European Commission

Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC

(Ref: VC/2017/0011)

Final Report for beryllium

Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

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Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Beryllium and its inorganic compounds

8 February 2018

Final Report

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List of acronyms

ABD	Acute beryllium disease
ACGIH	American Conference of Governmental Industrial Hygienists
ACEA	The European Automobile Manufacturers Association
ACSH	Advisory Committee on Safety and Health at Work
AfA	Application for authorisation
AGS	Ausschuss für Gefahrstoffe (Committee on Hazardous Substances)
ALARA	As low as reasonably achievable
ASA	ASA register (of occupational exposure hazards and procedures in Finland)
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food Safety, Environment and Labor, France)
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Safety and Health, Germany)
Be	Beryllium
BeS	Beryllium sensitisation
BeST	Beryllium Science and Technology Association
BGV	Benchmark guidance value
BLV	Biological limit value
CAPEX	Capital expenditure
CAS	Chemicals abstracts service
CBA	Cost-benefit analysis
CBD	Chronic beryllium disease
CFC	Closed-Faced Filter Cassette
CI	Confidence interval
C&L	Classification and Labelling
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMD	The Carcinogens and Mutagens Directive
COPD	Chronic obstructive pulmonary disease
CoRAP	Community rolling action plan
Cr (VI)	Hexavalent chromium
CRM	Critical Raw Materials
CSR	Chemical safety report
DALY	Disability adjusted life years
DNEL	Derived no effect limit
ECHA	European Chemicals Agency
EIG	Employers interest group
EFSA	European Food Safety Authority
eMSCA	Evaluating Member State competent authority
ERR	Exposure-risk relationship
ET-ASS	Electrothermal-Atomic Absorption Spectroscopy
F-AAS	Flame-Atomic Absorption Spectroscopy
GESTIS	Internationale Grenzwerte für chemische Substanzenm (International limits for chemical substances)
GF-AAS	Graphite Furnace Atomic Absorption Spectroscopy
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GM	Geometric mean
GSD	Geometric standard deviation
HSE	Health & Safety Executive, United Kingdom
IA	Impact assessment
IARC	International Agency for Research on Cancer

ICAP-AES	Inductively Coupled Argon Plasma-Atomic Emission Spectroscopy
ICP-AES	Inductively Coupled Plasma-Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma-Mass Spectroscopy
IFA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety of the German Social Accident Insurance)
IOM	Institute of Occupational Medicine
ISO	The International Organization for Standardization
JSOH	Japan Society for Occupational Health
LEV	Local exhaust ventilation
LOAEC	Lowest Observable Adverse Effect Concentration
LOD	Level of detection
LOQ	Limit of quantification
MCA	Multi criteria analysis
MEGA	IFA's workplace exposure database
MRL	Minimal risk level
MS	Member States
NACE	"**n**omenclature statistique des activités **é**conomiques dans la **C**ommunauté **e**uropéenne" or the Statistical Classification of Economic Activities in the European Community
NAIC	North American Industry Classification
NIOSH	National Institute for Occupational Safety and Health
NIPH	National Institute of Public Health, Czech Republic
NOAEC	No Observed Adverse Effect Concentration
NJMRC	National Jewish Medical Research Center
NOAEL	No-Observed Adverse Effect Level
OEL	Occupational exposure limit
OELV	Occupational exposure limit value
OPIN	Opinion
OR	Odds ratio
OPEX	Operating expenditure
OSH	Occupational health and safety
PAF	Population attributable fraction
PACT	(ECHA) Public Activities Coordination Tool
PBT	Persistent, bio-accumulative and toxic
PEL	Permissible exposure limit
PGS	Process generated substances
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
ppb	parts per billion
ppm	parts per million
PROC	The process categories
PSP	Product stewardship program
PV	Present value
QALY	Quality-adjusted life year
RAC	(ECHA) Committee for Risk Assessment
RAR	Risk assessment report
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RMM	Risk management measure
RMOA	Risk management options analysis
SBS	Structural Business Statistics
SCC	Strictly controlled conditions
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-economic analysis
SME	Small and medium-sized enterprise

SMR	Standardised mortality ratio
SU	Sector of Use
STEL	Short term exposure limit
SUMER	Surveillance médicale des expositions aux risques professionnels (Medical Monitoring Survey of Professional Risks)
SVHC	Substance of very high concern
SWEA	Swedish Work Environment Authority
TLV	Threshold limit value
tpa	Tonne per annum
TWA	Time weighted average
US-OSHA	Occupational Safety and Health Administration in the USA
VCM	Value of cancer morbidity
VM	Value of morbidity
VOLY	Value of a life year lost
VSL	Value of a statistical life
VSLY	Value of a statistical life year
WHO	World Health Organization
WTP	Willingness to pay

Executive summary

The Carcinogens and Mutagens Directive (Directive 2004/37/EC) protects workers from exposure to carcinogens or mutagens at work. The aim of this study is to support the European Commission's Impact Assessment of a potential Occupational Exposure Limit Value (OELV) for beryllium and its inorganic compounds. Ten industrial sectors are analysed, including construction. However, it is unclear where beryllium is found in construction and the industry has many workers. Therefore, construction is excluded from the values in the executive summary.

The costs and benefits (relative to the baseline) estimated in this report for the different target OELVs are summarised below. Firstly, in Figure 1 and Table 1, the cost-benefit analysis for the baseline with a static future burden and OPEX set to 10% of CAPEX is shown.

In the sensitivity analysis, a significant fall in benefits appeared likely due to future **productivity automation,** which reduces the number of exposed workers and exposure levels regardless of the OELV (dynamic future burden scenario). **OPEX as 20% of CAPEX** seems likely to cause a significant rise in costs particularly between 0.2 and 1 µg/m^3. In Figure 2 and Table 2, the cost-benefit analysis incorporating these variations is shown.

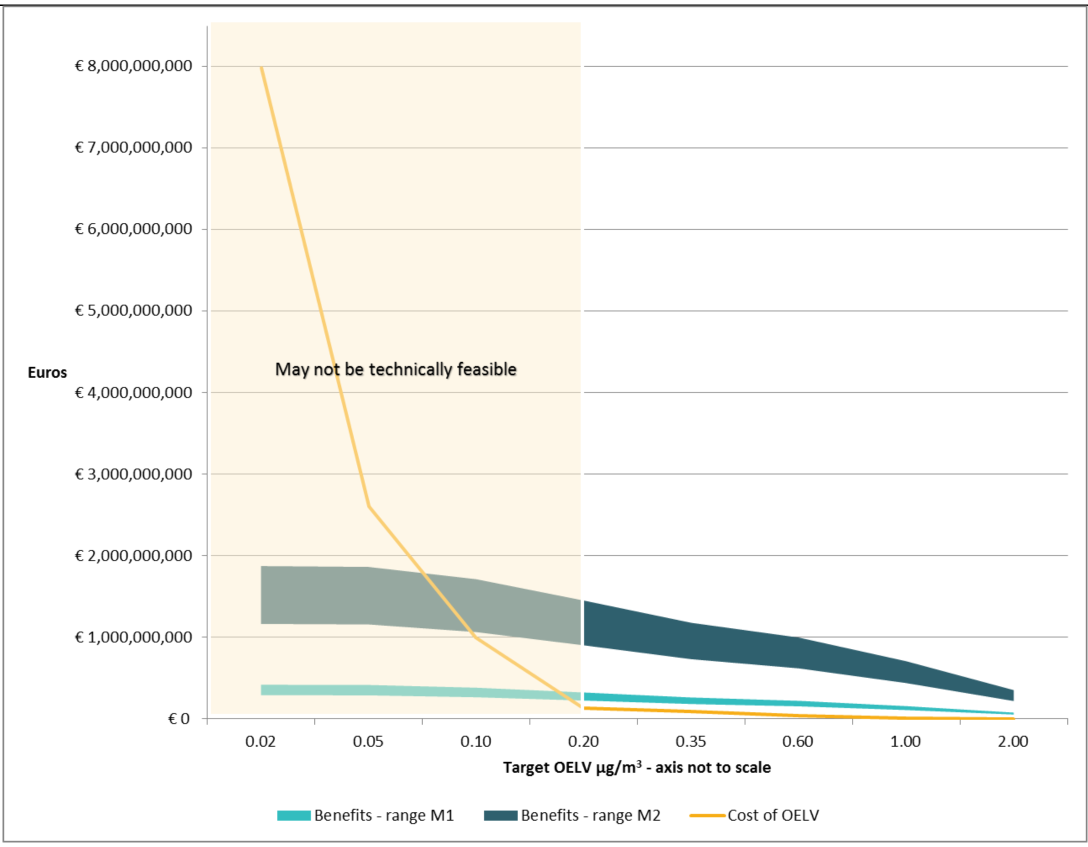

Figure 0-1: Estimated TOTAL cost (CAPEX and OPEX) and estimated benefits of having an OELV using Methods 1 and 2, with a static future burden and OPEX as 10% of CAPEX. For each Method, the benefits range from those with a constant workforce to a workforce with a turnover of 5% per year.

Notes: Dataset - EU/US; Exposure distribution - BeST; Nine sectors excluding construction; Target OELVs are inhalable; Values - € 60 year present value

Table 0-1: Summary of monetised costs and benefits (static discount rate, additional to the baseline) , with a static future burden and OPEX as 10% of CAPEX		
Target OELV inhalable	**PV benefits over 60 years (€ million)**	**PV costs over 60 years (€ million)**
2 µg/m3	55 - 355	2
1 µg/m3	111 - 709	15
0.6 µg/m3	156 – 1,000	41
0.35 µg/m3	184 – 1,181	87
0.2 µg/m3	227 – 1,454	133
0.1 µg/m3	268 – 1,716	1,003
0.05 µg/m3	291 – 1,865	2,603
0.02 µg/m3	293 – 1,876	7,989
Monetised costs and benefits	Avoided chronic beryllium disease compared with the baseline	Risk management measures, discontinuation of business, transposition costs
Source: Modelling by RPA. Notes: Dataset - EU/US; Exposure distribution – BeST; Sectors – nine sectors excluding construction; Values - €millions 60 years present value. All financial values are relative to the baseline. Target OELVs are inhalable.		

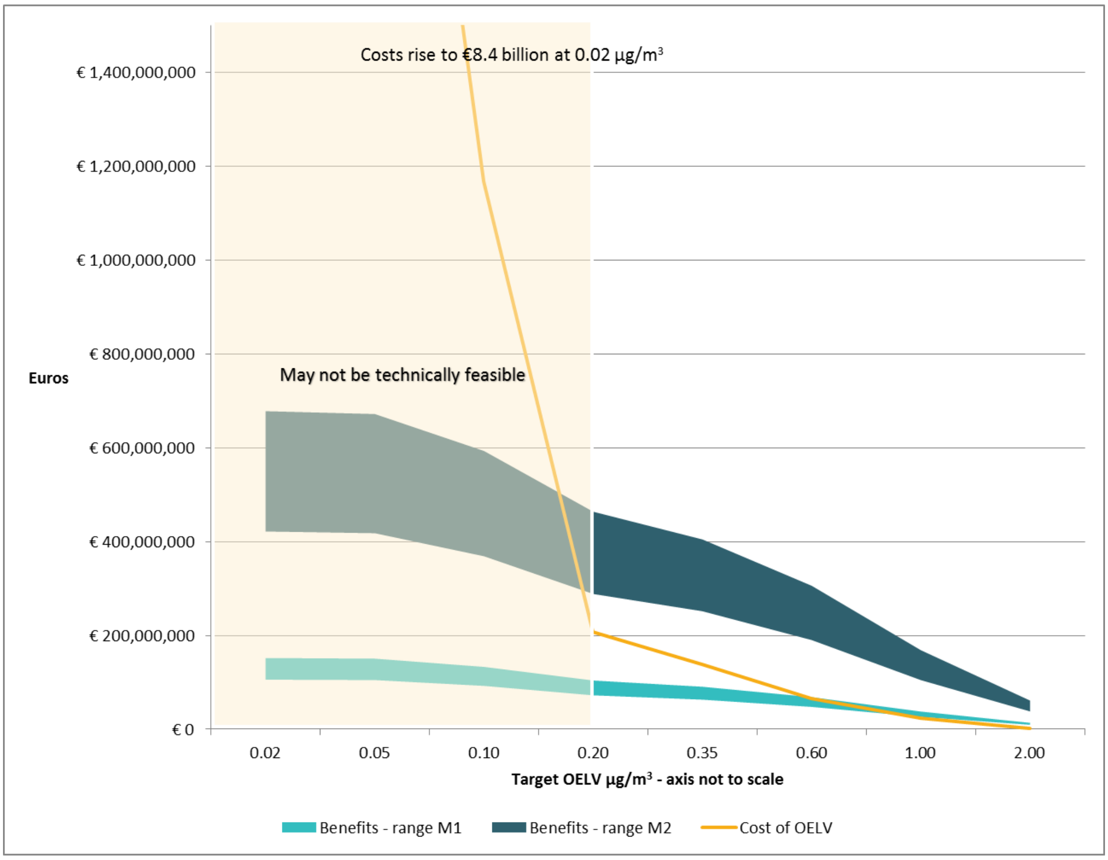

Figure 0-2: Estimated TOTAL cost (CAPEX and OPEX) for 60 year PV and estimated benefits of having an OELV using Methods 1 and 2, with a dynamic future burden and OPEX as 20% of CAPEX. For each Method, the benefits range from those with a constant workforce to a workforce with a turnover of 5% per year.
Notes: Dataset - EU/US; Exposure distribution - BeST; Nine sectors excluding construction. Target OELVs are inhalable; Values - € 60 year present value

Table 0-2: Summary of monetised costs and benefits (static discount rate, additional to the baseline), with a dynamic future burden and OPEX as 20% of CAPEX		
Target OELV inhalable	**PV benefits over 60 years (€ million)**	**PV costs over 60 years (€ million)**
2 µg/m3	10 - 61	2
1 µg/m3	26 - 168	23
0.6 µg/m3	48 - 306	65
0.35 µg/m3	63 - 404	138
0.2 µg/m3	72 - 464	208
0.1 µg/m3	92 - 593	1,168
0.05 µg/m3	105 - 671	2,883
0.02 µg/m3	107 - 678	8,440
Monetised costs and benefits	Avoided chronic beryllium disease compared with the baseline	Risk management measures, discontinuation of business, transposition costs
Source: Modelling by RPA. Notes: Dataset - EU/US; Exposure distribution – BeST; Sectors – nine sectors excluding construction; Values - €millions 60 years present value. All financial values are relative to the baseline. Target OELVs are inhalable		

The table below summarises both the monetised impacts and those assessed qualitatively.

Table 0-3: Beryllium: Multi-criteria analysis				
Impact	**Stakeholders affected**	**<=0.1 µg/m^3**	**0.2 - 0.6 µg/m^3**	**1 - 2 µg/m^3**
Economic impacts				
Compliance costs **	Companies	> €1 billion *	€40-130 million *	< €15 million *
Transposition costs	Public sector	€1.35 million	€1.15 million	€300,000
Benefits from reduced ill health	Reduction in cases (cancer)	0	0	0
	Reduction in cases (CBD)	2,800 -3,100	1600 – 2,400	600 - 1,200
	Reduction in DALYs	20,000 – 22,000	12,000 – 17,000	4,000 – 8,000
	Employers	> €17 million	€10 - 15 million	< €7 million
	Public sector	> €25 million	€15 - 21 million	< €10 million
Single-market: competition	Company closures	23 – 232 closures	*0*	*0*
Single-market: consumers	Consumers	*Limited impact expected*		
Single-market: competition/ level playing field	Companies	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 'no difference'	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 6	***Moderate positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 20
Specific MSs/regions	Member States	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK, plus IT, LU, MT, NL, PT	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT	EL plus IT, LU, MT, NL, PT

Table 0-3: Beryllium: Multi-criteria analysis				
Impact	**Stakeholders affected**	**<=0.1 µg/m³**	**0.2 - 0.6 µg/m³**	**1 - 2 µg/m³**
Health and social impacts				
Ill health (CBD) avoided including intangible costs	Workers & families	> €240 million	€140 - 200 million	< €100 million
Employment	Jobs lost	210 – 2,100	0	0
	Social cost ***	€17 – 180 million	0	0
Environmental impacts				
Environmental releases	All	*Neutral impact*		

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction; Values - Euros millions 60 years present value; Target OELVs are inhalable.

**Estimated using the cost model estimated for this study.*

***Includes company closures.*

****Social cost of displacement (assumes worker finds a new job but suffers from the disruption and stress involved in finding a new job).*

Several further issues require consideration.

Initially, the list of existing OELs in Table 3.1 appears to show that Germany, a Member State with many enterprises using beryllium, has an OEL of 0.14 µg/m³. Therefore, why not implement this low OEL across the EU? However, the **German OEL is not binding**. Companies are expected to implement the risk management measures laid down in the Technical Rules for Hazardous Substances (BauA 2017b) but, if the OEL cannot be achieved, there is no further sanction.

After many conversations with the beryllium industry, achieving an OELV of 0.6 µg/m³ appears reasonably straightforward but the actions required to achieve exposure levels below 0.6 µg/m³ are considerably more expensive. It is clear that companies have **no idea how certain processes could achieve OELs below 0.2 µg/m³** and the general view is that these processes would close or move outside the EU. In the USA, US-OSHA believes that the available evidence on feasibility suggests that 0.2 µg/m³ (total particulate) may be the lowest feasible permissible exposure limit (PEL). Taking a conversion factor of 3 from total particulate to inhalable, this implies that the lowest feasible OELV for the EU may be 0.6 µg/m³ (inhalable.) Furthermore, the importance of beryllium to industry is demonstrated by its presence on the **Critical Raw Materials list** for the third time in the list issued on 13 September 2017 (European Commission (2017)).

Based upon detailed information from industry association BeST, of the 61 melting and mechanical-machining processes, for 12 processes **no feasible measures** could be identified to meet levels at or below 0.2 µg/m³ and a further 24 would **no longer be economically viable** at or below 0.2 µg/m³, see Tables 3-5 and 3-6. For target OELVs below 0.2 µg/m³, **market concentration** and the closure of companies of **strategic, environmental and/or innovative** importance is likely to occur.

The analytical method with the **lowest limit of quantification** (LoQ) available with an 'A' ranking can achieve detection at levels of 0.05 µg/m³. To prove that a company is operating at a given OEL under the proposed new standards requires three readings at 10% of the OEL. Therefore, the lowest OEL that can currently be assessed by an 'A' ranking method is 0.5 µg/m³ (Table 3-26.)

The study team concludes that the lowest target OELV at which the monetised benefits are likely to exceed the costs is between 0.2 and 0.6 µg/m^3 (inhalable). For the reasons outlined in the sensitivity analysis and multi-criteria analysis, the study team believes that an **OELV of between 0.4 and 0.6 µg/m^3** (inhalable) may better reflect the breakeven point.

This is similar to the recommendation of the Advisory Committee on Safety and Health at Work (ACSH's) Working Group on Chemicals (2017) of an OELV of 0.2 µg/m^3 (inhalable) with a value of 0.6 µg/m^3 (inhalable) during a transitional period of 5 years.

The study team also recommends a transition period with an initial OELV of between 0.6 µg/m^3 (inhalable) and 1 µg/m^3 (inhalable). The study team recommends that the OELV is assessed again after a few years of the transition period to ensure that the industry has found ways of achieving the final value and analysis methods with limits of quantification down to 10% of the final OELV are available.

1 Introduction

1.1 Background

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), referred to throughout this report as the CMD, aims to protect workers against health and safety risks from exposure to carcinogens or mutagens at work. It sets out the minimum requirements for protecting workers that are exposed to carcinogens and mutagens, including the binding Occupational Exposure Limit Values (OELVs). For each OELV, Member States 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.

1.2 Objectives

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

- Methodological note
- OEL/STEL deriving systems
- Report for cadmium and its inorganic compounds;
- Report for beryllium and its inorganic compounds;
- Report for inorganic arsenic compounds including arsenic acid and its salts;
- Report for formaldehyde;
- Report for 4,4'-Methylene-bis(2-chloroaniline) (MOCA); and
- Report for Chromium (VI) in fumes from welding, plasma cutting and similar processes.

One of the key aims of the study is to provide the Commission with the most recent, updated and robust information on a number of chemical agents and 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 general objectives with regard to these chemical agents 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 Value (OELV) and, where appropriate, a Short-Term Exposure Limit (STEL) and a skin notation.

The specific objective of this report is to assess the impacts of introducing an OELV and a STEL for beryllium.

1.3 Structure of the report

The report is organised as follows:

- Section 2 sets out the background (SCOEL/RAC, ACSH documents) and the scope of the assessment for beryllium;
- Section 3 sets out the baseline;
- Section 4 sets out the benefits of the relevant measures;
- Section 5 sets out the costs of the relevant measures;
- Section 6 summarises the market effects;
- Section 7 describes the environmental impacts;
- Section 8 describes the distribution of any impacts;
- Section 9 provides the limitations and sensitivity analysis; and
- Section 10 provides the conclusions.

The report is complemented by an Annex, which summarises the consultation exercise.

2 Background and scope of the assessment

This section comprises the following subsections:

- Section 2.1: Background
- Section 2.2: Study scope
- Section 2.3: Background information on exposure sources of inorganic arsenic compounds including arsenic acid and its salts
- Section 2.4: Summary of epidemiological and experimental data
- Section 2.5: Deriving a Dose-Response Relationship (non-carcinogenic effects)
- Section 2.6: Reference OELVs

2.1 Background

On the 8th February 2017, the Scientific Committee on Occupational Exposure Limits (SCOEL) made a set of recommendations for beryllium and inorganic beryllium compounds, which are summarised in Table 2.1.

Table 2.1: SCOEL recommendations for beryllium	
Type	**Level**
Occupational exposure limit value (OELV) - 8-hour time weighted average (TWA)	0.02 µg/m^3 (inhalable fraction)
Short term exposure limit (STEL)	0.2 µg/m^3 (inhalable fraction)
Biological limit value (BLV)	None recommended
Benchmark guidance value (BGV)	0.04 µg beryllium/L urine (sampling time not critical)
Additional categorisation	Carcinogenicity group C (genotoxic carcinogen with a mode-of-action based threshold)
Notation	Sensitisation (dermal and respiratory) No skin notation
Source: SCOEL (2017)	

Three interest groups within the Advisory Committee on Safety and Health at Work (ACSH) Working Group on Chemicals (2017) discussed these recommendations at three meetings. On 21st March 2017, the Working Group on Chemicals agreed to recommend a binding OELV for beryllium and inorganic beryllium compounds. ACSH's recommendation is summarised in Table 2.2. ACSH suggests that the OEL in Annex III of the CMD includes a footnote to indicate the importance of biomonitoring for beryllium exposure risk management. ACSH recommend that the new OEL is adopted as soon as possible.

The three interest groups represented employers, governments and workers. The employers' interest group (EIG) had concerns that whilst the OELV recommended by ACSH will protect against chromic beryllium disease (CBD), other studies have identified higher no observed adverse effect levels (NOAEL) and that 0.2 µg/m^3 is a challenging target to achieve. The EIG asks that an impact assessment of adopting this level as a binding OELV is made and taken into consideration. The workers' interest group asks that the OELV for beryllium is reviewed in future; it would prefer a level of 0.02 µg/m^3, which protects workers from beryllium sensitisation.

Table 2.2: ACSH recommendations for beryllium	
Type	**Level**
Occupational exposure limit value (OELV) - 8-hour time weighted average (TWA)	0.2 µg/m^3 (inhalable fraction) with a value of 0.6 µg/m^3 (inhalable fraction) during a transitional period of 5 years
Short term exposure limit (STEL)	None recommended
Biological limit value (BLV)	None recommended
Benchmark guidance value (BGV)	0.04 µg beryllium/L urine (sampling time not critical)
Additional categorisation	Carcinogenicity group C (genotoxic carcinogen with a mode-of-action based threshold)
Notation	Sensitisation (dermal and respiratory) No skin notation
Source: ACSH (2017)	

SCOEL (2016a) received comments from several government authorities and associations during its consultation process. The comments referred to the same levels as those that it subsequently recommended. SWEA (Sweden), HSE (United Kingdom) and BAuA (Germany) broadly agree with the recommendations. NIPH (Czech Republic) want a lower limit and ANSES (France) want to see a skin notation. The Beryllium Science and Technology Association (BeST) questions whether beryllium sensitisation (BeS) is an adverse health effect and believes that the OELV should only be set to prevent chronic beryllium disease (CBD). BeST proposes an OELV of 0.2 µg/m^3 (total particulate) similar to the permissible exposure limit (PEL) set by the Occupational Safety and Health Administration (US-OSHA) in the United States. BeST also believes that there should be a conversion factor of approximately 3 between inhalable fraction and total particulate in line with a report by Kock et al (2015), and section 3.4.2. This would make the USA PEL of 0.2 µg/m^3 (total particulate) approximately equal to 0.6 µg/m^3 (inhalable) which is BeST's preferred level for a new OELV. SCOEL does not agree with the use of any conversion factor.

2.2 Study scope

This report assesses the issues and impacts surrounding the setting of an OELV and STEL for beryllium.

The objective of the SCOEL recommendations for OELV and STEL is to prevent chronic beryllium disease (CBD) and beryllium sensitisation (BeS). The prevention of cancer is not considered, but SCOEL believe that any OELV that prevents CBD will also prevent cancer.

The Benchmark Guidance Value (BGV) is not investigated in this report.

Throughout this report, all beryllium exposures concentrations are given in µg/m^3.

2.3 Background information on exposure sources of beryllium

The beryllium and inorganic beryllium compounds were screened as described in Table 2-3. Throughout this report, any reference to beryllium means beryllium and inorganic beryllium compounds.

Table 2-3: Beryllium – screening process	
Step	**Number of compounds**
Total number of beryllium compounds	66+beryllium silicates
Of which, compounds that are also self-classified	12
Of which, inorganic beryllium compounds (or Be)	9
Source: RPA	

The relevant compounds to be assessed in the study are summarised in Table 2-4: two are definitely considered (shown in bold) and seven could potentially be relevant.

Table 2-4: Beryllium and inorganic beryllium compounds – final selection	
Compound	**CAS No.**
Beryllium oxide	**1304-56-9**
Beryllium	**7440-41-7**
Beryllium chloride	7787-47-5
Beryllium fluoride	7787-49-7
Beryllium sulphate	13510-49-1
Beryllium nitrate	13597-99-4
Disodium tetrafluoroberyllate	13871-27-7
Beryllium(2+) ion tetrahydrate dinitrate	13510-48-0
Source: RPA	

During the study, only two compounds were ever considered: beryllium and beryllium oxide. The study team is not aware of any occupational exposure to any of the remaining seven compounds and thus they are not included. Copper, aluminium, magnesium and nickel are widely alloyed with beryllium. These are a cause of worker exposure and are included in the study.

Approximately 80% of all beryllium in the EU is used in the alloy copper beryllium (CuBe.)

2.4 Summary of toxicological and epidemiological background (cancer and non-cancer effects)

2.4.1 Identity and classification

Table 2-5: Beryllium identity and classification	
Chemical Substance	Beryllium
CAS-Number	7440-41-7
EC-Number	231-150-7
Sum Formula	Be
Chemical Structure	Be
Classification (ECHA, 2017)	Acute Tox. 3* (H301); Skin Irrit. 2 (H315); Skin sens. 1 (H317); Eye Irrit. 2 (H319); Acute tox. 2* (H330); STOT SE 3 (H335); Carc. 1B (H350i); STOT RE 1 (H372) (harmonised)
Unit Transformation	
Source: FoBiG, ECHA (2011) and ChemID (2017)	

The assessment data refer to beryllium and inorganic beryllium compounds, specifically those detailed in Table 2-4.

Beryllium has been selected as a candidate community rolling action plan (CoRAP) substance (ECHA, 2014). The substance evaluation report (MSCA, 2014) comments on the classification:

- For beryllium metal, this substance does not appear to fulfil the criteria for classification as "acute Tox.3*; H301", "Eye Irrit. 2; H319" or "Skin Irrit. 2; H315"
- Therefore, the legal classification for acute oral toxicity as "acute Tox.3*; H301", "Eye Irrit. 2; H319" or "Skin Irrit. 2;H315" might have been based on a combined evaluation of beryllium and its compounds
- STOT RE1, H372 should specify the route of exposure: "Causes damage to lungs through prolonged or repeated exposure by inhalation"
- In principle, H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled" should be added. However, this would not change risk management measures
- Classification as H350i (Carc. Cat. 1B) is confirmed by the evaluating Member State competent authority (eMSCA)

It is assumed that all selected beryllium compounds have similar toxicological properties. However, despite their similarities, some differences between beryllium compounds have to be acknowledged and indicate uncertainties in subsequent quantitative calculations.

2.4.2 General toxicity profile, critical endpoints and mode of action

Beryllium and inorganic beryllium compounds are primarily taken up by inhalation during occupational exposure. Only minor skin absorption of the less soluble beryllium compounds takes place. Negligible amounts (less than 1%) of absorption take place via the gastrointestinal tract. Deposition and retention in the lung depends on particle size and solubility in physiological media and may be different for the various beryllium compounds. Beryllium is not metabolised.

Beryllium is a classified local carcinogen in the respiratory tract (Carc.Cat. 1B (H350i)), however, probably with a low potency. The mode of action for the carcinogenic effects is not fully understood, but, in most recent assessments, the substance is regarded to act via indirect genotoxic and epigenetic mechanisms[1] and therefore considered a threshold carcinogen.

The main non-carcinogenic health effects are:

- Chronic beryllium disease (CBD)
- Beryllium respiratory sensitisation (BeS)

CBD is a cell-mediated immunological[2] reaction of delayed type, usually observed after a long latent period. BeS precedes CBD, but the progression from sensitisation to disease is not fully understood (SCOEL, 2017).

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[1] Genotoxic: "Capable of causing a change to the structure of the genome." Epigenetic: "Changes in an organism brought about by alterations in the expression of genetic information without any change in the genome itself (The genotype is unaffected by such a change but the phenotype is altered.)" IUPAC (2007).

[2] Cell-mediated immunity: "Immune response mediated by antigen-specific T-lymphocytes" IUPAC (2007), where antigens are a "Substance or a structural parts of a substance which causes the immune system to produce specific antibody or specific cells and which combines with specific binding sites on the antibody

In addition, with regard to non-cancer effects, skin sensitisation has to be considered. Systemic effects (affecting the heart, kidneys, liver and blood) are assumed to be induced secondary to functional respiratory effects and therefore do not represent critical endpoints. Information on reproductive toxicity is largely lacking, but the sparse data available do not indicate effects on fertility or developmental toxicity.

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

IARC (2012) classifies beryllium and beryllium compounds as "carcinogenic in humans (Group 1)" based on "sufficient evidence" in humans and in experimental animals. However, IARC provides no aggregated cancer risk quantification.

CLH (harmonised classification and labelling) - classification (Carc. Cat. 1B) is based on studies with experimental animals (Finch et al., 1996; Finch et al., 1998a; Finch et al., 1998b; Nickell-Brady et al., 1994; Reeves et al., 1967a; Reeves and Vorwald, 1967b; Schepers, 1957; 1961; 1964; Strupp, 2011; Vorwald, 1953; Vorwald and Reeves, 1959; Vorwald et al., 1966 and Wagner et al., 1969). Those data provide sufficient evidence for classification by a "weight of evidence" approach.

Epidemiological studies provide indications of lung cancer from occupational exposure to beryllium compounds and corresponding risk quantifications (Bayliss et al., 1971; Infante et al., 1980; Levy et al., 2007; Levy et al., 2002; Mancuso, 1979; 1980; Sanderson et al., 2001a; Sanderson et al., 2001b; Schubauer-Berigan et al., 2011a; Schubauer-Berigan et al., 2011b; Schubauer-Berigan et al., 2008; Steenland and Ward, 1991; Wagoner et al., 1980 and Ward et al., 1992).

From these, a cohort study by Ward et al. (1992) covered seven beryllium processing work sites in the US with 9,225 workers during the period 1940-1969 with a follow-up in 1988. Before 1949, high beryllium exposures (> 1000 µg/m³) were frequently observed. The standard mortality rate (SMR) was increased to 1.26, with a 95% confidence interval: 1.12-1.42. This risk quantification was applied by IOM (2011) within an impact assessment on beryllium. However, Levy et al. (2002) questioned this risk quantification in a re-analysis of the data and found that there is little evidence of statistically elevated lung cancer risk in the respective plants.

The cohort study by Wagoner et al. (1980) covered 3055 workers from the Reading plant, which were exposed from 1942-1967 with a follow-up until 1975. The SMR was significantly elevated (SMR: 1.37 (95% confidence interval: 1.01-1.81)) and increased with time since end of employment. This risk quantification was applied by EPA (2008) within an impact assessment on beryllium.

The most recent study (Schubauer-Berigan et al., 2011a) aggregated data from seven beryllium processing work sites (partly covered also in the earlier assessments) with 9,199 workers in total and found a SMR of 1.17 (95% CI 1.08-1.28) at exposures higher than 10 µg/m³ for both mean and maximum time-weighted average exposure (particle distributions not provided). This risk quantification is explicitly mentioned by SCOEL (2017) within their recent assessment on beryllium (but not used for quantitative cancer risk calculations). US-OSHA (2015) used the analyses by

or cells" IUPAC (2007) and T-lymphocytes are an "Animal cell which possesses specific cell surface receptors through which it binds to foreign substances or organisms, or those which it identifies as foreign, and which initiates immune responses" IUPAC (2007).

Schubauer-Berigan et al (2008), which was performed for NIOSH, for their cancer risk assessment on beryllium.

In a systematic review by Boffetta et al. (2012), all these assessments have been analysed. Despite the possibility of significant confounders, the authors found indications of an elevated lung cancer risk from early and very high exposures, but insufficient evidence for lung cancer at lower exposure levels. In a recent mortality study by Boffetta et al. (2016), which has not been covered by existing OEL assessments, a historical cohort study with 16,155 beryllium workers in 15 facilities was performed. The lung cancer standardized mortality ratio was 1.02 (95% confidence interval: 0.94-1.10) in the whole cohort and less than 1 in the subcohort exposed to insoluble beryllium.

Because of serious concern about the quality of cancer risk quantifications in human and animal studies on beryllium exposure, no specific cancer risk may be quantified and no latency period can be provided. In epidemiological studies, some exposed workers developed lung cancer much later in life after only less than one year's exposure to beryllium (implausibly from mode of action considerations). The Hutchings & Rushton (2012) estimate (solid tumours peak latency: 36 years) appears to be adequate for lung cancer. The study team has not assessed animal data for information about latency as these provide contradictory outcomes.

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

The key studies regarded relevant for CBD and BeS assessment are:

- Kelleher et al. (2001) analysed data in a nested case-control study with workers manufacturing precision parts since 1969 and working with metallic beryllium, alloys and beryllium oxide ("Cullman facility"). Average employment lasted for 11.7 years (1 month – 29 years). From 235 exposed workers, 226 persons participated in the study. There were 20 cases (n=7 BeS, 13 CBD) observed in total. Exposure was assessed as lifetime weighted (LTW) average concentration and provided a no observed adverse effect concentration (NOAEC) for BeS and CBD of <0.02 µg/m³ (total particulate), an incidence of n= 1 (2 %) BeS, n= 3 (6 %) CBD, n= 4 (8 %) BeS alone + CDB for exposure range (0.02-0.1 µg/m³ LTW, total particulate) and an incidence of n= 6 (4 %) BeS, n= 10 (6.5 %) CBD, n= 16 (11 %) BeS alone + CDB for exposure range (>0.1-1 µg/m³ LTW, total particulate). This study was used as one of the key studies for deriving an OEL by SCOEL (2017), AGS (2010), and US-OSHA (2015).
- Another follow-up study from the same facility (Madl et al., 2007) covered exposure until 2005 and included 7 more cases (n (total) = 27 cases). Exposure conditions had improved since the assessment by Kelleher et al. From 27 workers (total) with BeS or (subclinical or clinical) CBD 1 person had a median LTW of 0.02-0.05 µg/m³, 6 workers with such effects were exposed to 0.05-0.1 µg/m³, 8 workers with such effects were exposed to 0.1-0.2 µg/m³, 7 workers with such effects were exposed to 0.2-0.4 µg/m³, and finally 5 cases above 0.4 µg/m³. If the mean instead of the median exposure were compared, no cases occurred below 0.05 µg/m³. This study was used as one of the key studies for deriving an OEL by SCOEL (2017), AGS (2010), and US-OSHA (2015).
- US-OSHA (2015) published a further update on the facility already assessed by Kelleher et al. (2001) and Madl et al. (2007), which was performed by the National Jewish Medical Research Center (NJMRC). Exposure data were presented as long-term average exposure levels (in addition to a cumulative exposure and a "highest exposure job" measure of exposure) and probably also quantified as "total particulate", mostly assessed by breathing

zone assessments (personal sampling). Based on a total of 319 exposed workers, 8.2% (n=26) were sensitised and/or suffered from CBD. This study was used as one of the key studies for deriving an OEL, e.g., by SCOEL (2017) and US-OSHA (2015).

- Schuler et al. (2012) also assessed beryllium exposure and effects in a cross-sectional study in a facility, which produced beryllium metal and copper-beryllium alloys in strip and bulk forms. Exposure was measured as total particulate and as respirable article mass. From 264 exposed workers, 2.3% (n=6) showed CBD and 7.6% (n=20) had BeS. The exposure mean concentration covered a range from <0.09-16.26 µg/m³ (total particulate) or <0.05- 3.56 µg/m³ (respirable particle mass) and the duration was from 0.02 to 6 years. The lowest concentration for BeS was 0.04 µg/m³ (respirable particle mass) or 0.12 µg/m³ (total particulate). This study was used as one of the key studies for deriving an OEL by SCOEL (2017), AGS (2010), and US-OSHA (2015).
- Other studies with similar results have mostly been reported for supportive evidence or discussion purposes (e.g., Arjomandi et al., 2010; Bailey et al., 2010; Cummings et al., 2007; Deubner et al., 2001; Henneberger et al., 2001; Johnson et al., 2001; Rosenman et al., 2005; Schuler et al., 2005; Thomas et al., 2009 and Thomas et al., 2013), but were usually not applied as key studies for OEL derivation.
- Other studies addressed possible sensitive subgroups due to polymorphisms which may increase the risk for CBD or BeS. However, those studies (van Dyke et al., 2011a and van Dyke et al., 2011b) have not been employed for quantitative non-cancer threshold estimations and were criticised by ToxStrategies (2011). More recently, there are indications that people with specific polymorphism are at elevated risk for BeS and CBD (Rosenman et al., 2011; SCOEL, 2017and Silveira et al., 2012).
- Studies with animal exposure to beryllium compounds, such as Vorwald AJ et al., (1959), have not been used for non-cancer risk assessment.

The assessments documented above have been established recently. No new relevant data are included in this documentation.

Several non-cancer endpoints were considered by SCOEL (2017) and not selected to derive the OELV. These include:

- Single inhalation exposure to high beryllium concentrations (> 100 µg/m³) can cause acute beryllium disease (ABD) in humans. Signs and symptoms of ABD range from mild inflammation of the upper respiratory tract to tracheo-bronchitis and severe pneumonitis. ABD is likely to be due to direct toxicity, unlike the immune mechanism of chronic beryllium disease, ATSDR (2002), Greim (2005) and US EPA (2008).
- The lung is the main target organ in animals (rats, mice, hamsters, guinea pigs, rabbits, cats, dogs, pigs and monkeys) after repeated inhalation exposure to beryllium and its compounds (beryllium oxide, sulphate, fluoride or hydrogen phosphate). In rats, the lowest concentration tested of 0.006 mg/m³ (6 hours/day, 5 days/week for life) caused lung inflammation and fibrotic changes (Vorwald AJ et al., (1959). (Note that this may be identical to CBD, but it is not clear and therefore can be considered as a separate endpoint.)
- As a consequence of functional respiratory restrictions, repeated inhalation exposure to beryllium may also lead to secondary systemic effects. Cardiovascular, renal, hepatic and haematological effects and weight loss were observed Greim (2005). Two cases of granulomatous myocarditis were identified at the Department of Forensic Medicine in Stockholm. The first case was a 30-year old man exposed to beryllium for about 10 years

and the second case was a 40-year old man exposed to beryllium for more than 10 years (WHO 1990).

- Contact with soluble beryllium compounds causes conjunctivitis in humans (Van Ordstrand et al 1945). No data were available regarding dermal or eye irritation by beryllium compounds in laboratory animals. Beryllium metal was shown not to be irritant to skin or eye in animals (Strupp 2011a).
- Beryllium compounds have further been shown to be skin sensitisers in animal experiments. However some of these experiments were not carried out in accordance with standardised procedures. In a recent study, beryllium metal powder did not cause skin sensitisation in guinea pigs, Strupp (2011b).

2.5 Deriving a Dose-Response-Relationship (non-carcinogenic effects)

2.5.1 Starting point

The starting point for establishing a dose response relationship (DRR) estimate is an OEL of 0.02 µg/m³ (inhalable) derived by SCOEL (2017) for beryllium and inorganic beryllium compounds.

SCOEL assigns a “Carcinogenicity Group C” to beryllium and inorganic beryllium compounds, which can be described as a “genotoxic carcinogen with a mode-of-action based threshold”. Establishing an exposure risk relationship (ERR) is not regarded feasible. Therefore, the critical toxicological endpoint for this assessment is not cancer but chronic beryllium disease (CBD). An air concentration at the workplace of 0.02 µg/m³, inhalable fraction, (recommended OEL by SCOEL) will be associated with a threshold concentration (no elevated prevalence of CBD or beryllium sensitisation). At higher exposures most workers experiencing CBD will also show BeS. In addition, there will be a fraction of the exposed that will only experience BeS (with no subsequent CBD). However, BeS is only covered qualitatively in this assessment. Usually BeS occurs at slightly lower concentrations compared to CBD. This difference is not discriminated for defining the starting point and the subsequent estimation of the DRR on CBD.

SCOEL provides a notation on (respiratory and dermal) sensitisation to beryllium and inorganic beryllium compounds.

No biological limit value (BLV) is recommended by SCOEL.

The Short Term Exposure Limit (STEL) proposed by SCOEL (2017) of 0.2 µg/m³ is used as starting point for discussing expected health related consequences of a modified STEL. However, it is not regarded as feasible to establish a DRR for STELs.

The starting point, the recommended OEL by SCOEL (2017), differs from other assessments, which applied a transformation factor from “total particulate” to the “inhalable fraction”, before they derived a threshold. This opinion by SCOEL apparently is a matter of scientific discussion and entails uncertainties with regard to exposure concentrations (inhalable fraction vs total particulate) assigned to effect data. This uncertainty is further discussed in section 3.2.

2.5.2 Carcinogenic effects

Beryllium is a classified as a Carc. Cat. 1B carcinogen, CLP (classification, labelling and packaging). SCOEL (2017) does not assign quantitative excess risk levels to exposure concentrations of beryllium.

The committee is of the opinion that concentrations of 10 µg/m³ of beryllium lead to an elevated risk of lung cancer based on several epidemiological studies. However, SCOEL acknowledges that cancer risk quantifications at lower doses are highly uncertain and a qualified risk estimate is not feasible. However, from the identified mode of action SCOEL assumes that there will be a "practical" threshold for carcinogenicity at an undefined level below 10 µg/m³. An exposure concentration corresponding to this threshold is not provided and may not be calculated with sufficient reliability.

It is assumed in this impact assessment that the 0.02 µg/m³ (inhalable) recommended OEL by SCOEL is well below this threshold for carcinogenicity. At the other end of the range, a small but elevated excess risk for lung cancer cannot be excluded, if long term exposure levels are at 1 µg/m³ or above. This can be concluded from a documented elevated risk level at 10 µg/m³, as reported by SCOEL. However, quantification of this elevated risk level at, e.g., 1 µg/m³ or 10 µg/m³, are regarded not feasible due to the strong sub linearity of the ERR. It should be noted that Boffetta et al. (2016) question any elevated cancer risk at similar exposure concentrations.

2.5.3 Non-carcinogenic effects

The approach to derive a DRR based on CBD for beryllium uses three sources:

- The reported prevalence of chronic beryllium disease among 319 beryllium exposed workers as presented by US-OSHA (2015) and reported by SCOEL (2017)
- The reported prevalence of chronic beryllium disease among 184 beryllium exposed workers as presented by Kelleher et al. (2001) and reported by SCOEL (2017)
- A modelled predicted estimate of CBD-cases/1000 exposed with a baseline of 1995, as derived as part of the US-OSHA (2015) assessment, only partially reported by SCOEL (2017)

The given numbers are then rounded and averaged to avoid inadequate mathematical exactness for the purpose of this DRR presentation.

The data on the prevalence of chronic beryllium disease (CBD), 319 beryllium exposed workers, as reported by SCOEL (2017; Table 9a corresponding to Table VI-6 in US-OSHA (2015)) are shown in Table 2-6.

Table 2-6: Prevalence of CBD including midpoint estimate adopted from US-OSHA (2015)

Exposure (average) µg/m³ (n= group zize)	Used midpoint estimate (this assessment) µg/m³	CBD (%)
0.0-0.080 (n=91)	0.04	1.1
0.081-0.18 (n=73)	0.13	5.5
0.19-0.51 (n=77)	0.35	7.8
0.51-2.15 (n=78)	1.1	10.3
Source FoBiG, US-OSHA (2015)		

The shaded reference points in Table 2-7 were used to calculate the DRR equations which are given in Table 2-10. Note that the "averaged" affected percentage is much lower than the predicted from US-OSHA (2015) modelling. This prediction was associated with a very large confidence interval and appeared not to be supported by the few observational prevalence data (e.g., Schuler et al., 2012, as reported in SCOEL (2015), Table 7b, on sensitisation only). Above 2 µg/m³, a proportional increase was assumed (doubling of risk by doubling exposure) as a default (no adequate data). The risk is not defined beyond 8 µg/m³. Accordingly, the equations are shown on Table 2-8.

Table 2-7: Prevalence of CBD used for this assessment (aggregated data)				
Predicted from data (baseline 1995), (US-OSHA, 2015, Tables 5a,b,c) µg/m³	**Kelleher et al. (2001, Table 7) µg/m³ (n=group size)**	**Prevalence from 319 Be exposed workers µg/m³)**	**CBD (%)**	**Final assumed (rounded) percentage (%) CBD**
	<0.02 (n=22 controls)		0	
	0.02		0	0
		0.04	1.1	
	0.06 (range: 0.02-0.1 µg/m³; n=46)		6	
0.1			2.6	
		0.13	5.5	
0.2			3	
		0.35	7.8	
0.5			4.5	5
	0.55 (range: 0.1-1 µg/m³; n= 138)		6.5	
1			8.8	9
		1.1	10.3	
2			31.3	20
Source: Modelling by FoBiG				

Table 2-8: Dose-risk-relationship (DRR) equations for beryllium	
Exposure range	**Equation**
≤ 0.02 µg/m³ (inhalable)	y= 0
0.02 – 0.5 µg/m³ (inhalable)	y= 0.1042x – 0.0021
0.5 - 1 µg/m³ (inhalable)	y= 0.08x + 0.01
1 - 2 µg/m³ (inhalable)	y= 0.11x – 0.02
2 - 8 µg/m³ (inhalable)	y= 0.1x
Source: RPA, FoBiG *x = exposure in µg/m³* *y = percentage where 100% is expressed as 1.0*	
Source: Modelling by FoBiG	

The dose response relationship is illustrated Figure 2-1.

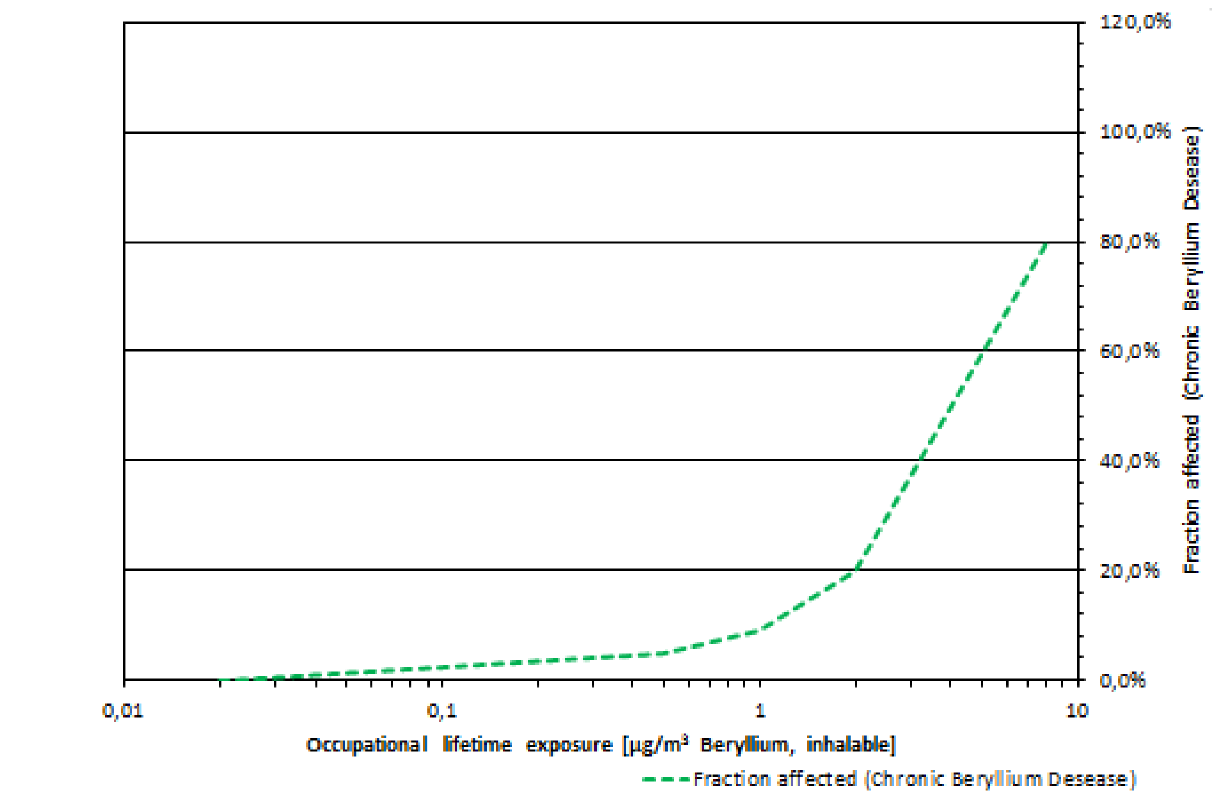

Figure 2-1: Dose Response Relationship (DRR) for non-cancer effects (right y-axis) from occupational exposure from occupational exposure to beryllium compounds (inhalable fraction)

Source: Modelling by FoBiG

Note: the x-axis is shown in log scale in this graphical presentation

The presented DRR for CBD has an unusually small increase in the predicted percentage of affected workers [0% → 9%] over a range of nearly two orders of magnitude in exposure [0.02 µg/m³ → 1 µg/m³] inhalable beryllium; note the logarithmic scale in the graphical presentation]. The affected fraction only increases significantly at higher concentrations (> 1 µg/m³). This shallow slope is remarkable, because usually the lowest observable adverse effect concentration (LOAEC) is associated with approximately 10% effect incidence and usually the no observed adverse effect concentration (NOAEC) is approximately three times higher. However, for beryllium, 1 µg/m³ is associated with a 9% incidence and a factor of 500 is needed to reach the threshold of 0.02 µg/m³.

Prediction data from US-OSHA (2015) was applied, only partly reported by SCOEL (2017), in addition to observational epidemiological prevalence data to support the derived DRR. However, there are further predictions by US-OSHA (2015) see Tables 5a, 5b and 5c, with even lower predicted CBD cases (usually < 1%) associated with respective alternative OELs. Some of the predictions with baselines in the years 1995 or 1999 and some of the reported prevalence data may underestimate exposure. This may be because earlier higher exposure levels influenced the reported prevalence (SCOEL discusses this potential confounder for the data of Kelleher et al., 2001). However, lower predictions were not used for several reasons:

- They would contradict the observed prevalence data
- Data with cumulative exposure do not support a dominating influence of early high exposures on incidence levels

- Lower predictions would not be plausible in combination with the given threshold of 0.02 µg/m³ for this analysis
- Lower incidences would not cover the experience with effect concentrations for BeS, which is observed often at lower concentrations compared to CBD

Estimating the DRR involves numerous uncertainties due to the effect of:

- Particle size distribution
- Solubility of the respective beryllium particles
- Influence of peak exposure
- Sampling method used (addressing "total particulate" or the "inhalable fraction" or the "respirable fraction")
- Correct measure of exposure (average vs cumulative vs highest exposed job) and duration of exposure
- Latency (years from first exposure to CBD)
- Inclusion or exclusion of clinical vs subclinical cases; definition and detection method of CBD

SCOEL does not use the approach taken by AGS, which used a factor of 2 to extrapolate exposure concentrations provided as "total particulate" (closed face cassette (CFC) 37 mm sampler) based on a recent study by Kock et al. (2015; publication date, a draft version was available to AGS before). SCOEL apparently did not discriminate exposure assessed with this sampling method and exposures to the "inhalable" fraction. Generally, SCOEL states: "the difference between total dust and inhalable dust strongly depends on the particle size distribution in a given situation, i.e. the smaller the particles, the less difference between total dust and inhalable dust". For the Cullman facility data, used to quantify the DRR, SCOEL describes the following particle size distribution: "the impactor sampling showed a bimodal particle mass fraction with about 30% with a diameter above 10 µm, 70% with a diameter less than 10 µm and 35% with a diameter less than 0.6 µm." As SCOEL linked effect data to the inhalable fraction (mostly based on "total particulate" data without transformation), this procedure is adapted in this impact assessment with the purpose of deriving the DRR.

The limited fraction of coarse particles not covered by CFC 37 and the small differences in the fraction affected derived either from "total particulate" or "respirable particles" – at least in the lower dose range – in the study by Schuler et al. (2012; see Table 7a, in SCOEL (2017)) indicates that exposure quantification uncertainties may not lead to a significant bias.

2.5.4 Biomonitoring values

SCOEL (2017) does not recommend a BLV, which is plausible, as the critical endpoint is local respiratory toxicity (cancer, BeS, CBD). However, a biological guidance value (BGV) is recommended by SCOEL to monitor current exposure to beryllium. This value has not been linked to adverse effect levels, but provides a comparison to background concentrations of beryllium in the non-exposed general population. No DRR is given for biological monitoring within the framework of this impact assessment.

2.5.5 Short term limit value (STEL)

SCOEL (2017) recommends a STEL of 0.2 µg/m³ (inhalable fraction) with reference to a study by Madl et al. (2007), who found (according to SCOEL): "that maintaining beryllium concentrations below 0.2 µg/m³ for 95% of the time may prevent BeS and CBD."

The ratio of 10 for STEL/OEL is unusually high. For example, the default methodology for short term exposures on local effects in the respiratory tract in Germany (AGS, 2012) is 1 with a maximum of 8, if supported by substance specific data. However, this high ratio corresponds to an extreme shallow slope in effect incidence by increasing exposure levels for long term exposure.

For the background of the STEL, further refer to a study by Henneberger et al. (2001), who observed positive reactions in 2 of 19 workers (11%) in a test for BeS (beryllium lymphocyte proliferation test): these workers had mean exposures below 0.1 µg/m³ with peak exposures below 0.4 µg/m³.

From these data and from the mode of action, it is assumed that BeS is more closely linked to peak exposures than CBD. However, adequate data are missing to quantify a threshold and a minimum duration of peak exposures to induce BeS.

There also are insufficient data to calculate a DRR for STEL, that is to derive a defined increased fraction of persons being affected if a higher STEL is selected. However, given the starting point of SCOEL with a permissible exposure (STEL) of 0.2 µg/m³ (inhalable fraction) and the reported indication of increased effects from peak exposure to < 0.4 µg/m³, any increase in STEL (absolute concentration, not linked to an OEL, which is set for long term exposure) can be assumed to increase the probability of adverse health effects from peak exposures.

2.6 Reference OELVs/STELs

Throughout the analysis of benefits and costs, eight reference levels are taken for OELs and four for STELs.

Table 2-9: Reference levels for beryllium OELVs

Level	Reason for inclusion
0.02 µg/m³ (inhalable)	OEL at the level proposed in SCOEL REC 175
0.05 µg/m³ (inhalable)	Intermediate level
0.1 µg/m³ (inhalable)	Lowest current national OEL in EU Member States (Finland)
0.2 µg/m³ (inhalable)	ACSH recommendation for OEL
0.35 µg/m³ (inhalable)	Intermediate level
0.6 µg/m³ (inhalable)	Equivalent to the USA PEL of 0.2 µg/m³ (total particulate). Several respondents believe this is the lowest economically viable level.
1 µg/m³ (inhalable)	Intermediate level
2 µg/m³ (inhalable)	Median and mode of national OELs in EU Member States

Source: RPA, see Table 3-1 for current OELs in Member States

Table 2-10: Reference levels for beryllium STELs	
Level	**Reason for inclusion**
0.2 µg/m^3 (inhalable)	STEL at the level proposed in SCOEL REC 175
0.4 µg/m^3 (inhalable)	Lowest current national STEL in EU Member States (Finland). Assumed inhalable since OEL is inhalable
5.77 µg/m^3 (inhalable)	Mean of current national STELs in EU Member States
8 µg/m^3 (inhalable)	Median of current national STELs in EU Member States
Source: RPA, see Table 3-1 for current STELs in Member States	

3 The baseline scenario

3.1 Introduction

This section comprises the following subsections:

- Section 3.2: Sampling methods – inhalable, total particulate or respirable
- Section 3.3: Existing national limits
- Section 3.4: Relevant sectors and processes
- Section 3.5: Exposure concentrations
- Section 3.6: Exposed employees and enterprises analysis
- Section 3.7: Exposed employees by sector and Member State
- Section 3.8: Exposed employees by exposure concentration by sector
- Section 3.9: Current risk management measures (RMMs)
- Section 3.10: Voluntary industry initiatives
- Section 3.11: Best practice
- Section 3.12: Standard monitoring methods/ tools
- Section 3.13: Relevance of REACH authorisations or restrictions
- Section 3.14: Market analysis
- Section 3.15: Alternatives
- Section 3.16: Current (past) and future burden of disease
- Section 3.17: Summary of baseline scenario

3.2 Sampling method - inhalable, total particulate, or respirable

There are three different methods of measuring exposure, which need to be defined alongside the OELV:

- Inhalable - particles inhaled though the mouth and nose, <100 µg
- Total particulate - inhaled particles penetrating beyond the larynx, <30 µg (also known as thoracic, total mass and total dust)
- Respirable - inhaled particles penetrating to the unciliated airways of the lung (alveolar region), <10 µg

Often it is unclear which method is used and several Member States do not state which applies to their OEL, resulting in confusion.

In the USA, companies sample using the total particulate method and their permissible exposure limit (PEL) is defined this way. In the EU, companies sample using the inhalable method and most OELs are defined as inhalable. Kock et al., (2015) calculated a conversion factor of 2.88 between the sampling methods, which is sometimes rounded up to 3.0. Therefore, the USA's 0.2 $\mu g/m^3$ total particulate PEL is often considered to be approximately equivalent to an EU OEL of 0.6 $\mu g/m^3$ inhalable.

SCOEL (2017) does not agree with having a conversion factor, but the study team believes it is essential as the inhalable sampling gives higher readings than total particulate sampling. After careful consideration, a conversion factor of 2 has been used throughout this analysis. All the US-OSHA exposure values taken from USA Department of Labor (2015) and used in the analysis have been multiplied by 2.0 to equate to the inhalable values used in the EU.

3.3 Existing national limits

3.3.1 OELs

OELs in different countries and internationally span from 0.02 µg/m³ (inhalable fraction) (SCOEL, 2017) to 5 µg/m³ (inhalable fraction) in Greece, Slovakia and Slovenia. The range of OELs is documented in Table 3-1. Some of these values also address carcinogenic endpoints, but most of them appear to focus on beryllium sensitisation (BeS) and chronic beryllium disease (CBD). Background documents were not always available to explain the rational of the respective OELs. The OEL of 0.02 µg/m³ (inhalable fraction, TWA) by SCOEL (2017) for beryllium and inorganic beryllium compounds, is mainly based on chronic beryllium disease (CBD) and beryllium sensitisation (BeS) observed in several epidemiological studies (Kelleher et al., 2001; Madl et al., 2007; Schuler et al., 2012). Different particle sizes have been associated with elevated risks and the applied lowest observable adverse effect concentration (LOAEC) is linked to the respirable fraction. However, total particulate data find CBD or BeS effects at similar concentrations.

In Germany, in an assessment by AGS (2017), the LOAEC for the respirable fraction was defined at 0.17 µg/m³ beryllium based on the study by Schuler et al. (2012). A LOAEC of 0.2 µg/m³ for total particulate was concluded by the same study. Applying an extrapolation factor of 3.0 (LOAEC-NOAEC) leads to an OEL of 0.06 µg/m³ for respirable fraction (ECHA, 2014) and of 0.07 µg/m³ for total particulate. However, total particulate is not the appropriate exposure concentration measure. Therefore, total particulate was transformed to the inhalable fraction by a factor of 2, selected by AGS from analytical data by Kock et al., 2015. Therefore the OEL for the inhalable fraction was set to 0.14 µg/m³ for Germany.

In the USA, ACGIH (2009) derived an OEL (TLV-TWA) of 0.05 µg/m³ for beryllium, inhalable particulate matter based on the data by Madl et al. (2007) and Kelleher et al. (2001), and supported by Schuler et al. (2005) to protect from BeS and CBD. ACGIH (2014) maintained the 0.05 µg/m³ (inhalable) and differentiated the sensitising potential, by assigning the category "dermal sensitiser" to soluble beryllium compounds and "respiratory sensitiser" to soluble and insoluble compounds.

In the USA, US-OSHA (2015) derived an OEL (PEL) of 0.2 µg/m³ for respirable beryllium. This OEL includes considerations of health impact (non-carcinogenic effects) at this and lower exposures, but it is not strictly health based. US-OSHA "has preliminarily determined that there is significant risk remaining at the proposed PEL of 0.2 µg/m³. However, the available evidence on feasibility suggests that 0.2 µg/m³ may be the lowest feasible PEL. Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. In addition, the recommended standard provided to US-OSHA by representatives of the primary beryllium manufacturing industry and the Steelworkers Union further supports the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (US-OSHA, 2015).

In France, ANSES (2010) derived their OEL-proposal of 0.01 µg/m³ (inhalable) based on an identical LOAEC for CBD of 0.2 µg/m³, which is based on earlier assessments (Kreiss et al., 1997; Rosenman et al., 2005). Note that INRS established a much higher OEL of 2 µg/m³. This limit value (VLEP= valeur limite d'exposition professionelle) by INRS is a recognised value with an indicative character, thus not legally binding, and originates from 1995.

There are discrepancies in "skin notation" internationally such as ANSES (2010) and SCOEL (2017) which is probably because some of the soluble beryllium compounds can be percutaneously absorbed to a significant extent.

SCOEL (2017) did not derive a risk estimate, but report a significant lung cancer risk quantification determined by Schubauer-Berigan et al. (2011b) at work place exposures (> 10 µg/m³); standardised mortality ration (SMR) = 1.17 (95% confidence interval: 1.08-1.28). However, there were controversial discussions after that publication where Bofetta et al. (2012) seriously questioned the results of this epidemiological study. SCOEL (2017) finally concludes, "the recommended OEL is not based on carcinogenicity and is considerably lower as compared to exposure estimates leading to lung cancer in humans." Therefore, SCOEL finds that "this controversy (about the validity of the Schubauer-Berigan et al. (2011b) cancer risk assessment) does not need to be resolved".

IARC (2012) finds that there is sufficient evidence in humans for the carcinogenicity of beryllium and beryllium compounds and furthermore, there is sufficient evidence from experimental animals for the carcinogenicity of beryllium and beryllium compounds. However, IARC does not provide quantitative cancer risk quantification data.

In an unpublished draft, AGS (result referred to in ECHA, 2014) also confirms an elevated cancer risk from beryllium exposure at high occupational concentrations. However, the committee was not able to quantify the respective excess risk. Also animal studies are acknowledged to demonstrate an elevated cancer risk, but are not regarded suitable to quantify this risk.

The REACH registrant for beryllium did not develop a derived no effect limit (DNEL) (ECHA Dissemination, 2017). ECHA (2014) acknowledges that "no DNEL for carcinogenicity is attributable".

IOM (2011) did not derive an excess lung cancer risk for beryllium. However, they used a significantly elevated standard mortality rate (SMR) at higher exposures (Ward et al., 1992) for their health impact assessment. For low (background) exposures, the risk estimate is assumed to be not elevated (SMR=1). ANSES (2010) reports risk quantifications from the earlier epidemiological studies, but does not link their OEL to carcinogenicity. They suggest the ALARA (As low as reasonably achievable) principle to minimize exposure. Similarly, ACGIH (2009) discusses the controversial results of epidemiological studies regarding lung cancer effects of beryllium (Brown et al., 2004; Levy et al., 2007; Levy et al., 2002; Sanderson et al., 2001b; Schubauer-Berigan et al., 2008 (26)), but the OEL (TLV) is based on non-carcinogenic endpoints.

EPA (2008) did not change the early unit risk estimate from 1998. The excess risk then was 4×10^{-4} (after transforming the EPA result to the workplace scenario) and was based on the study by Wagoner et al. 1980) However, they expected better data from an ongoing evaluation by Schubauer-Berigan et al. (2008), which was not available at the time, when the EPA draft was edited in 2008. They emphasised the significant uncertainties of this assessment.

Table 3-1: OELs and STELs for beryllium and inorganic compounds in EU Member States and selected non-EU countries						
Member State	**Value [µg/m³] (I) inhalable; (T) total particulate; (R) respirable**	**Specification of value‡ (year, established)**	**OEL definition**	**Study details**	**STEL [µg/m³]**	**Specification of STEL‡**
Austria	5 (I) 2 (I)	-Whetting of Be metals and alloys, SKIN -other uses, SKIN	SE/T	Not known or not specified	20 (I) 8 (I)	-whetting of Be metals and alloys, SKIN -other uses, SKIN
Belgium	2 (I)		SE/T		10 (I)	SKIN
Bulgaria	2		SE/T		-	N/A
Croatia	2	-except aluminium beryllium silicate	SE/T		-	N/A
Cyprus	2	-SKIN	SE/T		-	N/A
Czech Republic	1		HB		2	-ceiling
Denmark	1	- powder and compounds, SKIN	SE/T		-	N/A
Estonia	2		SE/T		-	N/A
Finland **	0.1 (I)	-SKIN	SE/T		4 (I)	-15 min, SKIN
France[1,6,7,§§]	2 [1,7,§§] [0.01 (I) [6]]	-in force -SKIN[6]	SE/T		2	
Germany[2]	0.14 (I) 0.06 (R)	-except aluminium beryllium silicate (2015) -except aluminium beryllium silicate (2015)	HB	Endpoint: CBD and BeS Species: human for Schuler et al. (2012) Kock et al. (2015)	0.14 (I) 0.06 (R)	-except aluminium beryllium silicate -except aluminium beryllium silicate
Greece	5		SE/T	Not known or not specified	-	N/A
Hungary	2		HB		-	N/A
Ireland	0.2	-SKIN[+]	HB		-	N/A
Italy	-		N/A		-	N/A
Latvia	1 (I)		SE/T		-	N/A
Lithuania	2 (I)		SE/T		-	N/A
Luxembourg	-		N/A		-	N/A
Malta	-		N/A		-	N/A
Netherlands	-		N/A		-	N/A
Poland	0.2 (I)		HB		-	N/A
Portugal **	0.05 (I)	-SKIN	HB		-	N/A
Romania	2		Not known		-	N/A
Slovakia	5 (I) 2 (I)	-refers to whetting of Be metals and alloys, except aluminium beryllium silicate -refers to other uses, except aluminium beryllium silicate	SE/T		-	N/A
Slovenia	5 (I)	- refers to grinding, except aluminium beryllium silicate	SE/T		20 (I)	- refers to grinding, except aluminium beryllium silicate

Table 3-1: OELs and STELs for beryllium and inorganic compounds in EU Member States and selected non-EU countries						
Member State	**Value [µg/m³] (I) inhalable; (T) total particulate; (R) respirable**	**Specification of value‡ (year, established)**	**OEL definition**	**Study details**	**STEL [µg/m^3]**	**Specification of STEL‡**
	2 (I)	- refers to other uses, except aluminium beryllium silicate			8 (I)	- refers to other uses, except aluminium beryllium silicate
Spain	0.2 (I)		SE/T		-	N/A
Sweden	2 (T)		SE/T		-	N/A
United Kingdom	2	-SKIN	SE/T		-	N/A
SCOEL[3]	0.02 (I)	(2017) Sensitisation (dermal and respiratory)	HB	Endpoint: CBD and BeS Species: human for Madl et al. (2007) Kelleher et al. (2001) Schuler et al. (2012)	0.2 (I)	
Non-EU-countries						
Australia	2		Not known	Not known or not specified	-	N/A
Brazil	-		N/A	Not known or not specified	-	N/A
Canada, Ontario	2		Not known	Not known or not specified	10	
Canada, Québec	0.15		Not known	Not known or not specified	-	N/A
China	0.5		SE/T	Not known or not specified	1.0	-15 min
India	2		SE/T	Not known or not specified	-	N/A
Japan	2		HB	Not known or not specified	-	N/A
South Korea[1]	2		SE/T	Not known or not specified	10	
Kazakhstan ***	1		Not known		-	N/A
Russia ***	1		Not known		-	N/A
Switzerland	2 (I)		Not known		-	N/A
USA; ACGIH[4]	0.05 (I)	-SKIN (2009) (2014) Sensitisation (dermal for soluble Be compounds), respiratory (all inorg. Be compounds)	HB	Endpoint: CBD and BeS Species: human for Madl et al. (2007) Kelleher et al. (2001) Schuler et al. (2012)	-	N/A
USA, OSHA[7,]	0.2 (T)	(2015)	SE/T	Endpoint: CBD and BeS Species: human for Madl et al.	2 (T)	

Table 3-1: OELs and STELs for beryllium and inorganic compounds in EU Member States and selected non-EU countries						
Member State	Value [µg/m³] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡ (year, established)	OEL definition	Study details	STEL [µg/m^3]	Specification of STEL‡
				(2007) Kelleher et al. (2001) Schuler et al. (2012)		
USA, NIOSH	#		SE/T	Not known or not specified	0.5	-ceiling

‡ Beryllium and inorganic beryllium compounds, for all occupations, as Be, if not stated otherwise in this column.
+ contradictory data from questionnaire responses or GESTIS.
- not established/assigned
SKIN: Skin notation assigned.
N/A = not applicable
SE/T = influenced by socio-economic and/or technical considerations;
HB = health or risk-based
*** Limit values are indicative*
**** Values provided by BeST*
§§ Limit values are recognised– not according to decree modified on 30 June 2004 – thus not legally binding.
 # No recommended exposure limits (RELs) established - Reference to "Appendix A - NIOSH (2016) Potential Occupational Carcinogens". NIOSH has changed policy with regard to carcinogenic substances. Under the old policy, RELs for most carcinogens were non-quantitative values labelled "lowest feasible concentration (LFC)." The effect of the new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL. Changes in the RELs and respirator recommendations that reflect the new policy will be included in future editions.

Sources:
Questionnaire information (this project) or GESTIS (IFA, 2017), or country specific lists of OEL from web-search, if not stated otherwise (references 2-7, below).
1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen
2: AGS (2017) Ausschuss für Gefahrstoffe. Begründung zu Beryllium und Berylliumverbindungen in TRGS 900
3: SCOEL (2017) Recommendation from the Scientific Committee on Occupational Exposure Limits for Beryllium and inorganic beryllium compounds.
4: ACGIH (2009; 2014) American Conference of Governmental Industrial Hygienists. Beryllium and its inorganic compounds.
5: ANSES (2010) Valeurs limites d'exposition en milieu professionnel. Le béryllium et ses composés.
6: INRS (2016) Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984, Octobre 2016.
7: US-OSHA (2017) Protecting Workers from Exposure to Beryllium and Beryllium Compounds: Final Rule Overview Online: https://www.osha.gov/Publications/OSHA3821.pdf

3.3.2 STELs

SCOEL (2017) recommends a STEL of 0.2 µg/m³ (inhalable fraction) with reference to a study by Madl et al. (2007), who found (according to SCOEL): "that maintaining beryllium concentrations below 0.2 µg/m³ 95 % of the time may prevent BeS and CBD."

For the background of the STEL further refer to a study by Henneberger et al. (2001), who observed in 2 of 19 workers (11%) positive reactions in a test for BeS (beryllium lymphocyte proliferation test): those workers had mean exposures below 0.1 µg/m³ with peak exposures below 0.4 µg/m³.

3.3.3 Biomonitoring values

SCOEL (2017) generally reports that beryllium exposure can be monitored in urine with no BLV recommended, but with a BGV of 0.04 µg/L urine (sampling time not critical), which is based on the upper end (95th percentile) on non-occupational exposure in two studies (Goullé et al., 2005; Heitland and Köster, 2004).

Similarly, a BAR ("biologischer Arbeitsplatzreferenzwert") is suggested in Germany, which is not based on health impact considerations but on background exposure, the level being 0.05 µg/L (Paul and Wenzlaff, 2013).

3.4 Relevant sectors, uses and operations

3.4.1 Sectors

The study identified ten industrial sectors as using beryllium and having employees at risk of exposure to beryllium. Several sources were investigated to establish this list:

- BeST provided the study with a detailed description of the sectors that they supply and the processes within them
- US-OSHA (2015) Table IX-2 - Characteristics of industries affected by US-OSHA's proposed standard for beryllium and Table IX-4 - Numbers of workers exposed to beryllium. The data in these tables was estimated by US-OSHA in 2012
- Eurostat and the Statistical Classification of Economic Activities in the European Community known as NACE codes (revision 2) (2007) provide the base information on sectors for 2015: employees and enterprises, split by size of enterprise, SME, Member States, and years for trends
- BAuA (2014) provides average exposure levels for various sectors at the 95th percentile, 2014.
- IOM (2011) provides estimates of exposed employees and exposure levels by sector, 2011
- CAREX EU (1990-1993 plus 1997) provides estimates of exposed employees by sector for many Member States
- Carex Canada provides estimates of exposed employees by sector
- French study from 2004-2006 (Vincent et al 2009) provides estimates of exposed employees and average exposure levels by sector

The data from these sources are shown in Table 3-2 and this was analysed to find coherent sectors that also could provide sufficient data for analysis. The final list of sectors with its associated NACE codes is shown in Table 3-3. The final list of sectors, together with any published relevant average exposure concentrations, is shown in Table 3-4.

Foundries and metal fabrication sectors are straightforward: all sources agree that beryllium is found in some of these enterprises and there are estimates of employees affected and exposure levels. Transportation, ICT and Medical devices are also relatively straightforward as all sources mention them and there is data available. Transportation and ICT crossover many NACE and North American Industry Classification (NAIC) codes, which means they may be less accurate. BeST believes that Transportation and ICT are the two largest industries using beryllium in the EU and therefore these are kept as separate sectors.

Specialised manufacturing brings together four industrial sectors identified by BeST (defence and security; fire-fighting and rescue; oil gas and electricity; and space and research). This was because of the significant crossover between the NACE codes C27, C28 and C33 to which they relate and between the sectors identified in the MEGA data BAuA (2017a). In the Carex Canada data set, "81 Other services (except public administration)" is thought to refer to repair and maintenance of machinery and is included in industries covered by NACE C28.

Medical devices was kept separate from Specialist manufacturing as the NACE code 32.50 covers manufacture of medical and dental instruments and supplies. Carex Canada "339 miscellaneous manufacturing" is nearly all health professionals, hence it maps to Medical devices.

Construction is retained because although BeST has no knowledge of the construction industry being supplied with beryllium, and there is little reliable data about exposed employees and affected enterprises, it has high exposure levels to beryllium listed in the MEGA data BAuA (2017a), although this was based on only 11 measurements. CAREX EU also mentions the construction sector although only in France, based on France's own estimate of 400 workers dating back in 1990. Also in France between 2004-2006, construction registered 9 measurements, all between 0 and 1 $\mu g/m^3$, with a mean of 0.5 $\mu g/m^3$, implying a 95th percentile over 1 $\mu g/m^3$, Vincent et al (2009). CAREX Canada also mentions construction with a relatively high estimate of exposed workers at 1550.

Three possible ways in which beryllium might be entering the construction industry have been investigated. The first is the use of fluorspar (fluorite) in cement manufacture as this can contain traces of beryllium. The second is the use of waste, slag or fly-ash in cement manufacture, which could contain traces of beryllium as outlined by Achternbosch et al, (2003). The third also relates to the use of slag, but in sandblasting activities Baltimore Sun (2012). However, the study team has been unable to find any further data to support these theories. Thus, even though construction is included, it is difficult to estimate the impact it has on workers. A further complication is that construction employs far more workers in the EU than any other sector included in the analysis, approaching 10 million workers. Therefore, throughout the analysis, construction is reported separately as it tends to overwhelm the other results.

Glass initially puzzled the study team as BeST has no knowledge of the glass industry being supplied with beryllium, but there was a high 95 percentile exposure level for glass in the MEGA data BAuA (2017a), even if there were only 19 measurements. However, it seems likely that ceramic insulator manufacturers, some of whom use beryllium, are the cause of these exposure levels and the NACE code for this industry is within C23 glass. There are no reports of any mainstream glass manufacturer using beryllium; several were contacted as part of the study because of their use of arsenic.

Laboratories are retained because this sector was mentioned in both the Carex Canada and ASA Finland data. BeST also agree that some laboratories are supplied beryllium, usually in very small quantities.

Recycling was retained because there is specific data about the exposure levels in the BAuA MEGA data (2014) and the Vincent et al (2009) data from France. One of the interviews conducted in the study confirmed exposure to beryllium occurred. BeST also confirmed that beryllium is present in some recycling facilities. BeST reports that 20 tonnes of beryllium is recycled each year, much as copper beryllium (CuBe). This indicates that approximately 50% of the beryllium imported into the EU is fed back into the system as recycling. Most of this is new scrap generated during manufacture and this is sent back to the producers. Some of the high tech industries such as defence and medical also recycle their goods at end of life. There is little beryllium recycling of consumer goods as the components are very small and they have a low percentage of beryllium. However, recyclers of consumer electronics may be exposed to these small amounts even if they are not attempting to recycle them.

Several industries such as textiles, chemicals, rubber, crude petroleum, electricity, gas and steam, and wholesale trade are mentioned in the Carex EU and Carex Canada data sets and by the IOM (2011) and Vincent et al (2009) (there are some variations in terminology). However, these industries do not appear in the analysis by US-OSHA or in the MEGA data BAuA (2017a) on exposure levels and BeST has no knowledge of the use of beryllium in these sectors. The IOM (2011) report indicates that any exposure levels in these sectors are likely to be low and this study has not found any data that contradicts this view. Therefore, these sectors are excluded from the analysis.

The Carex Canada data set also mentions both the wood and paper industries, but these are not mentioned by any other source and these sectors are excluded from the analysis.

Finally, the US-OSHA table of entities IX-2 lists "621210 Offices of dentists," indicating 1100 exposed employees in the total workforce of approximately 850,000, or 0.13%. However, the sector is not listed in the other US-OSHA table of workers exposed IX-4. Dentists' offices are not specifically stated by any other source, (dental laboratories are mentioned and included in medical devices.) Therefore, this sector is excluded from the analysis.

All of the exclusions are listed in the last row of Table 3-2.

Table 3-2: Evaluation of industrial sectors affected by beryllium

US-OSHA	NACE	BeST sectors	BAuA MEGA	Vincent et al	IOM	CAREX EU	Carex Canada	ASA Finland
USA	EU	EU	Germany	France	Germany	EU	Canada	Finland
Employees exposed and exposure levels	Total employees by NACE, MS, SME, year	Detail about processes and RMMs	Exposure levels	Exposure levels	Employees exposed & exposure levels	Employees exposed	Employees exposed	Employees exposed
Foundries								
331111 Iron and Steel mills 331221 Rolled steel shape 331513 Steel foundries (except * 332919 Other metal valve and * 332999 All other miscellaneous 331419 Primary smelting * 331421 Copper rolling, drawing * 331422 Copper wire (except 331521 Aluminium die-casting 331522 Nonferrous (except 331524 Aluminium foundries 331525 Copper foundries (except 331314 Secondary smelting & 331423 Secondary smelting 331492 Secondary smelting	C24 Manufacture of basic metals	Mentioned	16 Foundry	27, Manufacture of basic metals	Metals fabrication	371 Iron and steel basic industries 372 Non-ferrous metal basic industries	331-Primary metal manufacturing	None
Metal fabrication								
332117 Power metallurgy part * 332212 Hand and edge tool * 332312 Fabricated structural * 332313 Plate work manufacturing 332322 Sheet metal work 332323 Ornamental and * 332439 Other metal container * 332999 All other miscellaneous * 333414 Heating equipment * 333999 All other miscellaneous 337215 Showcase, partition * 331421 Copper rolling, drawing	C25 Manufacture of fabricated metal products, except machinery and equipment	Manufacture of injection moulds Stamping	20 Metalworking	28, Manufacture of fabricated metal products, except machinery and equipment	Metals fabrication	381 Manufacture of fabricated metal products,	332-Fabricated metal product manufacturing	None

Table 3-2: Evaluation of industrial sectors affected by beryllium								
US-OSHA	**NACE**	**BeST sectors**	**BAuA MEGA**	**Vincent et al**	**IOM**	**CAREX EU**	**Carex Canada**	**ASA Finland**
* 331422 Copper wire (except 332721 Precision turned product 336370 Motor vehicle metal 332116 Metal stamping 332612 Light gauge spring								
Transportation								
* 332439 Other metal container * 336211 Motor vehicle body 336214 Travel trailer and camper * 336399 All other motor vehicle 336510 Railroad rolling stock 336999 All other transportation * 336312 Gasoline engine and * 336330 Motor vehicle steering * 336340 Motor vehicle brake * 336340 Motor vehicle 336360 Motor vehicle seating * 336322 Other motor vehicle	C29 Manufacture of motor vehicles, trailers and semi-trailers C30 Manufacture of other transport equipment	Car and airplane components, airbags, ABS, bushings and bearings in aircraft landing gear, power steering and electronic control systems, anti-lock brakes, undersea earthquake and tsunami detection monitors, air traffic control radar and weather forecasting satellites	19 Engineering	35, Manufacture of other transport Equipment 51, Wholesale trade and commission trade, except of motor vehicles and motorcycles	Manufacturing	384 Manufacture of transport equipment 713 Air transport	336-Transportation equipment manufacturing 48-Transportation and warehousing	Motor vehicles, trailers and semi trailers Manufacture of other vehicles
ICT								
* 334220 Cellular telephones 334310 Compact disc players 334411 Electron Tube 334415 Electronic Resistor 334419 Other electronic 334510 Electromedical equipment 334417 Electronic connector	C26 Manufacture of computer, electronic and optical products	Battery contacts, electrical connectors in telecommunications infrastructure equipment (including Cu-Be housing for optic fibre cables), computers, mobile phones, avionics, etc.	22 Other industries	32, Manufacture of radio, television and communication equipment and apparatus	Manufacturing	None	334-Computer and electronic product manufacturing	None
Medical devices								
339116 Dental laboratories	C32.5 Manufacture of medical	Medical imaging	22 Other	33,	Manufacturing	933 Medical,	339-	

US-OSHA	NACE	BeST sectors	BAuA MEGA	Vincent et al	IOM	CAREX EU	Carex Canada	ASA Finland
	and dental instruments and supplies	equipment, medical lasers (e.g. optical), analytical equipment for blood analysis, electronic surgical instruments	industries	Manufacture of medical, precision and optical instrument, watches and clocks		dental, other health and veterinary services 385 Manufacture of instruments, photographic and optical	Miscellaneous manufacturing	
Specialised manufacturing								
* 332212 Hand and edge tool * 331422 Copper wire (except 335211 Warm electric housewares and 335212 Household vacuum 335221 House cooking 335222 Household refrigerator 335224 Household laundry 335228 Other major household 336321 Vehicular lighting * 333999 All other miscellaneous * 811310 Commercial and industrial	C27 Manufacture of electrical equipment C28 Manufacture of machinery and equipment n.e.c. C33 Repair and installation of machinery and equipment	**Defence & security** Components of weapons, guidance, surveillance and reconnaissance systems, electronic and electrical connectors, fasteners and structural components in aircraft, mirrors in tanks **Fire-fighting & rescue** Fire extinguishing systems, lightweight breathing systems **Oil, gas & electricity** Tooling (relies on non-sparking and non-magnetic properties of beryllium), clamps, beryllium-containing x-ray tubes and detectors, electrical terminals that join the components of thin-film solar panels	19 Engineering	29, Manufacture of machinery and equipment 36, Manufacture of furniture and other manufacturing industries	Manufacturing	382 Manufacture of machinery except electrical 383 Manufacture of electrical machinery, apparatus, appliances 385 Manufacture of instruments, photographic and optical 39 Other manufacturing industries	333-Machinery manufacturing 335-Electrical equipment, appliance and component manufacturing 81-Other services (except public administration) 327-Non-metallic mineral product manufacturing	Public admin and defence

Table 3-2: Evaluation of industrial sectors affected by beryllium

Table 3-2: Evaluation of industrial sectors affected by beryllium								
US-OSHA	**NACE**	**BeST sectors**	**BAuA MEGA**	**Vincent et al**	**IOM**	**CAREX EU**	**Carex Canada**	**ASA Finland**
		Space & research Heat shields, components, beryllium mirror, beryllium beam pipes						
Glass & glass products								
* 327113 Porcelain electrical supply * 336340 Motor vehicle brake * 336340 Motor vehicle	C23.1 Manufacture of glass and glass products	BeST not aware	17 Glass		Manufacturing	362 Manufacture of glass and glass products	None	None
Recycling								
None	E37.1 Materials recovery	Mentioned	13 Disposal, recycling	37, Recycling		None	None	
Laboratories								
None	M72 Scientific development	Mentioned	None			None	54-Professional, scientific and technical services	Scientific R&D Training
Construction								
None	F Construction	BeST not aware	14 Construction			5 Construction	23-Construction	None
Excluded								
621210 Offices of dentists		None		24, Manufacture of chemicals and chemical products 51, Wholesale	Crude petroleum Manufacture of textiles Manufacture of chemicals and chemical products Manufacture of rubber and	6 Wholesale and retail trade and restaurants and hotels 22 Crude Petroleum 41 Natural Gas Production Electricity, gas	22-Utilities 41-Wholesale trade 314-Textile product mills 321-Wood product manufacturing 322-Paper	None

Table 3-2: Evaluation of industrial sectors affected by beryllium

US-OSHA	NACE	BeST sectors	BAuA MEGA	Vincent et al	IOM	CAREX EU	Carex Canada	ASA Finland
				trade and commission trade, except of motor vehicles and motorcycles	plastic products Electricity, gas and steam Wholesale trade and commission trade: except of motor vehicles and motorcycles	and steam 321 Manufacture of textiles 351 Manufacture of industrial chemicals 355 Manufacture of rubber products	manufacturing 325-Chemical manufacturing	

Source: Analysis by RPA, MEGA data - BAuA (2017a), US-OSHA (2015), Vincent et al., (2009), IOM (2011), BeST, Carex Canada (undated), Carex EU (undated), ASA Finland (2014)
*Note: The source for the data had some NAIC codes with their text descriptor scut short. *US-OSHA items that map to more than one NACE code*

Table 3-3: Sectors in the EU affected by beryllium and associated NACE codes	
Sector	**Associated NACE codes**
Foundries	C24
Metal fabrication (includes manufacture of injection moulds and stamping)	C25
Transportation	C29 & C30
ICT	C26
Specialist manufacturers including defence, security, fire-fighting & rescue, oil gas and electricity, space and research	C27, C28, C33
Medical devices	C32.5
Glass	C23.1
Construction	F
Laboratories	M72
Recycling	E37.1
Source: Analysis by RPA	

Table 3-4: Sectors in the EU affected by beryllium and available average exposure concentrations		
Sector	**MEGA 95th percentile**	**France 90th percentile**
Foundries	1.05 (n=101)	16.06 (n=159)
Metal fabrication	0.228 (n=79)	0.6 (n=76)
Transportation	0.554 (n=14) **	0.015 (n=14)
ICT	0.512 (n=33) *	10.44 (n=29)
Specialist manufacturers	0.512 (n=33) *	-
Medical devices	0.512 (n=33) *	0.5 (n=74)
Glass	2.78 (n=16)	-
Construction	2.52 (n=10)	-
Laboratories	0.512 (n=33) *	-
Recycling	0.19 (n=116)	0.1 (n=30)
Source: Analysis by RPA, MEGA data BauA (2014), France 2004-2006 - Vincent et al., (2009) ** Based on "other sectors" in MEGA data BauA (2014)* *** Based on "engineering" in MEGA data BauA (2014)*		

3.4.2 Processes

Many processes are used by manufacturers using beryllium and its alloys. These are described in Table 3-5. The list was provided by BeST and also gives an indication of whether or not they believe the process would be technically feasible and economically viable at different OELVs. The processes are grouped into a smaller set of higher level processes to make analysis easier. The process groups are:

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

Table 3-5 shows that achieving an OELV of 0.6 µg/m^3 appears reasonably straightforward but the actions required to achieve exposure levels below at 0.6 µg/m^3 are considerably more expensive. After many conversations with the beryllium industry, companies have no idea how certain processes could achieve OELs below 0.2 µg/m^3 and the general view is that these processes would move outside the EU. The processes that industry is concerned about echo those indicated in Table 3-5 as not feasible below 0.2 µg/m^3.

Table 3-6 gives details about the specific process that are considered to be not feasible or no longer economically viable at different levels of OEL. Of the 18 melting processes used by foundries, transportation, specialist manufacturing, glass and recycling sectors, for 5 processes no feasible measures could be identified to meet levels at or below 0.2 µg/m^3, and a further 12 would no longer be economically viable at or below 0.2 µg/m^3. Of the 43 mechanical-machining processes used by all sectors except foundries and laboratories, for 7 processes no feasible measures could be identified to meet levels at or below 0.2 µg/m^3, and a further 12 would no longer be economically viable at 0.2 µg/m^3 (Tables 3-5 and 3-6.)

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m³**	**0.6 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.02 µg/m³**	**Process group**
Abrasive Blasting	A process for cleaning the surface of metals or ceramics which involves using compressed air to blow an abrasive material (i.e., sand) with considerable force through a hose against a surface.	C	C+	NF	NF	NF	Mechanical - machining
Abrasive Processing	Processes that involve cleaning or altering the surface of metals or ceramics by abrasive action, utilizing natural or manufactured abrasive materials.	C	C+	NF	NF	NF	Mechanical - machining
Abrasive Sawing	The process of sawing metals or ceramics by abrasive action.	C	C+	NF	NF	NF	Mechanical - machining
Adhesive Bonding	The process of joining two similar or non-similar materials (metals, plastics, composites, etc.) using an adhesive.	NA	NA	NA	NA	NA	Handling
Age Hardening (<950ºF)	The process of increasing the strength and hardness of a metallic material using a relatively low-temperature heat treatment.	NA	NA	C	C	C	Thermal
Annealing	The controlled heating and cooling of a metal to remove stresses and to make the material softer and easier to work with during subsequent operations such as rolling.	NA	NA	C	C	C	Thermal
Assembly	The fitting together of manufactured parts into a complete machine, structure or unit of a machine.	NA	NA	NA	NA	NA	Handling
Bending	The process in which metal is deformed by plastically deforming the material and changing its shape. The material is stressed beyond the yield strength, but below the ultimate tensile strength. The surface area of the material does not change much. Bending usually refers to deformation about one axis.	NA	NA	NA	NA	NA	Mechanical - shaping
Blanking	The process of cutting up a large sheet of stock into smaller pieces suitable for the next operation in stamping. Blanking can be as simple as a cookie cutter-type die to produce prototype parts, or high speed dies that run at 1000+ strokes per minute, running coil stock.	NA	NA	C	C	C	Mechanical - machining
Bonding	The process of joining two materials together by passing the metal between rolls which compress and bond the metals together.	NA	NA	NA	NA	NA	Handling
Boring	The formation of a cylindrical hole in a solid material cutting tool.	NA	NA	C	C	C	Mechanical - machining
Brazing	Joining metals by the fusion of alloys having a melting temperature above 800 degrees Fahrenheit, but below the melting temperature of the metals being joined. In ceramics, refers to the joining of a plated surface to another metal component at temperatures typically less than 1100 degrees Celsius.	NA	NA	C	C	C	Thermal
Bright Cleaning	A process in which metallic pieces are dipped into an acid solution in order to achieve a clean, bright surface.	C	C	C+	C+	NF	Chemical
Broaching	Multiple milling, accomplished by pushing a tool with stepped cutting edges along the part, usually through holes.	NA	NA	C	C	C	Mechanical - machining

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m³**	**0.6 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.02 µg/m³**	**Process group**
Brushing	The process of cleaning the surface of metal using a brush. The bristles of the brush can be soft or hard; natural, synthetic or metallic.	C	C	C+	C+	NF	Mechanical - machining
Buffing	The smoothing of a metal surface by means of flexible wheels.	C	C	C+	C+	NF	Mechanical - machining
Burnishing	The process in which a smooth hard tool (using sufficient pressure) is rubbed on the metal surface to flatten the high spots by causing plastic flow of the metal.	C	C	C+	C+	NF	Mechanical - machining
Casting	The process of pouring a heated liquid metal into a mould. Once the metal solidifies, taking the shape inside the mould, it is removed, resulting in a cast shape.	C	C	NF	NF	NF	Melting
Centreless Grinding	A grinding process that differs from other cylindrical processes in that the work piece is not mechanically held in place at the centre.	C	C+	NF	NF	NF	Mechanical - machining
Chemical Cleaning	The process of removing oil, dirt and scale from the surface of metals using caustic chemicals.	C	C	C+	C+	NF	Chemical
Chemical Etching	Involves removing the surface of a metal chemically or electrochemically.	C	C	C+	C+	NF	Chemical
Chemical Milling	The process of controlled removal of metal using corrosive chemicals.	C	C	C+	C+	NF	Chemical
CNC Machining	Computerized Numerically Controlled (CNC) machining refers to the computer control of machine tools for the purpose of repeatedly manufacturing complex parts in metal.	NA	NA	C	C	C+	Mechanical - machining
Cold Forging	Involves the working of metal at normal atmospheric temperatures, to a predetermined shape by the process of hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Cold Heading	A cold forming process that involves applying force with a punch to the end of a metal blank contained in a die to redistribute metal to a particular area.	NA	NA	C	C	C+	Mechanical - shaping
Cold Pilger	The drawing technique employed to produce seamless tubing using a die and mandrel.	NA	NA	C	C	C+	Mechanical - shaping
Cold Rolling	The process of shaping and reducing metal in thickness by passing it between rolls which compress, shape and lengthen the metal, at a temperature below the softening point of the metal to create strain hardening.	NA	NA	C	C	C	Mechanical - shaping
Coolant Management	Involves the handling and management of the liquids used to quench metals in heat treating, to cool and lubricate cutting tools and work pieces in machining, or those applied to forming tools and work pieces to assist in forming operations.	NA	C	C	C	C+	Handling
Cutting	The process of mechanically shearing metal.	NA	NA	C	C	C+	Mechanical - machining
Deburring (grinding)	A finishing step involving the removal of burrs or surface imperfections from materials using abrasive activities such as sanding.	C	C	C+	C+	C+	Mechanical - machining
Deburring (non-	The removal of burrs, sharp edges or fins from metal parts by processes other than grinding, such as	NA	NA	C	C	C+	Mechanical - machining

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m^3**	**0.6 µg/m^3**	**0.2 µg/m^3**	**0.1 µg/m^3**	**0.02 µg/m^3**	**Process group**
grinding)	filing, machining or tumbling.						
Deep Hole Drilling	To form deeply drilled holes with a rotary end cutting tool.	NA	NA	C	C	C+	Mechanical - machining
Destructive Testing	Refers to testing a work piece for comparison to standards, where the testing results in the destruction of the work piece.	C	C	C	C	C+	Mechanical - machining
Drawing	A manufacturing process for producing a wire, bar or tube by pulling the material through a die to reduce the diameter and increase its length.	NA	NA	C	C	C+	Mechanical - shaping
Drilling	The process of using a drill bit in a drill to produce holes in a solid material.	NA	NA	C	C	C+	Mechanical - machining
Dross Handling	The process of physically handling dross produced by the melting of metals and alloys throughout manufacturing, packaging and shipping.	C	C	NF	NF	NF	Melting
Dry Tumbling	A process used to remove burrs, sharp edges or fins from metal parts by rolling the work in a barrel with other materials.	NA	C	C+	C+	NF	Mechanical - machining
Electrical Chemical Machining (ECM)	The process of removing material using electrical energy created in an electrolyte solution to erode metal from the work piece.	C	C	C+	C+	NF	Chemical
Electrical Discharge Machining (EDM)	The process of removing material by a series of rapidly recurring electric arcing discharges between an electrode (the cutting tool) and the work piece, in the presence of an energetic electric field. This is sometimes referred to as spark machining or spark eroding.	C	C	C+	C+	NF	Melting
Electroless Plating	A process in which a layer of metal contained in an aqueous solution is deposited (coated) onto a surface without the use of external electrical power.	NA	NA	C	C	C+	Chemical
Electron Beam Welding (EBW)	A fusion joining process that produces a weld by impinging a beam of high energy electrons to heat the weld joint.	C	C	C+	C+	C+	Melting
Electroplating	A process in which a layer of metal contained in an aqueous solution is deposited (coated) onto an electrically conductive surface using an electrical current.	NA	NA	C	C	C+	Chemical
Etching (chemical)	A process which involves chemically or electrochemically removing the surface of a metal.	C	C	C+	C+	NF	Chemical
Extrusion	The process of shaping metal into a chosen continuous form by forcing it through a die of a desired shape.	NA	NA	C+	C+	C+	Mechanical - shaping
Filing by Hand	The non-mechanized process of using a metalworking hand tool (a file) to shape material.	NA	NA	C	C	C	Mechanical - machining
Forging	The process of working a heated metal to a predetermined shape by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Grinding	A process that uses friction with a rough surface, such as an abrasive wheel, on the work piece to	C	C+	NF	NF	NF	Mechanical - machining

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m^3**	**0.6 µg/m^3**	**0.2 µg/m^3**	**0.1 µg/m^3**	**0.02 µg/m^3**	**Process group**
	make very fine finishes or very light cuts.						
Gun Drilling	A process where a drill, usually with one or more flutes and with coolant passages through the drill body, is used to produce a deep-drilled hole.	NA	NA	C	C	C+	Mechanical - machining
Hand Solvent Cleaning	The non-mechanized process of cleaning the surface of a part using a solvent.	NA	NA	NA	NA	NA	Handling
Handling	The process of physically handling materials or products throughout manufacturing, packaging, distribution and shipping.	NA	NA	NA	NA	NA	Handling
Heading	A cold forming process that essentially involves applying force with a punch to the end of a metal blank contained in a die. Heading, which includes upsetting and extruding, is often performed in conjunction with other cold forming operations such as sizing, piercing, trimming, thread rolling, blank rolling and pointing.	NA	NA	C	C	C+	Mechanical - shaping
Heat Treating (inert atmosphere)	The process of heating and cooling solid metals, alloys or ceramics in an inert atmosphere, such as nitrogen gas, to obtain certain desired properties or characteristics. The inert atmosphere excludes oxygen and reduces the generation of oxides on the surface of the metal or alloy.	NA	NA	C	C	C	Thermal
Heat Treating (in air)	The process of heating and cooling solid metals, alloys or ceramics in normal atmosphere to obtain certain desired properties or characteristics.	C	C	C	C	C+	Thermal
High Speed Machining (>10,000 rpm)	Material-working processes that involve using a power-driven machine tool, such as a router or drill, at speeds in excess of 10,000 rpm to shape metal.	C	C	C+	C+	NF	Mechanical - machining
Honing	The process of finishing ground surfaces to a high degree of accuracy and smoothness with abrasive blocks applied to the surface under a light controlled pressure, with a combination of rotary and reciprocating motions.	NA	C	C+	C+	NF	Mechanical - machining
Hot Forging	The process of working a heated metal to a predetermined shape by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Hot Rolling	A metallurgical process in which the metal is passed through a pair of rolls while the metal is above its recrystallization temperature.	NA	C	C+	C+	NF	Mechanical - shaping
Inspection	The evaluation of a part for defects, imperfections and preferred characteristics and specifications.	NA	NA	NA	NA	NA	Handling
Investment Casting	The process of producing castings of a part using ceramic moulds produced by injection moulding.	C	C	NF	NF	NF	Melting
Lapping	An abrasive machining operation that scours the surface of the work piece with an abrasive in fluid.	C	C	C+	C+	NF	Mechanical - machining
Laser Cutting	A process which uses a laser to cut materials. The material to be cut either melts, burns or vaporizes	C	C	C+	C+	NF	Melting

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m³**	**0.6 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.02 µg/m³**	**Process group**
	away.						
Laser Machining	A process which uses a laser to machine materials. The material either melts, burns or vaporizes away.	C	C	C+	C+	NF	Melting
Laser Scribing	A process that uses a laser to cut grooves into the surface of thin material to facilitate mechanical breaking.	C	C	C+	C+	NF	Melting
Laser Marking	A process that uses a laser to mark the surface of a material for identification purposes.	C	C	C+	C+	NF	Melting
Laser Welding	A process that uses a laser to weld metals.	C	C	C+	C+	NF	Melting
Laundering	The washing and drying of work clothing, rags, etc.	C	C	C+	C+	NF	Handling
Machining	Material-working processes that involve using a power-driven machine tool such as a lathe, milling machine or drill to shape metal.	NA	NA	C	C	C+	Mechanical - machining
Melting	The processes of heating a solid substance to a point where it turns liquid.	C	C	NF	NF	NF	Melting
Metallography	The process of preparing a metal surface for analysis by grinding, polishing, and etching to reveal micro structural constituents.	NA	NA	C	C	C	Mechanical - machining
Milling	The machining or cutting of metal products with revolving cutters.	NA	NA	C	C	C+	Mechanical - machining
Packaging	The process of placing finished and/or semi-finished products into a container for shipping.	NA	NA	NA	NA	NA	Handling
Painting	The process of applying paint to the surface of a finished or semi-finished part.	NA	NA	NA	NA	NA	Handling
Physical Testing	An examination or formal evaluation process whereby a material, semi-finished or finished product, is tested and the results typically compared to specified requirements and standards. Can be destructive or non-destructive in nature.	NA	NA	C	C	C+	Mechanical - machining
Photo-Etching	A chemical etching process that dissolves material from unmasked areas of metallic parts. The design is photographically exposed on the work piece using ultraviolet light.	C	C	C+	C+	NF	Chemical
Pickling	The process of chemically removing oxides and scale from the surface of metal using inorganic acids.	C	C	C+	C+	NF	Chemical
Piercing	The process of cutting internal features (holes or slots) in stock.	NA	NA	C	C	C+	Mechanical - shaping
Pilger	The process employed to produce seamless tubing using a die and mandrel.	NA	NA	C	C	C	Mechanical - shaping
Plating	The process of applying a thin coating of metal onto another metal.	NA	NA	C	C	C+	Chemical
Point and Chamfer	A process used to grind or machine a point or bevel on the end of a rod or wire which facilitates insertion into a drawing machine.	C	C	C+	C+	NF	Mechanical - machining
Polishing	The process of creating a smooth and shiny surface by rubbing the surface with a fine abrasive	C	C	C+	C+	NF	Mechanical - machining

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m^3**	**0.6 µg/m^3**	**0.2 µg/m^3**	**0.1 µg/m^3**	**0.02 µg/m^3**	**Process group**
	material.						
Pressing	The process in which metal is deformed by plastically deforming the material and changing its shape. The material is stressed beyond the yield strength, but below the ultimate tensile strength. The surface area of the material does not change much.	NA	NA	C	C	C	Mechanical - shaping
Process Ventilation Maintenance	The preventive or reactive repair, maintenance or restoration of general or local exhaust ventilation systems. Process ventilation refers to ventilation systems designed to reduce exposure to contaminants.	C	C+	NF	NF	NF	Handling & Machining
Radiography/X-ray	A method of non-destructive testing. Internal examination of a metallic structure or component with X-ray or gamma radiation. Internal defects can be seen on a screen or recorded on film.	NA	NA	NA	NA	NA	Handling
Reaming	To enlarge or dress out a hole in metal with a reamer.	NA	NA	C	C	C+	Mechanical - machining
Resistance Welding	A process where heat to form the weld is generated by the electrical resistance of current through the work pieces.	C	C	C+	C+	NF	Melting
Ring Forging	The process performed by punching a hole in a thick, round piece of metal, and then rolling and squeezing (or in some cases, pounding) the seamless shape to a thin ring.	NA	C	C+	C+	NF	Mechanical - shaping
Ring Rolling	The process of forming seamless rings from pierced discs or thick-walled, ring-shaped blanks between rolls that control wall thickness, ring diameter, height and contour.	NA	C	C+	C+	NF	Mechanical - shaping
Roll Bonding	The process of bonding two metals together by passing the metal between rolls which compress and bond the metals together.	NA	NA	C	C	C	Mechanical - shaping
Roller Burnishing	The process in which a smooth hard roller tool (using sufficient pressure) is rubbed on the metal surface to flatten the high spots by causing plastic flow of the metal.	C	C	C+	C+	NF	Mechanical - shaping
Rolling	A term applied to the operation of shaping and reducing metal in thickness by passing the metal between rolls which compress, shape and lengthen the metal.	NA	NA	C	C	C	Mechanical - shaping
Rotary forging	A process designed to efficiently forge round (cylindrical) shapes by hammering, upsetting, pressing or rolling.	NA	C	C+	C+	NF	Mechanical - shaping
Sand Blasting	A process for cleaning the surface of metals or ceramics which involves using compressed air to blow sand with considerable force through a hose against a surface. In ceramics, commonly used to remove metallization as a rework operation.	C	C+	NF	NF	NF	Mechanical - machining
Sand Casting	The production of a metal casting made in a sand mould	C	C+	NF	NF	NF	Melting
Sanding	A process used to smooth or dress the surface of a work piece using an abrasive surface.	C	C+	NF	NF	NF	Mechanical - machining

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m^3**	**0.6 µg/m^3**	**0.2 µg/m^3**	**0.1 µg/m^3**	**0.02 µg/m^3**	**Process group**
Sawing (tooth blade)	A manufacturing process that involves cutting or severing of metal or other materials with a serrated blade.	NA	NA	C	C	C+	Mechanical - machining
Scrap Management (Clean)	Refers to the routine handling, transfer, segregating or transport of scrap materials.	C	C	C+	C+	NF	Handling
Sectioning	The process of obtaining a smaller piece of material from a larger sample of the material. The process can involve fracturing, sawing and/or abrasive cutting.	NA	NA	C	C	C+	Mechanical - machining
Shearing	The process of severing of metal, usually cold, between sharpened blades, as in a shear; to severe or rupture a part as a result of forces in parallel planes that slide across each other at right angles to a major axis of the part.	NA	NA	C	C	C+	Mechanical - shaping
Shipping	The process of transporting a finished and/or semi-finished product to a destination using various modes of transportation.	NA	NA	NA	NA	NA	Handling & Machining
Sizing	Refers to the various mechanical processes to bring a work piece to the proper shape and dimensions.	NA	NA	C	C	C	Mechanical - shaping
Skiving	A continuous shaving process which results in a smoother surface finish than is possible with milling.	NA	NA	C	C	C+	Mechanical - shaping
Slab Milling	The milling process used to remove large amounts of material, leaving a flat finished surface.	NA	NA	C	C	NF	Mechanical - machining
Slitting	The operation of cutting wide sheets of metal into narrower strips by passing them through rotary shears that cut it to finished width.	NA	NA	C	C	C+	Mechanical - shaping
Soldering	Joining metals by fusion of alloys that have relatively low melting points.	NA	NA	NA	NA	NA	Thermal
Solution Management	Refers to routine handling, transfer, transport or processing of beryllium-containing solutions, such as coolants, oils and other liquids containing beryllium, beryllium oxide or alloys of beryllium.	NA	NA	C	C	C+	Handling
Spot Welding	The process of welding two or more thin pieces of metal together using electrical resistance to heat the metal at the spot of the weld.	C	C	C+	C+	NF	Melting
Sputtering	The physical process where atoms of a solid target material are ejected into the gas phase due to bombardment of the material by energetic ions and deposited on a substrate.	NA	NA	C	C	c+	Melting
Stamping	The formation of light metal parts from metal sheet, strip or thin plate, using dies.	NA	NA	C	C	c+	Mechanical - machining
Straightening	Metal forming in which a bend is removed from a piece of metal by applying a force.	NA	NA	C	C	c	Mechanical - shaping
Stretch Bend Levelling	The process of making metal sheet or strip flat by stretching.	NA	NA	C	C	c	Mechanical - shaping
Stretcher Levelling	The process of making metal sheet or strip flat by stretching.	NA	NA	C	C	c	Mechanical - shaping

Table 3-5: Processes using beryllium, their technical feasibility and economic viability at different exposure levels, and their process group							
Process	**Detail**	**2 µg/m³**	**0.6 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.02 µg/m³**	**Process group**
Swaging	The process of using a die and mandrel along with hammering to change the size and shape of the outer and inter diameters of tubes and/or rods.	NA	NA	C+	C+	NF	Mechanical - shaping
Tapping	The process of cutting screw threads in a round hole with a tap (an internal thread cutting tool).	NA	NA	C	C	C	Mechanical - machining
Tensile Testing	A standard test piece is gripped at either end in a testing machine, which slowly exerts an axial pull so that the metal is stretched until it breaks.	NA	NA	C	C	C	Mechanical - machining
Thread Rolling	The process used for making external threads in round stock by pressing the rotating workpiece against a die containing the thread profile.	NA	NA	C	C	C	Mechanical - shaping
Torch cutting (i.e., oxy-acetylene)	The process of cutting metals by using an oxygen/fuel mixture to heat the metal above the melting point.	C	C+	C+	C+	NF	Melting
Trepanning	A type of boring where an annular cut is made into a solid material with the coincidental formation of a plug or solid cylinder.	NA	NA	C	C	c+	Mechanical - machining
Tumbling	A deburring operation that involves rolling the work in a barrel containing abrasives suspended in a liquid medium.	NA	C	C+	C+	NF	Mechanical - machining
Turning	The process used to produce cylindrical components in a lathe. A cylindrical piece of stock is rotated and a cutting tool is traversed along 2 axes of motion to produce precise diameters and depths.	NA	NA	C	C	c+	Mechanical - machining
Ultrasonic Cleaning	The process of cleaning the surface of materials using ultrasound (usually from 15-400 kHz) in an aqueous solution.	NA	NA	NA	NA	NA	Handling
Ultrasonic Testing	The process of using ultrasound to detect flaws or characterize materials.	NA	NA	NA	NA	NA	Handling
Upsetting	A cold forming process that involves applying force with a punch to the end of a metal blank contained in a die.	NA	C	C+	C+	NF	Mechanical - shaping
Water-jet Cutting	A process to cut metal parts using a very high-pressure stream of water.	C	C	C+	C+	NF	Mechanical - machining
Welding (ARC, TIG, MIG, etc.)	A process used to join metals by the application of heat.	C	C	C+	C+	NF	Melting
Wire Electrical Discharge Machining	The process of removing material by a series of rapidly recurring electric arcing discharges from a thin single-strand metal wire fed through the work piece.	C	C	C+	C+	NF	Melting

Source: Analysis by RPA and BeST

NA = No additional controls required beyond normal operating controls

C = Controls required including engineering work and best practice

C+ = Additional advanced controls are necessary but not likely to be economically feasible

NF = Not technically feasible

The sectors were then linked to the appropriate process groups and these are described in Table 3-6. Mechanical - machining and Mechanical - shaping were found to always appear together: they are amalgamated in mechanical. Handling is found in every sector and has little bearing on costs, so it is omitted. This information helped in the development of risk management measures (RMMs) for the cost model.

Table 3-6: Sectors and the group processes predominantly used for beryllium

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

Source: Analysis by RPA and BeST

3.5 Exposure concentrations

3.5.1 Overview

Several issues surrounding exposure concentrations need to be considered and defined before any work to assess existing exposure concentrations and evaluate potential limits to exposure concentrations can begin. These include:

- Which of the three different sampling methods is used: inhalable, total particulate (also known as thoracic or total mass or total dust), and respirable? See section 3.2;
- Time weighted averages (TWA) and sampling: averages and 95th percentiles;
- Impact of enforcement upon the exposure levels that companies aim for to conform with the OEL;
- Representative values for exposure ranges: lower, upper and midpoint;
- Exposure levels for benefit analysis – averages;

- Exposure levels for cost analysis – 95th percentiles; and
- Lifetime exposure and issue that sensitisation appears to happen relatively quickly in 2-5 years.

3.5.2 Enforcement, sampling, averages and 95th percentiles

The data on exposure concentrations measured by US-OSHA and BeST are all average values of TWA 8 hour samples. The averages could be mean or median, it is usually not stated.

This average level is used in the development of the benefits because the key base data is the number of employees currently exposed to average exposure values.

However, the cost analysis is based upon the actions that enterprises will take to comply with an OEL and a key consideration is how the OEL is enforced. Currently, the enforcement processes vary widely across the EU. But the draft standard, European Committee for Standardisation (2016), on measuring workplace exposure is being adopted by increasing numbers of Member States. This seems likely to be the standard adopted for any new beryllium OELV. The details of the screening test are replicated in Figure 3-1 and the key point in section 5.5.3 of Figure 3-1 is that the 95th percentile level needs to be below the OEL to comply. For the purposes of analysis, we have concluded that to compare data on enterprises' exposure levels to a new OELV to develop costs, any average exposure levels should be converted to the equivalent 95th percentile value.

5.5.2 Screening test

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

a) If all results are below:

   1) 0,1 OELV for a set of three exposure measurements or,

   2) 0,15 OELV for a set of four exposure measurements or,

   3) 0,2 OELV for a set of five exposure measurements

   then it is considered that the OELV is respected: **Compliance**.

b) If one of the results is greater than the OELV, it is considered that the OELV is not respected: **Non-compliance**. In case that the first measurement result is above the OELV, it is not necessary to perform any additional measurements.

c) If all the results are below the OELV and a result above 0,1 OELV (set of three results) or 0,15 OELV (set of four results) or 0,2 OELV (set of five results) it is not possible to conclude on compliance with the OELV. **No-decision.**

   In this situation additional exposure measurements shall be carried out in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OELV, as specified in 5.5.3.

5.5.3 Test of compliance with the OELV

The appraiser shall select a statistical test of whether the exposures of the SEG comply with the OELV. The test shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OELV.

Figure 3-1: Section 5.5.2 Screening test from the European Standard for Workplace exposure - Measurement DRAFT prEN 689
Source: European Committee for Standardisation (2016)

However, the ratio of 95th percentile exposure to median exposure varies with any different set of data. We have assumed that the ratio for exposure levels for companies in the EU measured by BeST will be similar to that for any other company exposure levels. A line of best fit was established as shown on Figure 3-2. The equation for the line of best fit is:

$$y = (600 * \exp(-2.8*x)) + 100$$

where:

x = exposure in μg/m^3

y = number of companies

The median for the y values of the line of best fit was 124 corresponding to an exposure of 1.15. The 95th percentile for the y values of the line of best fit was 100 corresponding to an exposure of 2.7. The ratio of 95th percentile to median value is therefore 2.3.

This multiplier was applied to both US-OSHA and BeST exposure data provided as averages when applied to enterprises. This takes the values to the 95th percentile so that they can be compared with the OELs directly when used as part of the cost calculations. This is in addition to the multiplier of 2 applied to the US-OSHA data to convert it from total particulate to inhalable sampling.

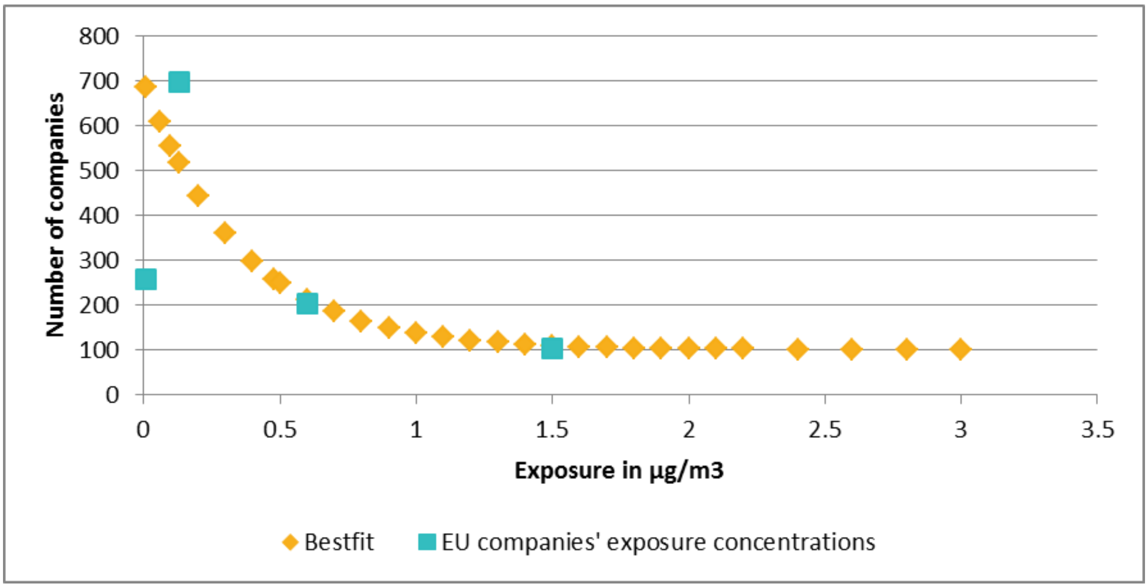

Figure 3-2: EU companies' exposure concentrations and line of best fit
Source: Modelling by RPA

3.5.3 Upper, lower or midpoints?

The BeST and US-OSHA data provides the numbers of employees and enterprises within ranges of exposure concentrations.

A key decision is deciding which value represents the range: lower, midpoint or upper. To calculate the midpoint, an upper value has to be assumed for the ranges above 2 μg/m^3 and 10 μg/m^3 is assumed for both sets of data. Taking the same value for every exposure range always resulted in at least one range looking particularly incorrect. We considered the distribution that the data always follows (lognormal) and selected the value that appeared to best represent the range at that point in the distribution.

- For the lowest range, samples will be concentrated just below the upper limit, so the upper limit is taken.
- The next range usually has the highest number of samples and is the range where the curve turns, so the midpoint is taken
- The remaining ranges have the number of samples falling steadily, so the midpoint is taken
- For the highest range, samples are likely to fall away quickly, so the lower limit is taken

The base numbers (prior to the application of the multipliers discussed in sections 3.2 and 3.5.2) are shown in Tables 3-7 and 3-8, with the values representing the ranges emboldened.

Table 3-7: BeST survey data of EU companies: ranges of exposure concentrations

Exposure range	Lower value	Midpoint	Upper value
Less than 0.06 µg/m^3	0	0.03	**0.06**
0.06 µg/m^3 - 0.2 µg/m^3	0.06	**0.13**	0.2
0.2 µg/ m^3 – 1 µg/m^3	0.2	**0.6**	1
1 µg/m^3 – 2 µg/m^3	1	**1.5**	2
Over 2 µg/m^3	**2**	6	10 (arbitrary)

Source: Modelling by RPA and BeST survey of customers 2015 (unpublished)
Note: values representing the ranges are in bold

Table 3-8: US-OSHA survey data of USA employees and companies: ranges of exposure concentrations

Exposure range	Lower value	Midpoint	Upper value
Less than 0.1 µg/m^3	0	0.05	**0.1**
0.1 µg/m^3 - 0.2 µg/m^3	0.1	**0.15**	0.2
0.2 µg/ m^3 – 0.5 µg/m^3	0.2	**0.35**	0.5
0.5 µg/ m^3 – 1 µg/m^3	0.5	**0.75**	1
1 µg/m^3 – 2 µg/m^3	1	**1.5**	2
Over 2 µg/m^3	**2**	6	10 (arbitrary)

Source: Modelling by RPA and US-OSHA
Note: values representing the ranges are in bold

3.5.4 Employee exposure levels for benefit analysis – averages

For the employee data that is used in the benefit analysis, the exposure ranges and representative exposure for the ranges for the BeST data are shown in Table 3-9. The multiplier explained in section 3.2 does not apply here because these samples were made in the EU and use the inhalable sampling method.

Table 3-9: BeST survey data of EU companies: ranges before and after conversion factors for employees and benefits analysis, together with representative value for range	
Exposure range (base)	**Representative value**
Less than 0.06 µg/m^3	0.06
0.06 µg/m^3 - 0.2 µg/m^3	0.13
0.2 µg/m^3 – 1 µg/m^3	0.6
1 µg/m^3 – 2 µg/m^3	1.5
Over 2µg/m^3	2
Source: Modelling by RPA and BeST survey of customers 2015 (unpublished)	

The exposure ranges and representative exposure for the ranges for the US-OSHA data are shown in Table 3-10. The ranges in the base data are multiplied by 2 which converts the samples made using the total particulate method used in the USA to inhalable as explained in Section 3.2.

Table 3-10: US-OSHA survey data of USA employees and companies: ranges before and after conversion factors for employees and benefits analysis, together with representative value for range		
Exposure range (base)	**Exposure range (converted)**	**Representative value**
Less than 0.1 µg/m^3	Less than 0.2 µg/m^3	0.2
0.1 µg/m^3 - 0.2 µg/m^3	0.2 µg/m^3 - 0.4 µg/m^3	0.3
0.2 µg/ m^3 – 0.5 µg/m^3	0.4 µg/ m^3 – 1 µg/m^3	0.7
0.5 µg/m^3 – 1 µg/m^3	1 µg/m^3 – 2 µg/m^3	1.5
1 µg/m^3 – 2 µg/m^3	2 µg/m^3 – 4 µg/m^3	3.0
Over 2 µg/m^3	Over 4 µg/m^3	4
Source: Modelling by RPA and US-OSHA		

3.5.5 Enterprise data on exposure levels for cost analysis – 95th percentile

For the enterprise data that is used in the cost analysis, the exposure ranges and representative exposure for the ranges for the BeST data are shown in Table 3-11. The multiplier of 2.3 explained in Section 3.5.2 is applied to move the range from averages to 95th percentiles.

Table 3-11: BeST survey data of EU companies: ranges before and after conversion factors for enterprises and costs analysis, together with representative value for range		
Exposure range (base)	**Exposure range (converted)**	**Representative value**
Less than 0.06 µg/m^3	Less than 0.138 µg/m^3	0.138
0.06 µg/m^3 - 0.2 µg/m^3	0.138 µg/m^3 - 0.46 µg/m^3	0.3
0.2 µg/m^3 – 1 µg/m^3	0.46 µg/m^3 – 2.3 µg/m^3	1.38
1 µg/m^3 – 2 µg/m^3	2.3 µg/m^3 – 4.6 µg/m^3	3.45
Over 2µg/m^3	Over 4.6 µg/m^3	4.6
Source: Modelling by RPA and BeST survey of customers 2015 (unpublished)		

The exposure ranges and representative exposure for the ranges for the US-OSHA data are shown in Table 3-12. The ranges in the base data are multiplied by 4.6 (2 x 2.3), which converts for both the sampling methods and the average/95th percentile as explained in sections 3.2 and 3.5.2.

Table 3-12: US-OSHA survey data of USA employees and companies: ranges before and after conversion factors for employees and benefits analysis, together with representative value for range		
Exposure range (base)	**Exposure range (converted)**	**Representative value**
Less than 0.1 µg/m^3	Less than 0.69 µg/m^3	0.46
0.1 µg/m^3 - 0.2 µg/m^3	0.69 µg/m^3 – 1.38 µg/m^3	0.69
0.2 µg/ m^3 – 0.5 µg/m^3	1.38 µg/ m^3 – 3.45 µg/m^3	1.61
0.5 µg/m^3 – 1 µg/m^3	3.45µg/m^3 – 6.9 µg/m^3	3.45
1 µg/m^3 – 2 µg/m^3	6.9 µg/m^3 – 13.8 µg/m^3	6.90
Over 2µg/m^3	Over 13.8 µg/m^3	9.20
Source: Modelling by RPA and US-OSHA		

3.6 Exposed workforce

3.6.1 Exposed employees and enterprises analysis

Introduction

There are seven sources of data and information used to derive the numbers of employees and enterprises affected by beryllium in all Member States and in each of the ten sectors:

- Eurostat (2015) data was used to provide the number of employees and enterprises in every EU Member State split by NACE codes, which are mapped to the ten sectors;
- US-OSHA (2015) Table IX-2 - Characteristics of industries affected by US-OSHA's proposed standard for beryllium and Table IX-4 - Numbers of workers exposed to beryllium. The data in these tables was estimated by US-OSHA in 2012;
- BeST Survey of EU companies (2015, not published) – number of workers exposed and number of enterprises affected, see Table 3.16. The survey is based upon 27 measurements, of which 12 were estimates, at 18 companies with 1317 exposed workers;
- Eurostat (2016) - data on the population and enterprises of the EU;
- US Census Bureau (2016) - data on the population of the USA;
- United States Census Bureau number of enterprises and employees by six digit NAIC codes; and
- Eurostat (38) - correspondence table between NACE and NAIC codes.

NACE and NAIC codes

Eurostat's (2007) NACE/NAIC correspondence table was used to work out the total number of employees and enterprises in the USA industries that correlate to the ten sectors chosen. It was also used to map every NAIC of US-OSHA's Tables IX-2 and IX-4 to the correct NACE code. In some cases, the NAIC code maps to more than one NACE code and these were allocated according to the percentage of total employees or total enterprises in the relevant NACE codes. For example, "331421 Copper rolling, drawing, and extruding" maps to both NACE codes C24 and C25. The ratio of USA employees in NAIC codes mapping to C24 and C25 are 17% and 83%. Therefore the records for this NAIC code on both tables are split so that 17% go to C24 and 83% go to C25.

The process of mapping NAIC codes to NACE codes is difficult: there is a many-to-many relationship between the code sets (there are many NAIC codes for any one NACE code and similarly many NACE codes for any one NAIC code). This brings into the calculations many NAIC and NACE codes that are completely unrelated to the NAIC and NACE codes relevant to this study. The study team is confident that the correct NACE codes that have been allocated against for each NAIC code. However, identifying all the NAIC codes for a wide NACE code, say C27, to include all of correlating employees and enterprises in the USA, is a particularly tricky manual process. A further complication is that census data, which provides the numbers for employees for the given NAIC codes, does not exactly match the NAIC codes in the correspondence table. This means that subjective judgements have to be made during this manual process.

Therefore, the calculations of total USA employees and enterprises for given NACE codes are less reliable. These numbers are used for one of the three methods of calculating both the estimated employees exposed to beryllium and estimated enterprises affected by beryllium. This method is included partly to demonstrate that the study team attempted to do this and partly as a check that the figures it predicts are in the same ball park as the other methods.

These estimated numbers are also used to divide up the employees and enterprises for NAIC codes that map to more than one NACE code. Even if these numbers are less reliable than the study team would like, they are better than splitting the employees and enterprises 50:50 for C24 and C25 in the example above, or dividing them according to the European NACE proportions of C24 and C25.

Analysis of exposed employees

The number of EU employees exposed to beryllium is an important input into the calculation of potential benefits, particularly when this is split into groups with different exposure concentrations.

Three different methods are used to arrive at estimates of the number of EU employees exposed to beryllium. All three methods use US-OSHA (2015) Table IX-2 – "Characteristics of industries affected by US-OSHA's proposed standard for beryllium". This provides the number of USA employees exposed to beryllium for each relevant NAIC code, which is mapped to the relevant NACE code(s). This data is available for seven of the sectors identified by the study, all except construction, laboratories and recycling. The three methods are referred to throughout the remainder of this report as BeST, EU/USA and US-OSHA. They are:

- **BeST** - BeST say that the total number of employees exposed to beryllium in the EU is 12,000 to 13,000. The higher number, 13,000, was split across the seven sectors according to the proportions of exposed employees. The higher number was taken as this number is more likely to be an understatement rather than an overstatement

- **EU/USA** - The number of exposed employees in each of the seven sectors is multiplied by 1.5, which is the proportion of EU population (510 million) to USA population (326 million)

- **US-OSHA** - The number of exposed employees in each of the seven sectors is divided by the total number of USA employees corresponding to the NACE code, see section 3.6.2, which gives the percentage of exposed employees in this industry. This is multiplied by the total number of EU employees for this NACE code

The method of estimating the number of employees exposed for the three sectors which are not covered by US-OSHA (2015) is described in section 3.6.5.

Number of enterprises

The number of EU enterprises affected by beryllium is an important input into the calculation of potential costs, particularly when this is split into groups with different exposure concentrations and different company size.

Three different methods are used to arrive at estimates of the number of EU enterprises that are affected by beryllium. All three methods use US-OSHA (2015) Table IX-2 – "Characteristics of industries affected by US-OSHA's proposed standard for beryllium". This provides the number of USA enterprises affected by beryllium for each relevant NAIC code, which is mapped to the relevant NACE code(s). This data is available for seven of the sectors identified by the study, all except construction, laboratories and recycling. The three methods are:

- **BeST** - BeST say that the total number of enterprises affected by beryllium in the EU is 540. This was split across the seven sectors according to the proportions of affected enterprises;

- **EU/USA** - The number of affected enterprises in each of the seven sectors is multiplied by 1.5, which is the proportion of EU population (510 million) to USA population (326 million);

- **US-OSHA** - The number of affected enterprises in each of the seven sectors is divided by the total number of USA enterprises corresponding to the NACE code, see section 3.6.5, which gives the percentage of affected enterprises in this industry. This is multiplied by the total number of EU enterprises for this NACE code.

The method of estimating the number of enterprises exposed for the three sectors which are not covered by US-OSHA (2015) is described in section 3.6.5. Eurostat data splits the data on the number of enterprises into five ranges of company sizes as shown in Table 3-13. In the later costs' calculations, the study reduces this to three ranges and the mapping between the two is also shown in Table 3-13.

Table 3-13: Eurostat size of companies mapped to the small, medium and large used in analysis

Eurostat enterprise sizes	Size band used in study
Enterprises with less than 9 employees	Small
Enterprises with 10-19 employees	Small
Enterprises with 20-49 employees	Medium
Enterprises with 50-249 employees	Medium
Enterprises with over 250 employees	Large
Source: Analysis by RPA	

Estimated percentages of employees and enterprises

For the three sectors where no employee or enterprise data are available from US-OSHA, the percentages are estimated for each of the three methods based on the other sectors, excluding medical devices as this is much higher than the other percentages. The three missing sectors are: construction, laboratories and recycling. Tables 3-14 and 3-15 show the estimated exposed employees and affected enterprises as a percentage of the total employees or enterprises in the EU for the given NACE code(s). The three sectors' estimated percentages are the average of the other sectors, excluding medical devices, which has much higher percentages and is felt to be less representative of the three sectors without data.

Table 3-14: Estimated percentages of USA employees exposed by beryllium by sector and RPA estimates for sectors where no US-OSHA data exists

Sector	Employees % exposed to Beryllium (BeST)	Employees % exposed to Beryllium (EU/USA)	Employees % exposed to Beryllium (US-OSHA)
Foundries	0.14% (USA)	0.55% (USA)	1.10% (USA)
Metal fabrication	0.15% (USA)	0.58% (USA)	0.81% (USA)
Transportation	0.03% (USA)	0.10% (USA)	0.13% (USA)
ICT	0.04% (USA)	0.16% (USA)	0.13% (USA)
Specialist manufacturers	0.04% (USA)	0.17% (USA)	0.28% (USA)
Medical devices	0.77% (USA)	3.08% (USA)	2.74% (USA)
Glass	0.02% (USA)	0.06% (USA)	0.07% (USA)
Construction	0.07% (RPA)	0.27% (RPA)	0.42% (RPA)
Laboratories	0.07% (RPA)	0.27% (RPA)	0.42% (RPA)
Recycling	0.07% (RPA)	0.27% (RPA)	0.42% (RPA)
Source: Analysis by RPA			

Table 3-15: Estimated percentages of USA enterprises affected by beryllium by sector and RPA estimates for sectors where no US-OSHA data exists

Sector	Enterprises % exposed to Beryllium (BeST)	Enterprises % exposed to Beryllium (EU/USA)	Enterprises % exposed to Beryllium (US-OSHA)
Foundries	0.14% (USA)	1.38% (USA)	5.38% (USA)
Metal fabrication	0.04% (USA)	0.37% (USA)	1.44% (USA)
Transportation	0.09% (USA)	0.87% (USA)	1.68% (USA)
ICT	0.04% (USA)	0.35% (USA)	0.76% (USA)
Specialist manufacturers	0.02% (USA)	0.18% (USA)	0.64% (USA)
Medical devices	0.40% (USA)	4.01% (USA)	16.13% (USA)
Glass	0.004% (USA)	0.04% (USA)	0.09% (USA)
Construction	0.05% (RPA)	0.53% (RPA)	1.67% (RPA)
Laboratories	0.05% (RPA)	0.53% (RPA)	1.67% (RPA)
Recycling	0.05% (RPA)	0.53% (RPA)	1.67% (RPA)
Source: Analysis by RPA			

Exposure concentrations

The exposure concentrations were then applied to the employee and the enterprise data. There are two sets of employee exposure data which may be used to allocate employees or enterprises to ranges of exposure concentrations:

- BeST survey of companies, details are shown in Table 3-16. These percentages were applied against all industries. The assumption is that the exposure concentrations vary in the same manner for all sectors. Foundries probably have more exposed workers at the higher level, but in this analysis, they are assumed to all be the same; and

- US-OSHA (2015) Table IX-4 provides the number of employees affected by beryllium by exposure concentration for seven sectors. The percentage split is calculated for each sector based upon the NACE codes as previously explained: these are shown in Table 3-17.

The exposure concentrations used by these two data sets and the representative ranges were explained in section 3.5. Throughout the analysis, these two exposure distributions are referred to as “BeST” and “US-OSHA” exposure distributions.

Table 3-16: BeST survey data of EU companies: number of employees working at different ranges of exposure concentrations

Exposure range (base)	Number of employees	% of employees
Less than 0.06 µg/m^3	212	20.46%
0.06 µg/m^3 - 0.2 µg/m^3	573	55.31%
0.2 µg/m^3 – 1 µg/m^3	166	16.02%
1 µg/m^3 – 2 µg/m^3	85	8.20%
Over 2 µg/m^3	0	0.00%
Total	1036	100.00%
Source: BeST survey of customers 2015 (unpublished)		

Table 3-17: US-OSHA data of USA companies: number of affected USA employees working at different ranges of exposure concentrations by sector

Exposure range (base)	Number of employees	% of employees
Foundries		
Less than 0.2 µg/m^3	1,312	40.24%
0.2 µg/m^3- 0.4 µg/m^3	537	16.46%
0.4 µg/m^3– 1 µg/m^3	665	20.38%
1 µg/m^3– 2 µg/m^3	318	9.75%
2 µg/m^3- 4 µg/m^3	159	4.89%
Over 4 µg/m^3	270	8.29%
Total	3,262	100.00%
Metal fabrication		
Less than 0.2 µg/m^3	9,492	79.73%
0.2 µg/m^3- 0.4 µg/m^3	1,002	8.41%
0.4 µg/m^3– 1 µg/m^3	844	7.09%
1 µg/m^3– 2 µg/m^3	248	2.08%
2 µg/m^3- 4 µg/m^3	97	0.82%
Over 4 µg/m^3	223	1.87%
Total	11,905	100.00%
Transportation		
Less than 0.2 µg/m^3	104	60.86%
0.2 µg/m^3- 0.4 µg/m^3	23	13.40%
0.4 µg/m^3– 1 µg/m^3	25	14.76%
1 µg/m^3– 2 µg/m^3	14	8.46%
2 µg/m^3- 4 µg/m^3	1	0.59%
Over 4 µg/m^3	3	1.94%

Table 3-17: US-OSHA data of USA companies: number of affected USA employees working at different ranges of exposure concentrations by sector		
Exposure range (base)	**Number of employees**	**% of employees**
Total	171	100.00%
ICT		
Less than 0.2 µg/m³	776	74.52%
0.2 µg/m³- 0.4 µg/m³	103	9.93%
0.4 µg/m³– 1 µg/m³	110	10.56%
1 µg/m³– 2 µg/m³	34	3.31%
2 µg/m³- 4 µg/m³	10	0.96%
Over 4 µg/m³	7	0.72%
Total	1,042	100.00%
Specialised manufacturing		
Less than 0.2 µg/m³	2,958	89.58%
0.2 µg/m³- 0.4 µg/m³	145	4.39%
0.4 µg/m³– 1 µg/m³	121	3.66%
1 µg/m³– 2 µg/m³	40	1.22%
2 µg/m³- 4 µg/m³	14	0.44%
Over 4 µg/m³	24	0.72%
Total	3,302	100.00%
Medical devices		
Less than 0.2 µg/m³	4	56.34%
0.2 µg/m³- 0.4 µg/m³	1	14.08%
0.4 µg/m³– 1 µg/m³	1	15.49%
1 µg/m³– 2 µg/m³	1	11.27%
2 µg/m³- 4 µg/m³	0	0.00%
Over 4 µg/m³	0	2.82%
Total	7	100.00%
Glass		
Less than 0.2 µg/m³	134	53.39%
0.2 µg/m³- 0.4µg/m³	37	14.74%
0.4 µg/m³– 1µg/m³	57	22.71%
1 µg/m³– 2µg/m³	15	5.98%
2 µg/m³- 4µg/m³	5	1.99%
Over 4 µg/m³	3	1.20%
Total	251	100.00%
Source: Analysis by RPA, US-OSHA (2015)		

3.6.2 Exposed employees by sector and Member State

Exposed employees by sector

The key information for exposed employees in each sector is given in Table 3-18. The predicted employees affected by beryllium using each of the three methods are given in Table 3-19. The relevant figures from the CAREX EU data are also displayed in Table 3-19.

Table 3-18: USA and EU data on employees by sector				
Sector	USA employees in associated NAIC sectors (US-OSHA)	USA employees in associated NAIC sectors affected by beryllium	% USA employees exposed to beryllium	Total employees in EU (Eurostat)
Foundries	297,333	3,262	1.10%	930,187
Metal fabrication	1,530,220	12,469	0.81%	3,341,115
Transportation	1,557,729	2,048	0.13%	3,155,749
ICT	778,433	1,042	0.13%	1,035,484
Specialist manufacturers	2,052,363	5,808	0.28%	5,368,786
Medical devices	297,762	8,148	2.74%	413,783
Glass	652,489	453	0.07%	287,788
Construction	9,784,621	-	0.42% *	9,789,969
Laboratories	710,059	-	0.42% *	606,352
Recycling	22,685	-	0.42% *	180,164
Sources: Modelling by RPA, Eurostat (2015), US-OSHA (2015), BeST *Note: *Based on estimated percentages of employees affected by beryllium, see Table 3.14*				

Table 3-19: Predicted employees affected by beryllium by sector				
Sector	Predicted number of EU employees exposed to beryllium (BeST)	Predicted number of EU employees exposed to beryllium (EU/USA)	Predicted number of EU employees exposed to beryllium (US-OSHA)	CAREX estimate of EU employees exposed to beryllium
Foundries	1,276	5,099	10,205	2,620
Metal fabrication	4,878	19,491	27,225	5,743
Transportation	801	3,202	4,149	4,394
ICT	408	1,628	1,386	3,798
Specialist manufacturers	2,272	9,079	15,193	46,265
Medical devices	3,188	12,737	11,323	1,040
Glass	177	709	783	2,129
Laboratories	410*	1,639*	2,556*	N/A
Recycling	122*	487*	760*	N/A
Total excluding construction	**13,532**	**54,071**	**73,580**	**65,989**
Construction	6,624*	26,469*	41,276*	490
Total	**20,156**	**80,540**	**114,856**	**66,479**
Source: Modelling by RPA, Carex (undated), US-OSHA (2015), BeST *Note: *Based on estimated percentages of employees affected by beryllium, see Table 3.14*				

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

A comparison of the estimates of workers exposed to beryllium is shown in table 3-20. CAREX EU and the IOM predicted approximately 65,000 workers exposed in the EU, but many stakeholders, not only BeST, consider this to be too high. The estimate using the EU/USA method arrives at a figure of 54,071 excluding construction, higher than the 13,000 of BeST and lower than the CAREX/IOM figure. Examining the data from the USA, and the number of workers in the EU in each of the sectors, the EU/USA figures are the most plausible. Throughout the remainder of the analysis, the EU/USA figures will be used, and the BeST and US-OSHA data is assessed in the sensitivity analysis.

Table 3-20: Occupationally exposed population in the EU-28	
Source estimate	**EU-28 extrapolation**
CAREX EU14+5 mid-1990s & IOM (2011)	65,000
ASA 2014 exposed workers in Finland	12,500
BeST	12,000 – 13,000
RPA - BeST	13,532, (20,156)
RPA – EU/US	54,071, (80,540)
RPA – US-OSHA	73,580, (114,856)
Source: Modelling by RPA, CAREX (undated), ASA Finland (2014), IOM (2011), BeST (unpublished) *RPA values exclude construction; values including construction are in brackets.* *Note: ASA Finland extrapolation is based on population.*	

As a check upon the EU/US numbers, figures for beryllium related cases of occupational exposure in Germany for years from 2000 to 2016 are produced by the DGUV (2016) and shown in Table 3-20. These seem likely to be cases of CBD rather than BeS. If the benefits model described in section 4 is run for the future baseline case (section 3.18) of Germany only, this would predict between 5 and 15 cases per year cases of CBD (between 4 and 11 cases if construction was excluded.) The range is between the cases predicted using a dynamic baseline and those predicted by a static baseline. Assuming a mortality rate of 10%, this indicates approximately one death per year. These predicted cases and deaths are in line with the data in Table 3-21 and help to validate the decision to use the EU/US dataset.

Table 3-21: Beryllium related cases of occupational exposure in Germany					
	2000	**2005**	**2010**	**2015**	**2016**
Notifications of suspected cases of occupational disease	14	7	18	32	29
Recognized cases of occupational disease	1	1	3	4	-
New occupational disease pensions	1	1	1	3	-
Fatalities due to occupational disease	-	-	-	4	1
Source: DGVU (2016)					

Exposed employees by Member State

The predicted exposed workers by sector are further broken down by Member State in Table 3-22.

Table 3-22: Predicted employees exposed to beryllium by sector and Member State												
Member State	Foundries	Metal fabrication	Transportation	ICT	Specialist manufacturers	Medical devices	Glass	Laboratories	Recycling	Total excluding Construction	Construction	Total including Construction
AT	196	421	39	33	198	244	19	26	6	1,182	702	1,884
BE	135	283	30	16	116	133	16	31	10	770	552	1,322
– BG	64	318	26	15	232	65	13	9	4	746	366	1,112
– CY	2	16	0	0	26	4	1	0	1	50	48	98
– CZ	242	875	182	64	1,085	388	34	30	12	2,912	572	3,484
– DE	1,448	4,910	995	527	2,247	5,398	144	471	85	16,225	5,120	21,345
– DK	32	228	8	31	140	136	10	39	5	629	447	1,076
– EE	3	75	4	9	25	0	3	3	1	123	116	239
– EL	44	120	4	4	135	66	8	64	4	449	273	722
– ES	313	1,184	190	37	462	481	51	119	23	2,860	2,050	4,910
– FI	80	226	15	38	128	51	9	14	4	565	433	998
– FR	418	1,799	381	207	854	1,428	69	151	82	5,389	3,543	8,932
– HR	24	174	11	9	37	37	7	7	5	311	245	556
– HU	94	427	95	69	137	394	15	40	7	1,278	451	1,729
– IE	14	74	3	0	8	0	5	13	5	122	199	321
– IT	623	2,416	240	144	913	1,177	85	67	61	5,726	2,102	7,828
– LT	3	82	6	5	92	0	5	4	4	201	260	461
– LU	7	60	4	3	16	20	1	2	1	114	167	281
– LV	0	21	0	0	41	16	3	0	0	81	113	194
– MT	0	6	0	0	79	0	1	0	0	86	21	107
– NL	107	481	38	41	375	333	12	102	11	1,500	807	2,307
– PL	335	1,575	223	90	399	515	76	29	22	3,264	1,599	4,863
– PT	42	438	38	14	136	133	23	15	9	848	680	1,528
– RO	164	522	202	50	169	163	24	37	33	1,364	984	2,348
– SE	177	382	86	24	199	220	11	39	12	1,150	838	1,988
– SI	46	169	14	0	67	62	4	0	4	366	136	502
– SK	122	291	71	22	128	110	9	6	3	762	202	964
– UK	366	1,917	296	176	635	1,165	50	323	72	5,000	3,445	8,445
– EU	5,099	19,491	3,202	1,628	9,079	12,737	709	1,639	487	54,071	26,469	80,540
Source: RPA												

Trends for exposed employees

According to the industry organisation BeST, the demand for beryllium is expected to continue to rise slowly particularly in the electronics and nuclear industries. Technological advances will lead the demand for beryllium, but this will be counteracted by ever smaller components and innovation seeking for less expensive materials. However, even if the use of beryllium increases, BeST expects the number of exposed workers to slowly decrease as automation is introduced into manufacturing in EU companies to increase productivity. The four Member States with the most exposed employees, Germany, France, Italy and the United Kingdom, are all investing heavily in automation to improve their productivity and the high technology industries that use beryllium are some of the most profitable and hence the most important to retain and improve.

Furthermore, regardless of OELs, BeST expects the exposure levels also to decrease slowly as many companies continually seek to improve health and safety. The increasing automation would also lead to lower exposure levels as well as reducing the number of workers exposed at all.

3.6.3 Exposed employees by exposure concentration and sector

The estimated numbers of employees exposed to different concentrations of beryllium in each sector are shown in Tables 3-23 and 3-24. These are based upon the EU/USA data set described in section 3.6.3 above.

Table 3-23 shows the estimates using the BeST survey data (hereafter called the BeST distribution); the percentage split of the exposure concentration range is the same for every sector. Table 3-24 shows the estimates of workers exposed using US-OSHA data (hereafter called the US-OSHA distribution) for the seven sectors available from the US-OSHA employee data. The percentage split of the exposure concentration range is different for each of the seven sectors. Table 3-23 also shows that each sector's 95% exposure concentration (MEGA) measured by BAuA (2014) and 90% exposure concentration measured in France from 2004 – 2006, see Vincent et al., (2009).

The data in Tables 3-23 and 3-24 have different exposure distributions. Comparisons between the two data distributions can only be made for the first seven sectors as the US-OSHA data only covers seven sectors. However, construction would need to be excluded as the numbers distort the analysis and the figures for laboratories and recycling are small. The BeST distribution predicts that 4,262 are exposed to over 1 $\mu g/m^3$ in the EU compared with the US-OSHA distribution which predicts 4,606 are exposed. Given the totally different methods of achieving these numbers, this is remarkably similar. The US-OSHA distribution also predicts that 1,791 workers are exposed to over 2 $\mu g/m^3$, which is at or above the OEL for nearly all Member States. These figures are similar to the IOM (2011) predictions of 3,000 workers exposed to higher levels of beryllium and under 10% exposed to 2 $\mu g/m^3$ or more. Both the BeST and US-OSHA predictions are for 8% of workers being exposed to 2 $\mu g/m^3$ or more

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

Table 3-24 shows that foundries are the sector where workers are exposed to the highest levels of beryllium: 13% are predicted to be working at over 2 $\mu g/m^3$.

The BeST distribution set in Table 3.23 is based upon a BeST customer survey made in the EU when companies had generally been working to an OEL of 2$\mu g/m^3$ (inhalable) or lower. However, as this is based upon a customer survey, it is possible that well-run companies operating at the lower exposure levels were more likely to respond, which may mean that the BeST distribution underestimates exposure levels.

The US-OSHA distribution in Table 3-24 is based upon data collected in the USA between 2007 and 2010 before the PEL of 0.2µg/m^3 (total particulate) was introduced and when US companies were working to a higher PEL of 2µg/m^3 (total particulate). This means that the US-OSHA distribution may overestimate the exposure levels.

In the analysis of benefits and costs in sections 4 and 5, the benefits and costs are developed for both data distributions.

Table 3-23: Estimated EU employees exposed to different exposure concentrations of beryllium: EU/USA data set and BeST distribution

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

Source: Modelling by RPA, BAuA MEGA data (2014), Vincent et al. (2009)
Notes: Dataset: EU/US, data distribution: BeST; Sectors, all ten sectors

Table 3-24: Estimated EU employees exposed to different exposure concentrations of beryllium: EU/USA data set and US-OSHA distribution									
Sector / Target OELV inhalable µg/m3	**< 0.2 µg/m³**	**0.2 µg/m³ - 0.4 µg/m³**	**0.4 µg/m³ – 1 µg/m³**	**1 µg/m³ – 2 µg/m³**	**2 µg/m³ – 4 µg/m³**	**> 4 µg/m³**	**Total employees exposed in sector**	**Exposure 95% MEGA**	**Exposure 90% France**
Foundries	2,052 (40%)	839 (16%)	1,039 (20%)	497 (10%)	249 (5%)	423 (8%)	5,099 (100%)	1.05	16.06
Metal fabrication	15,540 (80%)	1,640 (8%)	1,382 (7%)	405 (2%)	159 (1%)	365 (2%)	19,491 (100%)	0.228	0.6
Transportation	1,948 (61%)	429 (13%)	472 (15%)	271 (8%)	19 (1%)	62 (2%)	3,202 (100%)	0.554	0.015
ICT	1,213 (75%)	162 (10%)	172 (11%)	54 (3%)	16 (1%)	12 (1%)	1,628 (100%)	0.512	10.44
Specialist manufacturers	8,133 (90%)	398 (4%)	332 (4%)	111 (1%)	40 (0%)	65 (1%)	9,079 (100%)	0.512	NA
Medical devices	7,176 (56%)	1,794 (14%)	1,973 (15%)	1,435 (11%)	0 (0%)	359 (3%)	12,737 (100%)	0.512	0.5
Glass	378 (53%)	104 (15%)	161 (23%)	42 (6%)	14 (2%)	8 (1%)	709 (100%)	2.78	NA
Total (seven sectors)	**36,440 (70%)**	**5,366 (10%)**	**5,531 (11%)**	**2,815 (5%)**	**497 (1%)**	**1,294 (2%)**	**51,945 (100%)**	-	-
Laboratories	1,150 (70%)	169 (10%)	175 (11%)	89 (5%)	16 (1%)	41 (2%)	1,639	NA	NA
Recycling	342 (70%)	50 (10%)	52 (11%)	26 (5%)	5 (1%)	12 (2%)	487	NA	NA
Total excluding construction	**37,931 (70%)**	**5,586 (10%)**	**5,757 (11%)**	**2,930 (5%)**	**517 (1%)**	**1,347 (2%)**	**54,071**	-	-
Construction	18,568 (70%)	2,734 (10%)	2,818 (11%)	1,434 (5%)	253 (1%)	659 (2%)	26,469	NA	NA
Total including construction	**56,500 (70%)**	**8,320 (10%)**	**8,576 (11%)**	**4,365 (5%)**	**771 (1%)**	**2,006 (2%)**	**80,540**	-	-

Source: Modelling by RPA, US-OSHA (2015), BAuA MEGA data (2014), Vincent et al. (2009)
Notes: Dataset: EU/US, data distribution: US-OSHA, sampling conversion = 2; Sectors, all ten sectors
Laboratories, recycling and construction are estimated using the average percentages for the seven sectors.

3.7 Current risk management measures (RMMs)

3.7.1 Types of RMMs

The CMD describes a hierarchy of measures for managing the risk of exposure and these are shown in Table 3-25 together with th98e specific measures identified as being used to manage workers' exposure to beryllium.

Table 3-25 Hierarchy of measures to be applied by the employers, as listed in the CMD and as found in companies using beryllium		
Type of measure	**RMMs specified in the CMD**	**RMMs in use for beryllium**
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	Substitution Reworking processes
Reducing the number of workers exposed	(b) keeping as low as possible the number of workers exposed or likely to be exposed	Reworking processes
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	Reworking processes
	(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	Local exhaust ventilation • Full enclosure • Partial enclosure • Open hood • Pressurised and sealed enclosure • Simple worker's cab • General dilution ventilation
	(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	Organisational measures
	(f) application of suitable working procedures and methods	Organisational measures
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	Personal protective equipment • Breathing apparatus • Mask with HEPA filter • Simple mask
	(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces	Organisational measures
	(i) information for workers	Organisational measures
	(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	Organisational measures
	(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure	Organisational measures
Other measures	(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers	Organisational measures
Source: RPA and CMD		

3.7.2 Cost of RMMs

The costs of the different RMMs are described in the methodology report. One respondent gave estimates of the cost of the ventilation that they assume would be required to achieve the various OELVs and these costs were used to validate the model. This same respondent believed that they could not achieve 0.02 µg/m^3 and that any level beneath 0.2 µg/m^3 was likely to result in the closure of their plant.

3.7.3 RMMs used by different processes and sectors

In section 3.4.2, the processes used in the processing and manufacture of beryllium were described in Table 3-5. In this table, each process was allocated to a process group. In Table 3-6, the process groups used in each sector are explained.

A discussion with BeST helped to understand the RMMs that would be required for each process group at different target OELVs and this information helped to build the decision tree that are the heart of the cost model. The information about the RMMs required at different OELVs for different process groups is given in Table 3-26.

Table 3-26: RMMs required at different OELVs for different process groups			
OELVs/ Process group	Operating at 2 µg/m^3 already	Moving from 2 µg/m^3 to 0.6 µg/m^3	Going below 0.6 µg/m^3
Melting Note: Sputtering does not cause exposure during the activity which takes place entirely within a vacuum. The exposure hazard occurs when the vacuum container is cleaned.	Majority of companies using melting processes should be operating at or below 2 µg/m^3. To achieve this, they will be using ventilation.	To move from 2 µg/m^3 to 0.6 µg/m^3, the following RMMs would need to be introduced. Loosely, the first items on the list are less expensive and would reduce exposure so far, all or nearly all the measures would be required to achieve 0.6 µg/m^3: • Changes in work practices and processes • Cyclones and bag houses • Personal protection • Monitoring • Fully dusted systems • Increased extraction speeds • Separately ventilated control boxes for remote control • Everything enclosed. • Showers • Uniform service	BeST member Materion has tried to reduce the exposure levels towards 0.2 µg/m^3 and have not been able to. They are not aware of any other metal casting company that has achieved this. Vacuum casting is cleaner but considerably more expensive.
Mechanical – machining Note: Some mechanical – machining process are much higher in energy than others. The higher the energy, the greater the exposure risk and the more difficult and expensive it is to keep the exposure risk down.	Majority of companies using mechanical – machining processes should be operating at or below 2 µg/m^3.	Pure beryllium: only about 10-12 companies work with pure beryllium in EU. Highly specialised. Pure beryllium is brittle and breaks into small pieces. BeST believe best practices should allow these companies to achieve 0.6 µg/m^3. They may be able to go lower. CuBe: many more producers. BeST looked how a plastic injection mould maker could reduce exposure. They found that a bench with several tools could be covered by a hood costing €28,000 and that this would capable of reducing exposure below 0.6 µg/m^3 for high energy processes. Lower energy processes like SNS machining might already be operating at 0.6 µg/m^3	Likely to easier for those using low energy processes, difficult for those using high energy processes
Mechanical – shaping Note: Hot forging also causes issue with	Majority of companies using mechanical – shaping	Many operators of these processes should already be at or nearly at 0.6 µg/m^3	Would require additional engineering, work practices

Table 3-26: RMMs required at different OELVs for different process groups			
OELVs/ Process group	**Operating at 2 µg/m^3 already**	**Moving from 2 µg/m^3 to 0.6 µg/m^3**	**Going below 0.6 µg/m^3**
oxidisation if the metal cools in oxygen and an oxide forms. This is brittle and falls as dust. Housekeeping required.	processes should be operating at or below 2 µg/m^3.		
Thermal Note: These processes also have oxidisation issues, see above. A closed furnace can be used for annealing and heat treatment which reduces the oxidisation. Pickling is used to remove oxidisation.	Majority of companies using thermal processes should be operating at or below 2 µg/m^3	Handling/recycling process required to deal with waste Fine layer of dust still an issue, use wet cleaning	Would require additional engineering, work practices or best practices, plus ventilation and containment.
Chemical	Majority of companies using thermal processes should be operating at or below 2 µg/m^3	The chemical acids are already a serious issue, so the processes are already generally in place to reduce exposure to them anyway.	Would require additional engineering, work practices
Source: RPA study team conversations with BeST			

3.7.4 How RMMS may change in the future

According to the industry association BeST, the biggest impact upon risk management methods in the future is likely to be automation of manufacturing, as companies across the EU (but particularly in the countries such as Germany, France, Italy and the United Kingdom), involved in high quality, high cost and high value added activities begin to make such investments to improve productivity.

3.8 Voluntary industry initiatives

The Beryllium Science and Technology Association (BeST) has a voluntary initiative "Be Responsible, which it promotes amongst its customers in Europe. This campaign started in the spring of 2017. The key elements of this initiative are:

- Encouraging customers to achieve the Recommended Exposure Guideline (REG) of 0.6 $\mu g/m^3$ (inhalable), measured as an 8-hour time weighted average (TWA);
- Reducing beryllium exposures using all available methods methods (Hygiene measures, working clothes, engineering controls (e.g. local exhaust ventilation at the source), work practices (e.g. wet methods), access controls on the work area, regular and appropriate housekeeping (HEPA vacuums and/or wet methods in order to minimize dust generation); and
- Provide beryllium health and safety training information.

To enable this, BeST has produced 12 leaflets covering different aspects of managing exposure levels and each of the major industries using beryllium. The campaign is designed to go to all sectors. BeST members intend to circulate these to their customers during 2018 via mailshots, trade shows and personal contacts.

Currently, BeST has no information about the impact of this campaign, however BeST intends to include questions about the campaign in its next survey of customers, which is planned later in 2018. BeST is aware that some of its customers are not following the recommendations.

3.9 Best practice

Best practice varies greatly depending on the process. For example, if a company is working with beryllium in manner that creates dust or powder, it requires more RMMs than a company that is rolling, slitting and stamping copper beryllium alloys.

Two respondents gave examples of their best practice at each end of the spectrum. The first respondent are metal fabricators working with copper beryllium and using mechanical processes - specifically cold rolling, drawing and some thermal processes, such as heat treatment. This respondents' facility has managed to keep measured exposure levels low by implementing the following RMMs:

- Work process design;
- General dilution ventilation;
- Detecting unusual exposures – daily visual checks, measurements;
- Work clothing, gloves;
- Hygiene and cleaning work surfaces; and
- No respiratory protection.

Their exposure levels have always been measured at below at 2 μg/m^3 and average at 1μg/m^3. Many employees have worked at this facility for 20 to 30 years and there have been no reported cases of chronic beryllium disease (CBD): the facility is located in a small town where people are more likely to be aware of cases of CBD occurring after employment.

The second respondent undertakes manufacturing using beryllium in an inherently high risk process and uses the RMMs below to achieve their national OEL of at 2 μg/m^3:

- Strict daily monitoring: this is not required by law, but is instead voluntarily carried out by the company;
- Personal protective equipment, air extraction, and HEPA filters are used throughout the plant;
- Individual machines are fully enclosed and shut down if the door is opened. The air extracted goes through centrifuges to remove any contamination and this is disposed of in the correct manner;
- Vacuum cleaners also contain HEPA filters and there are segregated bins;
- Levels of exposure are not to be exceeded are posted on the walls for workers to see;
- Monitoring results are analysed and reported monthly, in addition to an annual study;
- Every member of staff has a medical check every six months and two doctors are on retainer;
- Of 25–30 employees, several have worked there for 30–38 years. The staff have specialised skills and require approximately 3 years of training (a long training cycle); and
- There are no known cases of CBD and, again, this facility is based in a small town where people know each other.

Many of the small and medium enterprises handling beryllium and beryllium-containing materials, such as stamping facilities, are accustomed to applying best practices for other metals such as nickel, cobalt, lead and cadmium as well as chemicals such as solvents for cleaning operations. Processing these metals and chemicals have similar inhalation risks and therefore require similar RMMs.

In general, personal protection equipment such as masks and respirators are not ideal as individuals are responsible for using it properly. Respiratory equipment is used as a back-up because, when handling, even if there are good controls, there is potential for exposure during malfunctions and emergencies. Respiratory equipment cannot be used to achieve binding limits.

3.10 Standard monitoring methods and tools

3.10.1Introduction

The 'GESTIS - Analytical methods' database, IFA (2017), is a unique source of available analytical methods for occupational hygiene monitoring. This 'database contains validated lists of methods from various EU member states, the USA and Canada described as suitable for the analysis of chemical agents at workplaces'. The database is the outcome of a project sponsored by the European Commission and the European Food Safety Authority (EFSA) that involved authorities and other stakeholders from nine EU Member States (Austria, Denmark, France, Germany, Hungary, Italy, Spain, Sweden and United Kingdom). The data are updated to some extent.

The database contains 'method sheets' that also include a ranking with an 'A' ranking being the best. An 'A' ranking indicates that all or most of the requirements of EN 482 are met, while a 'B' ranking indicates incomplete validation data, but a potential to meet the requirements of EN 482. Methods ranked ‘C’ in the original evaluation are not considered to be able to meet the requirements of the norm and are often not included in the ‘method sheets’. Full details on the ranking procedures are available on the website. In the evaluation below, methods with an ‘A’ ranking are given priority.

This database is considered a meaningful starting point to establish validated analytical methods for chemical agents. In some cases, more recent information may be used to supplement or revise the information extracted from the database.

3.10.2 Analytical methods

SCOEL (2017) indicate that beryllium and its compounds can be monitored in the air of the workplace by applying the following fully or partially evaluated methods listed in Table 3-27 below.

Table 3-27: Overview of sampling and analytical methods for monitoring total airborne beryllium in the workplace

Method	Sorbent	Analysis	Recovery/ Extraction efficiency (%)	LOQ/LOD	Flow rate/ Sample volume/ time	Concentration
Method BGI 505-13-02	FILTER (cellulose nitrate membrane filter)	GF-AAS (after acid digestion)	100	Absolute: 0.62 pg of beryllium (LOQ) Relative: 0.0019 µg/m^3 *	10 L/min for 2 hours	0.002-0.013 µg/m^3 based on an air sample volume of 1.2 m^3
NIOSH 7102	FILTER (cellulose ester membrane)	GF-AAS	98.2	0.005 µg per sample (LOD)	1 to 4 L/min; 25-1000L	0.5-10 µg/ m^3 for
NIOSH 7300	FILTER (cellulose ester membrane or polyvinyl chloride membrane)	ICAP-AES	98.4-106.8 (depending on the membrane and LOD used)	0.2 ng/ml (LOD)	1 to 4 L/min; 1250-2000L	5-2000 µg/ m^3 in a 500
NIOSH 7302	FILTER (mixed cellulose ester membrane)	ICAP-AES	95.8-103	0.009 µg/sample (LOD)	1 to 4 L/min; 1250 -2000L	Lower Level: 0.025 µg/sample Higher Level: 7.60 µg/sample
NIOSH 7301	FILTER (cellulose ester membrane or polyvinyl chloride membrane)	ICAP-AES	81.1-100.6 (depending on the membrane and LOD used)	LOD: 0.2 ng/ml	1 to 4 L/min; 1250-2000L	5-2000 µg/ m^3 for each element in a 500-L air sample
NIOSH 7303	FILTER (cellulose ester membrane	ICAP-AES	90-110	0.0025 µg /ml (LOQ) 0.00075 µg /ml (LOD)	1 to 4 L/min; 35-25,000,00	up to 100,000 µg /m^3 for each element in a 500-L sample. Minimum
NIOSH 7304	FILTER, (polyvinyl chloride	ICAP-AES	102.38 - 107.71 (depending on the LOQ)	0.008µg/ Sample (LOD) 0.00104	1 to 4 L/min; 1250-2000L	Lower Level: 0.0509 µg/sample Higher Level: 15.2 µg/sample

Table 3-27: Overview of sampling and analytical methods for monitoring total airborne beryllium in the workplace						
Method	**Sorbent**	**Analysis**	**Recovery/ Extraction efficiency (%)**	**LOQ/LOD**	**Flow rate/ Sample volume/ time**	**Concentration**
NIOSH 7306	Internal capsule cellulose acetate dome with inlet opening attached to mixed cellulose ester (MCE) membrane filter	ICP-AES	100-101	0.0064 µg/sample (LOD)	1 to 4 L/min; 10- >2000 L	0.04 to 10,000 µg /m^3 for each element in
NIOSH 7704	Filter (mixed cellulose ester or nylon membrane)	Field-portable UV/vis fluorometry	not available	0.00075 µg per filter (LOD)	(1 to 4) L/min; 240-2,000L	0.005 µg/m^3 to 6 µg/m^3 for an air sample of 1000 L
OSHA ID-206	Filter (mixed cellulose ester membrane filter)	ICP-AES	not available	0.00029 µg/mL (LOD, Qualitative)	2 L/min; 480 L	0.00086-10 µg/mL
OSHA ID-125G	Filter (mixed-cellulose ester membrane filter)	ICAP-AES	not available	0.013 µg (LOD, Qualitative) 0.043 µg (LOD, Quantitative)	2 L/min; 480 L	Upper Detection Limit: 5 µg/mL
Source: SCOEL (2017) ** for an air sample of 1.2 m^3, a sample solution of 20 mL (dilution factor 4) and an injection volume of 20 µL*						

Sampling of air (including airborne particles and gasses) in order to monitor airborne beryllium is usually carried out by air collection on filters, which are digested. The analytical methods used are Inductively Coupled Plasma-Atomic Emission Spectroscopy (ICP-AES), Inductively Coupled Argon Plasma-Atomic Emission Spectroscopy (ICAP-AES), Graphite Furnace Atomic Absorption Spectroscopy (GF-AAS) and field-portable UV/Vis fluorimetry.

Detection limits in air are in the range of ng/m^3 to µg/m^3. For water soluble forms of beryllium, a relatively mild digestion technique can be applied, and detection limits are low with ICP-AES and GF-AAS. For beryllium oxide, a more robust digestion is required, and Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) should be used instead, which typically has lower detection limits.

A new release of the NIOSH method 7704 was published in December 2015 for which the LOD is now 0.1 ng.

The 7302, 7304, 7306 NIOSH methods are fully evaluated methods. OSHA method ID-206 and ID-125G are completely validated. The NIOSH methods 7300, 7301, 7302, 7303, 7304, 7306 are simultaneous elemental analysis and are therefore not considered compound (Be) specific. It should be noted that the OSHA and NIOSH methods are not validated according to the European reference standards (EN 13890 and 482).

There are also three relevant ISO methods:

- ISO 10882-1:2011 for the sampling of airborne particles and gases in the operator's breathing zone;
- ISO 15202-3:2004 (Workplace air) for the determination of metals and metalloids in airborne particulate matter by inductively coupled plasma atomic emission spectrometry; and
- ISO 30011:2010 (Workplace air) for the determination of metals and metalloids in airborne particulate matter by inductively coupled plasma mass spectrometry.

The 'GESTIS - Analytical methods,' IFA (2017,) database contains 10 methods for "Beryllium and beryllium compounds (as Be)". Of these, two are assigned an 'A' ranking, six a 'B' ranking and two a 'C' ranking. Table 3-28 summarises the most important information for the two methods with an 'A' ranking.

Table 3-28: Analytical methods for beryllium and compounds ('A' ranking methods)

Standard	Year	Principle*	Flow rate/recommended air volume	LoQ [µg/m³]	Validated working range
ISO 15202	2004	InhSam ICP-AES	Flow rate: Sampler–dependent Recommended sampling time: 15 min–8 h	0.05 0.8	480 L 30 L
MDHS 29/2	1996	InhSam F-AAS ET-AAS	 2 L/min 2 L/min	 0.25 0.11	 480 L 30 L

Source: GESTIS, IFA (2017)
**InhSam: Inhalable sampler*

From this, it is concluded that:

- Lowest LoQ for methods with an indicative 'A' ranking: 0.05 µg/m³;
- There is a French method in the database with a slightly lower LoQ of 0.02 µg/m³ (MétroPol 003, ICP-AES, 'B' ranking, no performance data published in the method);
- No published methods cover ranges of OELs down to the current SCOEL recommended OEL of 0.02 µg/m³;
- Method suggested in Germany for controlling most recent OEL: ##Ident.no.: 6300 Beryllium, Status: October 2014, this analytical method may be used for sampling of the respirable fraction, is used with FSP-10 and adequate corresponding filter (priority since 2016, not included in ranking); and
- No information on discrimination of suitability for different particle sizes (inhalable, respirable, total).

3.10.3Limit of quantification and limit of detection

As the likely enforcement standard (European Committee for Standardisation, 2016) means that companies would try to achieve levels of 10% of the OEL, any OELV chosen needs to be measureable to at least 10% of this level. We understand that at least one testing laboratory has a limit of quantification (LOQ) for beryllium of 0.002 µg/m³ or lower. We are aware that many testing facilities currently cannot achieve this level.

One respondent reported that their tests are done by APAVE or Carso and neither can measure 0.02 µg/m^3. It is not clear whether this means to 0.02 µg/m^3 or to 0.002 µg/m^3, the level that needs to be measure to ensure 0.02 µg/m^3.

3.10.4Measuring OELs

BeST have described the current monitoring practices to measure exposure. To monitor exposure, the sampling devices are either worn by the workers or, if their job is in a fixed location, fixed in a location equivalent to to the position of their face. Monitoring of airborne beryllium is usually carried out by air collection on filters, with samples subsequently sent to a laboratory for analysis. Prior to analysis at the laboratory, samples are digested, diluted and then analysed using analytical methods. 'Good practice' recommends at least 15 samples from similarly exposed groups are analysed. The frequency of sampling will depend on the requirements of specific national authorities but repeat monitoring is probably unnecessary if the production process does not change.

Additionally, two consultation respondents reported their measurement regime. The first, a manufacturer working in metal fabrication, has two measurement campaigns per year, with four different workstations selected for each campaign. They pick different workstations for each campaign with the recorded exposure concentrations below 2 µg/m^3 and the majority below 1 µg/m^3. The second respondent, a manufacturer working with beryllium in an inherently high risk process, carries out strict monitoring on a daily basis, with sampling devices worn by workers.

3.10.5Background levels

SCOEL (2017) reports that the average exposure concentration in outdoor air is less that 0.00003 - 0.00007 µg/m^3, but in cities this can reach 0.0067 µg/m^3 (WHO, 2001). This may cause issues for an OELV of 0.02 µg/m^3 as many companies would try to achieve levels between 10% and 20% of the OEL, and the lower level is below the level seen in cities.

3.10.6Measuring STELs

SCOEL (2016) has declared that for beryllium, 15 minutes is not enough time for gathering a sufficient amount of matter in the filter for evaluating 15 minutes of exposure. SCOEL is investigating this further. Therefore, it appears that a STEL for beryllium is not viable.

We had no reports from organisations measuring STELs for beryllium and, therefore, there is no further analysis of STELs in this report.

3.11Relevance of REACH restrictions or authorisations

3.11.1REACH authorisations and restrictions

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

3.11.2REACH registrations

Beryllium has been registered at 10 – 100 tonnes per annum and has seven active registrants. Beryllium oxide is also registered, at 1 – 10 tonnes per annum, and has one active registrant.

3.11.3Risk management option analysis (RMOA)

ECHA's Public Activities Coordination Tool (PACT) highlights that, in 2016, the Germany authorities concluded an RMOA (BauA, 2016) on beryllium (as part of its process of developing its OEL and STEL). The RMOA conclusion document indicates that an Annex XV restriction dossier may be an appropriate action in the future. The tool also highlights that there is an ongoing RMOA for beryllium oxide. The inclusion date for this RMOA is cited as November 2017; no further information on the scope or findings of the RMOA is available at this time.

3.12 Market analysis

The importance of beryllium to the sectors that use it is demonstrated by its presence on the Critical Raw Materials list for the third time in the list issued on 13 September 2017 (European Commission (2017)). Beryllium's unusual chemical, thermal, and mechanical capabilities make it attractive for high technology equipment. According to BeST, the market for beryllium is increasing by 10% per year. The requirement for beryllium in large high technology projects like ITER (undated) is part of this growth.

The EU does not mine beryllium and does not import any beryllium ores. There is no processing activity in the EU. Europe imports all its beryllium, which totals between 40 and 50 tonnes per year. There are three primary suppliers of beryllium: the USA, Kazakhstan and China. About 80% of beryllium used in the EU is made into coppery beryllium alloys at between 0.1 and 2% beryllium. This is used to make high conductivity electrical terminals and mechanical components.

Approximately 15% of beryllium is used in a pure form as a metal containing over 50% beryllium and the remaining 5% is used as beryllium oxide ceramics. These are excellent electrical insulators with high thermal conductivity.

3.12.1Enterprises relevant to beryllium by sector

The key information for affected enterprises in each sector is given in Table 3-29. The predicted affected enterprises using each of the three methods are given in Table 3-30.

Table 3-29: USA and EU data on enterprises by sector				
Sector	**USA enterprises in associated NAIC sectors (US-OSHA)**	**USA enterprises in associated NAIC sectors affected by beryllium (US-OSHA)**	**% USA enterprises in sector affected by beryllium**	**Total enterprises in EU (Eurostat)**
Foundries	2,727	147	5.38%	16,574
Metal fabrication	63,691	915	1.44%	384,795
Transportation	11,273	190	1.68%	34,104
ICT	12,013	91	0.76%	40,582
Specialist manufacturers	59,807	382	0.64%	332,046
Medical devices	10,417	1,680	16.13%	65,527
Glass	27,811	25	0.09%	15,288
Construction	1,089,605	0	0.00%	3,417,609
Laboratories	14,789	0	0.00%	62,759
Recycling	1,064	0	0.00%	20,241
Total	NA	3430	NA	NA
Sources: Modelling by RPA, Eurostat (2015), US-OSHA (2015), BeST				

Table 3-30: Predicted number of EU enterprises relevant to beryllium using three methods			
Sector	**Predicted number of EU enterprises affected by beryllium (BeST)**	**Predicted number of EU enterprises affected by beryllium (EU/USA)**	**Predicted number of EU enterprises affected by beryllium (US-OSHA)**
Foundries	23	229	892
Metal fabrication	144	1,430	5,529
Transportation	30	297	575
ICT	14	143	309
Specialist manufacturers	60	597	2,119
Medical devices	264	2,626	10,568
Glass	4	39	85
Total (seven sectors)	**539**	**5,361**	**20,077**
Laboratories	34	335	1,045
Recycling	11	108	337
Total (excluding construction)	**584**	**5,804**	**21,459**
Construction	1,836	18,229	56,923
Total (including construction)	**2,420**	**24,033**	**78,382**
Sources: Modelling by RPA, US-OSHA (2015), BeST *Notes: For an explanation of methods (BeST, EU/USA and US-OSHA), see section 3.6.4*			

The first method, using the BeST estimate of the EU companies using beryllium, seems too low. BeST currently supply 540 companies using beryllium in EU, 40 large companies and 500 SMEs. Many of these companies will fabricate beryllium components and supply these to other companies down the supply chain. The total number of potentially relevant enterprises in Table 3-29 is 24,033 using the EU/USA method and this seems more appropriate, particularly if the construction enterprises are removed, which reduces the total to 5,804. It seems feasible that BeST's customers supply an average of ten further companies. As with the affected employees, the total using the US-OSHA method is much higher. Throughout the remainder of the analysis, the EU/USA figures will be used, and sensitivity analysis is carried out using the BeST and US-OSHA data.

3.12.2Enterprises relevant by beryllium by sector and size

The estimated numbers of enterprises relevant to the use of beryllium are provided by sector and by size of enterprise in Table 3-31. It is of note that the large majority of enterprises are small in size.

Table 3-31: Number of enterprises relevant to beryllium by size of enterprise by sector using BeST survey data for the exposure distribution

Sector	Small enterprises	Medium enterprises	Large enterprises	Total
Foundries	171	49	10	229
Metal fabrication	1,310	116	5	1,430
Transportation	231	50	15	296
ICT	122	19	2	143
Specialist manufacturers	534	57	6	596
Medical devices	2,413	94	7	2,514
Glass	36	3	0	39
Construction	17,842	376	10	18,229
Laboratories	306	16	2	323
Recycling	93	9	0	102
Total	**23,058**	**789**	**57**	**23,901**

Source: Modelling by RPA

Notes: Dataset - EU/US; Sectors – all.

There are some small differences in numbers due to the numbers of small, medium and large enterprises not always equalling the total in Eurostat data

3.12.3Enterprises relevant to beryllium by Member State

The estimated numbers of enterprises relevant to the use of beryllium by Member State are presented in Table 3-32.

Table 3-32: Estimated numbers of enterprises affected by beryllium by sector and Member State											
Member State	Foundries	Metal fabrication	Transportation	ICT	Specialist manufacturers	Medical devices	Glass	Laboratories	Recycling	Total excluding Construction	Construction	Total including Construction
AT	2	14	3	2	7	36	1	6	1	72	184	256
BE	4	26	3	2	7	37	1	4	2	86	548	634
BG	3	13	2	1	29	25	1	2	1	77	103	180
CY	0	4	1	0	1	3	0	0	0	9	39	48
CZ	13	167	15	11	47	98	3	6	4	364	920	1,284
DE	37	161	32	25	53	489	4	36	4	841	1,773	2,614
DK	2	10	3	2	8	17	0	3	1	46	166	212
EE	0	5	1	0	3	3	0	1	0	13	51	64
EL	6	35	7	2	15	63	1	39	1	169	439	608
ES	17	123	21	8	33	210	3	24	3	442	2,015	2,457
FI	2	17	5	2	8	18	0	3	1	56	222	278
FR	13	72	24	11	68	300	3	31	32	554	2,635	3,189
HR	2	12	4	2	4	8	0	1	1	34	94	128
HU	4	30	6	5	15	65	1	21	2	149	324	473
IE	5	11	2	0	0	0	0	3	1	22	270	292
IT	47	235	40	17	111	671	8	47	17	1,193	2,728	3,921
LT	0	7	1	0	4	13	1	3	0	29	155	184
LU	1	4	1	1	2	4	0	1	0	14	59	73
LV	0	1	0	0	2	2	0	0	0	5	19	24
MT	0	1	0	0	1	0	0	0	0	2	19	21
NL	6	42	19	6	23	77	1	24	2	200	857	1,057
PL	19	125	24	10	59	233	4	9	9	492	1,303	1,795
PT	5	43	8	1	10	39	2	9	3	120	416	536
RO	6	21	8	3	7	39	1	4	7	96	258	354
SE	6	39	17	6	19	42	1	21	2	153	528	681
SI	2	16	2	1	6	13	0	7	0	47	98	145
SK	4	98	4	3	13	39	1	3	2	167	453	620
UK	26	98	44	21	42	80	2	26	10	349	1,552	1,901
EU	229	1,430	297	143	597	2,626	39	335	108	5,804	18,229	24,033

Source: RPA, US-OSHA (2015), Eurostat (2015) Notes: Dataset -EU/US; Sectors – all. There are small differences in numbers due to the numbers of small, medium and large enterprises not always equalling the total in Eurostat data

3.13 Alternatives

Beryllium is hard to substitute. Some of the qualities that make it special are:

- Second lightest metal;
- Stronger than steel;
- Non-magnetic and non-sparking - important for aerospace and oil/gas industries;
- X-ray transparent – no other material is currently available to replace x-ray windows;
- Very high melting point of 1287°C;
- Good electrical conductivity;
- Easily formable – important for miniaturisation;
- Very low friction;
- High fatigue strength – it can be bent over and over again;
- Corrosion resistant – enabling it to be used under water;
- Retains its shape for a long time; and
- Withstands a wide temperature range from -180 to +180°C; it is the only connector certified by space authorities for use in these temperatures.

As an example of beryllium's properties, adding only 2% beryllium to copper to create a copper beryllium alloy not only retains much of the conductivity of copper but also yields a significant improvement in strength. This is illustrated in Figure 3-3.

The non-beryllium substitutes are only partial substitutes: the substitutes illustrated in Figure 3-3 might provide a satisfactory conductivity and strength, but fail because one of the other qualities listed above is compromised.

Several of the metals alloyed with copper in Figure 3-3 are substances of concern in their own right such as nickel, zinc, chromium and titanium. However, it is also quite possible that the specific alloy is safe for humans and the environment and further analysis of the many alloys is beyond the scope of this study.

Generally speaking, beryllium is an expensive metal. It is not traded and there are no price lists but, according to BeST, a machined component of pure beryllium costs approximately €300-1,500/kg. Copper beryllium alloy with 2% beryllium costs approximately €20-50/kg. As a result, it is only used when necessary. In general, most manufacturers using beryllium or beryllium alloys use the material specified by their customer and they always trying to find substitutes that can achieve their specification to reduce costs.

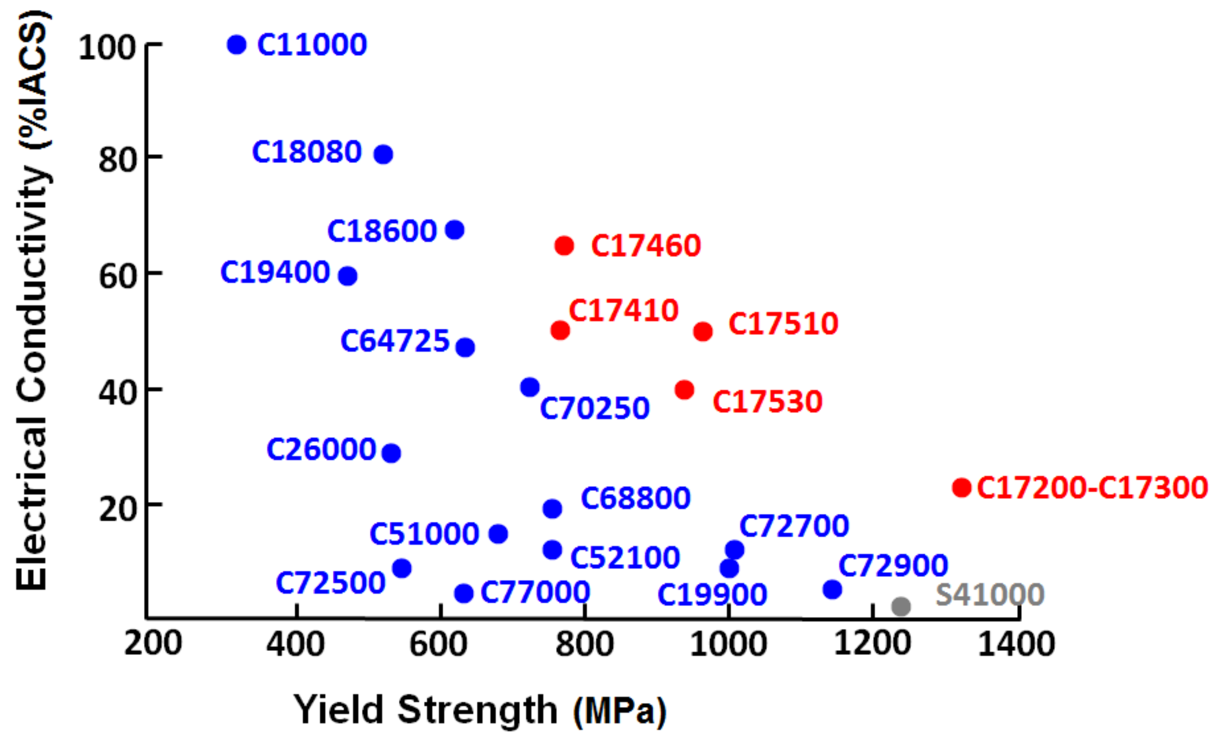

Figure 3-3: Alloy product properties - electrical conductivity v yield strength of copper beryllium alloys compared with other copper alloys

C11000 - Copper	*C26000 - Copper Zinc (Brass)*
C17200 - Copper Beryllium	*C51000 - Copper Tin Phosphorous (Bronze)*
C17300 - Copper Beryllium	*C52100 - Copper Tin Phosphorous (Bronze)*
C17410 - Copper Beryllium	*C64725 - Copper Nickel Zinc*
C17460 - Copper Beryllium	*C68800 - Copper Zinc Aluminium*
C17510 - Copper Beryllium	*C70250 - Copper Nickel Silicon*
C17530 - Copper Beryllium	*C72500 - Copper Nickel Tin*
C18080 - Copper Chromium Silver	*C72700 - Copper Nickel Tin*
C18600 - Copper Chromium Zirconium	*C72900 - Copper Nickel Tin*
C19400 - Copper Iron Zinc	*C77000 - Copper Nickel Zinc*
C19900 - Copper Titanium	*S41000 - Iron Nickel Chromium (Stainless Steel)*

Source: BeST

3.14 Current (past) and future burden of disease

3.14.1Current (past) burden of disease

The current burden of disease is estimated using the data in the preceding sections for all sectors excluding construction based on the EU/US data for exposed employees and the BeST distribution and shown in Table 3-33. The current burden of disease is the number of cases currently suffering from CBD based upon the last 40 years' exposure. It assumes that the numbers of workers in the relevant sectors have decreased by 1% per year and that exposure concentrations have decreased by 3% per year. This trend is approximated by applying the DRR to an estimated workforce/concentration halfway through a past assessment period of 40 years.

These estimates only relate to the sectors where exposure to beryllium **currently** occurs and do not represent the total burden of past occupational exposures to beryllium and inorganic beryllium compounds. The total burden from all past occupational exposure to beryllium would require consideration of sectors where occupational exposure no longer takes place and which are not relevant to the problem definition for this impact assessment.

Table 3-33: Current burden of disease (chronic beryllium disease) due to past exposure

Endpoint	Number of cases currently suffering from CBD
Seven sectors (US-OSHA distribution)	5,564
Seven sectors (BeST distribution)	3,657
Nine sectors (BeST distribution)	3,807
Ten sectors (BeST distribution)	5,670

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors)

3.14.2 Future burden of disease

The number of cases of chronic beryllium disease expected to occur in the future with a static workforce is given in Table 3-34 for both the scenarios including and excluding construction. These estimates are based on the assumption that the number of workers exposed to beryllium and its inorganic compounds and the associated exposure concentrations will remain unchanged. The present values (60 years) with a static discount rate are based on a rate of 4%: those for a declining discount rate are based on 4% for 20 years, then falling to 3%.

Table 3-34: Baseline burden of disease (chronic beryllium disease only) – constant workforce

Endpoint	Number of cases over 40 years	Number of cases over 60 years	Monetary value PV 60 years Method 1 – Method 2	
			Static discount rate (4%)	Declining discount rate (4% for 20 years, then 3%)
Seven sectors (US-OSHA distribution)	2,279	4,558	€430 million – €1.7 billion	€480 million – €1.8 billion
Seven sectors (BeST distribution)	1,473	2,946	€280 million – €1.1 billion	€310 million – €1.2 billion
Nine sectors (BeST distribution)	1,534	3,068	€290 million – €1.2 billion	€320 million – €1.2 billion
Ten sectors (BeST distribution)	2,284	4,568	€440 million – €1.7 billion	€480 million – €1.8 billion

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors)
All financial values are relative to the baseline.

The number of cases of chronic beryllium disease expected to occur in the future with a workforce that is not static, but has a turnover of 5% per year is given in Table 3-35 for both the scenarios including and excluding construction. These estimates are based on the assumption that the number of workers exposed to beryllium and its inorganic compounds and the associated exposure concentrations will remain unchanged.

Table 3-35: Baseline burden of disease (chronic beryllium disease only) – workforce turns over at 5% per year

Endpoint	Number of cases over 40 years	Number of cases over 60 years	Monetary value PV 60 years Method 1 – Method 2	
			Static discount rate (4%)	Declining discount rate (4% for 20 years, then 3%)
Seven sectors (US-OSHA distribution)	3,419	6,838	€620 million – €2.8 billion	€730 million – €3.0 billion
Seven sectors (BeST distribution)	2,210	4,420	€400 million – €1.8 billion	€470 million – €2.0 billion
Nine sectors (BeST distribution)	2,301	4,602	€420 million – €1.9 billion	€490 million – €2.0 billion
Ten sectors (BeST distribution)	3,426	6,852	€630 million – €2.8 billion	€730 million – €3.0 billion

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors).
All financial values are relative to the baseline.

The baseline burden of disease for cancer for both a constant workforce is shown in Table 3-36 and for a workforce turning over at 5% is shown in Table 3-37. There are no predicted cases of cancer and therefore there is the estimated present value for the burden is zero.

Table 3-36: Baseline burden of disease (cancer) – constant workforce

Endpoint	Number of cases over 40 years	Number of cases over 60 years	Monetary value PV 60 years Method 1 – Method 2	
			Static discount rate (4%)	Declining discount rate (4% for 20 years, then 3%)
Seven sectors (US-OSHA distribution)	0	0	€0	€0
Seven sectors (BeST distribution)	0	0	€0	€0
Nine sectors (BeST distribution)	0	0	€0	€0
Ten sectors (BeST distribution)	0	0	€0	€0

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors)
All financial values are relative to the baseline.

Table 3-37: Baseline burden of disease (cancer) – workforce turns over at 5% per year				
Endpoint	Number of cases over 40 years	Number of cases over 60 years	Monetary value PV 60 years Method 1 – Method 2	
			Static discount rate (4%)	Declining discount rate (4% for 20 years, then 3%)
Seven sectors (US-OSHA distribution)	0	0	€0	€0
Seven sectors (BeST distribution)	0	0	€0	€0
Nine sectors (BeST distribution)	0	0	€0	€0
Ten sectors (BeST distribution)	0	0	€0	€0

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors).
All financial values are relative to the baseline.

3.15 Summary of baseline scenario

Table 3-38: Beryllium – summary of the baseline scenario	
Carcinogen	***Beryllium and its inorganic compounds:*** Beryllium (CAS No. 1304-56-9) Beryllium oxide (CAS No. 7440-41-7) Beryllium chloride (CAS No. 7787-47-5) Beryllium fluoride (CAS No. 7787-49-7) Beryllium sulphate (CAS No. 13510-49-1) Beryllium nitrate (CAS No. 13597-99-4) Disodium tetrafluoroberyllate (CAS No. 13871-27-7) Beryllium(2+) ion tetrahydrate dinitrate (CAS No. 13510-48-0)
Classification	Carc. 1B
Key sectors used	Foundries Metal fabrication Transport ICT Specialist manufacturers Medical devices Glass Construction (excluded from all analysis below) Laboratories Recycling
Types of health effect caused	Chronic beryllium disease
No. of exp. workers	54,071 (excluding construction)
Change in exposure levels	Past: -3% per year Future: Expected 2% per year reduction
Change number of exposed workers	Past: -1% per year Future: Expected 3% per year reduction
Period for estimation	60 years (future)
Current disease burden (CDB) no. of cancer cases	None
Future disease burden (FDB) no. of cancer cases	None
Current disease burden (CDB) - no. of chronic beryllium disease cases	Exposure in sectors considered in this study over the past 40 years: 3,807
Future disease burden (FDB) - no. of chronic beryllium disease cases	Constant workforce 3,068 over 60 years (51 per year) Workforce turns over at 5% per year 4,602 over 60 years (77 per year)
Exp. no. of deaths (FDB) from cancer	0 over 60 years
Exp. no. of deaths (FDB) from chronic beryllium disease	Constant workforce 307 over 60 years (5 per year) Workforce turns over at 5% per year 460 over 60 years (8 per year)
Monetary value FDB from cancer	€ 0 million
Monetary value FDB from chronic beryllium disease	Constant workforce - €290 million (Method 1), €1.2 billion (Method 2) Workforce turns over at 5% per year - €420 million (Method 1), €1.9 billion (Method 2)

No avoided cases of cancer are predicted for the proposed OELs as the levels required to cause it (>10 µg/m^3) are well above those at which companies across the EU are currently operating. SCOEL concludes, "the recommended OEL is not based on carcinogenicity and is considerably lower as compared to exposure estimates leading to lung cancer in humans."

Only five Member States have no OEL and only one has an OEL above 2 µg/m^3 (Greece). Eight Member States have OELs below 2 µg/m^3. In addition, BeST is actively encouraging its customers to reduce their exposure levels to 0.6 µg/m^3 with its Be Responsible campaign. This means that most EU companies using beryllium are already operating at exposure levels within the target range of the OELVs, in other words, below 2 µg/m^3.

Note that this assessment does not capture the full burden of chronic beryllium disease and cancer (current and future) from historic exposures to beryllium for the following reasons:

- Not all past uses of beryllium are covered in the assessment; only current uses and hence current exposures are taken into account;
- The assessment of the burden of disease does not factor in the existence or not of OELs over the past 40 years. Nor does it take into account changes in national OELs over time.

The implications of these two factors is that the current burden of disease related to cancer cases may be underestimate, as may the burden of disease related to chronic beryllium disease. The former may be the most significant, given the high social value placed on avoiding cases of cancer within the worker population and the high latency or long time period over which cancer may develop. The latency of chronic beryllium disease is much lower and is therefore not expected to be as significant.

4 Benefits of the measures under consideration

4.1 Introduction

This section comprises the following subsections:

- Section 4.2: Summary of the assessment framework
- Section 4.3: Avoided cases of ill health
- Section 4.4: Benefits to workers & families
- Section 4.5: Benefits to the public sector
- Section 4.6: Benefits to employers
- Section 4.7: Aggregated benefits

4.2 Summary of the assessment framework

4.2.1 Summary of the key features of the model

The benefits of the potential measures to reduce worker exposure equal the costs of avoided cases of ill health. The model developed to estimate these costs takes into account the cost categories set out in the table below.

Table 4-1: The benefits framework

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

Source: Analysis by RPA

*Notes *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.*

The total avoided cost of ill health is calculated using the following two methods:

Method 1 (intangible costs estimated based on WTP to avoid a case):

$$Ctotal = Ch + Ci + Cp + Cvsl + Cvsm$$

Method 2 (intangible costs estimated based on monetised DALYs):

Ctotal= Ch+Ci+Cp+Cl+Cdaly

The abbreviations are explained below.

Table 4-2: Overview of cost categories

Category	Code	Cost
Direct	*Ch*	Healthcare
	Ci	Informal care
	Ce	Total cost to an employer
Indirect	*Cp*	Productivity loss due to mortality
	Cl	Lost earnings due to morbidity
Intangible	*Cvsl*	Value of statistical life
	Cvsm	Value of cancer morbidity/value of statistical morbidity
	Cdaly	Value of DALYs

Ce is not considered in the totals under both Method 1 and 2 to avoid double-counting. *Cl* is not considered under Method 1 since *Cvsl* may already include these costs.

The outputs of the model include:

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

Two key scenarios are modelled for the exposed workforce. Firstly, **ExW-Constant** where the workforce remains unchanged over 40 years (the same individuals, no replacement of workers afflicted by ill health), the whole workforce is replaced in year 41 with these individuals remaining in the exposed workforce over the next 40 years. This scenario does not take into account either the natural turnover of workers changing jobs or the turnover due to the ill health caused by exposure to the relevant chemical agents

Secondly, **ExW-Turnover** which assumes that there is a turnover of 5% per year (although this is lower than the turnover ratios in the published literature and Eurostat which are typically derived at the level of individual companies rather than sectors, a ratio of 5% is deemed appropriate to account for the fact that some workers may continue to work in the same sector and continue to be exposed). This means that the whole workforce is replaced every 20 years and no worker is exposed for the full 40 year period (this is modelled here as a group of workers being exposed for a 20 year period, followed by another group of workers exposed over the subsequent 20 years). This increases the number of cases for non-cancer endpoints. The turnover caused by treatment or early retirement due to the conditions considered in this report has not been modelled.

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 methodology report.

4.2.2 Relevant health endpoints for beryllium

For beryllium, the benefits (i.e. changes in the costs caused by ill health) have been quantified for one health endpoint: chronic beryllium disease. Other relevant endpoints which have not been quantified include beryllium sensitivity. As noted in Section 3.21, no future cancer cases are predicted under the baseline scenario for current exposures.

4.2.3 Summary of the key assumptions for beryllium

Onset of the disease

The time of diagnosis of the cases calculated over an average working life is determined taking into account the minimum and maximum time required to develop the condition (MinEx and MaxEx) and the distribution of new cases between these two points in time, combined with the latency period with which the effects are diagnosed.

The MinEx and MaxEx for chronic beryllium disease are summarised below.

Table 4-3: Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx)

Endpoint	MinEx (years)	MaxEx (years)
Chronic beryllium disease	1	2

Notes: *MinEx The minimum exposure duration required to develop the endpoint*
MaxEx The time required for all workers at risk to develop the endpoint

For chronic beryllium disease, it is assumed that no risk (i.e. not incidence but risk since incidence is delayed due to latency) arises until MinEx has expired. It is assumed that, subsequently, the distribution of risk is linear. Therefore, 0% of the excess risk arises in year 1 and 100% of the excess risk arises by year 2.

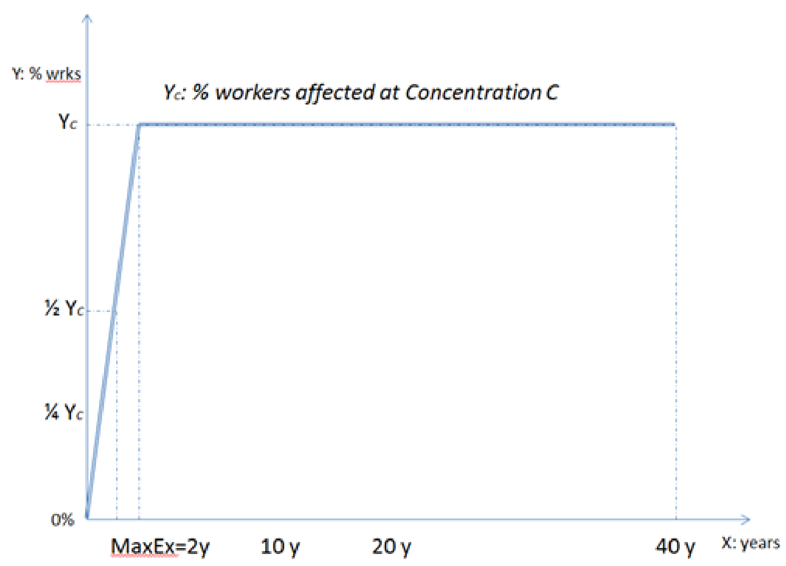

Figure 4-1: Chronic beryllium disease risk – % of workers over time
Source: Modelling by FoBiG

The estimated latency period for chronic beryllium disease is two years. There is very limited evidence for latency of chronic beryllium disease and these are study team assumptions derived for the purposes of the modelling for this study.

The effects of the disease

The key assumptions used for the modelling of the benefits from reduced exposure to beryllium are summarised below. For a detailed explanation of the model and the assumptions, please refer to the methodology report.

The key inputs and assumptions include:

- treatment periods;
- fatality rates;
- treatment cost;
- values for the Willingness to Pay (WTP) to avoid cases of chronic beryllium disease; and
- disability weights for the relevant endpoints.

Treatment period

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

Table 4-4: Treatment period

Endpoint	Treatment period (years)
Chronic beryllium disease	30

Fatality rate

The fatality rates used in the model are given below.

Table 4-5: Fatality rates

Endpoint	Fatality rate (%)
Chronic beryllium disease	10%

Cost of treatment

Chronic beryllium disease (CBD) predominantly affects the lungs and can lead to severe disability or death (Harber at al., 2009). As data for CBD are scarce, a useful proxy is sarcoidosis (which has very similar presentation to CBD) or chronic obstructive pulmonary disease (COPD). COPD is largely caused by smoking and is characterised by progressive, partially reversible airflow obstruction, systemic manifestations (skeletal muscle dysfunction, depression, and secondary polycythaemia), and increasing frequency and severity of exacerbations. The main symptoms, which are usually insidious in onset and progressive, are shortness of breath and inability to tolerate physical activity (McIvor, 2007).

First-line therapy for CBD is usually oral corticosteroids, with other agents, such as methotrexate, used as steroid sparing therapy. Corticosteroids have numerous side-effects, but improve symptoms, chest radiographs and lung function. Some patients respond initially, while others worsen. Treatment for CBD is the same as that for sarcoidosis (UCSF Medical Center, not dated):

- Prednisone is the immunosuppressive drug most commonly prescribed for CBD;
- Oxygen therapy is used as disease progresses; and
- Lung transplant may be required in severe cases.

The following sources were reviewed for cost data on sarcoidosis/granulomatous disease:

- UK NHS Reference costs 2015/16 (UK DoH, 2016); and
- Unit costs of health and social care.

Reference costs are used to set prices for NHS-funded services in England. They give the national average unit costs derived from the average unit costs of NHS provider in a given financial year. Providers determine reference costs on a full absorption basis, which means that all the running costs of providing these services are included. Each reported unit cost includes (UK DoH, 2016):

- Direct costs - relating directly to the delivery of patient care, such as medical staffing costs;
- Indirect costs - indirectly related to the delivery of care, but cannot always be specifically identified to individual patients, such as catering and linen; and
- Overhead costs - costs of support services that contribute to the effective running of the organisation, and that cannot be easily attributed to patients, such as payroll services.

As such, the UK NHS Reference costs 2015/16 can provide a comprehensive estimate of the costs associated with the treatment of the different conditions and these are shown in Table 4-6.

Table 4-6: NHS UK reference costs for sarcoidosis/granulomatous disease

Description	Unit cost
Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, with Interventions	€5,100
Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 5+	€2,300
Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 2-4	€1,100
Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 0-1	€700
Lung Transplant	€36,900
Average	***€9,000***
Average excl. lung transplant	***€1,000****

Source: UK DoH (2016)
*Notes: * It is recognised that some of the costs included in the average of unit treatment costs for sarcoidosis/granulomatous disease are one-off costs (lung transplant). A value of €1,000 is taken reflecting the fact that both lung transplants and severe cases of chronic beryllium are rare.*

Willingness to Pay (WTP) values

No WTP values have been identified in the literature for chronic beryllium disease and proxies or study team estimates are used. The median WTP to avoid a case of Chronic Obstructive Pulmonary Disorder (COPD) is around €20,000. This is broadly consistent with a WTP for reduced asthma severity according to NICE (2016). A value of €50,000 has been adopted for the purposes of this study.

Disability weights

As with the data for the cost of treatment, proxies for the disability weight for chronic beryllium diseases are taken from sarcoidosis and chronic obstructive pulmonary disease (COPD).

The disability weight for chronic beryllium disease is estimated from utility values for severe and very severe COPD (mean utility value 0.7) (NICE, 2016). Estimated disability weight for a severe case of CBD is 0.3, adjusted down to 0.2 to reflect a range of severities captured in this report. The disability weights used are shown below.

Table 4-7: Disability weights collated in European Burden of Disease study (2015)		
Type of cancer	Stage of disease	Disability Weight
Chronic beryllium disease		0.2

Summary

Table 4-8: Unit costs		
Category	Cost	Chronic beryllium disease
Direct	Healthcare	£1,000/year
	Informal care	£3,000/year *
	Cost for employers	€12,000 /case
Indirect	Mortality – productivity loss	€5,000 /year
	Morbidity – lost working days	£300/year **
Intangible	Approach 1 WTP: Mortality	€4,100,000 /case
	Approach 1 WTP: Morbidity	€20,000 /case
	Approach 2 DALY: Morbidity	Value of a DALY: €100,000
Sources: RPA Study team estimates based upon UK DoH (2016), NICE (2016) ** Estimated as proportional to healthcare costs: 3/7 ratio based on cancer healthcare and informal care costs.* *** Estimated as proportional to healthcare costs: 1/7 ratio based on the costs of cancer healthcare and lost working days.*		

4.3 Avoided cases of ill health

Benefits are calculated on the basis of average exposure concentrations (geometric mean or arithmetic mean of samples) whereas costs are calculated on the basis of 95th percentile exposure concentrations. The avoided cases of ill health for each of the target OELVs are shown in Tables 4.9 and 4-10.

Table 4-9: Avoided cases of chronic beryllium disease for each target OELV (Nine and ten sectors, BeST distribution)				
Target OELV inhalable	Avoided cases of chronic beryllium disease Nine sectors excluding construction		Avoided cases of chronic beryllium disease Ten sectors	
	40 years	60 years	40 years	60 years
2 µg/m^3	291	581	432	864
1 µg/m^3	580	1,160	863	1,726
0.6 µg/m^3	817	1,634	1,216	2,433
0.35 µg/m^3	966	1,931	1,437	2,875
0.2 µg/m^3	1,189	2,377	1,770	3,539
0.1 µg/m^3	1,403	2,805	2,088	4,177
0.05 µg/m^3	1,525	3,050	2,271	4,541
0.02 µg/m^3	1,534	3,068	2,284	4,568
Source: Modelling by RPA *Dataset - EU/US; Exposure distribution - BeS; Sectors – nine excluding construction and all ten sectors* *Avoided cases are relative to the baseline.*				

Table 4-10: Avoided cases of chronic beryllium disease for each reference OELV (seven sectors, BeST and US-OSHA distributions)				
Target OELV inhalable	**Avoided cases of chronic beryllium disease Seven sectors, BeST distribution**		**Avoided cases of chronic beryllium disease Seven sectors, US-OSHA distribution**	
	40 years	**60 years**	**40 years**	**60 years**
2 µg/m^3	279	557	1,135	2,269
1 µg/m^3	557	1,113	1,458	2,917
0.6 µg/m^3	785	1,569	1,674	3,349
0.35 µg/m^3	927	1,854	1,809	3,618
0.2 µg/m^3	1,142	2,283	1,976	3,952
0.1 µg/m^3	1,347	2,694	2,153	4,305
0.05 µg/m^3	1,465	2,929	2,270	4,541
0.02 µg/m^3	1,473	2,947	2,279	4,558

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling). Avoided cases are relative to the baseline.

These reference points have been used to plot the number of avoided cases of chronic beryllium disease over 40 years as continuous functions in Figure 4-2. The US-OSHA distribution indicates much higher avoided cases at the higher target OELVs. This is due to the US-OSHA distribution predicting higher numbers of workers operating at higher exposure levels. The US-OSHA distribution predicts that approximately 50% of cases are avoided at 2 µg/m^3, compared with approximately 20% for the BeST distribution.

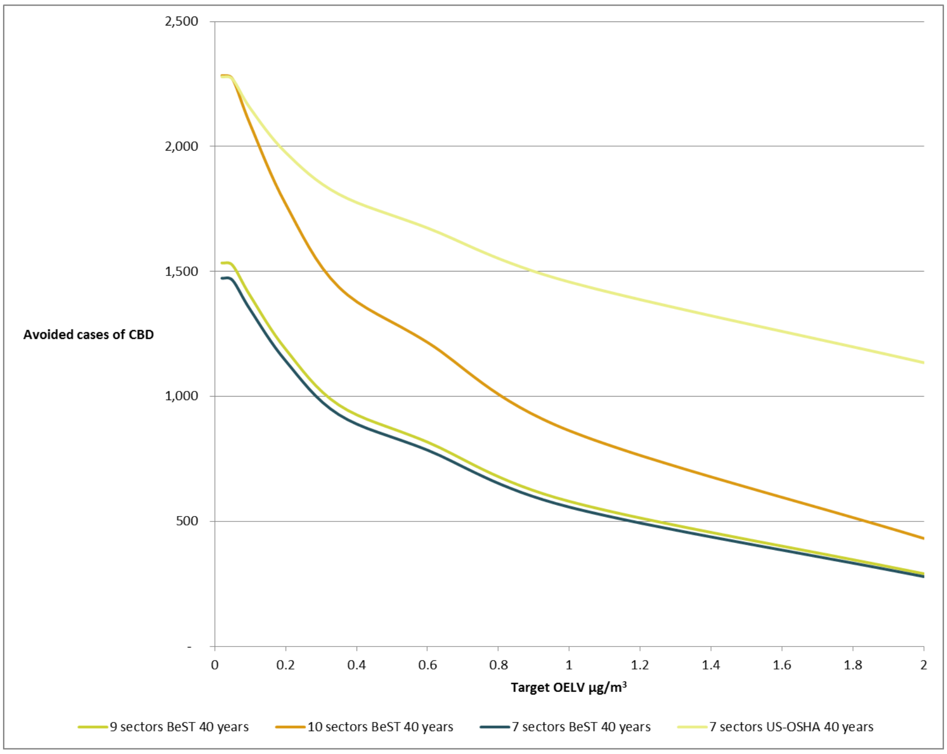

Figure 4-2: Avoided cases chronic beryllium disease cases due to occupational exposure to beryllium for each target OELV
Source: Modelling by RPA Notes: Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven (excluding construction, laboratories and recycling), nine (excluding construction) and ten (all sectors). Avoided cases are relative to the baseline.

The reduction in DALYs for each of the target OELVs for the nine and ten sector scenarios are shown in Table 4.11 and for the seven sector scenarios in Table 4.12. As with the avoided cases, the reduction in DALYs is approximately 50% at 2 µg/m^3 for the US-OSHA distribution compared with 20% for the BeST distribution.

Table 4-11: Reduction in DALYs for chronic beryllium disease for each reference OELV (Nine and ten sectors, BeST data distribution)

Target OELV inhalable	Reduction in DALYs for chronic beryllium disease - nine sectors excluding construction 60 years	Reduction in DALYs for chronic beryllium disease – all ten sectors 60 years
2 µg/m^3	4,125	6,131
1 µg/m^3	8,234	12,252
0.6 µg/m^3	11,604	17,272
0.35 µg/m^3	13,711	20,409
0.2 µg/m^3	16,879	25,129
0.1 µg/m^3	19,917	29,653
0.05 µg/m^3	21,656	32,244
0.02 µg/m^3	21,783	32,433

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeS; Sectors –nine excluding construction and all ten sectors

Table 4-12: Reduction in DALYs for chronic beryllium disease for each reference OELV (seven sectors, BeST and US-OSHA data distributions)

Target OELV inhalable	Reduction in DALYs for chronic beryllium disease - Seven sectors BeST distribution 60 years	Reduction in DALYs for chronic beryllium disease - Seven sectors US-OSHA distribution 60 years
2 µg/m^3	3,919	16,117
1 µg/m^3	7,895	20,718
0.6 µg/m^3	11,133	23,771
0.35 µg/m^3	13,163	25,688
0.2 µg/m^3	16,202	28,059
0.1 µg/m^3	19,127	30,573
0.05 µg/m^3	20,789	32,234
0.02 µg/m^3	20,917	32,362

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling

4.4 Benefits to workers & families

The benefits (avoided costs of ill health) for workers and their families are calculated using the two methods summarised below. These equal the cost of ill health under the baseline scenario, less the cost of ill health following the introduction of an OELV.

Table 4-11: 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 reference OELV are summarised below. Method 1 relies on WTP values for morbidity, while Method 2 relies on monetised DALYs for morbidity.

Table 4-12: METHOD 1: benefits to WORKERS & FAMILIES relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	**0.02 µg/m³**	**0.05 µg/m³**	**0.1 µg/m³**	**0.2 µg/m³**	**0.35 µg/m³**	**0.6 µg/m³**	**1 µg/m³**	**2 µg/m³**
Constant workforce								
Seven sectors (US-OSHA distribution)	394	393	372	342	313	290	252	196
Seven sectors (BeST distribution)	255	253	233	197	160	136	96	48
Nine sectors (BeST distribution)	265	264	243	206	167	141	100	50
Ten sectors (BeST distribution)	395	393	361	306	249	210	149	75
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	567	565	536	492	450	417	363	283
Seven sectors (BeST distribution)	367	365	335	284	231	195	139	69
Nine sectors (BeST distribution)	382	380	349	296	240	203	144	72
Ten sectors (BeST distribution)	569	565	520	441	358	303	215	108
Source: Modelling by RPA *Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.* *All financial values are relative to the baseline. Method 1 relies on WTP values for morbidity.*								

Table 4-13 METHOD 2: benefits to WORKERS & FAMILIES relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	0.02 µg/m³	0.05 µg/m³	0.1 µg/m³	0.2 µg/m³	0.35 µg/m³	0.6 µg/m³	1 µg/m³	2 µg/m³
Constant workforce								
Seven sectors (US-OSHA distribution)	1,693	1,686	1,599	1,468	1,344	1,244	1,083	843
Seven sectors (BeST distribution)	1,094	1,088	1,000	848	688	583	413	207
Nine sectors (BeST distribution)	1,139	1,133	1,042	883	717	607	431	216
Ten sectors (BeST distribution)	1,696	1,687	1,551	1,314	1,068	903	641	321
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	2,730	2,720	2,579	2,367	2,168	2,006	1,747	1,359
Seven sectors (BeST distribution)	1,765	1,754	1,613	1,367	1,110	940	667	334
Nine sectors (BeST distribution)	1,838	1,827	1,680	1,424	1,157	979	695	348
Ten sectors (BeST distribution)	2,736	2,720	2,502	2,120	1,722	1,457	1,034	517

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Method 2 relies on monetised DALYs for morbidity.

4.5 Benefits to the public sector

The benefits (avoided costs of ill health) for the public sector are calculated using the method summarised below. The benefits of each reference OELV are summarised in Table 4-14.

Table 4-14: Benefits to the PUBLIC SECTOR (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) **

Source: Modelling by RPA
*Notes: * Assumes 20% tax*

Table 4-15: Benefits to the PUBLIC SECTOR relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	0.02 µg/m³	0.05 µg/m³	0.1 µg/m³	0.2 µg/m³	0.35 µg/m³	0.6 µg/m³	1 µg/m³	2 µg/m³
Constant workforce								
Seven sectors (US-OSHA distribution)	283	282	268	246	225	208	181	141
Seven sectors (BeST distribution)	26	26	24	20	16	14	10	5
Nine sectors (BeST distribution)	27	27	25	21	17	15	10	5
Ten sectors (BeST distribution)	41	40	37	31	26	22	15	8
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	397	396	375	345	316	292	254	198
Seven sectors (BeST distribution)	37	37	34	28	23	20	14	7
Nine sectors (BeST distribution)	38	38	35	30	24	20	14	7
Ten sectors (BeST distribution)	57	57	52	44	36	30	21	11

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline.

4.6 Benefits to employers

The benefits (avoided costs of ill health) accrued by employers are calculated using the method summarised below.

Table 4-16: 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 reference OELV are summarised below.

Table 4-17: Benefits to the EMPLOYERS relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	**0.02 µg/m³**	**0.05 µg/m³**	**0.1 µg/m³**	**0.2 µg/m³**	**0.35 µg/m³**	**0.6 µg/m³**	**1 µg/m³**	**2 µg/m³**
Constant workforce								
Seven sectors (US-OSHA distribution)	29	29	27	25	23	21	18	14
Seven sectors (BeST distribution)	19	19	17	14	12	10	7	4
Nine sectors (BeST distribution)	19	19	18	15	12	10	7	4
Ten sectors (BeST distribution)	29	29	26	22	18	15	11	5
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	40	40	38	35	32	29	26	20
Seven sectors (BeST distribution)	26	26	24	20	16	14	10	5
Nine sectors (BeST distribution)	27	27	25	21	17	14	10	5
Ten sectors (BeST distribution)	40	40	37	31	25	21	15	8

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline.

4.7 Aggregated benefits

The benefits of each reference OELV are summarised below. These equal the cost of ill health under the baseline scenario, less the cost of ill health following the introduction of an OELV.

Method 1 relies on WTP values for morbidity.

Table 4-18: METHOD 1: Total BENEFITS relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	**0.02 µg/m³**	**0.05 µg/m³**	**0.1 µg/m³**	**0.2 µg/m³**	**0.35 µg/m³**	**0.6 µg/m³**	**1 µg/m³**	**2 µg/m³**
Constant workforce								
Seven sectors (US-OSHA distribution)	678	675	640	587	538	498	434	337
Seven sectors (BeST distribution)	281	279	257	218	177	150	106	53
Nine sectors (BeST distribution)	293	291	268	227	184	156	111	55
Ten sectors (BeST distribution)	436	433	398	338	274	232	165	82
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	965	962	912	836	766	709	618	481
Seven sectors (BeST distribution)	404	401	369	313	254	215	153	76
Nine sectors (BeST distribution)	420	418	384	326	265	224	159	80
Ten sectors (BeST distribution)	626	622	572	485	394	333	236	118

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Method 1 relies on WTP values for morbidity.

Method 2 relies on monetised DALYs for morbidity.

Table 4-19: METHOD 2: Total BENEFITS relative to baseline for target OELVs in € millions over 60 years of ill health								
Target OELV inhalable	0.02 µg/m³	0.05 µg/m³	0.1 µg/m³	0.2 µg/m³	0.35 µg/m³	0.6 µg/m³	1 µg/m³	2 µg/m³
Constant workforce								
Seven sectors (US-OSHA distribution)	1,976	1,969	1,867	1,714	1,569	1,452	1,265	984
Seven sectors (BeST distribution)	1,120	1,114	1,024	868	705	597	423	212
Nine sectors (BeST distribution)	1,167	1,160	1,067	904	734	622	441	221
Ten sectors (BeST distribution)	1,737	1,7278	1,588	1,346	1,093	925	656	328
Workforce turnover 5% per year								
Seven sectors (US-OSHA distribution)	3,128	3,116	2,955	2,712	2,483	2,298	2,002	1,557
Seven sectors (BeST distribution)	1,802	1,791	1,647	1,396	1,134	959	681	341
Nine sectors (BeST distribution)	1,876	1,865	1,716	1,454	1,181	1,000	709	355
Ten sectors (BeST distribution)	2,794	2,777	2,554	2,165	1,758	1,488	1,056	528

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Method 2 relies on monetised DALYs for morbidity.

5 Costs of the measures under consideration

5.1 Introduction

This section comprises the following subsections:

- Section 5.2: The cost framework
- Section 5.3: OELVs – compliance and administrative costs for companies
- Section 5.4: Sensitivity to a declining discount rate
- Section 5.5: OELVs – indirect costs for companies
- Section 5.6: OELVs – costs for public authorities

5.2 The cost framework

5.2.1 Summary of the cost assessment framework

The cost model is described in the methodology report accompanying this report. The cost model takes several inputs and calculates the predicted costs incurred for a range of target OELVs. There are ten types of inputs:

- Target OELs;
- Number of small, medium and large enterprises at each of the current exposure concentrations for each sector;
- Estimated breakdown of risk management measures (RMM) used by enterprises for each sector;
- Suitability of RMMs;
- Effectiveness of RMMs;
- Cost of RMMs, see section 3.7.2;
- Discount rates;
- Level of compliance with the target OEL; and
- Estimated average number of workers affected by beryllium and estimated average number of workstations for beryllium products small, medium and large enterprises.

The output is the cost of implementing the OELV split by:

- Sector;
- Company size: small, medium and large; and
- Capital expenditure (CAPEX) and operating expenditure (OPEX).

5.2.2 Target OELs

The cost model is set up to run for eight target OELVs, which are described in Table 2-5.

5.2.3 Number of enterprises at current exposure concentrations

The Eurostat enterprise data is provided by company size in five ranges. The cost model is based on three sizes of enterprise named small, medium and large. The mapping between these two groups is shown on Table 3-13.

To obtain a cost estimate for each sector, the numbers of small, medium and large companies affected by beryllium at different exposure levels are entered into the model for each target OELV. These numbers are based upon the analysis described in section 3.6.6, in which two different distributions of exposure level are made. The first is based upon the BeST survey of EU companies and gives a breakdown into four levels, which is the same for all sectors. The second is based upon the US-OSHA data that gives a breakdown of employees affected for seven of the sectors: construction, laboratories and recycling are excluded. This allows an alternative derivation of costs for these sectors. The scenarios based on the BeST distribution for each sector run through the model are shown in Table 5-1. The scenarios based on the US-OSHA distribution are in Table 5-2.

Table 5-1: Number of enterprises affected by beryllium at different target OELVs by size of enterprise by sector, for BeST distribution

Sector/Size	Small	Medium	Large	Total
Foundries	**171**	**49**	**10**	**229**
0.138 µg/m³	35	10	2	47
0.299 µg/m³	95	27	5	127
1.38 µg/m³	27	8	2	37
3.45 µg/m³	14	4	1	19
Metal fabrication	**1,310**	**116**	**5**	**1,430**
0.138 µg/m³	268	24	1	293
0.299 µg/m³	725	64	3	791
1.38 µg/m³	210	19	1	229
3.45 µg/m³	107	9	0	117
Transportation	**231**	**50**	**15**	**296**
0.138 µg/m³	47	10	3	61
0.299 µg/m³	128	28	8	164
1.38 µg/m³	37	8	2	47
3.45 µg/m³	19	4	1	24
ICT	**122**	**19**	**2**	**143**
0.138 µg/m³	25	4	0	29
0.299 µg/m³	67	10	1	79
1.38 µg/m³	19	3	0	23
3.45 µg/m³	10	2	0	12
Specialist manufacturers	**534**	**57**	**6**	**596**
0.138 µg/m³	109	12	1	122
0.299 µg/m³	295	32	3	330
1.38 µg/m³	85	9	1	96
3.45 µg/m³	44	5	0	49
Medical devices	**2,413**	**94**	**7**	**2,514**
0.138 µg/m³	494	19	1	515

Table 5-1: Number of enterprises affected by beryllium at different target OELVs by size of enterprise by sector, for BeST distribution				
Sector/Size	**Small**	**Medium**	**Large**	**Total**
0.299 µg/m³	1,335	52	4	1,391
1.38 µg/m³	387	15	1	403
3.45 µg/m³	198	8	1	206
Glass	**36**	**3**	**0**	**39**
0.138 µg/m³	7	1	0	8
0.299 µg/m³	20	2	0	22
1.38 µg/m³	6	0	0	6
3.45 µg/m³	3	0	0	3
Construction	**17,842**	**376**	**10**	**18,229**
0.138 µg/m³	3,651	77	2	3,730
0.299 µg/m³	9,868	208	6	10,082
1.38 µg/m³	2,859	60	2	2,921
3.45 µg/m³	1,464	31	1	1,496
Laboratories	**306**	**16**	**2**	**323**
0.138 µg/m³	63	3	0	66
0.299 µg/m³	169	9	1	179
1.38 µg/m³	49	3	0	52
3.45 µg/m³	25	1	0	27
Recycling	**93**	**9**	**0**	**102**
0.138 µg/m³	19	2	0	21
0.299 µg/m³	52	5	0	57
1.38 µg/m³	15	1	0	16
3.45 µg/m³	8	1	0	8

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Ten sectors; Numbers may not add up to totals exactly due to rounding.

Table 5-2: Number of enterprises affected by beryllium at different target OELVs by size of enterprise by sector, for US-OSHA				
Sector/Size	**Small**	**Medium**	**Large**	**Total**
Foundries	**171**	**49**	**10**	**229**
0.46 µg/m³	69	20	4	92
0.69 µg/m³	28	8	2	38
1.61 µg/m³	35	10	2	47
3.45 µg/m³	17	5	1	22
6.9 µg/m³	8	2	0	11
9.2 µg/m³	14	4	1	19
Metal fabrication	**1,310**	**116**	**5**	**1,430**
0.46 µg/m³	1,045	92	4	1,140
0.69 µg/m³	110	10	0	120
1.61 µg/m³	93	8	0	101
3.45 µg/m³	27	2	0	30

Table 5-2: Number of enterprises affected by beryllium at different target OELVs by size of enterprise by sector, for US-OSHA				
Sector/Size	**Small**	**Medium**	**Large**	**Total**
6.9 µg/m³	11	1	0	12
9.2 µg/m³	25	2	0	27
Transportation	**231**	**50**	**15**	**296**
0.46 µg/m³	141	31	9	180
0.69 µg/m³	31	7	2	40
1.61 µg/m³	34	7	2	44
3.45 µg/m³	20	4	1	25
6.9 µg/m³	1	0	0	2
9.2 µg/m³	4	1	0	6
ICT	**122**	**19**	**2**	**143**
0.46 µg/m³	91	14	2	107
0.69 µg/m³	12	2	0	14
1.61 µg/m³	13	2	0	15
3.45 µg/m³	4	1	0	5
6.9 µg/m³	1	0	0	1
9.2 µg/m³	1	0	0	1
Specialist manufacturers	**534**	**57**	**6**	**596**
0.46 µg/m³	478	51	5	534
0.69 µg/m³	23	3	0	26
1.61 µg/m³	20	2	0	22
3.45 µg/m³	7	1	0	7
6.9 µg/m³	2	0	0	3
9.2 µg/m³	4	0	0	4
Medical devices	**2,413**	**94**	**7**	**2,514**
0.46 µg/m³	1,360	53	4	1,417
0.69 µg/m³	340	13	1	354
1.61 µg/m³	374	15	1	390
3.45 µg/m³	272	11	1	283
6.9 µg/m³	0	0	0	0
9.2 µg/m³	68	3	0	71
Glass	**36**	**3**	**0**	**39**
0.46 µg/m³	19	2	0	21
0.69 µg/m³	5	0	0	6
1.61 µg/m³	8	1	0	9
3.45 µg/m³	2	0	0	2
6.9 µg/m³	1	0	0	1
9.2 µg/m³	0	0	0	0

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - US-OSHA; Seven sectors; Numbers may not add up to totals exactly due to rounding.

5.2.4 Estimated breakdown of RMMs used by enterprises

The model needs estimates for the current primary RMM in use and this is provided as a percentage of all enterprises of a given size as shown in Table 5-3. Discussions with BeST indicate that the majority of companies in the EU achieve exposure levels below 2 µg/m^3 using basic ventilation and masks, together with organisational measures such as good cleanliness and high awareness of the dangers.

Table 5-3: Percentage breakdown of RMMs currently used by enterprises

Type of RMM	% of small enterprises currently with this type of RMM	% of medium enterprises currently with this type of RMM	% of large enterprises currently with this type of RMM
Full enclosure	0%	0%	0%
Partial enclosure	0%	0%	0%
Open hood	10%	10%	10%
Pressurised or sealed	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
HEPA filter	5%	5%	5%
Simple mask	20%	20%	20%
Organisational measures	10%	10%	10%
General dilution ventilation	10%	10%	10%
Nothing	40%	40%	40%

Source: RPA study team estimates based upon interviews

5.2.5 Suitability of RMMs

Each sector, and the type of work using beryllium performed within it, has certain characteristics, which help to determine the type of RMMs that are suitable. This builds upon the information discussed in section 3.7.2 and particularly in Table 3-26. The kind of work characteristics split into three groups:

- Amount of exposure during the day
- Form of beryllium to which workers are exposed
- Extent to which beryllium spreads

The amount of exposure is split into work where the worker is exposed to beryllium 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 beryllium. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use personal protective equipment (PPE) such as masks with filters or breathing apparatus.

The form of substance to which workers are exposed varies considerably from dust and fibres to vapour, fumes, gas, mist and aerosol. Again, the form of substance has a direct bearing on the types of RMM that are suitable. For example, general dilution ventilation is not advised for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: dust which also includes fibres; and gas which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and causes exposure to workers beyond the area where the beryllium is being worked. This means that administrators, managers and sales staff may be exposed.

In Table 5-4, the percentage split between each form of substance used in the analysis is given for each sector. In Table 5-5, the types of RMM that are suitable or not for each amount of exposure, form of substance and extent of spread are shown. These values were built into the cost model.

The allocation of process groups to sector in Table 3-6 (section 3.4.2) helped to estimate appropriate percentages, particularly for dust or gas and local or diffuse. For example, process group mechanical – machining generally creates dust rather than gas. Thermal and chemical processing tends to produce gas rather than dust; they also tend to have a diffuse effect.

Table 5-4: Beryllium: amount of exposure, form of beryllium and extent of spread by sector

Sector	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
Foundries	50%	50%	20%	80%	0%	100%	0%
Metal fabrication	75%	25%	100%	0%	100%	0%	0%
Transportation	75%	25%	80%	20%	45%	45%	10%
ICT	75%	25%	50%	50%	45%	45%	10%
Specialist manufacturers	75%	25%	50%	50%	45%	45%	10%
Medical devices	75%	25%	50%	50%	45%	45%	10%
Glass	75%	25%	50%	50%	45%	45%	10%
Construction	75%	25%	100%	0%	0	100%	0%
Laboratories	75%	25%	50%	50%	100%	0%	0%
Recycling	75%	25%	80%	20%	0%	100%	0%

Source: RPA study team estimates based upon interviews
Note: Dust = dust and fibres, Gas = vapour, fumes, gas, mist and aerosol

Table 5-5: Suitability of various RMMs to amount of exposure, form of beryllium and extent of spread

Type of RMM	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
Discontinuation & Substitution	Y	Y	Y	Y	Y	Y	Y
Rework	Y	Y	Y	Y	Y	Y	Y
Full enclosure	Y	Y	Y	Y	Y	Y	Y
Partial enclosure	Y	Y	Y	Y	Y	Y	Y
Open hood	Y	Y	Y	Y	Y	Y	Y
No LEV	Y	Y	Y	Y	Y	Y	Y
Pressurised or sealed	N	Y	Y	Y	N	Y	Y
Simple enclosed cab	N	Y	Y	Y	N	Y	Y
No enclosure	Y	Y	Y	Y	Y	Y	Y

Table 5-5: Suitability of various RMMs to amount of exposure, form of beryllium and extent of spread							
Type of RMM	**<1h**	**>1h**	**Dust**	**Gas**	**Local**	**Diffuse**	**Peripheral**
Breathing apparatus	Y	N	Y	Y	Y	Y	Y
HEPA filter	Y	N	Y	Y	Y	Y	Y
Simple mask	Y	N	Y	Y	Y	Y	Y
No mask	Y	Y	Y	Y	Y	Y	Y
Organisational measures	Y	Y	Y	N	Y	Y	Y
No organisational measures	Y	Y	Y	Y	Y	Y	Y
General dilution ventilation	N	Y	N	Y	N	Y	Y
No general ventilation	Y	Y	Y	Y	Y	Y	Y
Source: RPA study team estimates based upon interviews							

5.2.6 Effectiveness of RMMs

Every RMM has a different level of effectiveness in reducing the workers exposure to beryllium. The percentage reduction in exposure for each type of RMM used in the analysis is shown in Table 5-6.

Table 5-6: Percentage reduction in exposure achieved with RMM	
Type of RMM	**% reduction in exposure**
Discontinuation & Substitution	100%
Rework	50%
Full enclosure	99.5%
Partial enclosure	90%
Open hood	80%
No LEV	0%
Pressurised or sealed	99.5%
Simple enclosed cab	80%
No enclosure	0%
Breathing apparatus	99.5%
HEPA filter	95%
Simple mask	60%
No mask	0%
Organisational measures	30%
No organisational measures	0%
General dilution ventilation	30%
No general ventilation	0%
Source: RPA study team estimates based upon interviews	

5.2.7 Discount rate

The static discount rate is 4%: this is taken over the 60 year period. A declining discount rate is discussed in section 5.4. The declining rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 40 years.

5.2.8 Affected workers and workstations

Each company size was assumed to have an average number of workers affected and associated workstations requiring adjustment, shown on Table 5-7.

Table 5-7: Number of workers and workstations by size of company

Size of company	Number of workers affected by beryllium	Number of workstation
Small	2	1
Medium	27	14
Large	75	40

Source: RPA study team estimates based upon interviews

5.3 OELVs – compliance and administrative costs for companies

5.3.1 Current level of actual exposure in the companies

The exposure concentrations in companies by sector are shown in Table 5-1 using BeST survey data for the exposure distributions and Table 5-2 using US-OSHA data. The base data is the EU/USA data described in section 3.14.1.

5.3.2 Marginal abatement cost curves

Three different costs, all present values for 60 years, are calculated: TOTAL (CAPEX + OPEX), CAPEX, and OPEX. These are shown for each target OELV by enterprise size in Tables 5-8 and 5-9. Table 5-8 shows the costs under the BeST distribution and Table 5-9 under the US-OSHA distribution. Table 5-8 is split into three sections for seven, nine and ten sectors. Figure 5-1 shows the TOTAL cost in Table 5-8 for ten and for seven sectors using the BeST distribution in graphical form. Similarly, Figure 5-2 shows the TOTAL cost for seven sectors using the US-OSHA distribution in Table 5-9 in graphical form.

Estimated costs based on BeST data – all ten sectors

Table 5-8: Beryllium: estimated CAPEX, OPEX and TOTAL costs as present value over 60 years in € millions by target OELV by size of enterprise for BeST distribution								
Enterprise size/ Target OELV inhalable	2 µg/m³	1 µg/m³	0.6 µg/m³	0.35 µg/m³	0.2 µg/m³	0.1 µg/m³	0.05 µg/m³	0.02 µg/m³
Seven sectors								
Small CAPEX	1	6	11	21	37	297	794	2,482
Small OPEX	-1	-1	6	18	19	55	106	184
Small TOTAL	**0**	**5**	**17**	**39**	**56**	**352**	**900**	**2,666**
Medium CAPEX	2	6	10	17	33	433	1,195	3,897
Medium OPEX	-1	1	6	14	17	45	84	139
Medium TOTAL	**1**	**6**	**16**	**31**	**50**	**479**	**1,279**	**4,036**
Large CAPEX	1	2	4	6	12	93	231	752
Large OPEX	0	1	3	6	8	20	35	57
Large TOTAL	**0**	**3**	**6**	**13**	**20**	**112**	**267**	**809**
Nine sectors								
Small CAPEX	1	6	12	23	40	322	860	2,689
Small OPEX	-1	-1	7	20	21	60	115	200
Small TOTAL	**0**	**5**	**19**	**42**	**60**	**382**	**976**	**2,889**
Medium CAPEX	2	6	10	18	35	460	1,271	4,141
Medium OPEX	-1	1	6	15	18	48	89	148
Medium TOTAL	**1**	**7**	**16**	**33**	**53**	**509**	**1,360**	**4,289**
Large CAPEX	1	2	4	6	12	93	232	753
Large OPEX	0	1	2	6	8	20	36	58
Large TOTAL	**0**	**3**	**6**	**13**	**20**	**113**	**268**	**811**
All sectors								
Small CAPEX	5	23	47	89	154	1,396	3,769	11,825
Small OPEX	-7	-8	23	77	71	228	462	826
Small TOTAL	**-2**	**14**	**70**	**166**	**225**	**1,624**	**4,231**	**12,651**
Medium CAPEX	3	10	18	32	59	867	2,418	7,877
Medium OPEX	-2	0	9	25	29	81	156	267
Medium TOTAL	**1**	**10**	**27**	**57**	**88**	**950**	**2,574**	**8,144**
Large CAPEX	1	3	5	8	15	115	293	941
Large OPEX	0	0	3	7	10	24	44	72
Large TOTAL	**0**	**3**	**7**	**15**	**24**	**139**	**337**	**1,013**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution - BeST; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value; All financial values are relative to the baseline.

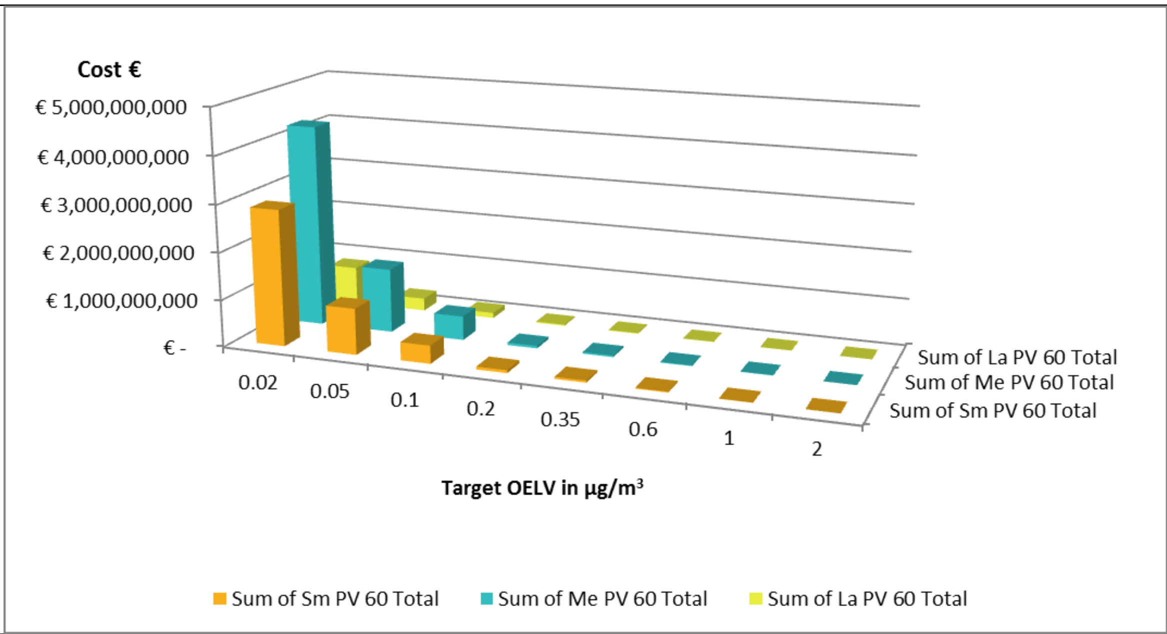

Figure 5-1: Share of PV at 60 years split between small, medium and large enterprises for different target OELVs, based on BeST exposure distribution

Source: Modelling by RPA Notes: Dataset - EU/US; Exposure distribution - BeST; Nine sectors excluding construction; Values - Euros 60 years present value. All financial values are relative to the baseline.

Estimated costs based on US-OSHA data – seven sectors only

Table 5-9: Beryllium: estimated CAPEX, OPEX and TOTAL costs as present value over 60 years in € millions by target OELV by size of enterprise for US-OSHA distribution

Enterprise size/ Target OELV inhalable	2 µg/m³	1 µg/m³	0.6 µg/m³	0.35 µg/m³	0.2 µg/m³	0.1 µg/m³	0.05 µg/m³	0.02 µg/m³
Seven sectors								
Small CAPEX	3	8	16	121	144	586	1,299	6,945
Small OPEX	0	3	9	12	57	90	166	232
Small TOTAL	**3**	**11**	**25**	**133**	**200**	**676**	**1,465**	**7,177**
Medium CAPEX	3	7	14	187	202	863	2,014	10,914
Medium OPEX	1	3	8	12	45	68	124	176
Medium TOTAL	**3**	**10**	**22**	**199**	**247**	**931**	**2,138**	**11,090**
Large CAPEX	1	2	5	29	35	150	326	1,772
Large OPEX	0	1	3	5	17	25	48	70
Large TOTAL	**1**	**3**	**7**	**34**	**52**	**175**	**375**	**1,842**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value.
All financial values are relative to the baseline.

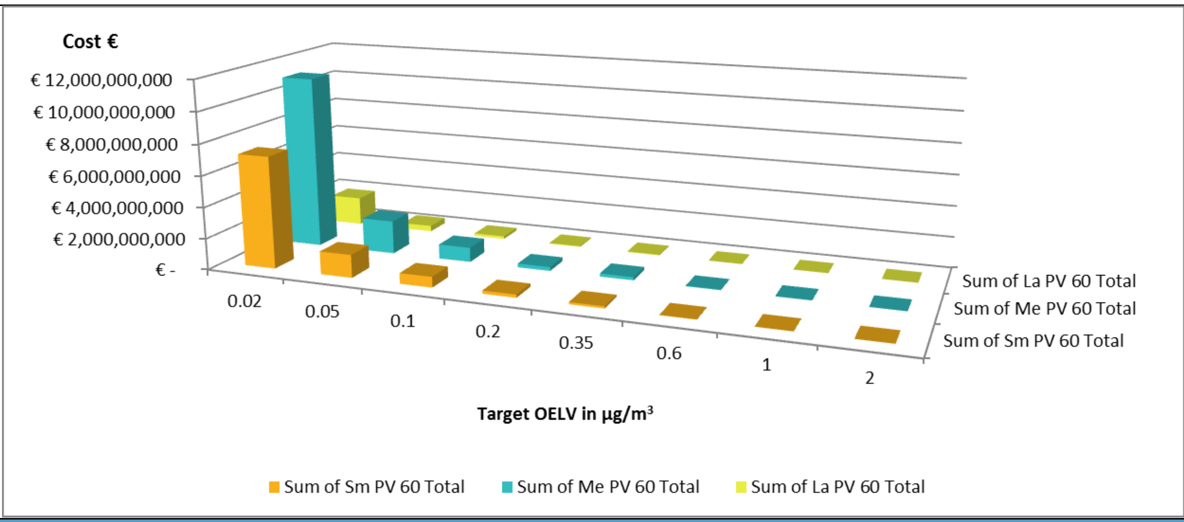

Figure 5-2: Share of TOTAL cost (present value at 60 years) in € split between small, medium and large enterprises for different target OELVs, based on US-OSHA exposure distribution
Source: Modelling by RPA Notes: Dataset - EU/US; Exposure distribution - US-OSHA; Seven sectors excluding construction, laboratories and recycling; Values - Euros 60 years present value; Target OELVs are inhalable. All financial values are relative to the baseline.

5.3.3 Sector specific cost curves

The TOTAL, CAPEX and OPEX (all present values for 60 years) are shown for a range of target OELVs for all ten sectors in on Tables 5-10 to 5-12, based upon BeST exposure distributions and in Tables 5-13 to 5-15, based upon US-OSHA exposure distributions. Figure 5-3 shows the TOTAL cost in Table 5.10 for nine sectors in graphical form. Similarly, Figure 5-4 shows the TOTAL cost in Table 5-13 in graphical form (note that the x-axis is not to scale.)

Estimated costs based on BeST data – all ten sectors

Table 5-10: Beryllium: estimated TOTAL costs (present value for 60 years) in € millions by target by sector (all ten sectors)

Sector/ Target OELV inhalable	2 µg/m³	1 µg/m³	0.6 µg/m³	0.35 µg/m³	0.2 µg/m³	0.1 µg/m³	0.05 µg/m³	0.02 µg/m³
Foundries	0	2	5	9	15	100	263	796
Metal fabrication	1	4	11	23	36	255	663	2,010
Transportation	0	2	4	9	14	111	294	893
ICT	0	0	1	3	4	38	90	305
Specialist manufacturers	0	2	5	10	15	121	321	981
Medical devices	0	4	13	28	41	316	808	2,502
Glass	0	0	0	0	0	3	7	22
Total (seven sectors)	**2**	**14**	**39**	**83**	**126**	**943**	**2,446**	**7,511**
Laboratories	0	1	2	4	6	40	114	314
Recycling	0	0	1	1	2	20	44	164
Total (excluding construction)	**2**	**15**	**41**	**88**	**134**	**1,003**	**2,604**	**7,989**

Table 5-10: Beryllium: estimated TOTAL costs (present value for 60 years) in € millions by target by sector (all ten sectors)								
Sector/ Target OELV inhalable	**2 µg/m³**	**1 µg/m³**	**0.6 µg/m³**	**0.35 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.05 µg/m³**	**0.02 µg/m³**
Construction	-2	13	63	151	203	1,710	4,538	13,819
Total (including construction)	**-1**	**27**	**105**	**239**	**337**	**2,713**	**7,142**	**21,808**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – BeST; Sectors – all ten sectors; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

Table 5-11: Beryllium: estimated CAPEX (present value for 60 years) in € by target OELV by sector (all ten sectors)								
Sector/ Target OELV inhalable	**2 µg/m³**	**1 µg/m³**	**0.6 µg/m³**	**0.35 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.05 µg/m³**	**0.02 µg/m³**
Foundries	1	2	3	5	9	87	242	760
Metal fabrication	1	4	7	12	23	220	599	1,906
Transportation	0	2	3	5	9	97	267	848
ICT	0	0	1	1	3	34	83	293
Specialist manufacturers	0	2	3	5	10	107	293	934
Medical devices	1	4	8	15	27	276	730	2,370
Glass	0	0	0	0	0	2	6	20
Total (seven sectors)	**3**	**14**	**24**	**44**	**82**	**823**	**2,220**	**7,130**
Laboratories	0	1	1	2	4	34	108	295
Recycling	0	0	0	1	1	19	41	158
Total (excluding construction)	**4**	**15**	**26**	**47**	**87**	**875**	**2,364**	**7,583**
Construction	4	21	44	82	141	1,504	4,117	13,061
Total (including construction)	**8**	**36**	**70**	**129**	**228**	**2,380**	**6,480**	**20,644**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – BeST; Sectors – all ten sectors; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

Table 5-12: Beryllium: estimated OPEX (present value for 60 years) in € millions by target OELV by sector (all ten sectors)								
Sector/ Target OELV inhalable	**2 µg/m^3**	**1 µg/m^3**	**0.6 µg/m^3**	**0.35 µg/m^3**	**0.2 µg/m^3**	**0.1 µg/m^3**	**0.05 µg/m^3**	**0.02 µg/m^3**
Foundries	0	0	2	5	6	12	21	37
Metal fabrication	0	1	5	11	13	34	63	104
Transportation	0	0	2	4	5	14	27	45
ICT	0	0	0	1	1	4	7	12
Specialist manufacturers	0	0	2	5	5	14	28	47
Medical devices	-1	0	5	13	14	40	78	132
Glass	0	0	0	0	0	1	1	2
Total (seven sectors)	**-2**	**0**	**15**	**38**	**44**	**120**	**225**	**380**
Laboratories	0	0	1	2	2	6	11	20
Recycling	0	0	0	1	1	2	3	6
Total (excluding construction)	**-2**	**0**	**16**	**41**	**47**	**128**	**240**	**406**
Construction	-7	-9	19	69	63	205	422	758
Total (including construction)	**-9**	**-8**	**35**	**110**	**109**	**333**	**662**	**1,164**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – BeST; Sectors – all ten sectors; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

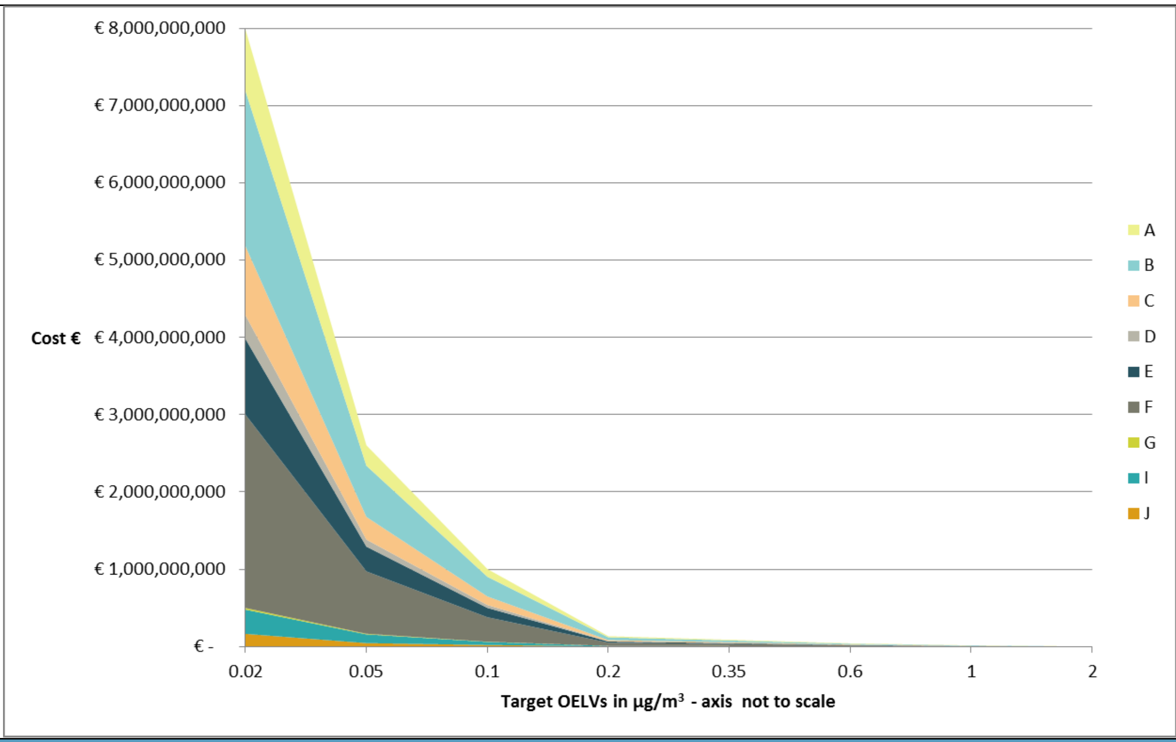

Figure 5-3: Share of TOTAL cost (present value at 60 years) in € split between sectors (except construction) for different target OELVs, based on BeST exposure distribution
Source: Modelling by RPA; Notes: Dataset - EU/US; Exposure distribution - US-OSHA; Sectors – nine (Sectors: A=Foundries, B=Metal fabrication, C=Transportation, D=ICT, E=Specialist manufacturing, F=Medical devices, G=Glass, I=Laboratories, J=Recycling); Values - Euros 60 years present value; Target OELVs are inhalable. All financial values are relative to the baseline.

Estimated costs based on US-OSHA data – seven sectors only

Table 5-13: Beryllium: estimated TOTAL costs (present value for 60 years) in € millions by target OELV by sector (seven sectors)

Sector/ Target OELV inhalable	2 µg/m³	1 µg/m³	0.6 µg/m³	0.35 µg/m³	0.2 µg/m³	0.1 µg/m³	0.05 µg/m³	0.02 µg/m³
Foundries	3	8	15	124	140	459	1,026	3,749
Metal fabrication	1	4	9	78	109	295	725	4,088
Transportation	0	2	5	27	43	178	400	2,306
ICT	0	0	1	3	8	28	74	574
Specialist manufacturers	0	1	1	8	20	56	139	1,455
Medical devices	2	10	23	123	177	761	1,579	7,810
Glass	0	0	0	1	2	4	24	126
Total (seven sectors)	**7**	**25**	**55**	**365**	**499**	**1,782**	**3,977**	**20,108**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – US-OSHA; Sectors – seven excluding construction, laboratories and recycling; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

Table 5-14: Beryllium: estimated CAPEX (present value for 60 years) in € by target OELV in € by sector (seven sectors)								
Sector/ Target OELV inhalable	**2 µg/m³**	**1 µg/m³**	**0.6 µg/m³**	**0.35 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.05 µg/m³**	**0.02 µg/m³**
Foundries	2	5	8	114	121	431	989	3,708
Metal fabrication	1	3	6	76	84	256	645	3,961
Transportation	1	2	4	24	29	157	368	2,247
ICT	0	0	1	3	5	23	63	557
Specialist manufacturers	0	0	1	10	13	44	108	1,401
Medical devices	3	7	15	108	127	685	1,444	7,635
Glass	0	0	0	1	1	3	22	123
Total (seven sectors)	**6**	**18**	**35**	**337**	**380**	**1,599**	**3,639**	**19,631**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – US-OSHA; Sectors – seven excluding construction, laboratories and recycling; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

Table 5-15: Beryllium: estimated OPEX (present value for 60 years) in € millions by target OELV by sector (seven sectors)								
Sector/ Target OELV inhalable	**2 µg/m³**	**1 µg/m³**	**0.6 µg/m³**	**0.35 µg/m³**	**0.2 µg/m³**	**0.1 µg/m³**	**0.05 µg/m³**	**0.02 µg/m³**
Foundries	1	3	7	10	20	28	38	41
Metal fabrication	1	1	4	2	25	39	79	127
Transportation	0	0	2	3	14	22	42	60
ICT	0	0	0	0	3	5	11	17
Specialist manufacturers	0	0	0	2	7	12	32	55
Medical devices	-1	2	8	15	50	76	135	175
Glass	0	0	0	0	1	1	2	3
Total (seven sectors)	**1**	**7**	**21**	**29**	**119**	**183**	**338**	**478**

Source: Modelling by RPA
Dataset - EU/US; Exposure distribution – US-OSHA; Sectors – seven excluding construction, laboratories and recycling; Values - Euros millions 60 years present value.
All financial values are relative to the baseline. Numbers may not add up to totals exactly due to rounding.

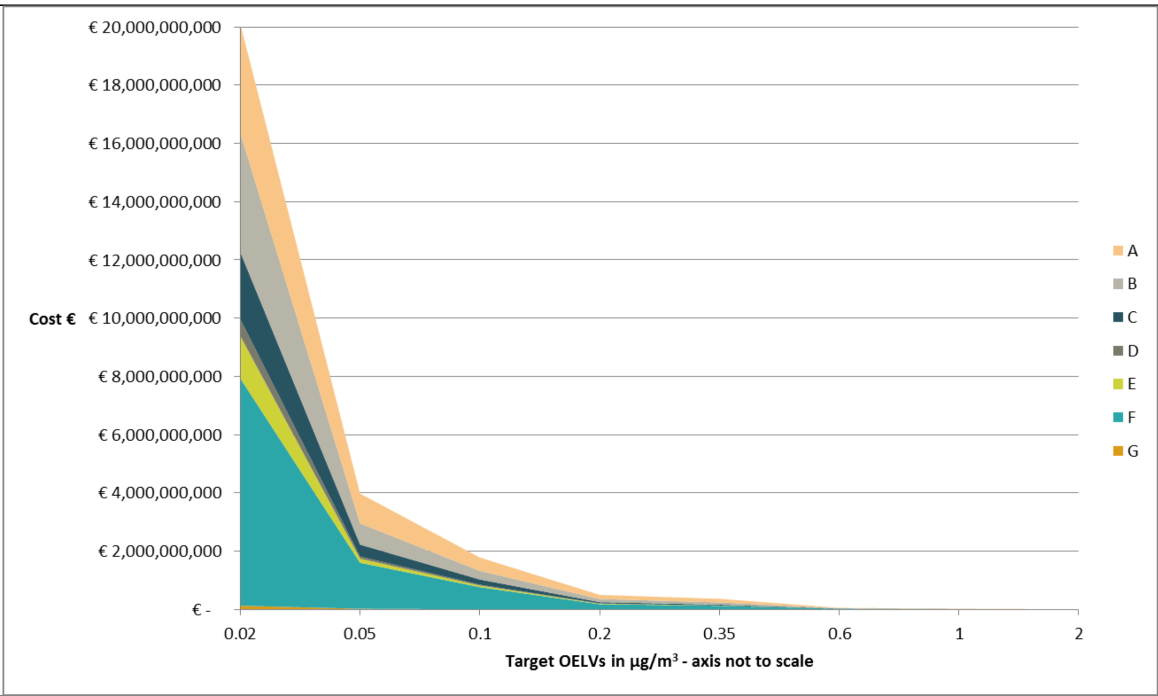

Figure 5-4: Share of TOTAL costs (present value for 60 years) in € split between sectors (seven) for different target OELVs, based on US-OSHA exposure distribution
Source: Modelling by RPA; Notes: Dataset - EU/US; Exposure distribution - US-OSHA; Sectors – seven (Sectors: A=Foundries, B=Metal fabrication, C=Transportation, D=ICT, E=Specialist manufacturing, F=Medical devices, G=Glass); Values - Euros millions 60 years present value; Target OELVs are inhalable . All financial values are relative to the baseline.

5.3.4 The total cost curve

The TOTAL cost (present value for 60 years), is shown for a range of target OELVs in Figure 5-5, for seven sectors and all sectors. This is based upon the numbers in Table 5-10 above. The curve for all sectors except construction is not shown because it is very similar to that of the seven sectors. These are based upon the BeST distribution for exposure concentrations. In Figure 5-6, similar data for seven sectors is shown based upon US-OSHA exposure distribution and based upon data in Table 5-13.

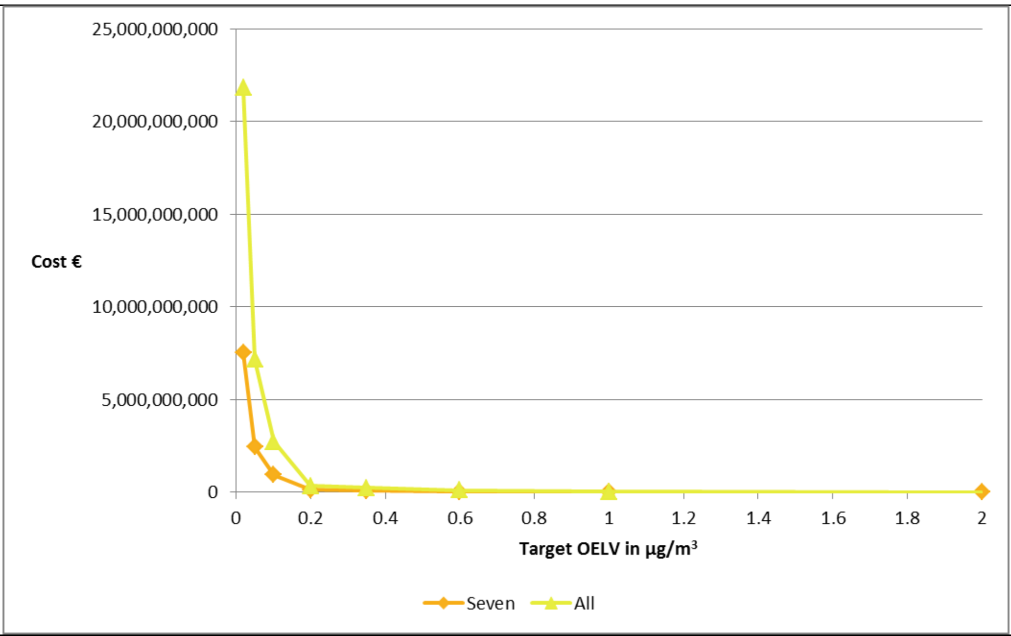

Figure 5-5 - Estimated TOTAL costs (present value for 60 years) in € against target OELVs for seven sectors and all sectors using BeST exposure distribution

Source: Modelling by RPA Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – seven sectors excluding construction, laboratories and recycling, all ten sectors; Values - Euros 60 years present value; Target OELVs are inhalable. All financial values are relative to the baseline.

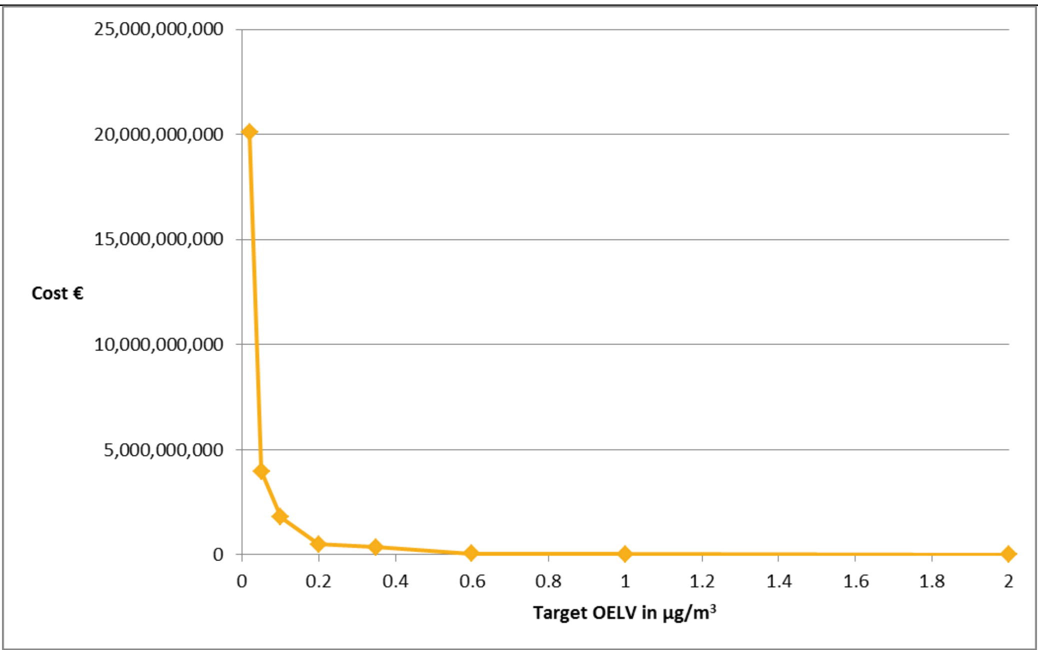

Figure 5-6 Estimated TOTAL costs (present value for 60 years) in € against target OELVs for seven sectors using US-OSHA exposure distribution

Source: Modelling by RPA Notes: Dataset - EU/US; Exposure distribution - US-OSHA; Sectors – seven; Values - Euros 60 years present value; . Target OELV's are inhalable. All financial values relative to the baseline.

The TOTAL costs in Figure 5-6 using the US-OSHA distribution do not include construction, which would significantly increase the costs at the OELVs below 0.2 µg/m^3.

IOM in 2011 found that to get to 2 µg/m^3, 6 - 12% of companies would need to change practices and that present value over 60 years would be €5 - 34 billion.

5.4 Sensitivity to a declining discount rate

The TOTAL costs for the four sector scenarios under a declining discount rate: 4% for the first 20 years and then 3% for the remaining 40 years is given in Table 5-16. The percentages are the change in value compared with the values for a static discount rate of 5% over 60 years shown in Tables 5-10 and 5-13. In general, the change due to a declining discount is to increase the total present value over 60 years by approximately 2% at 0.6 µg/m^3 rising to 8% at 0.02 µg/m^3.

Table 5-16: Beryllium: estimated TOTAL costs (present value for 60 years) in € millions by target OELV by sector for a declining discount rate (4% for 20 years and 3% for subsequent 40 years)

Sector/ Target OELV inhalable	2 µg/m^3	1 µg/m^3	0.6 µg/m^3	0.35 µg/m^3	0.2 µg/m^3	0.1 µg/m^3	0.05 µg/m^3	0.02 µg/m^3
Seven sectors (US-OSHA distribution)	7 (-0.8%)	35 (1.1%)	56 (2.2%)	382 (4.6%)	523 (4.8%)	1,883 (5.7%)	4,210 (5.9%)	21,345 (6.1%)
Nine sectors (BeST distribution)	1 (-16.3%)	14 (-1.9%)	40 (2.2%)	85 (3.3%)	128 (2.0%)	994 (5.4%)	2,586 (5.8%)	7,963 (6.0%)
Seven sectors (BeST distribution)	1 (-16.7%)	15 (-1.9%)	42 (2.2%)	91 (3.3%)	137 (2.0%)	1,057 (5.4%)	2,753 (5.8%)	8,470 (6.0%)
Ten sectors (BeST distribution)	-2 (110.6%)	26 (-4.9%)	107 (1.9%)	246 (3.3%)	344 (1.9%)	2,859 (5.4%)	7,552 (5.7%)	23,120 (6.0%)

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST and US-OSHA; Sectors – seven excluding construction, laboratories and recycling, nine excluding construction and all ten sectors; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Values in brackets are the percentage change relative to the baseline for a static discount rate shown in Tables 5-10 and 5-13. Percentages may not appear accurate due to rounding.

5.5 OELVs – indirect costs for companies

Indirect costs could include possible ripple effects through the value chain and the potential for costs to be passed on to users further down the value chain or to consumers.

Examples of indirect costs that could be incurred by economic actors as a result of achieving compliance with new limits include:

- Availability of products; and

- Choice of products.

Figure 5-7 below sets out a range of potential scenarios covering likely indirect impacts along the supply chain resulting from the introdution of harmonised OELVs. In the most severe case (in the event that a number of companies using beryllium are forced to close as a result of being unable to meet with the OEL requirements,) there may be shortages of certain products being supplied by EU companies, resulting in shortages. However, given the global nature of the final and intermediate products manufactured using beryllium, it is most likely that companies would obtain supplies of componets from outside the EU where the EU OELV restrictions would not apply. Under this scenario, jobs and profits may be lost to the EU (where other compliant EU producers are not able to expand their capacity), being taken up by workers and competitors in third countries.

A variation of the risk of companies closing operations in the EU, is where there are very few specialist companies supplying products of strategic importance to the defence and aerospace industries, and the lower OELV causes all the suppliers to close or leave the EU. These industries are likely to be concerned if they are made dependant upon suppliers outside the EU, particularly if there are very few suppliers worldwide and/or these suppliers are not based in friendly/allied countries. One respondent, whose company supplies the defence and aerospace industries, is one of two in the world, the other being in the USA; this company expects to close if the OELV is set below 0.6 µg/m³ and possibly below 1 µg/m³.

In the event that EU based companies continue production (as would most likely be the case), prices of intermediate products and components would potentially rise as companies using beryllium pass on the additional costs of meeting the OELVs to their customers. For certain final products (such as those manfactured for the aerospace industry), the contribution of beryllium to the final product is likely to be a very small part of the overall price composition, and in such cases, it is unlikely that there would be any significant effect on prices, if at all. However, in other products, the price of the component requiring the use of beryllium is likely to be more significant, and in such circumstances, there would more likely be an indirect impact on prices resulting from the introduction of OELs as cost increases are passed down the supply chain, although given the relatively small share of increased costs as a percentage of turnover, such increases are likely to be small.

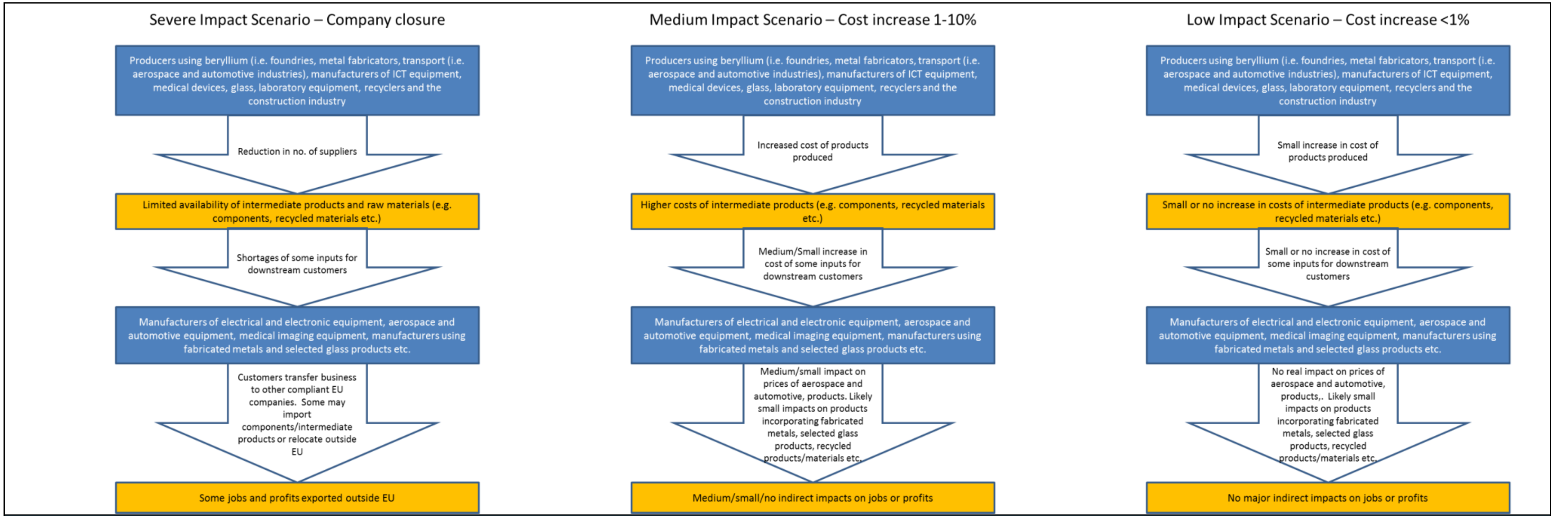

Figure 5-7: Indirect impacts under different scenarios

5.6 OELVs – costs for public authorities

The approximate cost of transposition for every Member State is €50,000 to alter their legislation because their current OEL is higher than the OELV being introduced. There is no cost if their OEL is already lower than the OELV, they do not need to change anything. The total cost of transposition by member states for each target OELV is given in Table 5-17.

Table 5-17: MS with OELs higher than proposed levels

Target OELV inhalable µg/m³	Member States who would need to introduce or alter legislation	Number of countries required to transpose	Total cost
0.02	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK	28	€1,400,000
0.05	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK	28	€1,400,000
0.1	AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE, EL, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK	27	€1,350,000
0.2	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, IT, LV, LT, LU, MT, NL, PT, RO, SK, SI, SE, UK	23	€1,150,000
0.35	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, IT, LV, LT, LU, MT, NL, PT, RO, SK, SI, SE, UK	23	€1,150,000
0.6	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, IT, LV, LT, LU, MT, NL, PT, RO, SK, SI, SE, UK	23	€1,150,000
1	AT, BE, BG, HR, CY, EE, FR, EL, HU, IT, LT, LU, MT, NL, PT, RO, SK, SI, SE, UK	20	€1,000,000
2	EL, IT, LU, MT, NL, PT	6	€300,000

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

6 Market Effects

This section comprises the following subsections:

- Section 6.1: Overall impact
- Section 6.2: Impact on research and innovation
- Section 6.3: Impact on the single market
- Section 6.4: Impact on competitiveness

6.1 Overall impact

Overall, market impacts (in terms of the effect on research and development, the single market, competitiveness of EU businesses and employment) is strongly influenced by the extent to which costs are incurred to comply with the OELs, and the extent to which any cost increases are a significant contributor to companies' overall costs. In extreme cases, companies will be forced out of business if they are unable to meet the OELs and absorb these additional costs or pass them on to customers and/or consumers.

The cost model developed for this study estimates the distribution of companies broken down by sector that would cease trading under the different OELs, see Table 6-1. For each target OELV, the model calculates current exposure levels and the RMMs that are most likely to be currently implemented, which is determined by the size of company. From this data, the model allocates a cost. If no RMMs would sufficiently reduce the OEL, it is assumed that the company will discontinue its business as substitution is rarely an option for beryllium. The model calculates the number of discontinued companies as part of its calculation of the cost of discontinuations.

Table 6-1: Estimates of companies that will cease trading under different OELs

Sector	Target OELV inhalable ug/m^3							
	0.02	0.05	0.1	0.2	0.35	0.6	1	2
Foundries	9	3	1	-	-	-	-	-
Metal fabrication	58	17	6	-	-	-	-	-
Transport	12	4	1	-	-	-	-	-
ICT	6	2	1	-	-	-	-	-
Specialist mfrs.	24	7	2	-	-	-	-	-
Medical devices	103	31	10	-	-	-	-	-
Glass	2	0	0	-	-	-	-	-
Construction	744	221	75	-	-	-	-	-
Laboratories	13	4	1	-	-	-	-	-
Recycling	4	1	0	-	-	-	-	-
Total	**977**	**290**	**98**	-	-	-	-	-

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten

Equivalent numbers for the first seven sectors in Table 6-1 above utilising US-OSHA data indicate that 624 companies would cease trading at the 0.02 µg/m^3 OEL, 106 at 0.05 µg/m^3, 46 at 0.1 µg/m^3, eight at 0.2 µg/m^3, and eight at 0.35 µg/m^3, with no companies leaving the market at higher OELs.

Table 6-2 below presents the average turnover per sector where companies are using beryllium.

Table 6-2: Average turnover by sector and size of enterprise									
Sector	Small			Medium			Large		
	Turnover /€m	No. firms	Ave. turnover /€	Turnover /€m	No. firms	Ave. turnover/€	Turnover /€m	No. firms	Ave. turnover/€
Foundries	12,753	12,357	1,032,000	85,663	3,512	24,392,000	240,691	691	348,323,000
Metal fabrication	109,305	352,429	310,000	241,919	31,070	7,786,000	129,797	1,281	101,325,000
Transport	17,260	26,587	649,000	93,239	5,770	16,159,000	1,128,223	1,693	666,404,000
ICT	19,673	34,500	570,000	64,906	5,370	12,087,000	198,446	691	287,187,000
Specialist mfrs.	113,719	296,865	383,000	348,766	31,762	10,981,000	658,487	3,284	200,514,000
Medical devices	11,483	60,217	191,000	16,951	2,345	7,229,000	26,180	847	30,909,000
Glass	29,126	85,860	339,000	79,771	7,312	10,910,000	98,506	738	133,477,000
Construction	806,082	3,345,212	241,000	508,806	70,490	7,218,000	337,800	1,887	179,014,000
Laboratories	5,529	57,374	96,000	21,906	2,926	7,487,000	38,381	318	120,693,000
Recycling	13,088	17,482	749,000	21,752	1,673	13,002,000	5,951	42	141,690,000
Average			456,000			11,725,000			220,954,000
Source: Modelling by RPA *Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten*									

Based on these figures, the model used to estimate the costs arising from the OELs utilised rounded average turnover figures as follows:

- Small - €500,000
- Medium - €10,000,000
- Large - €15,000,000

The figure of €15,000,000 has been assumed for large companies since it is likely that only a proportion of their business will be associated with the use of beryllium, and it is unlikely that large companies would have to close their entire business as a result of being unable to meet the stipulated OELs. These estimates are utilised to estimate the proportion of turnover represented by the envisaged increase in costs for meeting the OELs below.

Tables 6-3 to 6-5 provide estimates of the costs that will likely be incurred on a per company basis (discounted at 4% over 60 years). As noted above, some companies will cease trading because they cannot meet the OELs required these companies are not considered when it comes to calculating the average costs for firms in Table 6-3 to 6-5. Thus, the cost incurred by each company continuing for each size of company is:

$$A = (B - C*D)/(E-C)$$

A = Cost for a company continuing at a target OELV
B = Total cost of continuing at a target OELV
C = Number of companies discontinuing
D = Cost of discontinuation for a company
E = Number of companies currently

Tables 6-6 to 6-8 provide estimates of these costs as a % of the average turnover for small, medium and large companies.

Table 6-3: Costs per company for those continuing to trade - Small companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	80,483	80,264	74,413	73,703	74,413	74,442	75,721	69,625	80,177	70,434
0.05	48,116	47,744	43,710	43,286	43,710	43,726	44,679	40,409	47,668	41,117
0.1	28,577	27,119	23,987	23,747	23,987	23,996	24,615	21,425	27,063	21,875
0.2	14,904	12,876	10,861	10,778	10,861	10,865	11,165	9,214	12,840	9,515
0.35	10,185	8,660	7,727	7,664	7,727	7,729	7,944	6,963	8,636	7,172
0.6	4,940	3,969	3,360	3,325	3,360	3,361	3,461	2,862	3,959	2,938
1	1,743	1,330	876	880	876	876	891	505	1,325	539
2	179	119	-22	-22	-22	-22	-23	-138	118	-144

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling); Target OELV is inhalable; The negative numbers occur at the higher OELs because companies were already operating more safely than the limits and could dis-invest.

Table 6-4: Costs per company for those continuing to trade - Medium companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	691,714	794,374	711,208	724,172	711,208	713,479	468,847	642,799	836,127	615,239
0.05	444,460	490,089	433,271	461,685	433,271	436,982	184,770	386,778	503,000	386,001
0.1	259,811	284,670	240,748	261,425	240,748	243,491	76,095	204,865	288,764	208,254
0.2	143,295	144,814	116,407	134,025	116,407	118,669	13,529	93,318	139,944	104,377
0.35	87,290	87,552	74,428	86,574	74,428	75,930	0	63,778	84,409	70,112
0.6	48,792	44,232	35,811	41,060	35,811	36,451	0	28,947	43,652	30,785
1	21,730	19,771	13,446	16,332	13,446	13,813	0	8,311	18,453	11,206
2	3,630	3,685	1,697	2,186	1,697	1,761	0	71	2,878	97

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling); Target OELV is inhalable

Table 6-5: Costs per company for those continuing to trade - Large companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	2,452,142	2,990,634	2,594,836	847,202	2,594,836	2,743,924	0	2,632,297	1,453,776	0
0.05	1,635,940	1,842,812	1,587,058	313,864	1,587,058	1,844,318	0	1,627,693	556,311	0
0.1	960,519	1,056,151	874,846	158,284	874,846	1,067,616	0	865,441	284,676	0
0.2	536,688	523,497	413,589	32,958	413,589	571,862	0	394,128	95,931	0
0.35	336,131	311,966	257,420	0	257,420	355,079	0	260,106	0	0
0.6	189,276	154,784	124,452	0	124,452	162,981	0	122,084	0	0
1	85,148	69,789	48,580	0	48,580	73,104	0	37,876	0	0
2	14,052	13,350	6,584	0	6,584	11,377	0	1,270	0	0

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling); Target OELV is inhalable

Table 6-6: Costs per company as a % of turnover - Small companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	0.68%	0.68%	0.63%	0.63%	0.63%	0.63%	0.64%	0.59%	0.68%	0.60%
0.05	0.41%	0.41%	0.37%	0.37%	0.37%	0.37%	0.38%	0.34%	0.41%	0.35%
0.1	0.24%	0.23%	0.20%	0.20%	0.20%	0.20%	0.21%	0.18%	0.23%	0.19%
0.2	0.13%	0.11%	0.09%	0.09%	0.09%	0.09%	0.09%	0.08%	0.11%	0.08%
0.35	0.09%	0.07%	0.07%	0.07%	0.07%	0.07%	0.07%	0.06%	0.07%	0.06%
0.6	0.04%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%	0.02%	0.03%	0.02%
1	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.00%	0.01%	0.00%
2	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling); Target OELV is inhalable; Highlighted figures represent highest and lowest costs as a % of turnover.

Table 6-7: Costs per company as a % of turnover - Medium companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	0.29%	0.34%	0.30%	0.31%	0.30%	0.30%	0.20%	0.27%	0.36%	0.26%
0.05	0.19%	0.21%	0.18%	0.20%	0.18%	0.19%	0.08%	0.16%	0.21%	0.16%
0.1	0.11%	0.12%	0.10%	0.11%	0.10%	0.10%	0.03%	0.09%	0.12%	0.09%
0.2	0.06%	0.06%	0.05%	0.06%	0.05%	0.05%	0.01%	0.04%	0.06%	0.04%
0.35	0.04%	0.04%	0.03%	0.04%	0.03%	0.03%	0.00%	0.03%	0.04%	0.03%
0.6	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.00%	0.01%	0.02%	0.01%
1	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.00%	0.00%	0.01%	0.00%
2	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling); Target OELV is inhalable; Highlighted figures represent highest and lowest costs as a % of turnover.

Table 6-8: Costs per company as a % of turnover - Large companies										
OELV µg/m³	Sector/€									
	A	B	C	D	E	F	G	H	I	J
0.02	0.69%	0.85%	0.74%	0.24%	0.74%	0.78%	0.00%	0.75%	0.41%	0.00%
0.05	0.46%	0.52%	0.45%	0.09%	0.45%	0.52%	0.00%	0.46%	0.16%	0.00%
0.1	0.27%	0.30%	0.25%	0.04%	0.25%	0.30%	0.00%	0.25%	0.08%	0.00%
0.2	0.15%	0.15%	0.12%	0.01%	0.12%	0.16%	0.00%	0.11%	0.03%	0.00%
0.35	0.10%	0.09%	0.07%	0.00%	0.07%	0.10%	0.00%	0.07%	0.00%	0.00%
0.6	0.05%	0.04%	0.04%	0.00%	0.04%	0.05%	0.00%	0.03%	0.00%	0.00%
1	0.02%	0.02%	0.01%	0.00%	0.01%	0.02%	0.00%	0.01%	0.00%	0.00%
2	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – ten (A = Foundries, B = Metal Fabrication, C = Transport, D = ICT, E = Specialist Manufacturers, F = Medical devices, G = Glass, H = Construction, I = Laboratories, J = Recycling;); Target OELV is inhalable Highlighted figures represent highest and lowest costs as a % of turnover.

Overall, Section 3 estimates that 5,804 (not including construction) and 24,033 (including construction) enterprises in the EU are potentially involved in working with beryllium across the 10 sectors and the market effects of the introduction of OELVs at different levels will need to be considered across these companies.

The above information provides important input for the subsequent analysis of market impacts resulting from the introduction of OELs at different levels in the following sub-sections.

6.2 Research and innovation

Research and development are key activities in developing an industry's capacity to develop new products, as well as producing these and existing ones more efficiently and sustainably, and in a way that protects the safety of workers. In 2016, Eurostat reported that expenditure in the EU on R&D was approximately €300 billion in 2015, representing 2.03% of GDP. The largest contributor to this level of expenditure was the business enterprise sector, accounting for 65%, or approximately €195 billion.

The ability of the different sectors to engage in R&D activities is likely to be affected by:

- The availability of financial resources to invest in R&D;
- The availability of human resources to conduct R&D activities;
- The regulatory environment and whether or not it is conducive to investing in R&D activities

Table 6-9 below provides examples of sector-wide R&D expenditures in 2015 in a selection of MS in some of the sectors using beryllium.

Table 6-9: R&D Expenditure at national level per manufacturing sector involving beryllium (in €)

Member State	C24: Basic Metals	C25: Fabricated metal products, except machinery and equipment	C26: Computer, electronic and optical products	C27: Electrical equipment	C32.5: Medical and dental instruments and supplies
CZ	11,979,000	44,247,000	72,408,000	122,848,000	12,372,000
DE	531,000,000	824,000,000	7,541,000,000	2,249,000,000	561,000,000
IT	88,100,000	358,600,000	1,371,400,000	505,400,000	62,500,000
PL	22,562,000	78,918,000	48,637,000	83,889,000	11,161,000
UK	81,703,000	658,997,000	1,357,123,000	261,505,000	217,829,000

Source: Modelling by RPA

Research and development expenditures in sectors such as computers, electronic and electrical products, electrical equipment and fabricated metal products are significant (although it is noted that these figures cover the entire sector and not just R&D in production using beryllium).

Better Regulation Tool #21 (European Commission) indicates that "All compliance costs divert resources from other purposes, potentially including research and innovation." Whilst the estimates of costs arising from the implementation of the different OELs represent a relatively small percentage of overall turnover for all sizes of companies, they still represent an increase in costs compared to the current situation, and R&D expenditures may be put under pressure as a result.

This pressure on R&D expenditures may be exacerbated by the fact that the regulatory environment would become stricter, and companies may be doubtful about the future of beryllium as an input in their production process. Even if the final OELV implemented were at the higher end of the range, the perception could well emerge that other more stricter limits might be imposed in the future, leading to a lack of confidence in the future of the substance. This perception could then lead to a further reduction in R&D expenditures to develop new and more efficient products.

There are many examples of innovation made possible by beryllium, but the highest profile current example is the ITER beryllium blanket (ITER). In southern France, 35 nations are collaborating to build ITER, the world's largest tokamak, a magnetic fusion device that has been designed to prove the feasibility of fusion. The blanket completely covers the inner walls of the vacuum vessel protecting the steel structure and the superconducting toroidal field magnets from the heat and high-energy neutrons produced by the fusion reactions. Due to its unique physical properties (low plasma contamination, low fuel retention), beryllium has been chosen as the element to cover the first wall.

6.3 Single market

6.3.1 Competition

Potential impacts

Table 6-10 below includes the initial 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.

Table 6-10: Screening of competition impacts		
Impacts	**Key questions**	**Yes/No**
Existing firms	Additional costs?	Yes. Costs of RMMs to meet OELs (some capital, some on-going e.g. PPE, energy supply for LEVs))
	Scale of costs significant?	Yes. Capital and on-going (see costs as % of turnover in Tables 6-6 to 6-8 above, broken down by firm size)
	Old firms affected more than new?	Unlikely
	Location influences?	No. OELs will apply the same, irrespective of location
	Some firms will exit the market?	Yes
	Are competitors limited in growth potential?	No, assuming they can meet the OELs, but may be difficult
	Increased collusion likely?	Unknown
New entrants	Restrict entry?	Yes. High capital cost to meet OELs. Some sub-sectors require product qualifications taking years
Prices	Increased prices for consumers	Yes. Increased production costs. Potential increase in market power of those that do not exit the market
Non-price impacts	Product quality/variety affected?	No.

Table 6-10: Screening of competition impacts		
Impacts	**Key questions**	**Yes/No**
		Use of beryllium relatively low in Europe. Majority products come from overseas.
	Impact on innovation	Yes. Potentially as result of high increases in costs leading to fewer resources available for R&D (See Section on R&D above)
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. Although a restriction in the number of firms due to market exit may reduce bargaining powers of downstream supply chain.
Source: Analysis by RPA		

If it is not technically feasible and/or economically viable for a company to achieve the OELV, there are several potential effects: substitution, closure, market concentration and moving operations outside the EU. Substitution of alternatives is not easy for most companies as the material they work with is usually defined by their client, see section 3.16.

If the OELV has the effect of significantly increasing the cost of beryllium products, some sectors such as transportation and ICT devices may redesign to enable substitution to avoid using beryllium. This might then cause an even greater rise in prices, which the defence and aerospace sectors, in particular, would have to pay as they generally cannot find substitutes.

Closure - companies exiting the market

Table 6-1 above indicates that the number of firms likely to exit the market in the sectors identified as using beryllium is relatively small, and consequently, it is not expected that there would be any significant impacts on these broad markets. However, the uses of beryllium in sectors such as automotive (a sub-sector of transport) and electronic components (a sub-sector of ICT), are likely to be very specific and specialised in nature, due to the high cost of the substance. As such, there are likely to be fewer competitors in these specific markets. The overall impact on competition (with respect to numbers of firms trading in certain products) is therefore likely to be higher in some sub-sectors than it is in others.

The numbers of companies likely to cease trading in the different sectors are presented alongside the total numbers of companies dealing with beryllium in Table 6-11 below, with estimates of the % of companies likely to cease trading as a result of the three OELs where firms are likely to cease trading.

Table 6-11: Proportions of companies using beryllium that are likely to cease trading							
Sector	No. of firms working with beryllium	No. of firms (0.02 µg/m^3 inhalable)		No. of firms (0.05 µg/m^3 inhalable)		No. of firms (0.1 µg/m^3 inhalable)	
		No. of firms likely to cease trading	Likely to cease trading as a % of working with beryllium	No. of firms likely to cease trading	Likely to cease trading as a % of working with beryllium	No. likely to cease trading	Likely to cease trading as a % of working with beryllium
Foundries	229	9	3.93%	3	1.31%	1	0.44%
Metal fabrication	1,430	58	4.06%	17	1.19%	6	0.42%
Transport	297	12	4.04%	4	1.35%	1	0.34%
ICT	143	6	4.20%	2	1.40%	1	0.70%
Specialist mfrs.	597	24	4.02%	7	1.17%	2	0.34%
Medical devices	2,626	103	3.92%	31	1.18%	10	0.38%
Glass	39	2	5.13%	0	0.00%	0	0.00%
Construction	18,229	744	4.08%	221	1.21%	75	0.41%
Laboratories	335	13	3.88%	4	1.19%	1	0.30%
Recycling	108	4	3.70%	1	0.93%	0	0.00%
Total	5,804 (24,033)	232 (977)	4.00% (4.07%)	69 (290)	1.19% (1.21%)	23 (98)	0.40% (0.41%)

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction and all ten sectors in brackets

Table 6-1 at the beginning of this section estimated that no companies are likely to cease trading at OELs of 0.2 µg/m^3 and above. However, Table 6-11 suggests that as many as 4.00% of the companies operating across all sectors may exit the market at an OEL of 0.02 µg/m^3, with the glass sector seeing 5.13% of companies exiting the market. At the higher OEL of 0.05 µg/m^3, the sector most affected is estimated to be the ICT sector (1.40% of companies exiting the market), and under an OEL of 0.1 µg/m^3, the same sector may see 0.7% of companies exiting the market.

It is noted that the figures used to generate estimates of the proportion of turnover that increased costs resulting from expenditure on RMMs to meet the different OELs are based on both capital (CAPEX) and operational (OPEX) expenditures at different levels over the 60 year assessment period. In order to be permitted to continue operation, companies will need to invest significant sums in equipment (capital expenditure) upfront to reduce exposure levels to the stipulated OEL. Whilst the percentage of a company's turnover that the total (CAPEX plus OPEX) costs indicated above represent a relatively small amount of a company's turnover spread over 60 years, significant CAPEX expenditures in year 1 would represent a significant proportion of a company's turnover, especially for small companies. This high initial outlay requirement may result in companies being unable to continue operations, particularly where they are unable to secure finance for the investment (e.g. for necessary local exhaust ventilation (LEV) equipment).

One respondent, from an SME manufacturing components, which have to be made using an inherently dusty process, indicated that any OELV below 1 µg/m^3 was not likely to be economically viable for the company and that any OELV below 0.6 µg/m^3 was not likely to be technically feasible. Another concern relating to this company is that they are the EU's only supplier of this product: the only other supplier in the world is in the USA. The product is used by many sectors, but the majority of its sales are for defence and aerospace customers. This same respondent confirmed that they are meeting the national OEL, the majority of their workers had worked for them for over 20 years, and that they were not aware of any cases of chronic beryllium disease in over 30 years.

The impact on competition will be dependent to a degree on which specific companies (in terms of location) end up going out of business. In MS where there are limited numbers of companies operating in a particular sector, even a limited number of companies exiting the market could lead to a significant reduction in competition on the local market.

Given the high levels of capital expenditure required to provide adequate protection of workers and meet the OELs required, it will be difficult for new companies to enter the market. It is also the case that some markets require detailed qualifications of products meeting certain standards (such as electrical components in the automotive or aerospace sectors) for a company to be able to supply to customers, often requiring compliance with approval processes that can sometimes take years. This will further inhibit any gaps in the market being taken up by new entrants.

The costs to companies exiting the market as a result of the introduction of the different OELs will arise from the turnover lost from ceasing sales of their products. Based on the number of firms predicted to exit the different markets and the average turnover of large, medium and small companies using beryllium in the EU, it is possible to estimate the total losses arising at different OELs over the 60 year assessment period.

Based on the average turnover for small (€0.5m), medium (€10m) and large (€15m) companies estimated above, average turnover lost from ceasing operations (discounted at 4% over a 60 year period) for an average company in each size class would be:

- Small - €11,746,215
- Medium - €235,284,296
- Large - €352,926,444

Using the BeST data, based on these estimates and the numbers of firms estimated to discontinue activities related to beryllium in Table 6-1 above, the following table provides estimates of lost turnover resulting from firms exiting the market in response to the introduction of the different OELs.

Table 6-12: Turnover lost due to firms exiting the market

Target OELV inhalable $\mu g/m^3$	Lost turnover due to discontinuing activities, PV, 60 years			
	Small	Medium	Large	Total
0.02	€11.0 billion	€7.6 billion	€0.9 billion	€19.6 billion
0.05	€3.3 billion	€2.2 billion	€0.2 billion	€5.8 billion
0.1	€1.1 billion	€0.8 billion	€0.09 billion	€2.0 billion
0.2	-	-	-	-
0.35	-	-	-	-
0.6	-	-	-	-
1	-	-	-	-
2	-	-	-	-

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors –all ten sectors

Comparable totals using the OSHA data covering seven sectors (i.e. not including construction, laboratories and recycling) would be €19.2 billion for OEL 0.02 µg/m3, €3.3 billion for OEL 0.05 µg/m3, and €1.4 billion for OEL 0.1 µg/m3.

Due to the fact that only a relatively small number of companies (in relation to the total number operating in the different sectors using beryllium) would cease trading (the highest would be 977 at the 0.02 µg/m3 OEL, out of a total of 24,033 firms), and the majority of EU companies would continue supplying different markets, the trade lost by those companies exiting the market could be picked up by other EU companies who meet the requirements of the OELs.

Market concentration

Another aspect of the market changes is that in some sectors, for example metal fabrication, there are a relatively large number of companies supplying the market each of whom only perform a relatively small amount of beryllium related work. In the case of one site visit to a precision stamping plant for aerospace, automotive and medical components in the UK, there are about 20 companies doing similar work in the same region and beryllium accounts for less than 5% of their turnover. If the OELV is set at the lower levels, the likely result is that only one or two of the companies in the region will make the necessary investment and will soak up the work from the other companies leaving the market.

A respondent manufacturing beryllium alloys provided some further examples of regions of beryllium specialisation where they expect a reduction in OELV to results in market concentration:

- Vallée de l' Arve (near Grenoble) has a concentration of manufacturers specialising in turning.
- Besançon (Doubs - 25 - Franche-Comté region) several micro companies specialise in stamping working with different metals and alloys, including copper beryllium.
- Germany, these are concentrations of companies around Stuttgart and in the Ruhr.

The effect of market concentration is not only to reduce the level of competition and potentially cause prices to increase, but also to reduce the range of products and services that are available. This has an impact upon the capacity of their customers to innovate. A further risk is that the customers down the supply chain see the activities to manage a hazardous substance at the upper end of the supply chain and decide move all their operations using beryllium products (for activities that are not hazardous) outside the EU. Ironically, this leads to the risk that beryllium processing moves to locations with poor environmental and health regulations.

This market concentration is difficult to model and is not incorporated into the cost model, but it is potentially a significant effect. The sectors it is most likely to affect are foundries, metal fabrication, specialist manufacturers and medical devices.

Moving operations outside the EU

Some companies might choose to move outside the EU. However, over 90% of enterprises are small companies with less than 20 employees, see Table 3-31. Very few of these will be already operating in more than country or be willing to relocate their operations. Even if they wish to relocate, this would probably be difficult to finance. Less than 1% of enterprises are large companies with over 250 employees. These companies are more likely to already have operations in non EU countries and even if they do not, they are more likely to have access to finance. These large companies include Airbus, Siemens, ABB and GE Power and several more multinationals: these companies are likely move beryllium related operations outside the EU if OELV is set at a level that requires substantial investment to remain in the EU. However, for companies who want to supply the EU, leaving the EU is a difficult decision. Their main advantage over competitors outside the EU is both being close to their customer and having a perceived higher quality. Moving outside the EU jeopardises both these advantages.

The sector that is most likely to consider moving outside the EU is foundries as these currently operate at higher exposure levels and will have the most difficulty and incur the greatest costs achieving levels below about 0.6 µg/m^3.

6.3.2 Consumers

Table 6-11 above suggests that approximately 4% of companies across all sectors using beryllium may be forced to exit the market at the strictest OEL of 0.02 µg/m^3, with some sectors seeing even higher percentages of operating companies ceasing operation. This reduction in the number of companies operating in the different sectors, combined with the fact that those companies continuing operation will incur additional capital and operating costs, is likely to lead to some increase in overall prices paid by consumers, although it is not possible to determine the extent of such increases due to data limitations.

6.3.3 Internal market

It has not been possible to identify the extent of intra-EU trading in products produced using beryllium. Similarly, due to the methodological approach adopted for estimating the numbers of companies using beryllium in different MS, it has not been possible to identify the specific numbers of companies that are operating in more than one EU MS. However, it is highly likely that some companies will actually have plants in more than one MS (e.g. due to the fact that large companies are operating in significant numbers in a number of the sectors analysed) and this will require these companies to adhere to a range of regulatory requirements under the baseline scenario.

Time and resources will be required to research and regularly update information on different OELs in force in different MS and where these differ for a company operating in more than one MS, production processes may need to be adapted in order to be compliant. Harmonised OELs across all MS would remove the need to carry out this research and construct plants in different ways, using different processes and equipment in order to ensure regulatory compliance in each MS. This would consequently represent a cost saving for companies.

However, when asked about intra EU trading, the industry association BeST could think of only a handful of companies with beryllium operations is two or more EU Member States. Furthermore, the vast majority of enterprises using beryllium are small companies employing less than 20 people: Table 3-31 shows that 23,000 of the estimated 24,000 companies affected by beryllium are small. These companies are unlikely to have operations in more than one EU Member State. The harmonisation of the OEL for beryllium across might cut administrative costs for the few multinationals that have beryllium operations in more than one EU Member State, but it would make no difference to the administrative costs of the vast majority of companies.

6.4 Competitiveness of EU businesses

The global beryllium market is estimated to reach around 650,000 kg by 2020 (Global Industry Analysts Inc., undated), primarily driven by the growing use of beryllium alloy in applications associated with industrial and electronics use. The United States represents the largest market worldwide (approximately 65% of global resources are located there) and the Asia Pacific region is expected to record the fastest growth in the next few years. Again, strong growth in electronics, automotive and telecommunications industries is expected to be the main driver.

Key trends and drivers include:

- Increasing use of "behind-the-scenes" electronics in the automotive industry;
- Rising volumes of medical imaging procedures;
- Stable R&D investments in beryllium science and technology;
- Growth in the telecommunications sector leading to increased demand for beryllium alloys in optical transmission tools; and
- Increasing sales of smart phones.

It is estimated that 90% of global consumption in 2016 was in North America (Grand View Research, Inc., undated), primarily due to the level of demand in the industrial, consumer electronics, and defence sectors. Further growth is expected in the defence and aerospace sectors and the growing solar industry in Canada and USA is also expected to make a significant contribution. Only approximately 7.6% of global consumption occurs in Europe and it is predicted that any growth in the region would be sluggish in the period to 2025 due to the widespread use of alternatives. The Asia-Pacific region may see growth of 1.2% in the near future to 2025, with increasing manufacture of consumer electronics being a major source of demand for the substance in the region.

The automotive and consumer electronics sectors are key applications in the use of beryllium and these sectors are dominated on a global scale by companies in Japan, China and US.

The global nature of the markets using beryllium means that companies producing products using the substance outside of the EU will be at a competitive advantage where any regulatory requirements in force locally are lower than the proposed harmonised OELs. In such cases, customers of existing EU-based companies using beryllium may purchase from suppliers outside of the EU, and companies currently based in different MS may also choose to relocate their operations outside of the EU. This may particularly apply to large multi-national companies already having facilities in non-EU countries. Table 3-1 shows several non EU countries with OELs of 2 $\mu g/m^3$ that they might consider: Australia, several Canadian states (Canadian states have different OELs), India, Japan, South Korea and Switzerland. Russia and Kazakhstan have OELs of 1 $\mu g/m^3$. Kazakhstan is particularly relevant as it produces beryllium. The other beryllium producers, the USA and China have relatively low OELs of 0.6 $\mu g/m^3$ and 0.5 $\mu g/m^3$ respectively and are less likely to be the destination for a company relocating its beryllium operations.

7 Environmental Impacts

This section comprises the following subsections:

- Section 7.1: PBT screening
- Section 7.2: Current environmental levels in relation to hazard data
- Section 7.3: Current environmental exposure – sources and impact
- Section 7.4: Conclusion

7.1 PBT screening

The solubility of beryllium compounds considered here is diverse: beryllium and beryllium oxide are reported as insoluble in cold water. Beryllium sulfate (anhydrous) is insoluble in cold water, but converts to sulphate tetrahydrate in hot water, which is "extremely soluble", likewise beryllium fluoride. Beryllium chloride and nitrate are very soluble in water (NRC, 2007; WHO, 2001).

Little information is available on the environmental toxicity of beryllium and its compounds. For example, in the REACH registration dossier for beryllium (and also that for beryllium oxide), no predicted no effect concentrations (PNECs) were derived and the ecotoxicological[3] endpoints were waived. The other compounds covered within the scope of this project are not yet registered (ECHA Dissemination, 2017, as of November 2017). Justification for waiving is not provided, but it may be because it is practically insoluble in water as documented by WHO (2001).

Beryllium at high pH precipitates as phosphate in culture solutions of plants, making it unavailable to them. A soil level of 10,000 µg/kg has been observed for reduced yield of spring barley in sandy soil, and higher values are expected in other soils with higher adsorption (IARC, 2012).

Beryllium in the atmosphere is transported to water and soil by both dry and wet deposition[4]. It is not known if beryllium oxide in air reacts with sulphur or nitrogen oxides to produce beryllium sulphate or nitrate, but such a conversion to water-soluble compounds would accelerate removal of beryllium from the atmosphere by wet deposition. In most natural waters, the majority of beryllium is adsorbed into suspended matter or sediment, rather than dissolved. For example, in the US Great Lakes, beryllium is present in sediment at concentrations several orders of magnitude higher than its concentration in water. Beryllium in sediment is primarily adsorbed into clay, but some beryllium may be in sediment as a result of the formation and precipitation of insoluble complexes. At neutral pH, most soluble beryllium salts dissolved in water will be hydrolysed to insoluble beryllium hydroxide, and only trace quantities of dissolved beryllium will remain. However, at high pH, water-soluble complexes with hydroxide ions may form, increasing the solubility and mobility of beryllium.

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[3] Ecotoxicology: "Study of the toxic effects of chemical and physical agents on all living organisms, especially on populations and communities within defined ecosystems; it includes transfer pathways of these agents and their interactions with the environment." IUPAC, (2007)

[4] Deposition: "Process by which a substance sediments out of the atmosphere or water and settles in a certain place" IUPAC, (2007). Wet deposition is deposition through rain, snow, hail, fog or sleet: it is often known as acid rain. Dry deposition is deposition through gases and dust.

Solubility may also increase at low pH; detectable concentrations of dissolved beryllium have been found in acidified waters (WHO, 2001).

Beryllium is not significantly bio-concentrated[5] by aquatic species, bottom feeding molluscs or plants. It can be assumed not to be bio-accumulative[6] (IARC (2012); SCOEL (2017)). Beryllium oxide, which is most relevant for emissions (see below), is insoluble in water but strongly adsorbed by particulate matter. The bioavailable[7] fraction will therefore be low and reduced upon entry into water or soil by absorption. Therefore, while beryllium in oxidation state II is stable (persistent) in the environment, the bioavailable fraction generally will be very low.

7.2 Current environmental levels in relation to hazard data

A predicted no effect concentration (PNEC) of 0.16 µg/L is derived from acute data from three trophic levels (assessment factor 1000), fish being the most sensitive species with a LC50 of 160 µg/L at a hardness of 2,200 µg/L as calcium carbonate (WHO, 2001). Beryllium toxicity increases in acidic and soft water (IARC, 2012). Given the very high eco-toxic potential, low bioavailable concentrations may be sufficient for ecotoxicological effects.

Beryllium naturally enters waterways through the weathering of rocks and soils. It occurs in ground water and surface water (0.01-0.1 µg/L), and in sea water at about three orders of magnitude lower. Concentrations of beryllium in drinking water range from 0.010 to 1.22 µg/L with an average of 0.19 µg/L (ATSDR, 2002 and IARC, 2012). These concentrations are close to the PNEC.

A comprehensive soil analysis in Germany revealed median concentrations of beryllium in various soil types (sands, loam and clays) of 200 – 2,600 µg/kg, with 90th percentiles of 500 – 5,300 µg/kg (Utermann et al., 2008).

7.3 Current environmental exposure – sources and impact

Man-made sources of beryllium are landfill disposal of coal ash and municipal waste combustor ash, land burial of industrial wastes and land application of beryllium enriched sewage sludge, but quantitative emission data are not available (IARC, 2012; SCOEL, 2017).

Ambient air concentrations of beryllium are very low, with average values below 0.0005 µg/m^3 (n = 100) in the USA. Rural sites' air concentrations ranged from 0.00003 to 0.00006 µg/m^3, 0.00004–0.00007 µg/m^3 at suburban sites and 0.0001 – 0.0002 µg/m^3 at urban industrial sites (IARC, 2012). In the vicinity of plants, there were mean concentrations of about 0.0155 µg/m^3 and a maximum of 0.0827 µg/m^3 (IARC, 2012) but this data is from the late 1950s and may be lower now due to emission reduction.

[5] Bio-concentration: "Process leading to a higher concentration of a substance in an organism than in environmental media to which it is exposed." IUPAC (2007)

[6] Bio-accumulation: "Progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body." IUPAC (2007)

[7] Bio-available: "Able to be absorbed by living organisms." IUPAC (2007)

The major source of atmospheric beryllium is coal combustion. The most prevalent chemical form is probably the practically insoluble beryllium oxide, mainly bound to particles smaller than 1 µm. Based on USA emission data from 1987 (leading producer and consumer of beryllium products), natural emissions (windblown dust, volcanic particles) amount to a total of 5.2 tonnes/annum. Coal and fuel oil combustion result in emissions of 180 and 7.1 tonnes/annum respectively, whereas beryllium production and processing release is quantified between 8.9-9.5 tonnes/annum, i.e. about 4.5% of total air emissions (NRC, 2007 and WHO, 2001). Waste combustion, not considered by these authors, may also contribute to atmospheric pollution, because exhaust gas has been shown to contain 0.2 $\mu g/m^3$ beryllium (ATSDR, 2002).

Assuming as a worst case doubling of current emissions by a change of OELs, this would lead to an estimated increase of total beryllium emissions by about 4.5% into air. As the environmental impact due to the weathering of rocks and soils is not included, this percentage is expected to be even lower in a total view of beryllium emissions. A similar conclusion was derived in a preceding project, SHEcan (IOM, 2011). The authors of this work assume that lowering the OEL “may lead to more direct emissions of beryllium and beryllium compounds to the environment (through ventilation), but probably not to an increased overall environmental burden…”

7.3.1 Contamination in the food chain

There is no indication that the food or drinking water chain is contaminated from beryllium. As beryllium is not expected to accumulate in the food chain, the risk to wildlife from food chain transfer of beryllium is low (IARC, 2012).

7.3.2 Impact on other environmentally friendly initiatives

Beryllium and its alloys have many high performance qualities as outlined in section 3.16. It is used in many innovative and high technology products including many that will lead to developments that are clean and good for the environment.

All of the strengths discussed in section 3.16, but particularly the formability of beryllium and its alloys, mean that beryllium and its alloys can be made into complex small shapes, which enable other manufacturers to miniaturise components and devices. This often leads to reductions in the use of other materials and lower transportation costs, overall leading to a lower carbon footprint.

Beryllium and its alloys are prized for their performance and reliability. They tend to be used in products that are designed to have a long life, i.e. satellites and freezers. Any initiatives to encourage manufacturers of electrical or mechanical equipment to design and build products with a longer lifespan are likely to increase the demand for beryllium.

Magnesium and aluminium alloys are used to reduce the weight of cars enabling them to be more fuel efficient and produce fewer emissions. A small amount of beryllium is used in the recycling process to prevent oxidisation. Magnesium is no longer produced in the EU and recycling magnesium enables the EU to be less dependent upon China, the world’s largest producer of magnesium. Recycled magnesium is considerably cheaper than “new” magnesium as well as being much more environmentally friendly, with a lower carbon footprint.

Many green technologies such as electric cars and solar panels have high numbers of connectors and the reliability of their connection is important: finding disconnections is time-consuming and expensive. Copper beryllium is particularly prized for its excellent contact on female electrical connectors. If copper beryllium was not available, electric car manufacturers (and other manufacturers requiring reliability of large numbers of electrical connectors, such as aircraft and satellite manufacturers) would have a serious issue as no alternative is nearly as reliable.

Finally, if the ITER (undated) project is successful in achieving nuclear fusion and delivers unlimited clean energy, the demand for beryllium would increase as it plays a key role in the design of the tokomak, see section 6.2.

7.4 Conclusion

The "negative" environmental impact of beryllium is regarded as "moderate", but not "significant" or "substantial" due to the:

- probable T (toxic) properties of beryllium;
- environmental exposure/PNEC ratio close to 1;
- low contribution of industrial air emissions to the total emission; and
- low human exposure via the environment.

This characterisation is independent from an additional potential environmental impact from changes of the OEL. A quantitative calculation of an environmental impact due to OEL changes is not feasible, however, if the OELV is set at the lower levels, much of the manufacturing will leave the EU and this is likely to result in some reduction in emissions. Qualitatively, it is expected that this impact is minor and does not modify the overall assessment result for beryllium and inorganic compounds.

The "positive" environmental impact of beryllium, in that its properties are used to enable many environmentally friendly technologies, is difficult to quantify. However, it seems to be "moderate" to "significant" in its impact. This leads to the conclusion that overall, beryllium is neutral in its environmental impact and possibly slightly positive.

8 Distribution of the Impacts

The impacts identified under the previous tasks will be broken down by stakeholder type and a systematic analysis of who will bear the costs and accrue the benefits will be provided.

This section comprises the following subsections:

- Section 8.1: Businesses
- Section 8.2: SMEs
- Section 8.3: Workers
- Section 8.4: Consumers
- Section 8.5: Taxpayers/public authorities
- Section 8.6: Specific Member States/regions
- Section 8.7: Different timeframes for costs and benefits

8.1 Businesses

The burden of the cost of continuing to trade for those enterprises that are not forced to close is shown in Tables 6-3 to 6-5, disaggregated by size of company, sector and target OELV. The number of companies predicted to discontinue in described in Table 6.1 and the average cost of discontinuing (present value over 60 years) for small, medium and large companies are explained in section 6. Overall, approximately 4% of enterprises are predicted to discontinue if the OELV is set at 0.02 µg/m^3, reducing to zero for OELVs of 0.2 µg/m^3 and higher.

The benefits for employers are based upon the reduced cost of having an employee become ill with chronic beryllium disease and loss of productivity due to a death from chronic beryllium disease: how they relate to Method 1 is explained in Table 4.15 and the values are given in Table 4.16. The average benefits per enterprise for companies that continue in business are shown in Table 8.1. The benefits are based on either a constant workforce where everyone works for 40 years in a beryllium environment or a workforce with a turnover of 5%, which effectively means that on average workers spend 20 years working in a beryllium environment.

Table 8.1: Employers benefits over 60 years per enterprise continuing in business by target OELV

Target OELV inhalable µg/m^3	Benefits/enterprise Constant workforce Method 1	Benefits/enterprise Turnover workforce Method 1
0.02	€ 3,509	€ 4,869
0.05	€ 3,454	€ 4,777
0.1	€ 3,142	€ 4,336
0.2	€ 2,591	€ 3,583
0.35	€ 2,131	€ 2,958
0.6	€ 1,745	€ 2,389
1	€ 1,121	€ 1,543
2	€ 551	€ 772

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction

Comparing Table 8-1 with Tables 6-3 to 6-5, it is clear that the benefits for employers are considerably lower than the costs.

8.2 SMEs

The numbers of small, medium and large enterprises likely to have workers exposed to beryllium to some degree in the EU is estimated in Table 5-8 in Section 5.

Table 6-1 in Section 6 indicates that a number of companies are likely to cease trading as a result of the introduction of the OELVs. More companies will cease trading the stricter the OELV, and Table 8-2 below provides estimates across sectors at each of the different OELVs, broken down by size of company.

Table 8-2: Estimates of companies ceasing trading, by OEL and company size

Target OELV inhalable µg/m^3	Small	Medium	Large	Total
0.02	213 (942)	3 (32)	1 (2)	216 (977)
0.05	63 (279)	5 (10)	1 (1)	69 (290)
0.1	21 (95)	2 (3)	0 (0)	23 (98)
0.2	-	-	-	-
0.35	-	-	-	-
0.6	-	-	-	-
1	-	-	-	-
2	-	-	-	-

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction

It is noted that the above figures are heavily influenced by data from the construction sector, which, if excluded from the data, significantly reduce the number of companies estimated to cease trading under each of the OELVs.

Using the US-OSHA data for seven sectors, the number of companies that would be estimated to cease trading would be 573 small companies, 46 medium and 5 large under an OELV of 0.02 µg/m^3. Equivalent figures at 0.1 µg/m^3 would be 42 small, 3 medium and 0 large. At 0.35 µg/m^3, seven small companies and one medium company would still be expected to cease trading, whereas no companies would be expected to cease trading under the BeST estimates for 0.2 µg/m^3 and higher OELVs. However, these are very small numbers against the total numbers of companies using beryllium.

As noted in Tool #22 the SME test in the Better Regulation toolbox (European Commission), SMEs generally tend to *"find it more difficult to access capital and their cost of capital is often higher than for larger businesses."* Given the regulatory climate surrounding beryllium, the long term future of companies using it may be perceived by finance companies as being inherently more risky than other investment opportunities. This may make it more difficult for SMEs to secure any finance, or at least having a premium placed on it with the potential threat of further regulation in the future.

Many of the RMMs required to meet the OELVs involve significant capital expenditure, putting SMEs at a disadvantage due to the likely higher cost of finance, if they can secure it.

As indicated in Tables 6-6 to 6-8, the compliance costs associated with meeting even the strictest OELVs represent less than 1% of SMEs' total turnover in the different sectors that would be affected.

The percentage appears higher for small companies than it is for medium sized companies (e.g. 0.68% of turnover for small companies, and 0.36% for medium companies in the laboratories sector under an OEL of 0.02 µg/m^3), indicating that they will be burdened to a higher degree. However, the proportion of costs as a percentage of turnover for SMEs is calculated as being somewhat lower in general than for large companies. This would appear counterintuitive, since it would be expected that larger companies might benefit from economies of scale and have significantly higher levels of overall turnover than smaller ones. However, the methodological approach adopted for modelling the cost impacts of implementing the different measures required to ensure compliance with the proposed OEVLs has only considered a proportion of large companies' turnover associated with beryllium operations. In general, the total average turnover of large companies will be very significantly higher than the €15 million assumed in the model and the proportion represented by the increase in compliance costs will be significantly lower when placed in comparison with these much higher total turnovers.

Furthermore, when it comes to company decisions regarding investment in the different measures required to ensure compliance with the proposed OELs, larger companies will be able to make those decisions in relation to total turnover figures, and not necessarily only in relation to the smaller amounts represented solely by activities relating to beryllium.

Finally, it is unlikely that SMEs would be exempted from the OLEV requirements given the potential impacts on health and safety of workers from doing so.

8.3 Workers

As estimated previously, it is anticipated that up to 977 companies might close down at the strictest OEL proposed of 0.02 µg/m^3. As a result, all employees working in these enterprises would lose their jobs. From the perspective of the cost to the EU, these people would, however, be available for employment elsewhere and in time, may find other equivalent employment. However, the impacts associated with the potentially temporary loss of employment can be monetised based on the approach set out in ECHA (2016) and adapted from Haveman and Weimer (2015) and Duborg (2016). The impacts include the following components:

- The value of output/wages lost during the period of unemployment
- The costs of job search, hiring and firing employees
- The "scarring effect" of being made unemployed on future employment and earnings
- The value of leisure time during the period of unemployment.

Analysis carried out earlier in this report has indicated that 24,033 (5,804 excluding construction) companies are working with beryllium and have employees potentially exposed to beryllium, and in the event that an enterprise is unable to meet the prescribed OELVs for those workers, would be forced to close down specific operations using beryllium and these workers would lose their jobs. Table 8-3 below summarises the numbers of jobs of potentially exposed workers that would be lost at differing OELs.

Table 8-3: Numbers of firms and exposed workers					
Target OELV inhalable µg/m^3	Total no. of firms working with beryllium	No. firms exiting market	Total no. workers affected by beryllium	Total workers in firms exiting market	Total social cost (based on annual salary of €30,000)
0.02	5,804 (24,033)	233 (977)	54,071* (80,540)	2,171 (3,274)	€ 177,126,311 (€ 267,170,413)
0.05		69 (290)		643 (972)	€ 52,453,714 (€ 79,303,398)
0.1		23 (98)		214 (328)	€ 17,484,571 (€ 26,799,079)

Source: Modelling by RPA
Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction and all ten sectors shown in brackets. Assumes that workers are spread evenly across firms that cease trading
**See Section 3*

Based on a ratio of social cost per job loss over annual pre-displacement wage of 2.72 for EU28, as proposed by Duborg (2016), and excluding the construction sector, the overall social costs of almost 2,200 job losses (at an OEL of 0.02 µg/m^3) would be close to €180 million based on an average annual wage of €30,000. (This figure assumes that wage rate does not include employer taxes). Equivalent figures for OELs at 0.05 µg/m^3 and 0.1 µg/m^3 would be around 640 jobs lost at a cost of close to €50 million and 210 jobs lost at a cost of roughly €17 million.

However, the actual cost would most likely be significantly higher than these figures, since the jobs lost used in the calculations only consider those workers who are potentially exposed to beryllium. In the event that the whole company had to close (and not just the operations involving potential exposure to beryllium,) all employees at the company would lose their positions. Furthermore, it has not been possible to identify upstream and downstream effects on employment resulting from the employment losses in the sectors using beryllium. Multiplier effects could lead to additional losses in employment for suppliers and customers of those companies going out of business, although it is noted that since the vast majority of companies would continue operations, even at the strictest OELVs, it would be expected that these effects would most likely be temporary as previous employees at those companies exiting the market would be absorbed in other companies.

There are considerable benefits to workers and their families and these are based upon lost earnings, the cost of informal healthcare for the family, the value of a statistical life, value of statistical morbidity and value of a DALY: how they relate to Method 1 and 2 is explained in Table 4.10. The values over 60 years based upon Method 1 are provided in Table 4.11 and for Method 2 in table 4.12.

These benefits per exposed worker over 60 years are shown in Table 8.4. The benefits are based on either a constant workforce where everyone works for 40 years in a beryllium environment or a workforce with a turnover of 5%, which effectively means that on average workers spend 20 years working in a beryllium environment.

Table 8.4: Average benefit per exposed worker over 60 years by target OELV				
Target OELV inhalable µg/m^3	Benefits/worker Constant workforce Method 1	Benefits/ worker Turnover workforce Method 1	Benefits/ worker Constant workforce Method 2	Benefits/ worker Turnover workforce Method 2
0.02	€ 4,845	€ 10,967	€ 20,806	€ 33,548
0.05	€ 4,753	€ 10,782	€ 20,418	€ 32,938
0.1	€ 4,309	€ 9,765	€ 18,513	€ 29,868
0.2	€ 3,569	€ 8,082	€ 15,295	€ 24,690
0.35	€ 2,941	€ 6,658	€ 12,632	€ 20,362
0.6	€ 2,404	€ 5,437	€ 10,301	€ 16,626
1	€ 1,535	€ 3,477	€ 6,602	€ 10,634
2	€ 758	€ 1,720	€ 3,273	€ 5,271

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction Assumes a constant exposed workforce of 54,071, not adjusted to reduce workforce due to companies discontinuing at the lowest target OELVs.

Overall, workers and their families are those with the most to gain from reductions in the OELV. Effectively, the "benefits" may occur long after the worker has left the beryllium environment and remove suffering that, if it had happened, might never have been linked to the original cause.

8.4 Consumers

Table 6-11 in section suggests that approximately 4% of companies across all sectors using beryllium may be forced to exit the market at the strictest OEL of 0.02 µg/m^3, with some sectors seeing even higher percentages of operating companies ceasing operation. This reduction in the number of companies operating in the different sectors, combined with the fact that those companies continuing operation will incur additional capital and operating costs, is likely to lead to some increase in overall prices paid by consumers, although it is not possible to determine the extent of such increases due to data limitations.

The reduction in competition due to market concentration which is discussed in Section 6.3.1 is also likely to lead to an increase in overall prices paid by consumers. Overall, the costs are likely to be relatively low for consumers, but there are no direct benefits. Indirectly consumers benefit as taxpayers.

8.5 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: how they relate to Method 1 is explained in Table 4-13. The values are presented in Table 4-14.

The average benefits per worker for taxpayers and public authorities are shown in Table 8.5. The benefits are based on either a constant workforce where everyone works for 40 years in a beryllium environment or a workforce with a turnover of 5%, which effectively means that on average workers spend 20 years working in a beryllium environment.

Table 8.5: Taxpayers and public authorities benefits per exposed work over 60 years by target OELV in € millions		
Target OELV inhalable µg/m³	Benefits/worker Constant workforce Method 1	Benefits/ worker Turnover workforce Method 1
0.02	€ 497	€ 699
0.05	€ 488	€ 686
0.1	€ 444	€ 623
0.2	€ 366	€ 514
0.35	€ 301	€ 424
0.6	€ 246	€ 346
1	€ 157	€ 222
2	€ 78	€ 109

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction. Assumes a constant exposed workforce of 54,071, not adjusted to reduce workforce due to companies discontinuing at the lowest target OELVs.

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.

8.6 Specific Member States/regions

8.6.1 MS national limits

OELs already exist in different Member States but these differ from Member State to Member State. Table 3-1 in Section 3 of this report sets out the OELs in force in the MS (where these are known) and it can be seen that a number of MS would already have equivalent or lower OELs in place than those being proposed. Table 8-6 below summarises the information on national OELs for beryllium and lists those MS at each proposed OEL that currently have a higher limit, indicating which MS would be impacted by the introduction of each specific OEL.

Table 8-6: MS with OELs higher than proposed levels		
Target OELV inhalable µg/m³	Member States where current limits are higher	Notes regarding national limits
0.02	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	
0.05	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	
0.1	AT, BE, BG, HR, CY, CZ, DK, EE, FR, DE*, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK	DE: 0.06 (R), except aluminium beryllium silicate; 0.14 (i) except aluminium beryllium silicate
0.2	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK	
0.35	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK	
0.6	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT,	

Table 8-6: MS with OELs higher than proposed levels		
Target OELV inhalable µg/m³	Member States where current limits are higher	Notes regarding national limits
	RO, SK, SI, SE, UK	
1	AT, BE, BG, HR, CY, DK*, EE, FR, EL, HU, LT, RO, SK, SI, SE, UK	DK: Powders and compounds
2	AT*, HR*, EL, SK*, SI*	AT: Current limit of 2(i) for "other uses,"; 5 for "whetting of beryllium metals and alloys" HR: Except aluminium beryllium silicate SK: 5(i), except aluminium beryllium silicate, whetting of beryllium metals and alloys; 2(i), Except aluminium beryllium silicate, other uses SI: 5(i), except aluminium beryllium silicate, grinding; 2 (i), Except aluminium beryllium silicate, other uses
Source: Analysis by RPA *i = inhalable, R = respirable* **Indicates that MS has more than one limit, at least one of which is higher than the proposed OEL, or that it is not clear if all uses are covered by the limit*		

8.6.2 Numbers of companies affected in different MS

Estimates have been made in Section 3 of this report of the number of companies operating with beryllium across the EU28 Member States. These estimates are reproduced below in Table 8-3 ranked by the highest total numbers of companies (excluding construction), across the 10 sectors. The five MS with the highest number of companies are Italy, Germany, France, Poland and Spain. When construction is included, the MS with the highest number of companies across the sectors are Italy, France, Germany, Spain and UK.

MS with the highest numbers of companies working with beryllium in each sector are likely to experience the greatest impacts, (in terms of both costs and benefits) from the introduction of harmonised OELs across the EU; Table 8-7 provides details on the MS with the highest number of companies broken down by each sector.

Table 8-7: The 5 MS with the highest numbers of companies working with beryllium, by sector	
Sector	Top 5 MS
Foundries	IT, DE, UK, PL, ES
Metal fabrication	IT, CZ, DE, PL, ES
Transport	UK, IT, DE, FR, PL
ICT	DE, UK, IT, FR, CZ
Specialist manufacturing	IT, FR, PL, DE, CZ
Medical devices	IT, DE, FR, PL, ES
Glass	IT, DE, PL, FR, ES
Construction	IT, FR, ES, DE, UK
Laboratories	IT, EL, DE, FR, UK
Recycling	FR, IT, UK, PL, RO
Source: Analysis by RPA	

8.7 Different timeframes for costs and benefits

The majority of chronic beryllium disease cases appear to occur within two years of exposure. This relatively short development time means that costs and benefits are occur at a roughly at the same time. Therefore, discounting has no significant effect upon the costs and the benefits.

9 Limitations and Sensitivity Analysis

9.1 Uncertainty about toxicological parameters

The benefits of alternative OELs for beryllium depend on the toxicological parameters, which enable the calculation of a dose response relationship (DRR) derived in Section 2. Firstly, only one combined critical endpoint, chronic beryllium disease (CBD) and/or beryllium sensitisation (BeS), is included. Secondly, our methodology allows for only one effect and one level of severity, whereas in reality the effects and severity may vary between higher and lower doses.

9.1.1 Uncertainty about cancer end-points

For beryllium, any risk quantification for cancer is rejected in this report in accordance to the SCOEL (2017) assessment, which assumes that beryllium is a threshold carcinogen with very low potency. The only cancer end-point is lung cancer. Elevated risk of cancer arises only at high exposure concentrations (over 10 µg/m^3) that are no longer seen in the EU. However, some cancer risk estimates indicate some elevated lung cancer risk at lower concentrations of occupational beryllium exposure (Schubauer-Berigan et al., 2011b). These analyses have been criticised (Boffetta et al., 2012; 2016) and were not adopted. The incidence of lung cancer from experimental animal studies do not quantitatively match the cancer potency (excess risk) derived from human data and the studies' design does not provide meaningful information on the exposure risk relationship (ERR) for beryllium. This means that a quantitative sensitivity analysis of an ERR for cancer effects is not feasible, but it may be concluded that the exclusion of any cancer risk at typical occupational exposure levels means some uncertainty and may underestimate health effects.

9.1.2 Uncertainty about non-cancer end-points

Regarding non-cancer effects, the exposure concentration corresponding to a threshold for chronic beryllium disease (CBD) and for beryllium sensitisation (BeS) are discussed at length in literature, without agreement. In this assessment, the starting point for the derived dose response relationship (DRR) is the OEL suggested by SCOEL as a threshold for non-cancer health effects. This is lower than the OEL in any other country and, therefore, is regarded as conservative. The DRR is based upon data taken from a recent US-OSHA (2015) assessment: this includes various modelling assumptions with significant uncertainties at higher exposure concentrations. Moreover, it is currently uncertain, whether everyone who experience CBD will also suffer from BeS and vice versa. Therefore the "true" DRR for CBD may differ from the "true" DRR for BeS.

In addition to CBD and BeS, there may be other non-cancer end-points such as adverse local respiratory effects, secondary haematological effects and skin sensitisations as a result of dermal contact: if these occur, they are likely to happen at higher occupational exposures, see section 2.5.4. However, a quantitative sensitivity analysis of these other effects is not feasible for three reasons. Firstly, these other non-cancer endpoints have not been selected for OEL derivation by SCOEL, secondly, the studies often do not provide a DRR validated for the occupational exposure scenario and thirdly, those studies are not equally reliable. For the reasons mentioned, the inclusion of only the CBD and BeS end-points tends to underestimate the total number of non-cancer cases after occupational exposure to beryllium at higher exposure levels and it tends to overestimate non-cancer risk at low exposures because of the conservative character of the OEL as derived by SCOEL.

Because the majority of the exposed workers tend to be operating at the lower levels of occupational exposure, with over 70% of workers operating at below 0.2 μg/m^3, see Tables 3-22 and 3-23, this implies that the benefits may be more likely to be overestimated.

9.2 Uncertainty about cost-benefit analysis

9.2.1 Uncertainty surrounding estimates of costs and benefits

Datasets

In arriving at the values for the baseline benefits and costs, several issues cause significant uncertainty. To predict the numbers of exposed employees and affected enterprises, three very different datasets (BeST, EU/US and US-OSHA) were created, see Section 3 and Table 9-1. The "middle" dataset EU/US was chosen as it seems the most suitable. As benefits are based on employees and costs on enterprises, the considerable difference in the ratios between these variables means that the cost-benefit analysis would vary significantly between the three datasets.

Table 9-1: Predicted exposed employees and affected enterprises for the three datasets, excluding construction

Dataset	BeST	EU/US	US-OSHA
Predicted exposed employees	13,532	54,071	73,580
Predicted affected enterprises	584	5,804	21,459
Ratio of employees to enterprises	23	9	3
Source: Modelling by RPA, see Tables 3.19 and 3.30			

The benefits are calculated from the number of exposed employees and exposure distributions based on average levels, because the Dose-Response Relationships are calculated from average exposure levels. The costs are calculated from the number of affected enterprises operating at exposure distributions based on 95th percentile levels, because companies aim to operate at much lower levels than the OEL to ensure that they can easily prove compliance to the authorities.

Altering the dataset has a significant effect upon the balance of costs to benefits. In conclusion, the study team believes that the BeST dataset probably underestimates the number of exposed workers and affected enterprises and that the US-OSHA dataset overestimates them. The best estimate maybe with the adjustment of 50% made to the foundries and medical devices sectors, see below, which overall would reduce the exposed workers to 4,377 and affected enterprises to 47,699. But the impact on both the benefits and costs would be approximately in proportion.

Number of workers in specific sectors

When the estimates of exposed workers were examined, two sectors may be overestimating the number of exposed workers because of the difference between the USA and the EU. Firstly, in the case of foundries, the USA mines beryllium and some of the foundries in the USA data are the foundries where the beryllium is smelted. No beryllium is mined in the EU, the foundries mainly specialise in other metals. Beryllium smelting and casting is usually a small element of a foundry's operation. The study team believes that a better estimate is to reduce the number of employees and enterprises in the foundries sector by 50% (2,500 fewer exposed workers and 115 fewer affected enterprises.)

Secondly, in the case of medical devices, the USA data appears to be mainly for dental laboratories. Although beryllium is not banned in dental devices, its use has been greatly reduced and is much safer compared with 20-30 years ago. However, as can be seen in Table 9-4, the impact of altering these alters both the benefits and costs by roughly the same proportion. The study team believes that a better estimate is to reduce the number of employees and enterprises in the medical devices sector by 50% (6,400 fewer exposed workers and 1,300 fewer affected enterprises.)

Distribution

Altering the distribution has a complex impact, but the increase in costs is at least as great as the increase in benefits. In general, the US-OSHA distribution takes the current exposure levels to a higher level than the BeST distribution. The impact on benefits and costs are shown in Tables 9-2 and 9-3: the changes are significant for both and vary considerably depending upon OELV. The BeST distribution is based upon a BeST customer survey made in the EU when companies had generally been working to an OEL of 2µg/m^3 (inhalable) or lower. It is also possible that well-run companies operating at the lower exposure levels were more likely to respond, which may mean that the BeST distribution underestimates exposure levels. The US-OSHA distribution is based upon data collected in the USA between 2007 and 2010 before the PEL of 0.2µg/m^3 (total particulate) was introduced and when US companies were working to a higher PEL of 2µg/m^3 (total particulate). This means that the US-OSHA distribution may overestimate the exposure levels.

Overall, it seems quite possible that the BeST distribution understates the levels of exposure in the EU and that the distribution is closer to the US-OSHA distribution. In particular, it seems likely that there are at least a few companies operating above 5 µg/m^3.

Average to 95th percentile conversion

For the cost analysis, average exposures have to be converted to 95th percentile values, but the ratio of 95th percentile to average varies with every dataset. For the beryllium study, a conversion factor of 2.3 was derived from a similar dataset. However, this factor could realistically have been set anywhere between 2 and 5 or higher. The study team estimates that the former would have slightly reduce costs and the latter would increase them significantly, probably doubling or more. There is no corresponding change in benefits.

Analysis method conversion

Throughout the analysis, any data from US-OSHA was measured using the total particulate method, whereas all European measurements and OELs are based upon the inhalable method. There are differing views on the use of a conversion factor between total particulate and inhalable results. SCOEL does not think there should be a conversion factor; research by Kock et al, (2015) derived a value of 2.88; and an assessment by AGS in Germany to set their OEL used a conversion factor of 2. For this beryllium study, a conversion factor of 2 was used. If a conversion factor of 2.88 or 3 had been used, the study team estimates that the costs and benefits would both increase by about 50%. If a conversion factor of 1 had been used, the study team estimates that the costs and benefits would both decrease by about 50%. Overall, the effect would be neutral.

Construction

Construction is kept separate during the analysis because it is unclear where, if at all, beryllium is found in the industry and because the sector is large, so it has a large impact upon the results.

Delay between costs and benefits

Because the onset of chronic beryllium disease occurs relatively quickly after exposure to beryllium, usually within five years, the benefits begin to occur within a few years of the reduction in exposure levels and the implementation costs.

9.3 Sensitivity analysis

9.3.1 Sensitivity analysis – benefits

The benefits model was run with several variables in turn altered to understand the sensitivity to each variable. The TOTAL benefits for the baseline (BeST distribution, Method 1, constant workforce, static future burden and static discount rate of 4%) is compared with four other scenarios (US-OSHA distribution, Method 2, workforce turns over a 5% per year), dynamic future burden and declining discount rate of 3% after 20 years) in Table 9-2. The scenario for the dynamic future burden of disease is for exposed workers decreasing by 3% per year and exposure levels decreasing by 2% per year (in addition to any changes caused by introducing an OELV.)

Table 9-2: Sensitivity analysis for beryllium: estimated TOTAL benefits (present value for 60 years) in € millions by target OELV for baseline compared with scenarios which alter one variable

Variable/ Target OELV inhalable	2 µg/m^3	1 µg/m^3	0.6 µg/m^3	0.35 µg/m^3	0.2 µg/m^3	0.1 µg/m^3	0.05 µg/m^3	0.02 µg/m^3
Baseline	55	111	156	184	227	268	291	293
US-OSHA distribution *	337 (536%)	434 (309%)	498 (232%)	538 (204%)	587 (169%)	640 (149%)	675 (142%)	678 (141%)
Method 2	221 (299%)	441 (299%)	622 (299%)	734 (299%)	904, (299%)	1,067 (299%)	1,160 (299%)	1,167 (299%)
Workforce turns over at 5% per year	80 (44%)	159 (44%)	224 (44%)	265 (44%)	326 (44%)	384 (44%)	418 (44%)	420 (44%)
Dynamic future burden exposed workers -3% pa & exposure levels -2% pa	10 (-83%)	26, (-76%)	48 (-69%)	63 (-66%)	72 (-68%)	92 (-65%)	105 (-64%)	106 (-64%)
Declining discount rate 3% after 20 years	61 (10%)	122 (10%)	172 (10%)	203 (10%)	250 (10%)	295 (10%)	321 (10%)	322 (10%)

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Values in brackets are the percentage change relative to the baseline for a static discount rate shown in Table 4-18. Percentages may not appear exactly accurate due to rounding.

** Values for seven sectors, percentages compared with BeST distribution for seven sectors*

9.3.2 Sensitivity analysis – costs

The costs model was run with several variables in turn altered to understand the sensitivity to each variable. The TOTAL costs for the baseline (BeST distribution, static discount rate of 4%, CAPEX incurred every 20 years, OPEX set to 10% of CAPEX) is compared with four other scenarios (US-OSHA distribution, declining discount rate of 3% after 20 years, CAPEX every 10 years, CAPEX every 15 years, OPEX of 20% and OPEX of 50%) in Table 9-3.

Table 9-3: Sensitivity analysis for beryllium: estimated TOTAL costs (present value for 60 years) in € millions by target OELV for baseline compared with scenarios which alter one variable

Variable/ Target OELV inhalable	2 µg/m³	1 µg/m³	0.6 µg/m³	0.35 µg/m³	0.2 µg/m³	0.1 µg/m³	0.05 µg/m³	0.02 µg/m³
Baseline	2	15	41	88	134	1,003	2,604	7,989
US-OSHA distribution *	7 (250%)	25 (79%)	55 (41%)	365 (340%)	499 (296%)	1,782 (89%)	3,977 (63%)	20,108 (168%)
Declining discount rate 3% after 20 years	2 (0%)	15 (0%)	42 (2%)	91 (3%)	137 (2%)	1,057 (5%)	2,753 (6%)	8,470 (6%)
CAPEX every 10 years	2 (30%)	19 (28%)	53 (27%)	110 (25%)	168 (26%)	1,078 (7%)	2,731 (5%)	8,192 (3%)
CAPEX every 15 years	2 (10%)	16 (9%)	45 (9%)	95 (8%)	145 (9%)	1,028 (2%)	2,646 (2%)	8,057 (1%)
OPEX 20% of CAPEX	2 (39%)	23 (56%)	65 (58%)	138 (57%)	208 (56%)	1,168 (16%)	2,883 (11%)	8,440 (6%)
OPEX 50% of CAPEX	4 (143%)	42 (181%)	120 (189%)	254 (189%)	373 (179%)	1,515 (51%)	3,441 (32%)	9,354 (17%)

Source: Modelling by RPA

Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction; Values - Euros millions 60 years present value. All financial values are relative to the baseline. Values in brackets are the percentage change relative to the baseline for a static discount rate shown in Tables 5-12 and 5-15. Percentages may not appear exactly accurate due to rounding.

** Values for seven sectors, percentages compared with BeST distribution for seven sectors*

9.3.3 Sensitivity analysis - summary

The impact of altering the many variables is summarised in Table 9-4.

Table 9-4: Sensitivity analysis – parameters that could have a significant impact upon the benefits , costs and overall

Variable	Benefits	Costs	Overall
BeST dataset	Significant reduction (-75%)	Significant reduction (-90%)	Reduction in costs compared with benefits
US-OSHA dataset	Increase (+30%)	Significant increase (+250%)	Significant increase in costs compared with benefits
Halve number of employees and enterprises in the foundries sector	Neutral (+5%)	Neutral (+2%)	Neutral
Halve number of employees and enterprises in the medical devices sector	Reduce (-12%)	Reduce (-22%)	Neutral
US-OSHA distribution	Significant increase (+150 to +500%)	Significant increase (+50 to +350%)	Varying
Discount rate changes to 3% after 20 years	Neutral (+10%)	Neutral (+5%)	Neutral
Benefits model – method 2	Significant increase (+300%)	Not applicable	Significant increase in benefits (+300%)
Staff turnover of 5% per year	Increase (+40%)	Not applicable	Increase in benefits (+40%)
Dynamic future burden of disease with exposed workers decreasing by 3% per year and exposure levels decreasing by 2% per year	Significant decrease (-70%)	Not applicable	Significant decrease in benefits (-70%)
CAPEX every 10 years	Not applicable	Increase (+25%) *	Increase in costs (+25%) *
CAPEX every 15 years	Not applicable	Neutral	Neutral
OPEX 20% of CAPEX	Not applicable	Increase (+50%) *	Increase in costs (+50%) *
OPEX 50% of CAPEX	Not applicable	Increase (+200%) *	Increase in costs (+200%) *

Source: Modelling by RPA
** Over 0.2 µg/m^3*

9.3.4 Sensitivity analysis - conclusion

The study team believes that several of the changes discussed above are probably closer to reality that the baseline and these should be included conclusions. Only non-neutral changes are considered. These are:

- Staff turnover at 5% per year;
- Dynamic future burden;
- OPEX at 20% of CAPEX; and
- US-OSHA distribution.

The study team believes that the impact of staff turnover is should be included. This increases the benefits by approximately 50%.

The dynamic future burden, which allows for workforce and exposure levels to annually decrease, has a significant impact upon benefits, reducing them by approximately 70%. Exposed workers were set to decrease by 3% per year and exposure levels decrease by 2% per year. These rates appear high, but during the study it has become apparent that automation to improve productivity will potentially have the largest impact upon exposure levels. The four Member States with the most exposed employees, Germany, France, Italy and the United Kingdom, are all investing heavily in automation to improve their productivity and the high technology industries that use beryllium are some of the most profitable and hence the most important to retain and improve.

The study team is concerned that the costs in the range of 0.2 to 1 $\mu g/m^3$ appear too low and realises that the OPEX, which is set as a percentage of the CAPEX, is probably set too low at 10%. If this percentage is raised to 20%, as some respondents have indicated would be more appropriate, costs rise by 50%: interestingly the rise occurs specifically in the range of target OELVs between 0.2 and 1 $\mu g/m^3$.

These three variables combined are estimated to give an overall increase in costs of about 50% compared with benefits. The greatest uncertainty is the exposure distribution. If the EU does have higher exposure levels than the BeST survey implies and they are more in line those of the USA, then the costs and thus company closures, and the benefits could be very significantly different to those predicted.

10 Conclusions

10.1Cost-benefit assessment

The cost-benefit analysis compares the costs of implementing an OELV with the benefits of having an OELV. Figure 10-1 provides the data for costs and benefits (Methods 1 and 2) based on the EU/US dataset and the BeST distribution shown in Tables 4-18, 4-19 and 5-10. The band for each method represents the range from the lower benefits associated with a constant workforce to the higher benefits associated with a workforce that turns over at 5% per year. The construction sector is excluded. The x-axis of the graph is not to scale (i.e. it is not linear): the costs rise steeply below 0.2 µg/m^3.

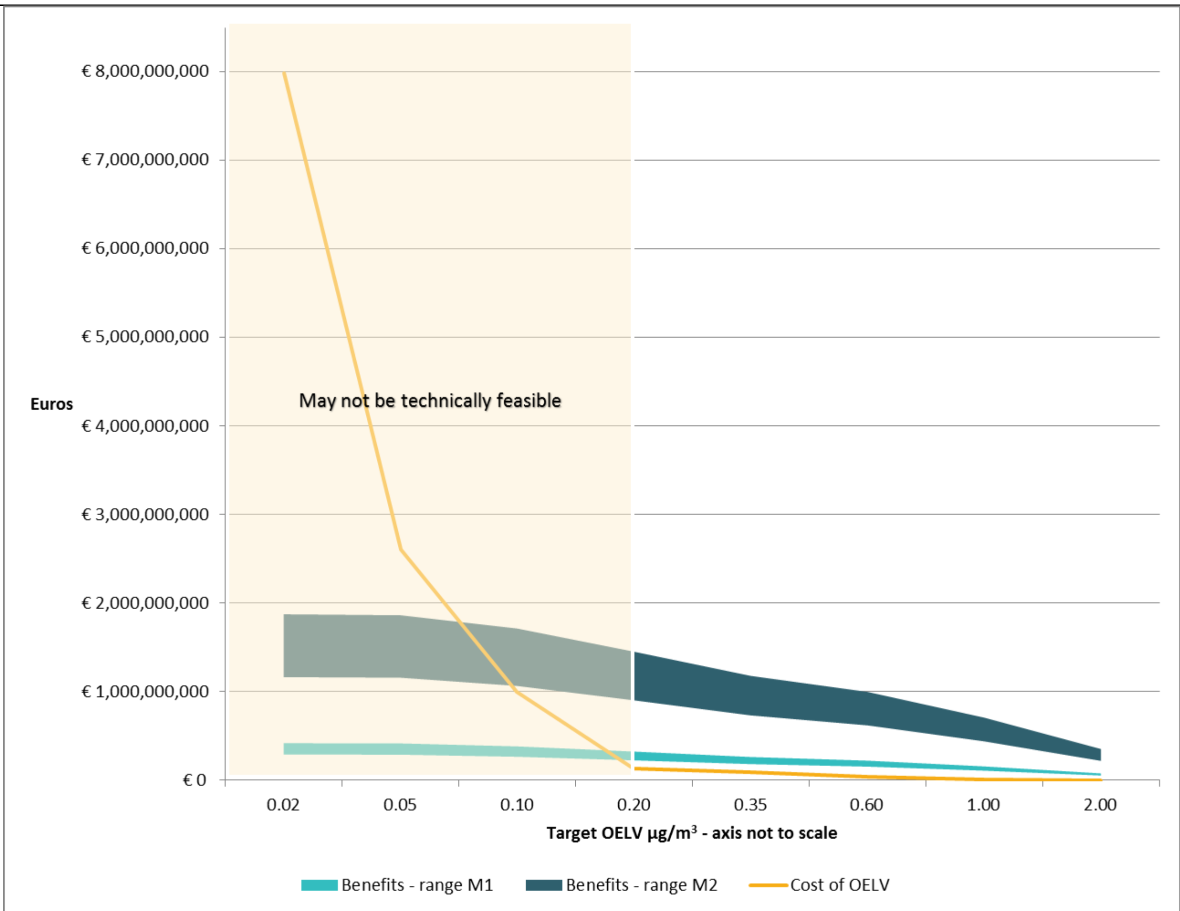

Figure 10-1 Estimated TOTAL cost (CAPEX and OPEX) for 60 year PV and estimated benefits of having an OELV using Methods 1 and 2, with a static future burden and OPEX as 10% of CAPEX. For each Method, the benefits range from those with a constant workforce to a workforce with a turnover of 5% per year.
Notes: Dataset - EU/US; Exposure distribution - BeST; Nine sectors excluding construction; Values - €millions 60 years present value. All financial values are relative to the baseline. Target OELVs are inhalable

Figure 10-2 provides the data for costs and benefits (Method 1 and 2) based on the EU/US dataset and the US-OSHA distribution shown in Tables 4-18, 4-19 and 5-11.

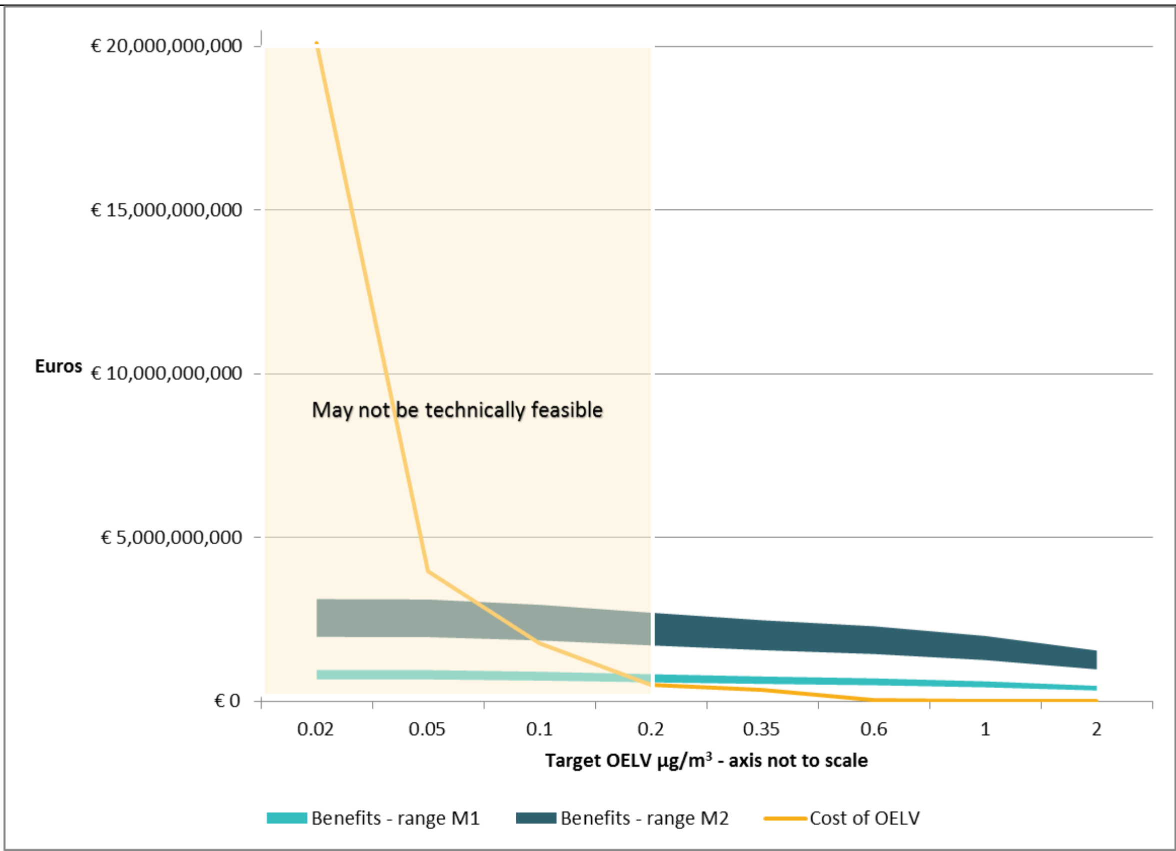

Figure 10-2 Estimated TOTAL cost (CAPEX and OPEX) for 60 year PV and estimated benefits of having an OELV using Methods 1 and 2, with a static future burden and OPEX as 10% of CAPEX. For each Method, the benefits range those with a constant workforce to a workforce with a turnover of 5% per year.
Notes: Dataset - EU/US; Exposure distribution - OSHA; Seven sectors excluding construction, laboratories and recycling; Values - €millions 60 years present value. All financial values are relative to the baseline. Target OELVs are inhalable

Looking at the Method 1 results in Figures 10-1 and 10-2, the point where the costs exceed the benefits is at 0.2 µg/m^3. With Method 2, costs exceed the benefits between 0.05 µg/m^3 and 0.1 µg/m^3. There is considerable uncertainty between the two Methods. However, in every cost calculation made in the study, the costs climb steeply below 0.2 µg/m^3.

The sensitivity analysis in section 9.3 concluded that four variables were likely to be important:

- Staff turnover at 5% per year;
- US-OSHA distribution.
- Dynamic future burden;
- OPEX at 20% of CAPEX; and

Two of the variables are already included within the data for Figures 10-1 and 10-2. In both figures, the ranges for each Method are from the benefits with a constant workforce to the benefits with a workforce turning over at 5% per year. In Figure 10-2, the impact of using the US-OSHA distribution is shown.

The effect of incorporating the other two variables is shown in Figure 10-3. This illustrates the impact of a dynamic future burden, where the number of exposed workers falls by 3% per year and exposure levels fall by 2% per year, and OPEX taken as 20% of the CAPEX. In this scenario, the costs rise above the Method 1 benefits at 0.6 µg/m^3.

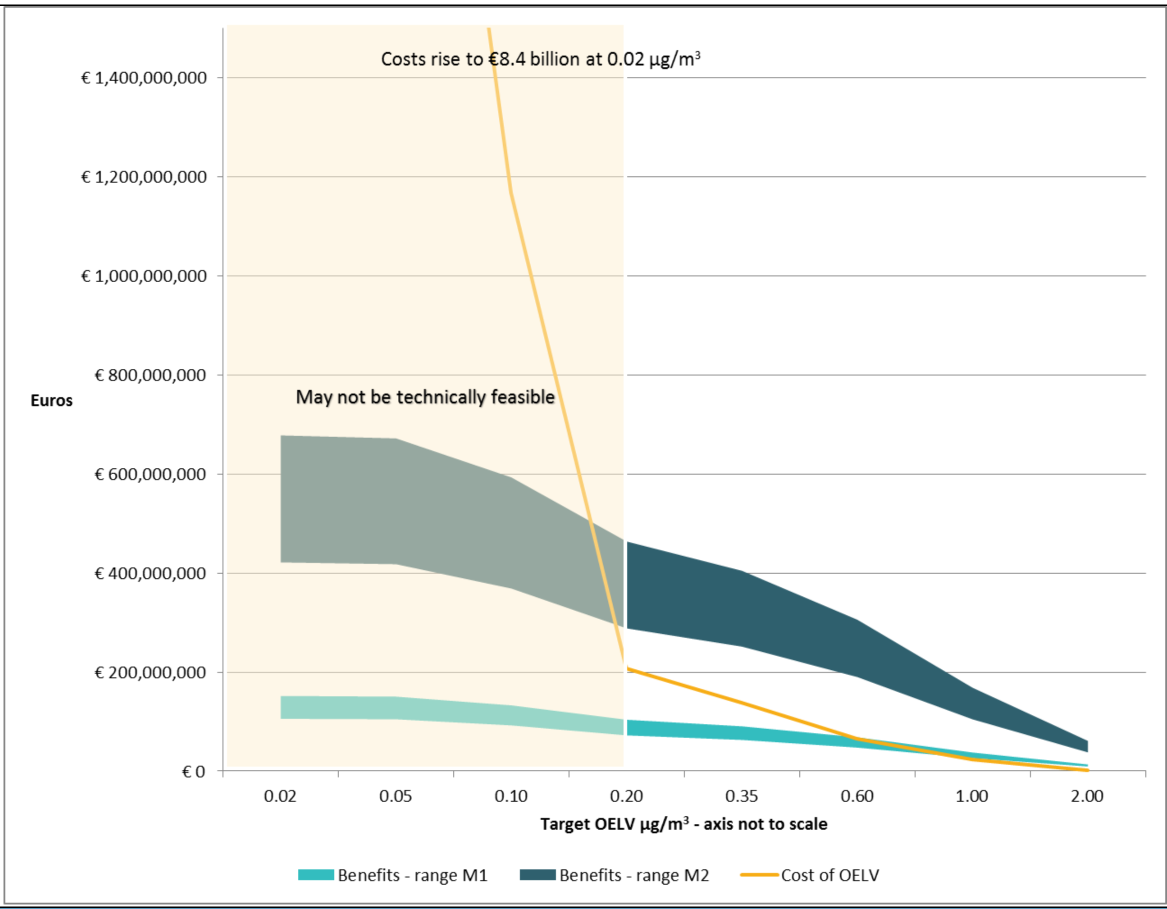

Figure 10-3 Estimated TOTAL cost (CAPEX and OPEX) for 60 year PV and estimated benefits of having an OELV using Methods 1 and 2, with a dynamic future burden and OPEX as 20% of CAPEX. For each Method, the benefits range from those with a constant workforce to a workforce with a turnover of 5% per year.
Notes: Dataset - EU/US; Exposure distribution - BeST; Nine sectors excluding construction; Values - €million 60 years present value. All financial values are relative to the baseline. Target OELVs are inhalable

10.2Multi-criteria analysis

Table 10-1 below summarises both the monetised impacts and those assessed qualitatively.

Table 10-1: Multi-criteria analysis (beryllium)

Impact	Stakeholders affected	<=0.1 µg/m^3	0.2 - 0.6 µg/m^3	1 - 2 µg/m^3
Economic impacts				
Compliance costs **	Companies	> €1 billion *	€40-130 million *	< €15 million *
Transposition costs	Public sector	€1.35 million	€1.15 million	€300,000
Benefits from reduced ill health	Reduction in cases (cancer)	0	0	0
	Reduction in cases (CBD)	2,800 -3,100	1600 – 2,400	600 - 1,200
	Reduction in DALYs	20,000 – 22,000	12,000 – 17,000	4,000 – 8,000
	Employers	> €17 million	€10 - 15 million	< €7 million
	Public sector	> €25 million	€15 - 21 million	< €10 million
Single-market: competition	Company closures	23 – 232 closures	*0*	*0*
Single-market: consumers	Consumers	*Limited impact expected*		
Single-market: competition/ level playing field	Companies	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 'no difference'	***Significant positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 6	***Moderate positive*** Reduction of highest OEL/lowest OEL ratio from 50 to 20
Specific MSs/regions	Member States	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK, plus IT, LU, MT, NL, PT	AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT	EL plus IT, LU, MT, NL, PT
Health and social impacts				
Ill health (CBD) avoided including intangible costs	Workers & families	> €240 million	€140 - 200 million	< €100 million
Employment	Jobs lost	210 – 2,100	0	0
	Social cost ***	€17 – 180 million	0	0
Environmental impacts				
Environmental releases	All	*Neutral impact*		

Source: Modelling by RPA

*Notes: Dataset - EU/US; Exposure distribution - BeST; Sectors – nine excluding construction; Values - Euros millions 60 years present value. *Estimated using the cost model estimated for this study. **Includes company closures.***Social cost of displacement (assumes worker finds a new job but suffers from the disruption and stress involved in finding a new job).*

There are several further issues requiring consideration.

At first sight, the list of existing OELs in Table 3.1 appears to show that Germany, a Member State with many enterprises using beryllium, has an OEL of 0.14 μg/m^3. Therefore, why not implement this low OEL across the EU? However, the **German OEL is not binding**. In Germany, companies are expected to implement the risk management measures laid down in the Technical Rules for Hazardous Substances (BauA 2017b) but, if the OEL cannot be achieved, there is no further sanction. Finland also has a low OEL at 0.1 μg/m^3 but Finland effectively has no beryllium industry.

Based upon detailed information from industry association BeST and all the industry respondents, achieving an OELV of 0.6 μg/m^3 appears reasonably straightforward but the actions required to achieve exposure levels below 0.6 μg/m^3 are considerably more expensive. After many conversations with the beryllium industry, it is clear that companies have **no idea how certain processes could achieve OELs below 0.2 μg/m^3**: the general view is that these processes would close or move outside the EU. In the USA, US-OSHA believes that the available evidence on feasibility suggests that 0.2 μg/m^3 (total particulate) may be the lowest feasible PEL. Taking a conversion factor of 3 from total particulate to inhalable, this implies that the lowest feasible OELV for the EU may be 0.6 μg/m^3 (inhalable.) Furthermore, the importance of beryllium to industry is shown by its presence on the **Critical Raw Materials list** for the third time (European Commission (2017)).

Based upon detailed information from industry association BeST, of the 18 melting processes used by foundries, transportation, specialist manufacturing, glass and recycling sectors, for five processes **no feasible measures** could be identified to meet levels at or below 0.2 μg/m^3 and a further 12 would **no longer be economically viable** at or below 0.2 μg/m^3. Of the 43 mechanical-machining processes used by all sectors except foundries and laboratories, for seven processes no feasible measures could be identified to meet levels at or below 0.2 μg/m^3 and a further 12 would no longer be economically viable at 0.2 μg/m^3 (Tables 3-5 and 3-6.)

The analytical method with the **lowest limit of quantification** (LoQ) available with an 'A' ranking can achieve detection at levels of 0.05 μg/m^3. To prove that a company is operating at a given OEL under the proposed new standards requires three readings at 10% of the OEL. Therefore, the lowest OEL that can currently be assessed by an 'A' ranking method is 0.5 μg/m^3 (Table 3-26.)

In the sensitivity analysis, **staff turnover** seems likely to the study team to cause a significant rise in benefits and a similarly significant fall in benefits may result from the effect of future **productivity automation** which seems likely to reduce the number of exposed workers and exposure levels regardless of the OELV. **OPEX as 20% of CAPEX** seems likely to cause a significant rise in costs particularly between 0.2 and 1 μg/m^3.

The **greatest uncertainty is exposure distribution**. If parts of the EU do have higher exposure levels than the BeST survey implies and closer to the USA distribution, then the costs, and hence company closures, would be significantly higher at all target OELVs: benefits are also significantly higher.

BeST has a **voluntary initiative** "Be Responsible, which started in 2017. This encourages customers to achieve the Recommended Exposure Guideline (REG) of 0.6 μg/m^3 (inhalable), measured as an 8-hour time weighted average (TWA). Currently, BeST has no information about the impact of this campaign and it is difficult to estimate what impact it might have upon exposure over time.

For target OELVs below 0.2 μg/m^3, **market concentration** and the closure of companies of **strategic, environmental and/or innovative** importance is likely to occur. The burden of implementing measures to achieve lower OELVs falls **disproportionately upon SMEs**, particularly companies employing less than 20 people.

10.3Recommendations

Overall, the study team believes that the breakeven point for an OELV for beryllium is between 0.2 and 0.6 µg/m^3 (inhalable). For the reasons outlined in the sensitivity analysis and multi-criteria analysis, the study team believes that an OELV of between 0.4 and 0.6 µg/m^3 (inhalable) may better reflect the breakeven point.

This is similar to the recommendation of the Advisory Committee on Safety and Health at Work (ACSH's) Working Group on Chemicals (2017) of an OELV of 0.2 µg/m^3 (inhalable) with a value of 0.6 µg/m^3 (inhalable) during a transitional period of 5 years.

The study team also recommends a transition period with an initial OELV of between 0.6 µg/m^3 (inhalable) and 1 µg/m^3 (inhalable). The study team recommends that the OELV is assessed again after a few years of the transition period to ensure that the industry has found ways of achieving the final value and analysis methods with limits of quantification down to 10% of the final OELV are available. It may be sensible to increase the transition period to seven or ten years to enable this intermediary check to take place.

In Table 3-1, several member States have OELs which have a higher level for whetting of beryllium metals and alloys (otherwise known as grinding) or specifically for grinding. The study does not believe that there should be a distinction between grinding and other activities. Grinding is a hazardous activity and should be subject to the same OELVs as other activities.

In line with many Member States, see Table 3-1, the study also recommends that aluminium beryllium silicate is exempt from the OELV.

Further primary research, which monitors exposure levels, is required to investigate whether there is an issue with beryllium in construction. It seems likely that any exposure to beryllium occurs in specific construction processes and it is important to identify exactly which these are. The study team recommends that the first construction processes to be investigated are abrasive blasting (sandblasting) and cement/concrete production and use.

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Annex 1 Summary of consultation responses

Responses to consultation relevant to beryllium are given in Table A1-1

Table A1-1: Number of responses relevant to beryllium	
Questionnaire responses	3
Interviews	4
Site visits	3
Total	**9**

Other consultation activities included a face-to-face one day meeting was carried out with all members of BeST – the Beryllium Science and Technology Association and a further half day meeting in mid January 2018. There was also a telephone call meeting with key members of US-OSHA, including the project manager responsible for the recommendation from US-OSHA to set the USA PEL at 0.2µg/m^3 (total particulate). There was however a relatively smaller number of questionnaire responses, interviews and site visits overall for beryllium due to the difficulty in identifying users. Some of the uses identified were also difficult to account for, with many of those questioned not aware of some of the more specific and limited uses.

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