Co/m³
Policy option 2 OELs (For the inhalable fraction, currently the lowest OEL in EU Member States)	Inhalable fraction: 10 µg Co/m³ Respirable fraction: 2.5 µg Co/m³
Policy option 3 OELs (intermediate level)	Inhalable fraction: 5 µg Co/m³ Respirable fraction: 1.25 µg Co/m³
Policy option 4 OELs *(Based on the Risk Assessment Committee's (RAC) opinion on the OEL)*	Inhalable fraction: 1 µg Co/m³ Respirable fraction: 0.5 µg Co/m³

If your company measures only either inhalable or respirable fraction, you may not have the necessary data to assess the RMMs that would be needed to comply with both OELs. In this case, you may either provide data for just one fraction or you may try to convert the measured concentrations based on typical conversion factors. Some average ratios for respirable and inhalable fraction are provided in the table below.

Group	No of Samples	Mean value (AM)		
		Respirable µg/m³	Inhalable µg/m³	R/I
Working activities:				
High temperature processing	145	2	7	1/3
Filling/transport/storage	49	8	97	1/13
Machining/abrasive techniques	234	3	26	1/8
Sub-groups:				
Welding	96	1.2	2.7	1/2
Grinding	161	3	27	1/9

The estimates are based on aggregated German data from a number of processes and companies as reported by Wippich et al. (2022). Estimating cobalt exposure in respirable dust from cobalt in inhalable dust. Int J Hyg Environ Health. 242:113965.

The following questions cover the most important additional RMMs that would help you to achieve each policy option.

If you have data on **both** the inhalable and respirable fraction (from measurements or estimated), please consider for each process which of the OELs would be **most costly** to comply with and base your answer on this.

If you have data for **one of the fractions only**, please base all answers on the fraction for which you have data.

D1) Please select one of the following if you have data for one of the fractions only and base the answers on this. Otherwise leave the response blank.

- ○ All answers concern the OELs for the inhalable fraction only
- ○ All answers concern the OELs for the respirable fraction only

D2) If you have data for both the inhalable and respirable fraction (from measurements or estimated) and have considered which OELs would be the most costly to comply with for each process, please indicate it below.

	Process 1	Process 2	Process 3	Process 4
OEL for inhalable fraction	☐	☐	☐	☐
OEL for respirable fraction	☐	☐	☐	☐

D3) If the OEL was *Inhalable fraction: 20 µg Co/m³ or Respirable fraction: 4.2 µg Co/m³*, which *additi onal* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐

Substitution or discontinuation

	Process 1	Process 2	Process 3	Process 4
Partial substitution of substance	☐	☐	☐	☐
Substitution of substances	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction

	Process 1	Process 2	Process 3	Process 4
Installing closed systems	☐	☐	☐	☐
Installing partially closed systems	☐	☐	☐	☐
Installing open hoods over equipment or local extraction ventilation	☐	☐	☐	☐
Installing general ventilation	☐	☐	☐	☐
Installing pressurised or sealed control cabs	☐	☐	☐	☐
Installing simple enclosed control cabs	☐	☐	☐	☐

PPE (Personal Protective Equipment)

	Process 1	Process 2	Process 3	Process 4
PPE is considered to be indispensable regardless of the OEL	☐	☐	☐	☐
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, faceshields, 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

	Process 1	Process 2	Process 3	Process 4
Further training and education	☐	☐	☐	☐

Further cleaning	☐	☐	☐	☐
Further provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D4) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 20 µg Co/m³ or Respirable fraction: 4.2 µg Co/m³?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- €1 -10 million
- > €10 million

D5) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 20 µg Co/m³ or Respirable fraction: 4.2 µg Co/m³?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D6) If the OEL was Inhalable fraction: 10 µg Co/m³ or Respirable fraction: 2.5 µg Co/m³, which *additi onal* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐

Substitution or discontinuation

	Process 1	Process 2	Process 3	Process 4
Partial substitution of substance	☐	☐	☐	☐
Substitution of substances	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction

	Process 1	Process 2	Process 3	Process 4
Installing closed systems	☐	☐	☐	☐
Installing partially closed systems	☐	☐	☐	☐
Installing open hoods over equipment or local extraction ventilation	☐	☐	☐	☐

Installing general ventilation	☐	☐	☐	☐
Installing pressurised or sealed control cabs	☐	☐	☐	☐
Installing simple enclosed control cabs	☐	☐	☐	☐

PPE (Personal Protective Equipment)

	Process 1	Process 2	Process 3	Process 4
PPE is considered to be indispensable regardless of the OEL	☐	☐	☐	☐
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, faceshields, 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

	Process 1	Process 2	Process 3	Process 4
Further training and education	☐	☐	☐	☐
Further cleaning	☐	☐	☐	☐
Further provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D7) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 10 µg Co/m³ or Respirable fraction: 2.5 µg Co/m³?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- €1 -10 million
- > €10 million

D8) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 10 µg Co/m³ or Respirable fraction: 2.5 µg Co/m³?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D9) If the OEL was Inhalable fraction: 5 µg Co/m³ or Respirable fraction: 1.25 µg Co/m³ which *additio nal* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐

Substitution or discontinuation

	Process 1	Process 2	Process 3	Process 4
Partial substitution of substance	☐	☐	☐	☐
Substitution of substances	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction

	Process 1	Process 2	Process 3	Process 4
Installing closed systems	☐	☐	☐	☐
Installing partially closed systems	☐	☐	☐	☐
Installing open hoods over equipment or local extraction ventilation	☐	☐	☐	☐

Installing general ventilation	☐	☐	☐	☐
Installing pressurised or sealed control cabs	☐	☐	☐	☐
Installing simple enclosed control cabs	☐	☐	☐	☐

PPE (Personal Protective Equipment)

	Process 1	Process 2	Process 3	Process 4
PPE is considered to be indispensable regardless of the OEL	☐	☐	☐	☐
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, faceshields, 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

	Process 1	Process 2	Process 3	Process 4
Further training and education	☐	☐	☐	☐
Further cleaning	☐	☐	☐	☐
Further provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D10) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 5 µg Co/m³ or Respirable fraction: 1.25 µg Co/m³?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- €1 -10 million
- > €10 million

D11) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 5 µg Co/m³ or Respirable fraction: 1.25 µg Co/m³?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D12) If the OEL was Inhalable fraction: 1 µg Co/m³ or Respirable fraction: 0.5 µg Co/m³, which *additi onal* RMMs would be the most important in helping you to achieve this?

	Process 1	Process 2	Process 3	Process 4
No action required as OEL already achieved	☐	☐	☐	☐

Substitution or discontinuation

	Process 1	Process 2	Process 3	Process 4
Partial substitution of substance	☐	☐	☐	☐
Substitution of substances	☐	☐	☐	☐
Discontinuation of process using the substance	☐	☐	☐	☐
Reducing the amount of substance used	☐	☐	☐	☐
Reducing the number of workers exposed	☐	☐	☐	☐
Rotating the workers exposed	☐	☐	☐	☐
Redesign of work processes	☐	☐	☐	☐

Ventilation and extraction

	Process 1	Process 2	Process 3	Process 4
Installing closed systems	☐	☐	☐	☐
Installing partially closed systems	☐	☐	☐	☐
Installing open hoods over equipment or local extraction ventilation	☐	☐	☐	☐

Installing general ventilation	☐	☐	☐	☐
Installing pressurised or sealed control cabs	☐	☐	☐	☐
Installing simple enclosed control cabs	☐	☐	☐	☐

PPE (Personal Protective Equipment)

	Process 1	Process 2	Process 3	Process 4
PPE is considered to be indispensable regardless of the OEL	☐	☐	☐	☐
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, faceshields, 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

	Process 1	Process 2	Process 3	Process 4
Further training and education	☐	☐	☐	☐
Further cleaning	☐	☐	☐	☐
Further provision of separate storage facilities for work clothes	☐	☐	☐	☐
Formal/external RPE cleaning and filter changing regime	☐	☐	☐	☐
Continuous measurement to detect unusual exposures	☐	☐	☐	☐

Other measures

	Process 1	Process 2	Process 3	Process 4
Other (please specify)				

D13) What is your estimated range of initial investment costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 1 µg Co/m³ or Respirable fraction: 0.5 µg Co/m³?

- < €10,000
- €10,000 - €100,000
- €100,000 - €1 million
- €1 -10 million
- > €10 million

D14) What is your estimated range of annual recurrent costs for additional RMMs required at this facility to achieve an OEL with Inhalable fraction: 1 µg Co/m³ or Respirable fraction: 0.5 µg Co/m³?

- < €1,000
- €1,000 - €10,000
- €10,000 - €100,000
- > €100,000

D15) Would the level of costs as incurred by Policy Option 3 (inhalable OEL 5 µg Co/m³, respirable OEL 1.25 Co/m³) affect the competitiveness of your company?

Competitors in EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact
Competitors outside of EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact

D16) Would the level of costs as incurred by Policy Option 4 (inhalable OEL 1 µg Co/m³, respirable OEL 0.5 µg Co/m³) affect the competitiveness of your company?

Competitors in EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact
Competitors outside of EU	Significant positive impact Moderate positive impact Limited/no impact Moderate negative impact Significant negative impact

D17) Any other comments on this section?

.

E) Indirect Benefits

E1) Do you think your company will benefit from any of these indirect benefits if an EU-wide OEL for cobalt and its inorganic compounds is introduced? Please tick all that apply.

	Select
Healthier staff	☐
Increased productivity of workers	☐
Improved public image	☐
Easier to recruit staff	☐
Easier to retain staff	☐
Reduced cost of recruitment	☐
Easier monitoring of exposure	☐
Savings because company currently has multiple locations in different Member States with different regulations or OELs	☐
Level playing field with EU competitors	☐
Other indirect benefits, please specify	☐
There will be no indirect benefits	☐

Please specify

F) Would compliance with the newly introduced OELs for other substances influence the exposure to cobalt and inorganic compounds?

In order to comply with newly introduced OELs for other carcinogenic substances you may have planned further implementation of RMMs which may also lead to reduced exposure to cobalt and inorganic cobalt compounds in processes where both substance groups are used.

F1) Are newly introduced OELs expected to result in reduced exposure to cobalt and inorganic cobalt compounds as compared to the exposure concentrations reported in this questionnaire?

Nickel compounds	Yes, exposure is expected to be reduced by more than 50% Yes, exposure is expected to be reduced by less than 50% No
Chromium VI	Yes, exposure is expected to be reduced by more than 50% Yes, exposure is expected to be reduced by less than 50% No
Arsenic acid and its salts, as well as inorganic arsenic compounds	Yes, exposure is expected to be reduced by more than 50% Yes, exposure is expected to be reduced by less than 50% No
Other	Yes, exposure is expected to be reduced by more than 50% Yes, exposure is expected to be reduced by less than 50% No

If other, please specify

G) Is your company working to meet voluntary industry targets?

Voluntary Industry Targets

	Answer
G1) Is your company trying to meet voluntary industry targets? If yes, please specify the targets (concentration, units)	
G2) What are the main challenges in meeting the voluntary targets?	
G3) Have you made any assessment of the possible costs of meeting the voluntary targets? If yes, please provide information on costs and cost structure.	

H) Any other comments

H1) Do you have any other comments relevant to this study that you would like to make?

I) Further communication

I1) Please tick if you are happy for the study team to contact you for further clarification or discussion about your responses?

- Yes
- No

I2) Please tick if you would be willing to host a site visit for the study team at this facility. This can be carried out under a non-disclosure agreement.

- Yes
- No

I3) 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!

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