Ref. Ares(2018)1092770 - 27/02/2018

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 cadmium and its inorganic compounds

February – 2018

Social Europe

LEGAL NOTICE

Manuscript completed in February 2018

Luxembourg: Publications Office of the European Union, 2019

PDF ISBN 978-92-76-07991-0 doi:10.2767/695769 KE-02-19-399-EN-N

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

Cadmium and its inorganic compounds

8 February 2018

Final Report

Quality Assurance	
Project reference / title	J967/DGEmp OELVs 3
Report status	Final Report
Main Authors	Daniel Vencovsky (RPA), Meg Postle (RPA), Dr Fritz Kalberlah (FoBiG), David Fleet (RPA), Jan Oltmanns (FoBiG)
Approved for issue by	Meg Postle (RPA)
Date of issue	8 February 2018

Document Change Record			
Report	**Version**	**Date**	**Change details**
Draft Final Report	2.0	3 January 2018	
Draft Final Report	3.1	26 January 2018	
Final Report	4.0	8 February 2018	

Disclaimer

The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

Acknowledgement

This study has received financial support from the European Union Programme for Employment and Social Innovation "EaSI" (2014-2020). For further information please consult: http://ec.europa.eu/social/easi

This project is funded by
the European Union

Table of contents

List of abbreviations and acronyms ... 12

Executive summary ... 15

1 Introduction ... 1

1.1 Background ... 1

1.2 Objectives ... 1

1.3 Structure of the report ... 2

2 Background and scope of the assessment ... 3

2.1 Background ... 3

2.1.1 SCOEL/OPIN/336 ... 3

2.1.2 ACSH Doc. 663/17 ... 3

2.2 Summary of epidemiological and experimental data ... 4

2.2.1 Identity and classification ... 4

2.2.2 General toxicity profile, critical endpoints and mode of action ... 4

2.2.3 Cancer endpoints – toxicological and epidemiological key studies (existing assessments) 6

2.2.4 Non-cancer endpoints – toxicological and epidemiological key studies (existing assessments) ... 7

2.2.5 Biological monitoring – toxicological and epidemiological key studies (existing assessments) ... 8

2.2.6 Different toxicological properties for various inorganic cadmium compounds ... 8

2.3 Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects) ... 8

2.3.1 Starting point ... 8

2.3.2 ERR for carcinogenic effects (air concentration) ... 9

2.3.3 DRR for non-carcinogenic effects (air concentration) ... 12

2.3.4 DRR for carcinogenic and non-carcinogenic effects (biomonitoring) ... 15

2.4 Study scope ... 17

2.4.1 Selection of the relevant measures ... 17

2.4.2 Selection of the relevant compounds ... 17

2.5 Background information on cadmium and its inorganic compounds ... 18

2.5.1 Cadmium ... 18

2.5.2 Cadmium alloys ... 19

2.5.3 Cadmium chloride ... 20

2.5.4 Cadmium fluoride ... 20
2.5.5 Cadmium sulphate ... 20
2.5.6 Cadmium sulphide ... 21
2.5.7 Cadmium oxide ... 21
2.5.8 Cadmium carbonate ... 22
2.5.9 Cadmium hydroxide ... 23
2.5.10 Cadmium nitrate ... 23
2.5.11 Cadmium sulfate hydrate ... 23
2.6 Reference points for the assessment (OELVs) ... 23

3 The Baseline Scenario ... 25
3.1 Introduction ... 25
3.2 Existing national limits ... 25
3.3 Relevant sectors, uses, and operations ... 31
3.4 Exposed workforce ... 33
3.4.1 Total number of exposed workers ... 33
3.4.2 Comparison of data for France from the different data sources ... 36
3.4.3 Sectoral break-down ... 38
3.4.4 Trends ... 40
3.4.5 Exposed workers: conclusion ... 40
3.5 Exposure concentrations ... 40
3.5.1 Current exposure concentrations ... 40
3.5.2 Trends ... 44
3.6 Current Risk Management Measures (RMMs) ... 45
3.7 Voluntary industry initiatives ... 49
3.8 Best practice ... 55
3.8.1 Risk Management Measures ... 55
3.9 Standard monitoring methods/tools ... 56
3.9.1 Analytical methods identified from desk research and consultation ... 56
3.10 Relevance of REACH Restrictions and Authorisation ... 58
3.10.1 Introduction ... 58
3.10.2 Cadmium Compounds on the Candidate List for Authorisation ... 59
3.10.3 Restriction ... 60
3.11 Market analysis ... 62
3.12 Alternatives ... 64
3.13 Current disease burden (CDB) ... 64
3.14 Future disease burden (FDB) ... 65
3.15 Summary of the baseline scenario ... 66

4 Benefits of the measures under consideration ... 68
4.1 Introduction ... 68
4.2 Summary of the assessment framework ... 68
4.2.1 Summary of the key features of the model ... 68
4.2.2 Relevant health endpoints for cadmium ... 70
4.2.3 Summary of the key assumptions for cadmium ... 71
4.3 Avoided cases of ill health (cancer and non-cancer) ... 75
4.4 Benefits to workers & families ... 77
4.5 Benefits to the public sector ... 79
4.6 Benefits to employers ... 81
4.7 Aggregated benefits ... 83

5 Costs of the measures under consideration ... 86
5.1 Introduction ... 86
5.2 The cost framework ... 86
5.2.1 Summary of the cost assessment framework ... 86
5.3 OELVs – compliance costs for companies ... 88
5.3.1 Introduction ... 88
5.3.2 Current exposure levels ... 90
5.3.3 Sector/use-specific cost curves ... 93
5.3.4 Measurement costs ... 97
5.4 OELVs – indirect costs for companies ... 99
5.5 OELVs – costs for public authorities ... 102
5.5.1 Costs of transposition ... 102
5.5.2 Enforcement costs ... 103
5.6 Aggregated costs ... 103
5.6.1 Extrapolation from Cap Ingelec (2017) ... 103
5.6.2 Cost data estimated by the model developed for this study (unadjusted) ... 104
5.6.3 Cost data estimated by the model developed for this study (adjusted) ... 104
5.6.4 Comparison of the three cost estimates ... 104
5.6.5 Conclusion ... 106

6 Market Effects ... 107
6.1 Overall impact ... 107
6.2 Research and innovation ... 108
6.3 Single market ... 109
6.3.1 Competition ... 109
6.3.2 Consumers ... 111

6.3.3 Internal market 112
6.4 Competitiveness of EU businesses 113
6.4.1 Cost competitiveness 113
6.4.2 Capacity to innovate 114
6.4.3 International competitiveness 114
6.5 Employment 115

7 Environmental Impacts 117
7.1 PBT screening 117
7.2 Current environmental levels in relation to hazard data 117
7.3 Current environmental exposure – sources and impact 118
7.3.1 Cadmium in food 119
7.3.2 Potential impacts from relocation of industries 119
7.4 Conclusion 121

8 Distribution of the Impacts 122
8.1 Businesses 122
8.2 SMEs 123
8.3 Workers 125
8.4 Consumers 125
8.5 Taxpayers/public authorities 126
8.6 Specific Member States/regions 126
8.7 Different timeframes for costs and benefits 128

9 Limitations & sensitivity analysis 129
9.1 Overview of limitations and uncertainties 129
9.2 Key limitations and uncertainties 130
9.2.1 Conversion factor between respirable and inhalable 130
9.2.2 Exposed workforce greater than 10,000 131
9.2.3 Additional ill-health endpoints 131
9.2.4 ERRs/DRRs 132
9.2.5 Air concentrations vs Cd-U 133
9.2.6 Future trends 135
9.2.7 Discount rate 135
9.2.8 Use of AM/GM vs P95 in the case of a threshold substance 135
9.2.9 Assessing the effects of elevated proteinurea 136

10 Conclusions 137
10.1 Cost-benefit assessment (CBA) 137

10.1.1 Overview of the benefits for the reference OELVs ... 137
10.1.2 Overview of the costs for the reference OELVs ... 138
10.1.3 CBA for the reference OELVs ... 138
10.2 Multi-criteria analysis (MCA) ... 140

11 References ... 143

Annex 1 Summary of Consultation ... 150

Annex 2 Summary of the Cap Ingelec (2017) study ... 151
A2.1 Introduction ... 151
A2.1.1 Scope of the study ... 151
A2.1.2 Summary of the methodology ... 151
A2.2 Methods for specific sectors ... 152
A2.2.1 Industrial battery production ... 152
A2.2.2 Zn/Cd refining ... 155
A2.2.3 Other segments ... 158
A2.3 Overall results ... 159

Annex 3 Estimates of ESRD Cases ... 161

List of abbreviations and acronyms

ACGIH	American Conference for Governmental Industrial Hygienists
ACSH	Advisory Committee of Safety and Health at Work
AGS	Committe for Hazardous Substances (Ausschuss für Gefahrstoffe)
AM	Arithemetic Mean
BIV	Biological Limit Value
CAPEX	Capital Expenditure
CBA	Cost Benefits Analysis
CDB	Current Disease Burden
CFC	Closed-Faced Filter Cassette
CGA	Comprehensive Geriatric Assessment
CI	Confidence interval
C&L	Classification and Labelling
CKD	Chronic Kidney Disease
CLH	Harmonised classification and labelling
CMD	The Carcinogens and Mutagens Directive
CSR	Chemical safety report
DALY	Disability adjusted life years
DNEL	Derived No Effect Level for substances
DRR	Dose Response Relationship
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ERR	Exposure-risk relationship
ESKD	End Stage Kidney Disease
ESRD	End Stage Renal Disease
EU-OSHA	European Agency for Safety and Health at Work
EQS	Environmental Quality Standard
FDB	Future Disease Burden
FIOH	Finnish Institute of Occupational Health
GDV	General Dilution Ventilation
GFR	Glomerular Filtration Rate
GM	Geometric mean
IA	Impact Assessment
IARC	International Agency for Research of Cancer
ICdA	International Cadmium Association
IFA	Institute for Occupational Safety and the German Statutory Accident Insurance (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung)
IIAC	Industrial Injuries Advisory Council
INRS	The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases
KEMI	Swedish Chemicals Agency (Kemikalieinspektionen)
LEV	Local exhaust ventilation
LFC	Lowest Feasible Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOD	Level of detection
LOQ	Limit of quantification
MCA	Multi-Criteria Analysis
MoA	Mode of Action
MRL	Minimal risk level
MS	Member States
NIOSH	National Institute for Occupational Safety and Health
OCdAIR	Observatory of Occupational Cd AIR exposure
OEL	Occupational exposure limit

OELV	Occupational exposure limit value
OPEX	Operational Expenditure
OPIN	Opinion
OSH	Occupational health and safety
PBT	Persistent, Bio-accumulative and Toxic
PEL	Permissible Exposure Limit
PNEC	Predicted No Effect Concentrations
POD	Point of Departure
PPE	Personal protective equipment
ppb	parts per billion
ppm	parts per million
PROC	The process categories
PV	Present value
PVC	Polyvinyl Chloride
R&D	Research and Development
RAC	Committee for Risk Assessment
RAR	Risk assessment report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REL	Recommended Exposure Limits
RMM	Risk Management Measure
RMOA	Risk Management Options Analysis
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-economic analysis
SEG	Same Exposure Group
SME	Small and medium-sized enterprise
STEL	Short-Term Exposure Limits
SU	Sector of Use
SVHC	Substance of very high concern
tpa	Tonne per annum
TWA	Time weighted average
UVCB	Substance of Unknown or Variable Composition, Complex Reaction Products or Biological Materials
VOLY	Value of a life year lost
vPvB	Very Persistent and Very Bio-accumulative
VSL	Value of a statistical life
VSLY	Value of a statistical life year
WEEE	Waste Electronical and Electronic Equipment Recycling
WHO	World Health Organisation
WTP	Willingness to pay

Executive summary

The objective of this study is to support the European Commission's Impact Assessment of a potential Occupational Exposure Limit Value (OELV) for cadmium and its inorganic compounds under the Carcinogens and Mutagens Directive (Directive 2004/37/EC).

The costs and benefits (relative to the baseline) estimated in this report for the different reference OELVs are summarised in the tables below.

Table 1: Summary of monetised costs and benefits (static discount rate, additional to the baseline)		
Reference OELV	**PV benefits* over 60 years (€2017 million)**	**PV costs over 60 years (€2017 million)**
25 µg/m³ (inhalable fraction)	(0.9-) 2–6	4 (179)
10 µg/m³ (inhalable fraction)	(4-) 8–34	14 or 44 (591)
5 µg/m³ (inhalable fraction)	(5-) 12–58	71 or 116 (711)
4 µg/m³ (inhalable fraction)	(6-) 13–64	79 or 116 (735)
1 µg/m³ (inhalable fraction)	(7-) 14–66	448 (758)
Monetised costs and benefits	Avoided lung cancer and elevated proteinurea cases vis-à-vis the baseline	RMMs Discontinuation of business** Transposition costs Measurements
Notes: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. *Values in brackets relate to sensitivity analysis using Cd-U DRR, lowest value of all scenarios. **Some methods (e.g. extrapolation from Cap Ingelec (2017) do not include these costs).		

However, it should be noted that, due to the large number of uncertainties surrounding the estimates, the costs and benefits in the CBA and MCA should only be taken as an indication of the order of magnitude of the potential impacts of the OELVs. Therefore, the final conclusion should go beyond a simple comparison of the costs and the benefits that could be monetised in this study and should take into account all the information presented in this report, including the impacts that could not be monetised and the limitations and uncertainties of the analysis.

The overall costs and benefits of establishing an OELV at the different reference levels are shown in Figure 1 for a number of reference scenarios, illustrating the many uncertainties inherent in the analysis presented in this report. The scenarios presented in Figure 1 are summarised below. Please refer to Sections 3,4, and 9 of the report for a more detailed description of the scenarios.

Table 2: Description of the scenarios in Figure 1	
Scenario code	**Description**
Benefits-C-M1-C	Benefits - Core Scenario - Method 1 - Constant Workforce
Benefits-C-M2-T	Benefits - Core Scenario - Method 2 - Workforce 5% p.a. turnover
Benefits-S-M1-C-Cd-U DRR A2000 M	Benefits - Sensitivity - Method 1 - Constant Workforce - Cd-U DRR workers after 2000, middle of range values
Benefits-S-M2-C-Cd-U DRR All T	Benefits - Sensitivity - Method 2 - Workforce 5% turnover - Cd-U DRR, all workers, top of range values
Costs-C-Mod-Ad	Costs - Core Scenario - RPA Model - Adjusted based on additional ICdA data
Costs-C-Mod-N	Costs - Core Scenario - RPA Model - Not adjusted (underestimate)
Costs-C-Cap Ingelec 2017	Costs - Core - Extrapolation from Cap Ingelec (2017)

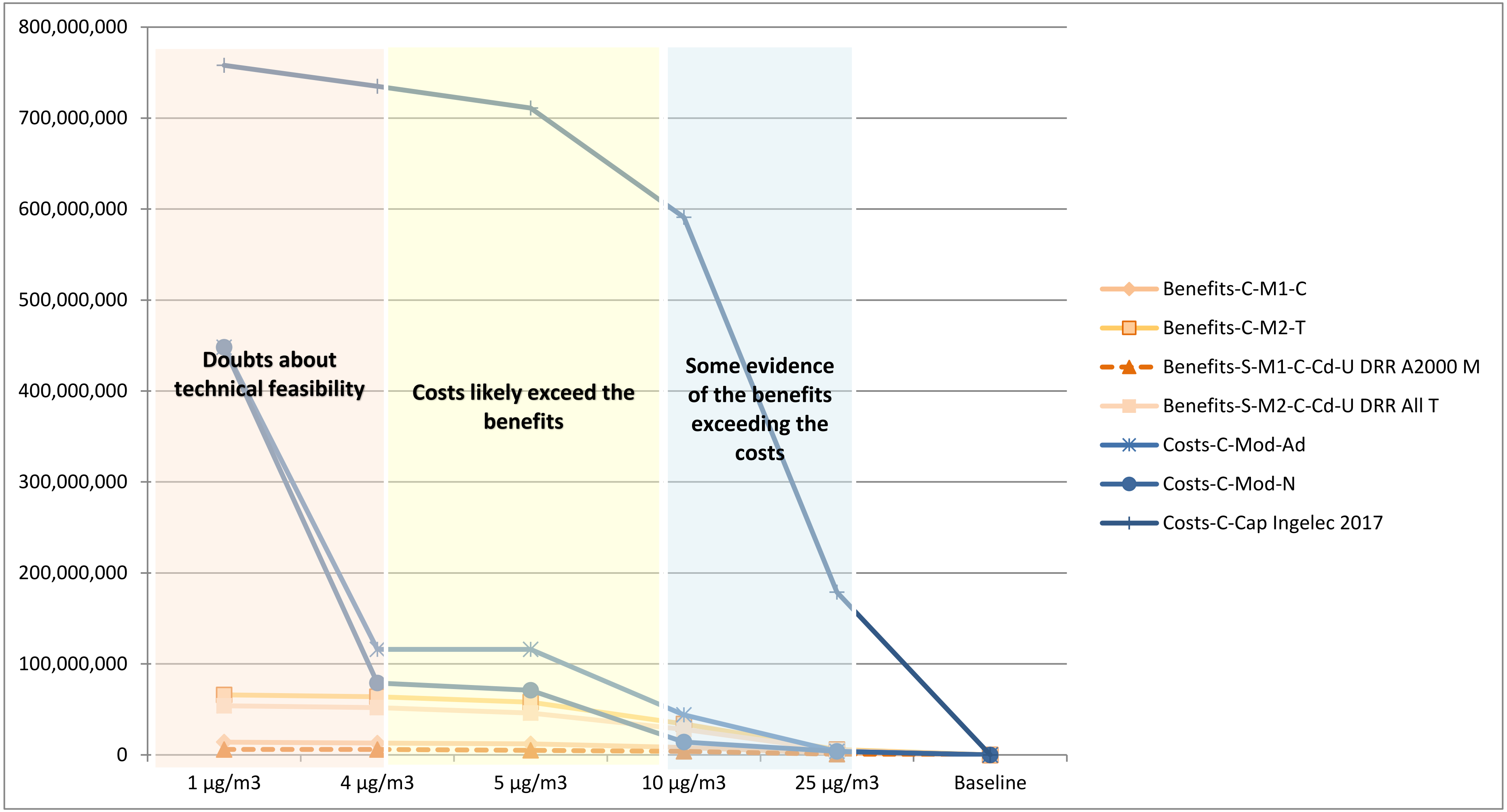


Figure 1: Comparison of the costs and the benefits estimated using the different methods

Bearing in mind that the benefits could not be monetised for some health endpoints, it can be concluded that the lowest reference OELV at which the monetised benefits are likely to exceed the costs is around 10 µg/m³ (inhalable fraction), i.e. 4 µg/m³ (respirable fraction) – see shaded rectangles in Figure 1. Please note that these rectangles are for illustrative purposes only, e.g. there is no precise concentration at which feasibility issues are expected to start occurring.

The table below summarises both the monetised and qualitative impacts.

Table 3: Multi-criteria analysis (cadmium and its inorganic compounds) (all impacts over 60 years and additional to the baseline)						
Impact	**Stakeholders affected**	**1 µg/m³**	**4 µg/m³**	***5 µg/m³****	***10 µg/m³****	***25 µg/m³****
Economic impacts						
Compliance costs**	Companies	€447 million (€758 million)	€79 or 116 million (€735 million)	€71 or 116 million (€711 million)	€14 or 44 million (€591 million)	€4 million (€179 million)
Transposition costs	Public sector	€1.2 million	€1.1 million	€1 million	750,000	600,000
Benefits from reduced ill health (values in brackets relate to sensitivity analysis using Cd-U DRR – lowest value of all scenarios)	Reduction in cases (lung cancer)	6	6	5	4	1
	Reduction in cases (elevated proteinurea)	(30-)181	(28-)176	(25-)159	(15-)92	(3-)17
	Reduction in DALYs	(310-) 1,600–2,800	(300-) 1,600–2,800	(260-) 1,400–2,400	(180-) 800–1,500	(40-) 150–300
	Employers (avoided costs)	(€0.2-) €1–1.4 million	(€0.2-) €0.9–1.3 million	(€0.2-) €0.8–1.2 million	(€0.1-) €0.5–0.7 million	(€0.02-) €0.1 million
	Public sector (avoided costs)	(€0.9-) €4.6–€6.7 million	(€0.8-) €4.5–€6.5 million	(€0.8-) €4.1–€5.9 million	(€0.4-) €2.4–€3.4 million	(€0.1-) €0.4–€0.6 million
Single market: competition	No. of company closures	8 companies or business units close or substitute	1 company or business unit closes or substitutes	1 company or business unit closes or substitutes	0 closures	0 closures
Single-market: consumers	Consumers	Limited impacts expected				
Single market: internal market*****	Companies	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 2
International competitiveness	Companies	Significant negative impact	Significant negative impact	Significant negative impact	Moderate impact	Limited impact
Specific MSs/regions	MSs that would have to change OELs	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL,	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL?, HU,	AT, BE, BG, HR, CY, CZ, DK?, FI, FR, EL?, HU, IE,	AT, BG, HR, CY, CZ, DK?, FR, HU, IE, LV,	AT, BG, HR, CY, CZ, FR, HU?, IE,

Table 3: Multi-criteria analysis (cadmium and its inorganic compounds) (all impacts over 60 years and additional to the baseline)						
Impact	**Stakeholders affected**	**1 µg/m³**	**4 µg/m³**	***5 µg/m³****	***10 µg/m³****	***25 µg/m³****
		HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	IE, LV, LT, NL, PL, SI, ES, SE, UK	LV, LT, NL, PL?, SI, ES?, SE, UK	LT, NL, SI, SE, UK	LT?, SI, SE, UK?
Social impacts						
Ill health avoided, incl. intangible costs (values in brackets relate to sensitivity analysis using Cd-U DRR, lowest value of all scenarios)	Workers & families	(€6m-) €9m–€59m	(€5m-) €9m–€57m	(€5m-) €7m–€51m	(€4m-) €5m–€30m	(€0.8m-) €1m–€6m
Employment	Jobs lost*****	280	35******	35******	0	0
	Social cost*****	€23 million	€3 million	€3 million	€0	€0
Environmental impacts						
Environmental releases	Environment	No impact/limited impact				
Recycling – loss of business	Recycling companies	Negative impact	No impact/limited impact			

Notes:
All costs/benefits are incremental to the baseline (PV over 60 years).
*Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
**The two business compliance costs presented are the model estimates (unadjusted or adjusted) and the figure in brackets is the value extrapolated from Cap Ingelec (2017).
***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).
*****Illustrative only: significant uncertainties about national OELs remain. Many OELs also apply only to specific sectors and have a specific role within the national enforcement system.
*****Worst-case, does not take into account the possibility of substitution. Not included in the totals in the CBA.
****** Average per input data (SEG or company).

1 Introduction

1.1 Background

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereinafter the CMD, protects workers from exposure to carcinogens or mutagens at work. The minimum requirements for protecting workers that are exposed to carcinogens and mutagens, include Occupational Exposure Limit Values (OELVs)[1]. 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 RPA Risk & Policy Analysts (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 with the view to support the European Commission in the preparation of an Impact Assessment report to accompany a potential proposal to amend Directive 2004/37/EC.

The 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 Limits (STEL) and a skin notation.

The specific objective of this report is to assess the impacts of introducing an OELV for cadmium and its inorganic compounds.

[1] See http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:c11137

1.3 Structure of the report

The report is organised as follows:

- Section 2 sets out the background (SCOEL and ACSH[2] documents) and the scope of the assessment for cadmium and its inorganic compounds;
- 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 an overview of the limitations and the sensitivity analysis; and
- Section 10 provides the conclusions.

This report is complemented with three annexes.

[2] Advisory Committee for Safety and Health at Work

2 Background and scope of the assessment

This section comprises the following subsections:

- Section 2.1: Background
- Section 2.2: Summary of epidemiological and experimental data
- Section 2.3: Deriving an Exposure-Risk Relationship (carcinogenic effects) and a Dose-Response Relationship (non-carcinogenic effects)
- Section 2.4: Study scope
- Section 2.5: Background information on cadmium and its inorganic compounds
- Section 2.6: Reference OELVs

2.1 Background

2.1.1 SCOEL/OPIN/336

The SCOEL opinion for cadmium and its inorganic compounds (SCOEL/OPIN/336, hereinafter SCOEL 2017) was adopted on 8 February 2017. The key conclusions of SCOEL (2017) are:

- Inhalation is the main route of exposure for exposed workers but additional uptake can occur through the consumption of contaminated food and/or tobacco smoking;
- Cadmium is a Category C carcinogen[3]: a genotoxic[4] carcinogen for which there is a mode of action-based threshold (a so-called 'practical threshold');
- A combination of an OELV (4 µg/m^3 respirable fraction) and a BLV (Biological Limit Value[5]) (2 µg Cd/g creatinine in urine) was proposed. In the absence of urinary organic-metrological follow-up, an OELV of 1µg/m3 (inhalable fraction) is proposed;
- There insufficient evidence to support a proposal for a STEL; and
- There is no need to apply a skin notation.

2.1.2 ACSH Doc. 663/17

ACSH WPC (2017) has proposed two possible approaches to the implementation of the SCOEL opinion:

- **Approach 1:** An OELV of 1 µg/m^3 (inhalable fraction), with a transition period of 7 years (to end no later than 2027) at 4 µg/m^3 (inhalable fraction).

- **Approach 2:** A BLV of 2 µg/g creatinine in urine in conjunction with an OELV of 4 µg/m^3 (respirable fraction).

[3] "Agent (chemical, physical or biological) which is capable of increasing the incidence of malignant neoplasms, thus causing cancer." (IUOAC, Accessed Feb2018)

[4] "Capable of causing a change to the structure of the genome." (IUPAC, Accessed Feb2018)

[5] Intended to help protect workers from harmful effects related to exposure to the chemical in question, this can be over a medium or long-term period. BLVs act as a biological exposure marker (Anses, 2017, Biological Limit Values for Chemicals used in the Workplace.).

According to ACSH WPC (2017), both approaches present adequate technical means of protecting workers' health.

2.2 Summary of epidemiological and experimental data

2.2.1 Identity and classification

The identity and classification given below refers to metallic cadmium. Classification may vary for other inorganic cadmium compounds. However, all cadmium compounds addressed in this report are regarded to be carcinogens (Cat. Carc. 1B).

Table 2-1: Cadmium – identity and classification	
Chemical Substance	Cadmium
CAS-Number	7440-43-9
EC-Number	231-152-8
Sum Formula	Cd
Chemical Structure	Cd
Classification (ECHA C&L Inventory, 2017)	For Cas-Nr. 7440-43-9: Pyr. Sol. 1 (H250); Acute Tox. 2 (H330); Muta. 2 (H341); Carc- 1B (H350); Repro. 2 (H361fd); STOT RE 1 (H372); Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410); (harmonised)
Unit Transformation	depends on specific Cd compound
Sources: Data taken from ECHA (2011) and ChemID (2017)	

According to IARC (2012) there is *sufficient evidence* in humans for the carcinogenicity of cadmium and cadmium compounds. Cadmium and cadmium compounds may cause cancer of the lung. Also, positive associations have been observed between exposure to cadmium and cadmium compounds and cancer of the kidney and of the prostate. There is *sufficient evidence* on experimental animals for the carcinogenicity of cadmium compounds. There is *limited evidence* in experimental animals for the carcinogenicity of cadmium metal. Cadmium and cadmium compounds are *carcinogenic in humans* (Group 1) (IARC, 2012).

2.2.2 General toxicity profile, critical endpoints and mode of action

Toxicokinetics[6]

Cadmium is absorbed to a limited extent via inhalation (≤ 50%), depending on the water solubility and the particle size distribution. Fumes are absorbed to a larger extend (25–50%) compared to micrometer-sized dust (10–30%) (AGS, 2014; SCOEL, 2017). The oral absorption usually is below 5%, but may be higher in case of zinc deficit and reduced iron status in humans and may be increased during gestation and lactation. Dermal absorption is low (AGS, 2014; SCOEL, 2017). However, some readily soluble cadmium compounds may lead to systemic effects after percutaneous uptake (AGS, 2014). Distribution in the body is similar and indepent of the route of uptake. In blood, cadmium is mostly bound to erythrocytes and to plasma proteins (e.g., metallothioneine and cysteine). Biological

[6] "Generally, the overall process of the absorption (uptake) of potentially toxic substances by the body, the distribution of the substances and their metabolites in tissues and organs, their metabolism (biotransformation), and the elimination of the substances and their metabolites from the body." (IUPAC, Accessed Feb2018)

half-life is about 10–30 years in kidneys. Cadmium accumulates in the bones. Excretion is via the urinary and faecal pathway in about equal quantities (AGS, 2014; SCOEL, 2017).

Target organs

Major target organs for non-cancer effects of cadmium and inorganic cadmium compounds are:

- The kidneys;
- The bones;
- The respiratory tract (from inhalation exposure).

Cadmium and inorganic cadmium compounds are also classified as reproductive toxicants.

Kidney toxicity is often regarded as critical toxicity, already at or slightly above elevated environmental levels (uptake of cadmium via food and smoking). Tubular proteinuria[7] is the first sign of renal toxicity (ECHA, 2013d; EFSA, 2011; SCOEL, 2017). However, some authors question that minor proteinuria is already indicative of an adverse effect induced by cadmium (e.g., Byber et al., 2016; Byber et al., 2017).

Osteoporosis can also be increased by cadmium. Some studies indicate effects associated with similar cadmium exposures as for first kidney effects (Åkesson et al., 2014; Buha und Matovic, 2016; Suwazono et al., 2010; Wallin et al., 2016) and may not be secondary to kidney impairment (Engström et al., 2009).

Respiratory effects (including, but not limited to, carcinogenicity; see below) are a very important endpoint from inhalation of cadmium particles, often regarded as a critical effect or occurring at only slightly higher exposures compared to systemic effects. A moderate increase in residual volume (first sign of respiratory toxicity) has been reported in workers exposed to cadmium fumes (respirable fraction) at cumulative exposure levels below 500 µg Cd/m^3-years (with an excretion of 3 µg Cd/l in urine) (Cortona et al., 1992). This study was used by SCOEL to derive the (former) OEL based on respiratory toxicity (SCOEL, 2010).

Even though, cadmium and inorganic cadmium compounds are classified as reproductive toxicants, this endpoint is currently not a focus, when OELs are derived. Apparently, effect concentrations are above those relevant compared to the other mentioned effects (SCOEL, 2017).

There are contradictory data on dermal sensitisation and no data on sensitisation of the respiratory tract from cadmium exposure (SCOEL, 2017).

Mode of action for carcinogenicity

Cadmium and inorganic cadmium compounds are carcinogenic. According the Classification and Labelling Inventory this group of compounds is classified 1B, pointing to sufficient evidence from animal studies, which are supported by human data in the case of cadmium. Direct interactions with DNA appear to be of minor importance. There are a number of mechanisms leading to secondary genotoxicity. Cadmium has been shown to interact with DNA repair systems, cell cycle regulation, tumor suppressor functions and cellular signaling. As one example, Fischer et al. (2016) demonstrate that cadmium *in vitro* activated genes coding for the stress response, anti-oxidative defense, mitotic signaling and cell cycle control as well as the intrinsic apoptotic pathway. It further induced damage response genes but down-regulated genes coding for specific DNA repair proteins involved in all major

[7] "Excretion of excessive amounts of protein (derived from blood plasma or kidney tubules) in the urine." (IUPAC, Feb2018)

DNA repair pathways. All of these interactions mirror the manifold interactions of cadmium supposed to be involved in cadmium-induced carcinogenicity (see also, e.g., Hartwig, 2013; Schwerdtle et al., 2010).

For some potential additional cancer-sites other modes of action are also discussed, e.g. for breast cancer, endometrium cancer and cancer of the prostate, endocrine disturbances may contribute (Byrne et al., 2009; 2013; Lappano et al., 2017; Nagata et al., 2013; Pacini et al., 2009; Rahim et al., 2013). However, these tumour sites from cadmium exposure have not been definitely confirmed up to now.

Finally, the organ specific content of metallothioneine probably has a relevant influence on retention in the organ and on organ specific tumour development (Bay et al., 2006; Benbrahim-Tallaa et al., 2009; Cannino et al., 2009; Klaassen et al., 2009).

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

Based on the evidence of cancer compounds in experimental animals, some assessments are based on an inhalation study by Takenaka et al. (1983), where Wistar rats were exposed for 18 months 23h/d; 7d/w, to 12.5, 25, or 50 µg/m³ Cd /m³ as cadmium chloride, with a 13-month post-exposure observation of the animals. Tumours of the lung (including carcinoma) increased from control (zero %) to 17.9, 52.6, or 74.3% in the low, medium and high dose exposure groups, respectively. These study results were largely supported by other studies with experimental animals (Glaser et al., 1990; Heinrich et al., 1989; Oldiges et al., 1989). OEL- assessments, e.g. in Germany (AGS, 2014) and in France by ANSES (2012)[8], are based on the rat study by Takenaka et al. (1983). SCOEL (2017) mentions the study, but does not adopt the assessment results.

For OELs, which are based on carcinogenicity and human data, the study by Thun et al. (1985) is the most frequently cited key study. Thun et al. performed a cohort study in a cadmium production facility, where 576 workers were exposed, from which 16 died from lung cancer. There is a discussion on a potential exposure to arsenic. Cumulated exposure to cadmium is provided in mg/m³-days (≤58, 585–2920, ≥2921) with standard mortality rates (SMR) of 0.53, 1.52 or 2.8, respectively, compared to the white male general U.S. population. The Tun et al. study was used for the unit risk quantification by the US environmental protection agency within IRIS (EPA, 1998). This IRIS assessment is the background of many national OELs for cadmium based on cancer risk.

The Thun et al. study was further updated by Park et al. (2012) with a closer analysis of the influence of arsenic coexposures. For mean cumulated exposures from 230, 1,470, 4,460, 11,130, 19,960 and 33,080 µg Cd/m³-years the authors describe an increase in cancer risk (SMR) of 0.77, 0.9, 0.90, 2.24, 2.98, 8.93 or 1.12, respectively, after adjustment for ethnicity and exposure to arsenic. These data were used by Haney (2016) to derive a unit risk for the general population, using background risk data from Texas or from the US general population and taking into account a 5-year lagged cumulative exposure. From this, the authors calculated a lifetime air concentration of 20 ng Cd/m³ corresponding to an excess risk of 10^{-5} (general population). This risk estimate was reported, but not adopted by SCOEL (2017).

[8] https://www.anses.fr/fr/content/lanses-propose-de-nouvelles-valeurs-toxicologiques-de-r%C3%A9f%C3%A9rences-pour-deux-substances%C2%A0-le, assessed December 09, 2017

IARC (2012) provides a summary and discussion on epidemiological studies for lung cancer and further potential tumour sites.

Latency

For lung cancer, the recent assessment by Haney (Haney, 2016) assumed a 5-year lag time from exposure to occurrence of cancer (lung cancer from cadmium workplace exposure). However, usually for lung cancer, e.g. for chromium or arsenic compounds, much longer latency periods[9] are reported (Butz, 2012). Rushton et al. (2012) assume for solid tumours a latency between 10 and 50 years.

For potential bladder cancer from cadmium, a UK committee reports an assumed latency period of >20 years for their calculations (IIAC, 2009). A similar latency is assumed in one assessment for prostatic cancer by cadmium (IARC, 2012). Overall, there is relevant uncertainty on appropriate latency assumptions and a high variability. For cadmium there is additional uncertainty about latency, because, even though lung cancer is the cancer site with highest evidence, there may be other cancer sites with different latency times.

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

Respiratory (non-cancer) toxicity is a major endpoint from occupational inhalation exposure to cadmium. Cumulative exposure of 500 µg Cd/m³ x years cadmium oxide vapours (equivalent to 12.5 µg Cd/m³ for 40 years) lead to changes in the residual lung volume, as indicated by an epidemiological study by Cortona et al. (1992). Despite some limitations, this study is used in many assessments for establishing an OEL of 4 µg/m³ (respirable fraction) for non-cancer endpoints.

Kidney toxicity has been observed from environmental and occupational exposure to cadmium. Usually observed effects are identified from urinary markers like increased elimination of proteins indicative for tubular or (at higher concentrations) glomerular renal impairment. Therefore, biological monitoring is often regarded as providing the best correlations of cadmium body burden and kidney effects (see Section 2.2.5). There have been attempts to correlate biological markers to cumulative cadmium concentrations in air and derive an OEL accordingly. Thun et al. (1991) examined the prevalence of tubular proteinuria by cumulative exposure to cadmium in seven cross-sectional studies and concluded that "*the prevalence of nephropathy begins to rise at cumulative exposures of between 100 and 499 µg/m³-years (equivalent to a PEL [permissible exposure limit] of between 2.2 and 11.1 µg/m³ over 45 years, assuming no safety margin).*"

Bone toxicity occurs at similar dose levels as nephrotoxicity[10] and may be regarded as an independent toxicological endpoint (not secondary to renal toxicity). There are indications for changes in bone mineral density due to cadmium exposure and indications for increased risk for bone fractions (ECHA, 2013a; KEMI, 2011). However, data on bone toxicity have not been used as critical study to derive an OEL yet. They are usually reported as supporting evidence.

9 "Delay between exposure to a harmful substance and the manifestations of a disease or other adverse effects." (UIPAC, Feb2018)

10 "Chemically harmful to the cells of the kidney" (IUPAC, Feb2018)

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

Biological monitoring is often regarded to provide best correlations of cadmium body burden and kidney effects. In many assessments, 5–10 µg Cd/g creatinine was assumed as threshold concentration (e.g., Elinder et al., 1985; Järup et al., 1993; Mason et al., 1988; Roels et al., 1993), also supported by recent studies (e.g., Hambach et al., 2013). However, from analysis of effects in the general population, elevated proteinuria was also found correlated to lower cadmium excretions of, e.g., 2 µg Cd/g creatinine (Buchet et al., 1990; Järup und Alfvén, 2004; Jin et al., 2002). Usually those data are applied for a "weight of evidence" approach to derive a biological limit value.

2.2.6 Different toxicological properties for various inorganic cadmium compounds

Cadmium substances covered in this report are not discriminated with respect to potency considerations. However, in some national assessments such discriminations were done. One criterion influencing potency could be the different water solubility (e.g., Cd metal: insoluble; cadmiumchloride: 1,400 g/l at 20°C). It cannot be excluded that the difference in cancer risk potency of the specific cadmium compounds may be influenced by water solubility (or by: solubility in physiological fluids).

Note that cadmium pigments (CAS-Numbers: 808-07-5; 58339-34-7) are regarded as "practically insoluble" with no harmonised classification (SCOEL, 2017). As noted above, in some countries, cadmium pigments were attributed distinct OELs in some national assessments.

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

2.3.1 Starting point

The data in SCOEL (2017) provide the starting point for quantifying the exposure risk relationship (ERR) for carcinogenic effects and the dose response relationship (DRR) for non-cancer effects in this impact assessment.

SCOEL (2017) proposes a limit of 1 µg cadmium/m³ (inhalable fraction), regarded as being protective for occupational exposure (carcinogenic and non-carcinogenic effects). With regard to non-carcinogenic local effects in the respiratory tract, SCOEL concludes that 4 µg cadmium/m³ (respirable fraction) is sufficiently protective, although no separate OEL is established for this toxicological endpoint.

SCOEL also suggests a biological limit value (BLV) of 2 µg Cd/g creatinine, mainly derived to protect from nephrotoxicity[11] due to occupational cadmium exposure. However, this BLV is also assumed to protect from systemic carcinogenicity and to protect from other systemic effects (e.g. osteoporosis) with only slightly higher endpoint specific thresholds linked to the biological monitoring data.

SCOEL summarises: "a set of OELs (8h-TWA, BLV) should be protective that prevents toxicity in workers, both locally with regard to the airways and systemically with regard to the kidneys".

[11] "Chemically harmful to the cells of the kidney." (IUPAC, Accessed Feb2018)

Apparently, this conclusion on this “set of OELs” is linked to the combination of 4 µg/m³ (respirable fraction) as an OEL and 2 µg Cd/g creatinine (BLV), as SCOEL explicitly states: “Accordingly, an OEL (8h-TWA, not connected with biological monitoring) for Cd and its inorganic compounds should be 1 µg/m³”.

SCOEL does not foresee a “skin notation” and derives no short-term exposure limit (STEL).

In the earlier assessment by SCOEL only the assumed threshold for non-carcinogenic effects in the respiratory tract was quantified (4 µg/m³; respirable fraction) and the BLV of 2 µg/g creatinine (unchanged in 2017) was provided. In 2017 the lower OEL of 1 µg/m³ (inhalable fraction) was added, in order to avoid both, potential nephrotoxicity (or further systemic effects) and (systemic or local) carcinogenicity without the necessity to perform biological monitoring.

This updated OEL is provided for the inhalable fraction, as usually the inhalable fraction is regarded as the relevant exposure measure at workplaces. However, 1 µg/m³ (inhalable) corresponds implicitly to a lower respirable concentration. In the ANNEX XV- report from the Swedish Competent Authority[12] a transformation factor of 2 to 2.5 is mentioned to estimate a concentration for the respirable fraction from the data on the inhalable fraction (or vice versa). Even though this is a rather uncertain transformation, it permits a pragmatic estimate with reference to other particle size distributions, if the empirical data do not provide direct information. Therefore, within this report we also apply a transformation factor of 2.5 for respective calculations as a substance specific default. We, therefore, conclude that SCOEL (2017) implicitly provides a threshold of 0.4 µg/m³ for cadmium (respirable fraction). Uncertainty of this transformation appears to be negligible compared to the overall ambiguity of this potency discussion. This transformation is important for the assessment of the carcinogenic potency (above threshold) as in this specific case, both epidemiological data and experimental animal data on local carcinogenicity (lung cancer), refer to the respirable fraction.

2.3.2 ERR for carcinogenic effects (air concentration)

Approach

SCOEL (2017) assumes a threshold for carcinogenic effects of 1 µg Cd/m³ (inhalable fraction). This concentration – for the purposes of this project – is regarded as identical to a threshold of 0.4 µg Cd/m³ (respirable fraction).

SCOEL (2017) documents two recent risk quantifications linked to cadmium carcinogenic potency, both without threshold:

a) The cancer risk quantification by AGS with an ERR of 2.5×10^{-3} per µg/m³, respirable fraction (AGS, 2014) based on animal data (Takenaka et al., 1983); and

b) The cancer risk quantification by Haney (2016) for the Canadian Authorities based on epidemiological data (Park et al., 2012; Thun et al., 1985) with an ERR of 8.8×10^{-5} per µg/m³ respirable fraction, after transformation to the workplace scenario (an excess risk of 1/1,000 at 2 µg/m³, general population, is transformed: x 7/5 (days/week); x 20/10 (volume per 8 hrs, not 24 hrs) = 5.6 µg/m³ corresponds to 1/1,000 excess risk).

12 http://www.complianceandrisks.com/regulations/eu-cadmium-sulphide-as-svhc-under-reach-annex-xv-dossier-submitted-by-sweden-september-2013-19737/, accessed November 10, 2017

Those two risk estimates are regarded as incompatible (factor ≈ 15 differences in potency). Therefore, the AGS estimate is taken for further potency quantification, however, only after adaption (for the background of this decision see discussion below).

The AGS estimate with a linear extrapolation is incompatible at low concentrations with the SCOEL excess risk and the assumed threshold. Therefore, in order to adapt to the SCOEL understanding of the mode of action, the respective methodology by AGS (2013) to approximate a sublinear exposure risk relationship has been applied on the data by Takenaka et al. (1983). As indicated by SCOEL, no appreciable cancer risk is expected, if exposure is well below the threshold for non-cancer respiratory effects: SCOEL provides a margin of safety of 10 between the implicit threshold for cancer of 0.4 µg/m³ (respirable) and the threshold for non-cancer effects of 4 µg/m³ (respirable). This SCOEL assessment is best approximated by a sublinear ERR slope.

Before the respective ERR can be calculated, all data were transformed into "inhalable" concentrations using the default transformation factor of 2.5 (see above for justification).

Specifically, it should be noted that:

- The SCOEL (2017) "practical threshold" of 1 µg/m³ (inhalable fraction) is maintained, corresponding to an assumed excess risk of zero.

- The threshold for non-cancer respiratory effects (SCOEL, 2017) of 4 µg/m³ (respirable) is transformed into a corresponding inhalable concentration of 10 µg/m³.

- A hockey stick approximation of a sublinear ERR is performed with the data from Takenaka et al. according to AGS (2013), with a sharp bend at 10 µg/m³ (inhalable fraction) and a "point of departure" (POD[13]) of 100 µg/m³ (inhalable), corresponding to the BMD10 in that study, suggesting a much steeper slope of the ERR at concentrations above the threshold for non-cancer respiratory effects and a rather flat slope below this level (see discussion below for further justification).

With this procedure, we conclude on the following ERR.

Table 2-2: ERR	
Excess risk (≤1 µg/m³, inhalable)	zero
Excess risk (>1–10 µg/m³, inhalable)	y=0.0001x
Excess risk (>10 µg/m³, inhalable)	y=0.0011x – 0.01
Source: derived by the study team	

The corresponding 'hockey stick' ERR is presented in Figure 2-3.

[13] "Related to the dose at which a biological response is first observed and is a basis for making extrapolations needed for assessing risks" (Sturla, S. J., 2018, Point of Departure, Department of Health and Sciences and Technology. Available at: https://pubs.acs.org/doi/10.1021/acs.chemrestox.7b00341)

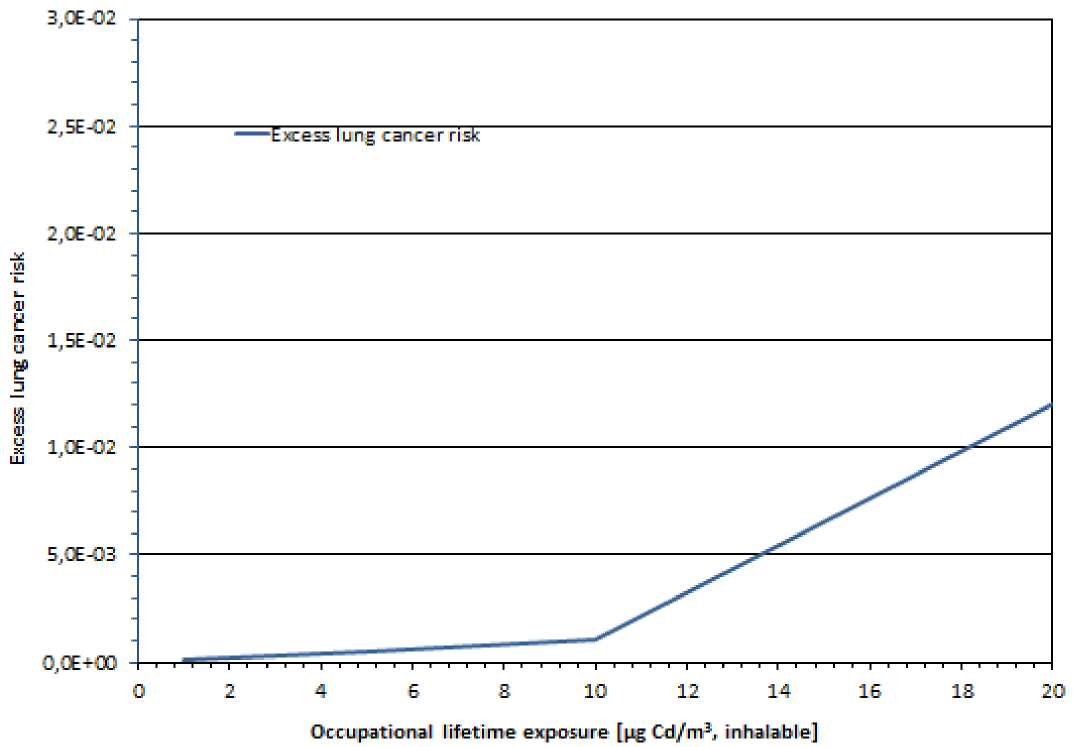


Figure 2-1: Exposure Risk Relationship (ERR) for lung cancer from occupational exposure to cadmium and inorganic compounds (inhalable fraction). Source: Derived by the study team

Discussion

As SCOEL (2017) provides no slope for the ERR which should be selected, this ERR was estimated taking into account the SCOEL conclusions (threshold for non-cancer effects; mode of action with a "practical threshold" for cancer; reference to the inhalable fraction; reporting of human data on secondary genotoxicity above threshold) and applying the AGS assessment data (from Takenaka et al. study) and assessment methodology ("hockey stick function" for approximation of sublinearity). Therefore, the approach is regarded as compliant with the SCOEL provisions.

There was a choice to select either epidemiological data (Haney, 2016) or animal data (Takenaka et al., 1983) to derive a sublinear ERR above the "practical threshold". However, both estimates differed extremely and are regarded as incompatible to each other. The epidemiological data were not used for the following reasons:

- Formally, cadmium is classified as a Carc. Cat. 1B carcinogen in CLP-regulation. This indicates that human (epidemiological data) are not sufficiently certain to justify classification as Carc. Cat. 1A and therefore cannot be regarded as sufficient to quantify carcinogenic potency.

- In a small study on chromosomal effects in humans Forni et al. (1992) observed significant secondary genotoxicity at >1000 µg/m³ x years of exposure (i.e. 25 µg/m³ on average for 40 years cumulative exposure) with insignificantly elevated effects at lower concentrations (pointing to a threshold <25 µg/m³ for these chromosomal effects). This indicates still secondary genotoxicity at or below these concentrations, which are associated with very low risk in epidemiology, thus, questioning the reliability of respective assessment outcomes. The International Cadmium Association has recently (2017)[14] launched a study to validate or improve quantifications on (secondary) genotoxicity potency of cadmium.

- Carcinogenicity of cadmium probably is not limited to the respiratory tract, whereas Haney (2016) only addresses this local carcinogenic endpoint. There were no qualified cancer potency quantifications for other potential cancer sites published at the point in time of the SCOEL assessment. More recent cancer estimates from epidemiology have not been assessed by competent committees responsible for deriving OELs. In the SCOEL opinion on cadmium (2017) the committee refers to such other potentially relevant cancer sites only in general. Therefore, even if the lung cancer risk calculation from the animal data overestimates lung cancer risk in humans, the experimental cancer potency estimate may well be adequate for other cancer sites in humans. The specific assumptions used to derive the hockey stick ERR are related to lung cancer, however, a similar sublinear slope to threshold concentration for the non-cancer endpoints in other cancer sites may be assumed from the mode of action of cadmium.

- By applying the AGS 'hockey stick' methodology to the data from Takenaka at al., the risk estimate based on relevant concentrations above the SCOEL threshold of 1 µg/m³ (inhalable fraction) will reduce significantly compared to the original linear assessment by AGS, as long as the exposure is below 10 µg/m³ (inhalable fraction) and, thus, may be regarded more reasonable, if compared to epidemiological experience.

2.3.3 DRR for non-carcinogenic effects (air concentration)

Approach

SCOEL (2017) established an OEL of 1 µg/m³ (inhalable fraction) to protect from non-cancer systemic effects (and from local or systemic cancer). This is regarded as the starting point for establishing the "dose response relationship" (DRR). SCOEL does not directly provide data to be used within this impact assessment.

Backgrounds for the OEL with regard to systemic effects from cadmium exposure were modelling data by Kjellstroem et al. (1977) from which WHO (2000) and AGS (2014) deduced that nephrotoxic effects could arise in about 1% of the workforce after 40 years of airborne exposure to 4 µg Cd/m³ (inhalable fraction) and a publication by Thun et al. (1991), from which an air concentration of 100–199 µg/m³* years (i.e. 2.5–5 µg/m³, inhalable fraction, average working lifetime exposure) is associated with a potentially elevated risk for proteinuria. A discussion on the adequacy of this OEL with the justification provided is given in the discussion section on this DRR (below).

In order to assess an adequate air standard for cadmium, which also covers systemic effects, Thun et al. (1991) also provided a dose response for prevalence of tubular proteinuria linked to cumulative air concentrations. This dose response was modelled by a "metabolic model" and compared to an US-OSHA model by the authors. In order to derive a DRR based on proteinuria for cadmium, the results of this "metabolic model" were used for the transformation of air concentrations into effect data (% of exposed with tubular proteinuria). The additional prevalence of elevated proteinuria above background was modelled. Therefore, the background prevalence (2.5%) was subtracted from total prevalence (9% - 2.5% = 6.5%), leading to an end-of-second-segment point located at (10; 6.5%).

[14] Personal communication from ICdA; October, 2017

However, these modelling data were only applied in the range up to 20 µg/m³. In higher concentrations, the deviation of experimental data to the model result was regarded as being too large to still justify the use of the model. Therefore, a specific data set by Mason et al. (1988) was used to estimate the affected fraction. Having in mind the earlier OEL in many countries of 50 µg/m³, the rapid increase of the affected fraction, as derived from the modelled prevalence curve, was regarded as not sufficiently plausible in this dose range. Proteinuria for these data was defined by excess ß2-microglobulinuria concentration in urine above a cut off of about >310 µg ß2M /g creatinine and was regarded as indication of cadmium-induced proteinuria.

From these data the following DRR was established.

Table 2-3: DRR	
Increased prevalence (≤1 µg/m³, inhalable)	y=0
Increased prevalence (>1–10 µg/m³, inhalable)	y=0.722x – 0.722
Increased prevalence (> 10–20 µg/m³, inhalable)	y= 3x - 23.502
Increased prevalence (>20 µg/m³, inhalable)	y= 0.5x + 26.498
Source: Derived by the study team	

The resulting DRR is shown in a graphical presentation in the figure below.

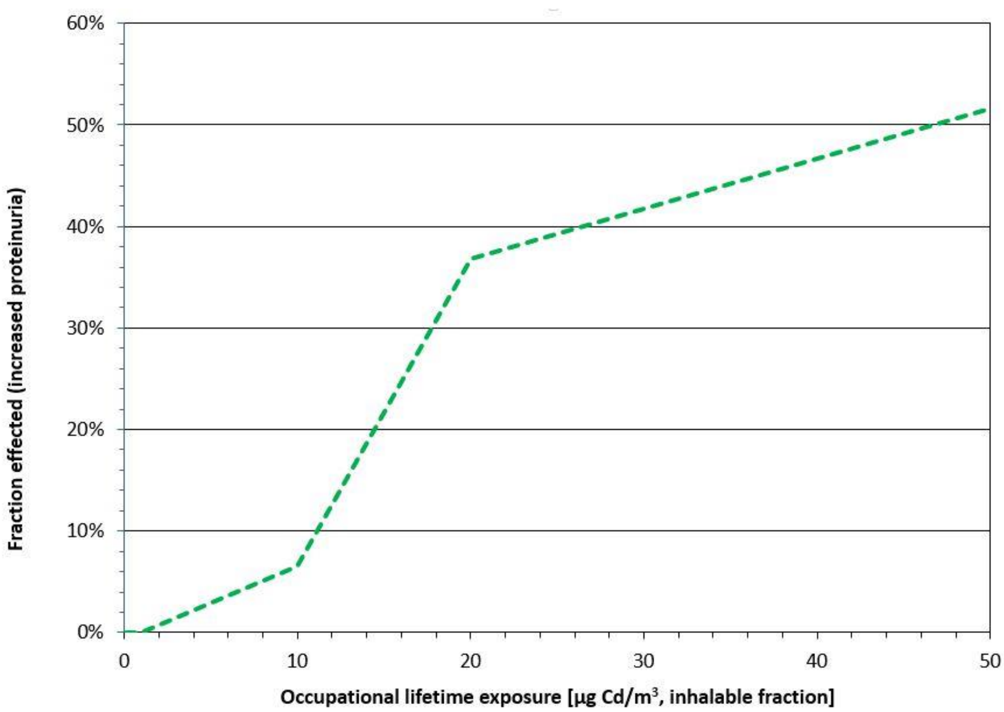


Figure 2-2: Dose Response Relationship (DRR) for proteinuria (increase above background) from occupational exposure to cadmium compounds with more severe nephrotoxic effects at elevated concentrations (inhalable fraction). Source: Derived by the study team

According to the methodology, the fraction affected is associated with increased prevalence of proteinuria. The effects on the kidney will be minor at low concentrations (e.g. below 10 µg/m³ (inhalable fraction)) and will become worse, and unambiguously adverse, only at higher concentrations. The transition point from proteinuria to clinically relevant kidney damage is the subject of a controversial discussion. The discussion below provides reasons as to why this DRR is regarded as a meaningful quantification on the health effects occurring at cadmium exposures above the threshold set by SCOEL.

Discussion

It should be acknowledged that

- The correlation between exposure concentration in air [µg/m³] and biological indicators of proteinuria (like ß2-microglobulin excretion) are weak and therefore imply significant uncertainty on the slope of the DRR;
- The cut off to regard elimination concentrations of ß2-microglobulin as an adverse effect is discussed controversially, with the selected cut off often regarded as non-adverse elevation from normal (and also observed in a small fraction of general population not exposed occupationally to cadmium); and
- Recent new data provide some evidence that ß2-microglobulin elimination may not be an adequate indicator of cadmium induced nephrotoxicity at low exposure concentrations.

SCOEL (2017) comments on the problem of adversity:

"Some authors believe that these changes represent the earliest dysfunction of the renal tubular cells and should be considered as an adverse effect because the aim of public health is to detect and prevent effects at their earliest stage in the most sensitive groups of the population …. Others, however, believe that these changes most likely reflect benign, non-adverse responses …. The main arguments to support the latter interpretation are that:

- *variations of tubular parameters observed at these Cd-U levels remain within a normal range,*
- *statistical associations with Cd-U remain weak (r^2 <10 %), and*
- *similar associations are observed with other non-nephrotoxic metals in urine (e.g. Cu) …,*
- *variations of this amplitude are reversible when exposure decreases timely, and*
- *such changes are not predictive of an alteration of the renal function."*

Despite this analysis, SCOEL derived the OEL and BLV reported above.

Thun et al. (1991) discuss that the background incidence of slightly elevated ß2-microglobulin in urine above cut off of 2.5% (or up to 5% according to the Cadmibel-study; Buchet et al., 1990) is not significantly influenced by cadmium exposure. Therefore, if small fractions of cadmium-exposed workers exhibit slight proteinuria, this may not be attributable to the cadmium. This observation is frequently rejected as many studies show correlations between cadmium in urine at 1 µg Cd/ g creatinine or even less in general population and increased protein elimination (e.g., EFSA, 2009).

However, as Akesson et al. (2014) summarise:

"It is possible that normal physiological variability in renal reabsorption of low molecular weight proteins causes the increase in U-Cd by inhibiting tubular uptake of metallothionein (MT-)-bound Cd; in other words, this is a possible case of reverse causality… . Although there is no reason to question the effect of Cd exposure on renal tubules at high exposure (U-Cd > 4 µg/g cr), the associations

observed at low levels could be influenced by the [such] factors …. Other factors should also be considered, such as the ability to synthesize MT and the occurrence of MT antibodies…. Thus, although a toxic effect cannot be ruled out at exposures corresponding to U-Cd < 1 µg Cd/g cr (values that generally occur among nonsmokers in many populations worldwide), normal physiology is likely to be an important determinant… This makes it difficult to interpret any associations."

This analysis is based on several recent studies (e.g. Chaumont et al., 2011; Chaumont et al., 2013) and was subsequently supported by other authors (e.g., Bernard, 2016; Byber et al., 2016). Chaumont et al. (2011) demonstrate a significant increase in proteinuria in correlation to cadmium exposure only above > 6 µg Cd/ g creatinine with a sharp rise at 10 µg/g creatinine.

Even though adverse kidney effects are not clearly linked to the threshold provided by SCOEL provided above, the DRR as established above is regarded as reliable potency quantification:

- The threshold including the data used in this project report for DRR quantification are based on a recent assessment of a knowledgeable and competent committee and the more recent opinions have not been accordingly assessed and discussed with unambiguous conclusions.
- In fact, some recent data are contradicted by further study results (Eom et al., 2017; Woo et al., 2015) and earlier data compilations (Järup and Akesson, 2009) and even most of the recent analyses do not draw definite conclusions but only emphasise the overall uncertainty.
- Apparently, the "lowest observed adverse effect level" (LOAEL[15]) for other but nephrotoxic effects like osteoporosis, respiratory effects and cardiovascular effects are linked to similar concentrations (however, those results are provided with correlation to cadmium in urine and not directly assessed for air concentrations at the workplace). For example, Akesson et al. (2014) believe that other adverse effects from cadmium could occur at comparable low concentrations. Therefore, the OEL and DRR also provide proxies to address further cadmium induced health effects.

SCOEL points to the uncertainties of effect potency in correlation to air concentrations and proposes, to be on the safe side, the low OEL of 1 µg/m³ (inhalable). As an alternative, SCOEL recommends implementing a set of OELs (air-concentration plus biological monitoring BLV) to assess and control exposure. Therefore, any isolated impact assessment with application of just one assumed regulatory value would include this extended uncertainty. In 2017, the International Cadmium Association launched a study to find better data on the correlation of air concentrations and cadmium excretion in urine in order to reduce uncertainties and to demonstrate their hypothesis that biological monitoring only may be a conservative and adequate way to control from adverse health effects from cadmium exposure including local effects in the respiratory tract[16].

2.3.4 DRR for carcinogenic and non-carcinogenic effects (biomonitoring)

Approach

SCOEL (2017) also provides a BLV for cadmium bio-monitoring as 2 µg Cd/g creatinine. Even though SCOEL does not directly calculate a DRR expressed by a concentration of cadmium in biological media, the data reported in the SCOEL assessment combined original sources are sufficient to derive this DRR

[15] The lowest concentration or amount of substance, found by experiment or observation, which causes an adverse alteration of morphology, functional capacity, growth, development, or life span (CJUCJ, accessed Feb2018)

[16] Personal communication from ICdA, October 2017

from effect data associated with certain cadmium concentrations in urine after occupational exposure.

Specifically, the elimination of several markers of early renal changes induced by workers exposed to cadmium, as reported by Roels et al. (1993). It is important to realise that other markers, exceptß2-microglobulin, are elevated to abnormal values for cadmium exposed workers in a dose related way and help to estimate the respective dose response.

In combination with a threshold set by SCOEL and the data by Roels et al the DRR is derived with respect to renal effects:

Table 2-4: DRR	
Increased prevalence (2 µg/g creatinine)	y=0
Increased prevalence (>2 – 5 µg/g creatinine)	y=1.7x -3.5
Excess risk (> 5 µg/g creatinine)	y=2.3x-6.5
Source: derived by the study team	

The resulting DRR is shown in a graphical presentation below.

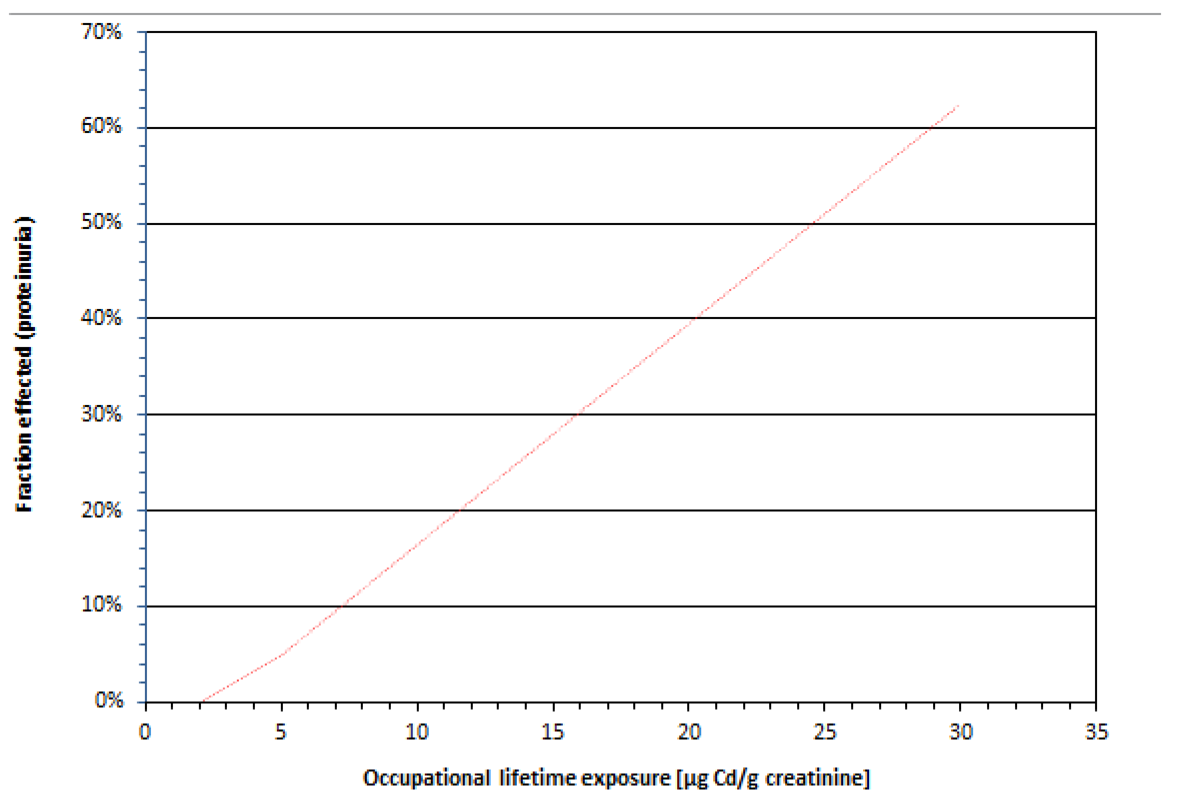


Figure 2-3: Dose Response Relationship (DRR) for proteinuria (increased proteinuria above background with more severe nephrotoxic effects at higher concentrations of cadmium in urine) from occupational exposure cadmium compounds. Source: derived by the study team

According to the methodology, the fraction affected is associated with increased prevalence proteinuria. The effects on the kidney will be minor at low concentrations (e.g. below 5 µg Cd/g creatinine) and will become worse and unambiguously adverse only at higher concentrations. The transition point from proteinuria to clinically relevant kidney damage is the subject of a controversial discussion. Discussion below will provide reasons as to why this DRR is regarded as a meaningful quantification on the health effects occurring at cadmium exposures above the threshold set by SCOEL.

Discussion

Most discussion points were already raised above, when the DRR for increased incidence of renal effects in correlation to air concentrations was analysed (see above). However, also in agreement with Akesson et al. (2014), renal adverse effects at concentrations above 4 µg Cd/g creatinine is a well-established LOAEL and therefore 5 µg Cd/g creatinine is reasonably associated with an incidence fraction of about 8% of the exposed. Therefore, uncertainties are regarded lower than for the reported DRR on air concentrations.

Again, this DRR is not only suitable for kidney effects, but also is a proxy for other health effects (e.g. osteoporosis) and systemic carcinogenicity at similar cadmium exposure levels.

SCOEL points to the uncertainties of effect potency in correlation to air concentrations and recommends implementing a set of OELs (air-concentration plus biological monitoring BLV) to assess and control exposure, if the higher OEL (4 µg/m³, respirable fraction) is maintained. Therefore, any isolated impact assessment with the application of the higher regulatory value (4 µg/m³ respirable or 10 µg/m³ inhalable fraction) would include this extended uncertainty.

2.4 Study scope

2.4.1 Selection of the relevant measures

This report assesses the impacts of introducing an OELV for cadmium and inorganic cadmium compounds. The assessment in this report is based on the assumption that only an OELV would be introducted and it would not be accompanied by a BLV.

The impacts of introducing a STEL for cadmium and inorganic cadmium compounds are not considered in this report.

2.4.2 Selection of the relevant compounds

The scope of this study with regard to cadmium and its compounds is defined as follows: *cadmium and inorganic compounds as far as under the scope of the CMD*

Criteria for the determination of the relevant compounds

The following screening criteria have been applied to select the cadmium compounds that are assessed in the study:

- Does the compound pass the initial test of relevant (not an erroneous entry, not a reaction mass, not a UVCB[17])?
- Is there a CLH 1A or 1B for the compound? If the compound only has a self-classification as Carc. 1A or 1B, is the compound also registered?

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

- Where compounds also contain another carcinogen, is cadmium clearly the driver of the carcinogenic potency or the "mode of action" (MoA)?

Final selection

The relevant substances that remain within the scope of the study following the screening process are summarised in Table 2-1 below, and the compounds assessed in the study are listed in Table 2-2.

Table 2-5: Cd – screening process	
Step	**Number of compounds**
Total number of Cd compounds identified	364
Of which, pass the first test of relevance (not clearly erroneous, not a reaction mass, not a UVCB, etc.)	120
Of which, compounds with CLH Carc. 1A or 1B or self-classified as Carc. 1A or 1B and registered	16
Of which, Cd driver of carcinogenic potency or the mode of action	11

Table 2-6: Cadmium and inorganic Cd compounds – final selection	
Compound	**CAS No.**
Cadmium oxide	1306-19-0
Cadmium sulphide	1306-23-6
Cadmium	7440-43-9
Cadmium fluoride	7790-79-6
Cadmium chloride	10108-64-2, 35658-65-2
Cadmium sulphate	7790-84-3, 10124-36-4, 31119-53-6
Cadmium nitrate	10022-68-1[18], 10325-94-7
Cadmium hydroxide	21041-95-2
Cadmium carbonate	513-78-0
Cadmium sulfate hydrate	15244-35-6

2.5 Background information on cadmium and its inorganic compounds

This section of the report provides a general introduction to cadmium and it inorganic compounds. Specific sectors and uses that are considered relevant to occupational exposure are summarised in Section 3.3 (Relevant sectors, uses and operations).

2.5.1 Cadmium

Cadmium is a rare element not found in its pure state in nature. Instead, it occurs mainly as cadmium sulphide (or 'greenockite') in deposits of zinc (National Toxicology Program, 2014).[19]

Today, most cadmium metal is produced as a by-product of the extraction, smelting and refining of zinc, lead and copper. In addition, cadmium is also produced from the recycling of spent nickel-

[18] Also covers cadmium(2+) ion bis(nitric acid)/cadmium nitrate tetrahydrate (CAS No. 10022-68-1).

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

cadmium batteries (its largest use), and secondary or recycled cadmium now accounts for about 23% of total cadmium supply (ICdA, 2016).[20] Cadmium is commercially available in purities ranging from 99 - 99.9999%, as powders, foils, ingots, slabs, sticks and crystals (National Toxicology Program, 2014).

Information on cadmium uses, as identified by the Cd REACH Consortium (2012a) is provided in the following figure[21].

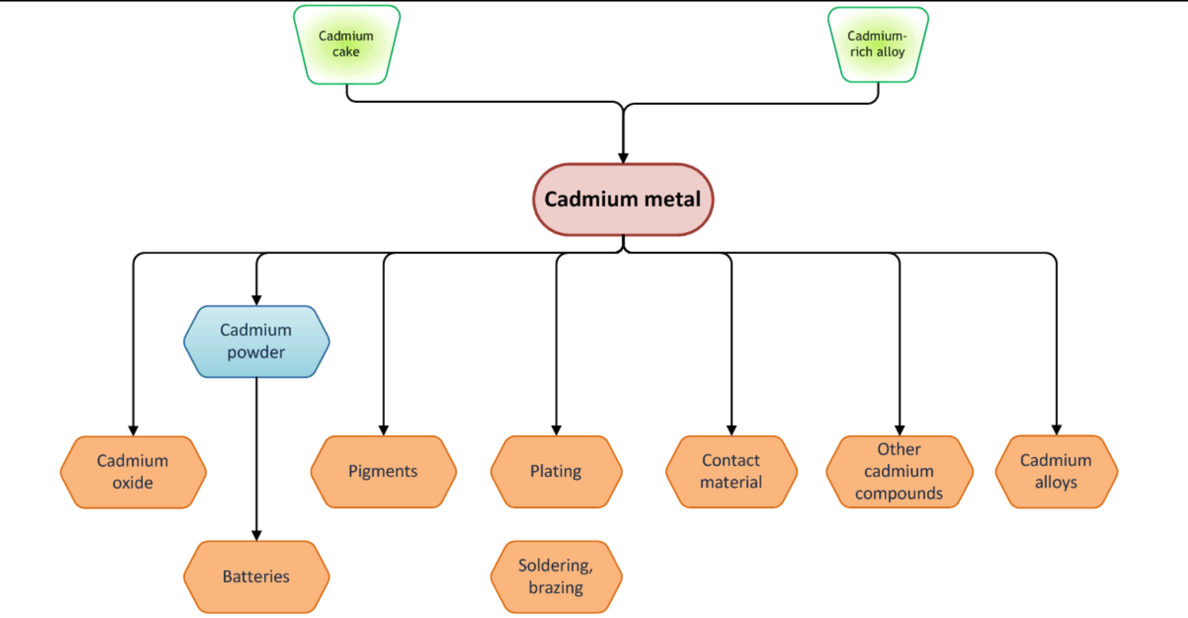


Figure 2-4: Initial overview of cadmium uses
Source: Cd REACH Consortium (2012a)

2.5.2 Cadmium alloys

The widespread use of cadmium in such alloys is of importance to a number of sectors[22]. For example, AIA in ECHA (2013b)[23] highlights the use of cadmium as an alloying element in copper, tin and zinc alloys used in the aerospace industry. In the same document, the UK ADS notes that silver electric contacts (silver-cadmium oxide) incorporating 10 to 15% cadmium are useful in many heavy duty electrical applications such as relays, switches, circuit breakers and thermostats in the aerospace and defence sector. The presence of cadmium improves resistance to material transfer and electric erosion.

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

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

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

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

2.5.3 Cadmium chloride

Cadmium chloride is produced by reaction of molten cadmium and chlorine gas at 600 °C or by dissolving cadmium metal or the oxide in hydrochloric acid, subsequently vaporising the solution (Pubchem, undated).[24]

ICdA in ECHA (2014a)[25] provides more specific information, noting that the reported manufactured (or imported) tonnage of cadmium chloride in the EU fluctuates from year to year, depending on the demand of photovoltaic panels but is in the range of 5-8 t/y.

As well as photovoltaic applications, the Cd REACH consortium highlights that following uses of relevance associated with the substance[26]:

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

2.5.4 Cadmium fluoride

ICdA in ECHA (2014b) notes that the compound is probably limited to minor laboratory reagent uses[27].

2.5.5 Cadmium sulphate

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

Despite the intermediate only registration, available literature does suggest that the compound may have a wider scale of uses to consider. For example, Rajadurai et al. (2013)[28] highlights that cadmium sulphate is an important inorganic cadmium compound which is widely used in semiconductor industry with many excellent physical and chemical properties.

---

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

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

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

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

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

2.5.6 Cadmium sulphide

Cadmium sulphide (CdS) can be manufactured by passing hydrogen sulphide gas into cadmium chloride solution ($CdCl_2 + H_2S = CdS\downarrow + 2HCL$). Another method is to acidify a solution of cadmium sulphate with hydrochloric acid and to add a freshly made solution of sodium sulphide ($CdSO_4 + NA_2S = CdS\downarrow + NA_2SO_4$) (NIIR Board, 2003)[29]. Information within the Candidate List 'Response to Comments' (RCOM) document for the compound[30] suggests it is used mainly for the manufacture of photovoltaic panels and as an intermediate in the manufacture of other cadmium compounds, including pigments. It is also used in small quantities as intermediate in glass colouration.

Uses as identified by the Cd REACH Consortium[31] have been listed below:

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

2.5.7 Cadmium oxide

Figure 2-2 presents a flow diagram for the production of cadmium oxide which includes the fusion of metal ingots at temperatures higher than 320°C, followed by oxidation on contact with air to produce cadmium oxide in a powder form which is subsequently collected in bag filters.

Information on cadmium oxide uses, as identified by the Cd REACH Consortium are provided in Figure 2-3. The substance is one of the main precursors to other cadmium compounds.

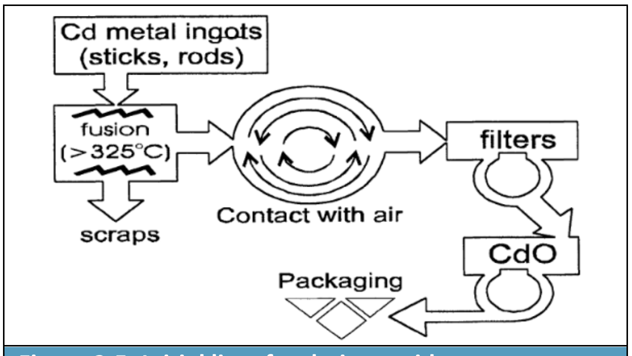


Figure 2-5: Initial list of cadmium oxide uses
Source: Cd REACH Consortium (2012b)

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

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

31 See http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-sulphide-2151478.

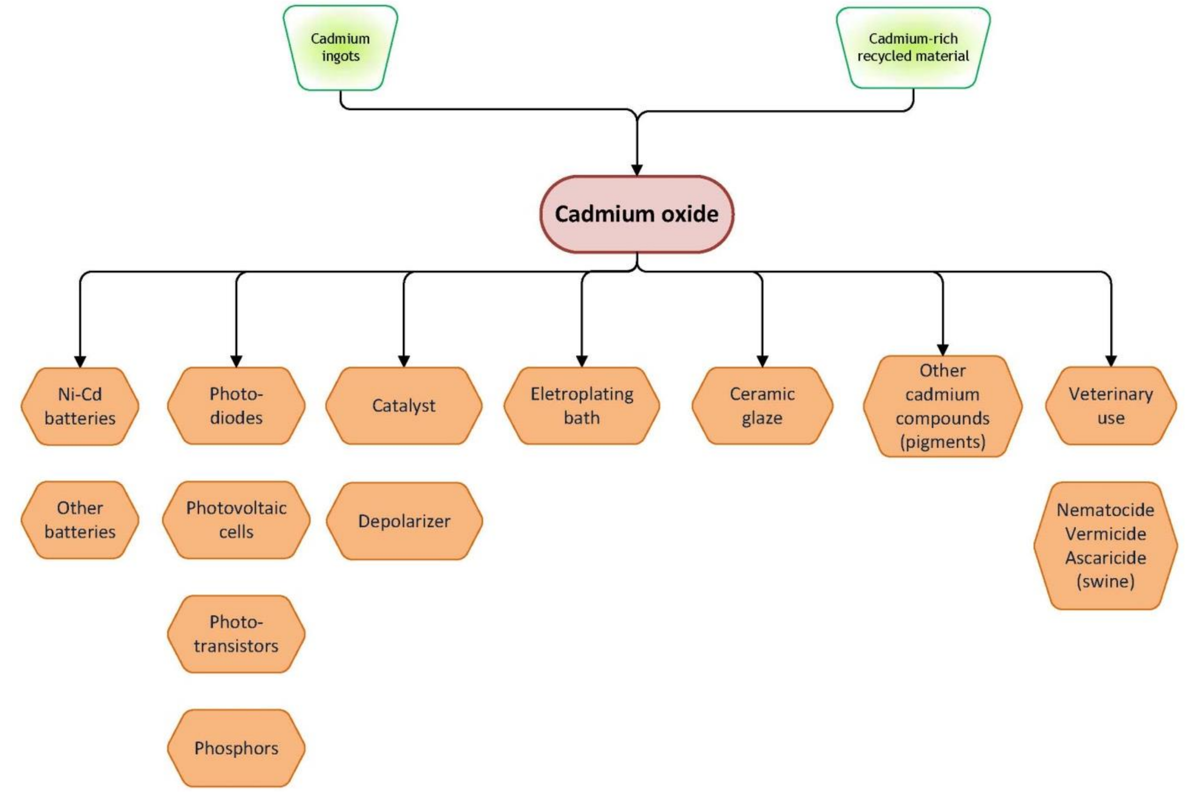


Figure 2-6: Initial overview of cadmium oxide uses
Source: Cd REACH Consortium (2012b)[32]

2.5.8 Cadmium carbonate

According to Considine (1995), cadmium carbonate is produced by the reaction of cadmium hydroxide and carbon dioxide or upon precipitation of a cadmium salt with ammonium carbonate. The Cd REACH Consortium[33] has identified the following uses of cadmium carbonate:

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

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

[33] See http://www.reach-cadmium.eu/substance-information-exchange-forum/substance-uses/cadmium-carbonate-2081689.

2.5.9 Cadmium hydroxide

The Cd REACH Consortium[34] has identified the following uses of the compound:

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

2.5.10 Cadmium nitrate

The Cd REACH Consortium[35] has identified the following uses of the compound:

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

2.5.11 Cadmium sulfate hydrate

The substance is not REACH registered and no information on uses has been identified.

2.6 Reference points for the assessment (OELVs)

The objective of the study is to provide a comparison of the costs and benefits for a range of potential OELVs (as opposed to one or several specific OELVs). This range starts at the lowest technically feasible limit[36] and ends at the current OELs, and encompasses the value in the SCOEL opinion.

Specific values have, however, been established for the purposes of the consultation exercise to provide reference points to the consultees who may otherwise have found it impossible to provide data on the costs of the measures being considered. The reference points used for cadmium are summarised below.

---

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

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

[36] However, please also see the discussion on the feasibility of 1 µg/m3 (inhalable) later in this report.

Table 2-7: OELVs acting as reference points for this study		
Option	**Respirable fraction (µg/m³)**	**Inhalable fraction (µg/m³)**
SCOEL/OPIN/336 & ACSH Doc. 663/17	*0.4 µg/m³*	1 µg/m³
ACSH Doc. 663/17 (transition period)	*1.6 µg/m³*	4 µg/m³
REACH DNEL[37] & ICdA Guidance	4 µg/m³	*10 µg/m³*
Lowest national OEL (BE, IE, PL, ES)	2 µg/m³	*5 µg/m³*
Mean, median, and mode of current national OELs	10 µg/m³	*25 µg/m³*
Notes: Values in italics in shaded cells denote calculations by the study team using a Respirable->Inhalable conversion factor of 2.5. Where there are several OEL values in a Member State, the lower value was used for the calculation of mean, median and mode. Where particle size for Cd OEL has not been specified, it has assumed (for the purposes of calculating the mean, median and mode) that this is respirable since those Member States that specify the particle size of their OEL more often use 'respirable'.		

The factor for converting from respirable to inhalable measurements used in this report is 2.5. Although the establishment of a general factor is highly uncertain, such a factor is necessary for the purposes of this study, which needs to bring together data and suggestions expressed as different particle sizes. A ratio of 2.5 was selected to be protective of workers. The use of a higher ratio of 4 (which industry sources consulted for this study believe to be the average value) or 6 (which an industry source sees as a best case scenario) would be less protective to workers.

Other conversion factors are considered within the framework of the sensitivity analysis to ensure that the costs to industry are not underestimated. This is necessary because, when estimating compliance costs to ICdA member companies, which have for a number of years been measuring air concentrations as respirable fraction (in line with SCOEL/SUM/136 2010), the use of a conversion factor of 2.5 multiple (a low value hypothesis) to generate a theoretical inhalable value could result in an underestimation of the true compliance costs. A higher 'real life' conversion factor would mean that more companies would not be in compliance with the potential OELV than estimated on the basis of a factor of 2.5.

[37] Derived No Effect Level for substances. The level of exposure above which humans should not be exposed (ECHA, 2015).

3 The Baseline Scenario

3.1 Introduction

This section comprises the following subsections:

- Section 3.2: Existing national limits
- Section 3.3: Relevant sectors, uses, and operations
- Section 3.4: Exposed workforce
- Section 3.5: Exposure concentrations
- Section 3.6: Current Risk Management Measures (RMMs)
- Section 3.7: Voluntary industry initiatives
- Section 3.8: Best practice
- Section 3.9: Standard monitoring methods/tools
- Section 3.10: Relevance of REACH Restrictions and Authorisation
- Section 3.11: Market analysis
- Section 3.12: Alternatives
- Section 3.13: Epidemiological and experimental data
- Section 3.14: Current and future burden of disease

3.2 Existing national limits

Apart from one outlier (Slovenia with an OEL of 120 µg/m³ inhalable), most OELs for cadmium and inorganic cadmium compounds are in the range of 10-50 µg/m³ (inhalable or total dust). These OELs are based on non-cancer effects and assume that protection from non-cancer effects would also largely protect from cancer risk.

Identified national OELs for cadmium and relevant cadmium compounds are presented in Table 3-1. All OEL and STEL values in this table are expressed as mg/m³.

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

Member State/Chemical agent	Value [mg/m³] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡	OEL definition	Study details	STEL [mg/m³]	Specification of STEL‡
Austria	0.03 (I) 0.015 (I)	-manufacture of batteries, thermic extraction of zinc, lead and copper, welding of Cd containing alloys	SE/T	Not known or not specified	0.12 (I) 0.06 (I)	-battery production, zinc-, lead- or copper winning, welding of cadmium containing alloys -other uses

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for cadmium and inorganic compounds						
Member State/Chemical agent	Value [mg/m³] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡	OEL definition	Study details	STEL [mg/m³]	Specification of STEL‡
		-other uses				
Belgium	0.01 (I) 0.002 (R)		SE/T		-	n.a.
Bulgaria	0.05		SE/T		-	n.a.
Croatia**	0.03 (R) 0.025	-CdS and pigments -CdF_2, CdO, $CdCl_2$	SE/T		0.05	-CdO
Cyprus	0.05 (T)	-metal powder and fumes, SKIN	SE/T		-	n.a.
Czech Republic	0.05	SKIN	HB		0.1	-ceiling
Denmark	0.005	–powder, dust, and smoke+	SE/T		-	n.a
Estonia	0.05 (T) 0.01 (I)		SE/T		-	n.a.
Finland**	0.004 (R)		SE/T	Endpoints: respiratory Species : human. Studies : (Cortona et al., 1992)	-	n.a.
France§§	0.05 (I)	+	SE/T	No published background	0.05	-CdO
Germany	0.001 µg/m³ (I) 0.0016 (R) 0.00016 (R)	–only for non-carcinogenic effects nephrotoxicity -"tolerable risk" (cancer risk value higher than OEL for nephrotoxicity) * -"acceptable risk"	HB	Endpoints: renal effects ; cancer Species : human. Animal (rat) Studies : (Takenaka et al., 1983; Thun et al., 1991; WHO, 2000) (lung carcinogen & renal effects)	0.008 (I)	
Greece	0.025		SE/T	Not known or	0.1	

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for cadmium and inorganic compounds						
Member State/Chemical agent	**Value [mg/m³] (I) inhalable; (T) total particulate; (R) respirable**	**Specification of value‡**	**OEL definition**	**Study details**	**STEL [mg/m³]**	**Specification of STEL‡**
Hungary	0.05 0.015	-CdF_2, $CdCl_2$, CdO -except CdF_2, $CdCl_2$, CdO^+	SE/T	not specified	-	n.a.
Ireland	0.03 (R) 0.01 (T) 0.025 (R) 0.002 (R)	-CdS and CdS pigments -except CdO fume and CdS pigments -CdO -except CdO fume and CdS pigments	HB		0.05 (R)	-CdO, fume or respirable dust
Italy	-		n.a.		-	n.a.
Latvia	0.01		SE/T		0.05	
Lithuania	0.05 (I) 0.01 (R)		SE/T		-	n.a.
Luxembourg	-		n.a.		-	n.a.
Malta	-		n.a.		-	n.a.
Netherlands	0.005 (R)	-CdO, CdS, $CdCl_2^+$	HB	Endpoints: renal, respiratory effects, Species : human Studies : (Cortona et al., 1992) (respiratory)	-	n.a.
Poland	0.01 (I) 0.002 (R)		HB	Endpoints: renal, Cancer Species : human Studies : (Thun et al., 1985), cancer	-	n.a.
Portugal**	0.01 (I) 0.002 (R)		HB	Not known or not specified	-	n.a.
Romania	0.05		Not known		-	n.a.

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for cadmium and inorganic compounds						
Member State/Chemical agent	Value [mg/m³] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡	OEL definition	Study details	STEL [mg/m³]	Specification of STEL‡
Slovakia	0.15 (I) 0.03 (I)	-others -production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals	SE/T		-	n.a.
Slovenia	0.03 (I) 0.015 (I)	-production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals -others	SE/T		0.12 (I) 0.06 (I)	-production of batteries, production of zinc, lead and copper after heat treatment, welding of cadmium-alloyed metals -other uses
Spain	0.01 (I) 0.002 (R)		SE/T	Not known or not specified	-	n.a.
Sweden	0.02 (T) 0.002 (R)		SE/T		-	n.a.
United Kingdom	0.03 0.025	-CdS and CdS pigments, SKIN⁺ -except CdS pigments, SKIN⁺	SE/T		0.05	-CdO fume, SKIN
SCOEL[2,**]	0.001 (I)		HB	Endpoints: renal, respiratory effects, cancer Species : human Studies : (Cortona et al., 1992) (respiratory)		n.a.

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for cadmium and inorganic compounds						
Member State/Chemical agent	Value [mg/m^3] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡	OEL definition	Study details	STEL [mg/m^3]	Specification of STEL‡
Selected non-EU countries						
Australia	0.01		Not known	Not known or not specified	-	n.a.
Brazil	-		n.a.	Not known or not specified	-	n.a.
Canada, Ontario	0.01 (I) 0.002 (R)	+ +	Not known	Not known or not specified	-	n.a.
Canada, Québec	0.025	-except CdO fume and CdS pigments+	Not known	Not known or not specified	-	n.a.
China	0.01		SE/T	Not known or not specified	0.02	
India	0.05		Not known	Not known or not specified	-	n.a.
Japan, JSOH**	0.05		HB	Not known or not specified	-	n.a.
South Korea[1]	0.01 (T) 0.002 (R)		SE/T	Not known or not specified	-	n.a.
USA; ACGIH[3,**]	0.01 (I) 0.002 (R)		HB	Endpoints: renal effects, cancer Species : human Studies : (Thun et al., 1985) (carc.), (Kjellström et al., 1977) (renal)	-	n.a.
USA, OSHA	0.005 (T)		SE/T	Not known or not specified	-	n.a.
USA, NIOSH**	#		SE/T	Not known or not specified	-	n.a.

‡ Cadmium and inorganic cadmium compounds, for all occupations, as Cd, 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.*
§§ Limit values have an indicative character – according to decree modified on 30 June 2004 – thus not legally binding.
** This concentration is not regarded as a fixed OEL in Germany (AGS; TRGS 910; https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=4), but as an upper limit, determined by non-cancer effects, for which the threshold*

Table 3-1: OELs and STELs in EU Member States and selected non-EU countries for cadmium and inorganic compounds						
Member State/Chemical agent	Value [mg/m³] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡	OEL definition	Study details	STEL [mg/m³]	Specification of STEL‡
for non-cancer effects was lower than the excess cancer risk of 4:1000. However, exposure below the "tolerable risk level" but above the "acceptable risk level" needs to be minimised in order to avoid cancer risk. *# No recommended exposure limits (RELs) established - Reference to "Appendix A - NIOSH 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.* *References:* *Questionnaire information (this project) or GESTIS (IFA, 2017), or country specific lists of OEL from web-search, if not stated otherwise (references 2-3, below).* *1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen.* *2: SCOEL (2017) Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compunds* *3: ACGIH (2016) American Conference of Governmental Industrial Hygienists. TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.*						

3.3 Relevant sectors, uses, and operations

This section provides an overview of the sectors, uses, and activities in which occupational exposure is likely to take place. For a general introduction to cadmium and its compounds, please refer to Section 2.

Table 3-2: Cadmium and inorganic Cd compounds – sectors and uses		
Sector	**Uses and/or activities**	**Notes**
1: Zn & Cu smelting and Cd refining	Extraction and refining of Cd	
2: Speciality chemicals	Mechanical or chemical transformation of Cd metal into specialised compounds, mainly for the battery, PV panels and pigments sectors	
3: Ni-Cd batteries	Production of Ni-Cd batteries	
4: Pigments	Production of pigments	ICdA: Cd compounds not classified hazardous vs. SUMER 2010: Cadmium sulphide
5: Aerospace & defence	Parts[38], connectors and fasteners undergo Cd surface treatment	
	Brazing alloys	
6: Surface treatment contractors	Subcontracted surface treatment for Sector 5, includes repair & maintenance[39]	
7: Niche manufacturing	PV panels, low temperature infra-red detectors, high performance contact materials	
8: Recycling	Post-industrial waste, used batteries, treatment of ZnO dust captured in Zn smelters' bag houses, metals	
	WEEE recycling (shredding of electronic waste)	Consultation for this study[40] indicates that exposure to Cd is a result of: a) shredding of older TVs, where Cd was used in fluorescent resin powder in cathode ray tubes (CRTs) b) small Ni-Cd batteries which have accidentally not been removed during the recycling process
9: Mining of non-ferrous metal ores	A: Exposure at all stages of production processes (mining, beneficiation, haulage) B: Maintenance workers and process operators	CdS in ore, Cd in ore

38 Assumed to include landing gears.

39 See http://dublinaerospace.com/landing-gear/

40 Information provided by a) a WEEE recycling company and b) ICdA which collected the information from the the European Electronics Recyclers Association (EERA).

Table 3-2: Cadmium and inorganic Cd compounds – sectors and uses		
Sector	**Uses and/or activities**	**Notes**
10 Metals fabrication	Smelting (steel), foundries, refining	Cadmium is sometimes measured in foundry dust. Cd is a part of the amalgam of castings alloys, in low concentrations. Therefore, exposure to these substances through foundry activities is no source of concern to the companies. The exposure is below the present OELs.
11 Glass	Production of frit	Cadmium carbonate
12 Cement	Cement & clinker production	
13 Other (ASA, excl. those already mentioned above and those with fewer than 20 exposed workers)	Real estate and landscaping Office and institutional detergents etc.; Agricultural and industrial machinery installers and repairers Laboratories Waste incineration and water treatment plants process managers Electrical, gas and heat supply, cooling business Scientific research and development Architectural and engineering services; technical testing and analysis Public administration and defense, compulsory social insurance Paper, paper and board products manufacturing Electronics and automation equipment installers and repairers Office cleaners in offices, hotels and other institutions Pipe fitters Paper pulp and paper and board manufacturing process workers Insulators	
14 Other (consultation)	Welding, Cement Energy generation Glass	
Source: consultation and literature review		

There is a number of sectors that have been identified from consultation or the Finnish Register of Workers Exposed to Carcinogens (ASA Register) but for which exposure could not be corroborated from other sources. In Finland, employers are obliged to provide data on the exposure of workers to certain carcinogens to the Finnish Institute of Occupational Health (FIOH)) so that it can be entered into the ASA register (EU-OSHA, 2014)[41]. Although this is an obligation for employers, Kauppinen et al. (2007) note that it is likely some do not submit data.[42]

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

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

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

Table 3-3: Sectors in REACH registration CSRs that are relevant to Cd metal, Cd oxide, Cd carbonate
Cadmium metal production RLE
Cadmium metal production by pyrometallurgy
Storage of ingots-slabs in warehouses
Production of chemicals (pyro)
Production of chemicals (hydro)
Additive for production of inorganic catalysts
Melting, alloying and casting
Production of "targets" by (EB) PVD
Cadmium casting and rolling
Wire and rods manufacturing
Component for brazing products
Component for soldering products
Downstream use of Cadmium based brazing products
Downstream use of cadmium-based soldering products
Cadmium (alloyed) powder manufacturing
Powders for contact materials
Use of active powders for batteries
Use of fine powders for mechanical plating
Manufacturing of Cadmium containing-alloys
Use of cadmium containing Ag alloys
Electroplating
PVD / coating

3.4 Exposed workforce

This section first summarises the estimates at the EU-28 level, showing that the different sources provide a range of estimates. The key issues with regard to the different data sources are subsequently illustrated using the example of France. Next, a sector breakdown is provided. The last section provides conclusions.

3.4.1 Total number of exposed workers

Published sources (including extrapolations)

The only identified multi-country estimate is the CAREX database, with further estimates being available for the Czech Republic, Finland, France, and the UK (although the data for the UK are based on CAREX). These estimates are summarised below in Table 3-4. Extrapolations of the data above to the EU-28 are then summarised in Table 3-5.

Table 3-4: Published data – workforce exposed to Cd and Cd compounds			
Study	**Country**	**Year/period**	**No. of exposed workers**
Carex	EU-14	1990-1993 (mean)	207,000
	France	1990-1993	22,034
	Finland	1990-1993	1,040
	EU-5	1997	86,000
ICdA[43]	EU-28	2017	2,900
INRS[44]	France	2005	2,250-6,600
INRS (adjusted by ICdA)	France	2017	900-1,100
SUMER	France	2003	27,700
		2010	39,700
ASA[45]	Finland	2005	964
		2014	1,550
Regex	Czech Republic	2009-2016	49*
Note: *Cd only			

Table 3-5: Occupationally exposed population in the EU-28 (Cd and Cd compounds)	
Source estimate	**EU-28 extrapolation**
A: SUMER 2010 exposed workers in FR	300,000
B: CAREX EU14+5 mid-1990s	
D: ASA 2014 exposed workers in FI	140,000
E: ASA 2005 exposed workers in FI	90,000
F: INRS 2005 FR exposed workers in FR	17,000-50,000
G: INRS 2005 adjusted by ICdA for 2017, exposed workers in FR	6,800-8,400
H: ICdA 2017+consultation with individual companies	6,000-8,000
K: Regex 2009-16, exposed workers in CZ	2,400
Note: All extrapolations have been carried out on the basis of population. Extrapolation for estimate H also includes extrapolation on the basis of WEEE recycling statistics.	

Consultation carried out for this study

Using data from its occupational exposure biomonitoring programme, the International Cadmium Association (ICdA) estimates that approximately 2,900 workers are occupationally exposed to Cd and Cd compounds in the EU. The distribution of these across different sectors is provided in Table 3-6.

[43] ICdA (2017a): Where and how many workers are occupationally exposed to Cd and Cd compounds in the EU?

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

[45] See http://www.julkari.fi/bitstream/handle/10024/131073/ASA_2014.pdf?sequence=1

Table 3-6: Workforce exposed to Cd					
Sector	Use/operation	ICdA data			
		ICdA OCdAir coverage	Reported in OCdBIO	Estimate	Adjustment for currently exposed
Segment 1: Zinc smelters and cadmium refiners	Cd is extracted during zinc refining	Complete	1,350		850
Segment 2: Speciality chemicals manufacturers	Mechanical or chemical transformation of Cd metal into specialised compounds	Complete	80		50
Segment 3: Industrial battery manufacturers	Production of Ni-Cd batteries	Complete	1,400		880
Segment 4: Pigment manufacturers	Cd compounds not classified hazardous	Complete	70		40
Segment 5: Speciality aerospace & military mechanical parts, connectors and fasteners	Parts, connectors and fasteners undergo Cd surface treatment	Not in OCdBIO		350	
Segment 6: Surface treatment contractors	Subcontracted surface treatment for Segment 5	Not in OCdBIO		200	
Segment 7: Miscellaneous		Good	350		220
Segment 8: Recyclers of Cd containing waste	Post-industrial waste, used batteries, treatment of ZnO	Complete	450		280
Total			3,700*	550	2,900 (2330+550)*
Note: *ICdA estimates that only 63% of the workers that continue to be biomonitored are still in positions where they are exposed (workers continue to be bio-monitored even where exposure has ceased). This means that the current total in sectors covered under OCdBIO is 2,330 exposed workers. Source: ICdA final estimate in ICdA (2017a): Where and how many workers are occupationally exposed to Cd and Cd compounds in the EU?					

Consultation with companies that are not ICdA members provides either direct evidence or indications that a further 3,000-5,000 workers not captured in the table above may be exposed to cadmium and its inorganic compounds. This means that the total number of workers exposed to Cd, as indicated by consultation for this study, is between 6,000-8,000. However, it is unlikely that all the relevant companies have responded to the consultation exercise and it is therefore possible that the total exposed workforce is greater than 6,000-8,000.

3.4.2 Comparison of data for France from the different data sources

The differences between the data reported by the different sources can be illustrated using the data for France.

CAREX & SUMER

Data are also reported by the Medical Monitoring Survey of Professional Risks (Surveillance médicale des expositions aux risques professionnels, SUMER). These data are extrapolations from a sample of workers who self-declare exposure in a survey administered by company medical officers during the workers' regular compulsory medical examination[46]. For example the data reported for 2003 were extrapolated from a sample of 84 workers which declared that they may have been exposed to cadmium and its compounds[47].

Table 3-7: Workers exposed to Cd and Cd compounds in the SUMER survey

Year	Total no.	% of workforce	Duration of exposure	Extent of exposure
2010	39,700	0.2%	No indication: N/A <2h 27,900 (70%) 2-10h N/A 10-20h N/A >20h 5,100 (13%)	Not declared: 11,000 (28%) Very low: 23,100 (58%) Low: 4,800 (12%) High: N/A
2003	27,700	0.2%	No indication: 600 (2%) <2h 16,400 (59%) 2-10h 4,300 (16%) 10-20h 700 (3%) >20h 5,600 (20%)	Not declared: 4,000 (14%) Very low: 13,800 (50%) Low: 6,000 (22%) High: 3,100 (11%) Very high: 800 (3%)
1994	10,000	0.1%		

Note: Low exposure: less than 50% of OEL, High exposure: >50% of OEL, Very high exposure: may exceed exceed OEL. The indicate inhalable OEL in France is 50 µg/m3.
Source: SUMER reports
http://dares.travail-emploi.gouv.fr/IMG/pdf/synthese_stat_no_13_-_les_expositions_aux_produits_chimiques.pdf
http://dares.travail-emploi.gouv.fr/IMG/pdf/de118fichchimiecor.pdf
http://dares.travail-emploi.gouv.fr/IMG/pdf/Fiches_produits_chimiques_Sumer_1994.pdf

INRS (2005) & ICdA

By contrast, the INRS (2005) and ICdA datasets provide lower estimates. The INRS (2005) and ICdA were derived at different times but rely on comparable methods and the results are broadly consistent. The differences can be explained by recent developments.

[46] See https://www.eurofound.europa.eu/observatories/eurwork/articles/working-conditions/france-working-conditions-and-occupational-risks-sumer-2010

[47] See http://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/074000542.pdf

Table 3-8: ICdA and INRS data for France				
Sector	**INRS (2005)**	**ICdA (2017)**	**ICdA comments**	**INRS & ICdA combined***
S1: Zn smelting and Cd production	0	80		80
S3: Industrial batteries	500-1,000	400	The total headcount for the 3 French Ni-Cd plants is 900.	400
S4: Pigments and colourants	150-500	0	1 pigment company in 2005, closed down 2010	0
S5&6: Surface treatment	<100	220		220
S8: Recycling	0	50		50
S9: Textile finishing	1,500-5,000	0	Use for special coloring uses, non-carcinogenic zinc cadmium sulfide (ZnCdS) or cadmium sulfoselenide (CsSSe) are used.**	0
Other segments		150		150
Total	2,250-6,600	900	Reduce INRS (2005) by 1,650-5,500, resulting in 600-1,100	900
Note: *Follows ICdA suggestions. **Source: Pers. comm. with ICdA. Original source: oral communication between ICdA and the French textile industry organization, Union des Industries Textile (UIT) in October 2017.				

Comparison of the estimates

Although the two data sets appear to provide very different data, it is of note that the SUMER estimates are based on self-declaration and encompass a large number of workers that are exposed to low concentrations for short periods of time (in the 2010 dataset, the majority of workers are exposed to 'very low' concentrations for less than 2 hours per week). As noted in the explanatory note for the SUMER 2013 survey, the respondents were considered exposed as soon as the agent was present at the workplace, regardless of the duration and intensity of exposure. As a result, workers in the SUMER dataset should be treated as 'potentially exposed' rather than exposed to specific concentrations, in particular since the exposure levels are extrapolated from a limited set of self-estimated values.

In addition, the SUMER data do not take into account the possibility that some cadmium compounds do not have a classification as a carcinogen. The scope of the data in the SUMER database thus appears to be broader than the scope of this study. The selection in Section 2.4 of this report results in ten Cd compounds (in addition to Cd metal) being retained for assessment in this study. However, the scope of the SUMER survey is 'cadmium and its compounds' and may thus include compounds that are outside the scope of this study.

For example, the introduction to the cadmium section in SUMER 2010 notes that the relevant compounds include cadmium stearate (CAS No: 2223-93-0) which has a self-classification as non-carcinogenic and cadmium acetate (CAS No: 5743-04-4) which has 24 self-classifications as non-carcinogenic and one self-classification as carcinogenic.

On the other hand, 'Cd and the five Cd compounds' identified in the INRS (2005)[48] study as being used in the French industry[49] are among 'Cd and the ten compounds' selected for prioritisation in Section 2 of this report; the whole workforce in INRS (2005) is thus relevant to this study.

3.4.3 Sectoral break-down

A breakdown by sector of the data collected through consultation is provided below.

Table 3-9: Cadmium and inorganic Cd compounds – exposed workforce		
Sector	**Uses and/or activities**	**No of workers**
1: Zn & Cu smelting and Cd refining	Extraction and refining of Cd	ICdA: 850 Consultation: <500 Total: <1,350
2: Speciality chemicals	Mechanical or chemical transformation of Cd metal into specialised compounds, mainly for the battery, PV panels and pigments sectors	ICdA: 50
3: Ni-Cd batteries	Production of Ni-Cd batteries	ICdA: 880
4: Pigments	Production of pigments	ICdA: 40
5: Aerospace & defence	Parts[50], connectors and fasteners undergo Cd surface treatment	ICdA: 350 exposed workers (parts: 200, connectors: 100, fasteners: 50)
	Brazing alloys	Estimated to be very limited
6: Surface treatment contractors	Subcontracted surface treatment for Sector 5, includes repair & maintenance[51]	ICdA: 200
7: Niche manufacturing	PV panels, low temperature infra-red detectors, high performance contact materials	ICdA: 220
8: Recycling	Post-industrial waste, used batteries, treatment of ZnO dust captured in Zn smelters' bag houses, metals	ICdA: 280
	WEEE (shredding of electronic waste)	Estimate: 2,000[52]
9: Mining	Mining of ore & processing	Consultation: >1,100
10 Metals fabrication	Smelting (steel), foundries, refining	<2,000*
11 Glass	Production of frit	<10*
12 Cement	Cement & clinker production	<10 in relevant SEGs, <200 potentially exposed*

48 See http://www.inrs.fr/publications/bdd/cmr.html

49 The INRS (2005) data are based on a survey of 2,000 industrial sites in 30 industrial sectors. The following compounds have been considered: Cd metal, cadmium chloride, cadmium sulphate, cadmium fluoride, cadmium sulphide, cadmium oxide.

50 Assumed to include landing gears.

51 See http://dublinaerospace.com/landing-gear/

52 Consultation response, extrapolated to the EU on the basis of WEEE collection statistics, source of WEEE data: http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Waste_electrical_and_electronic_equipment_(WEEE),_total_collected,_by_EEE_category,_2014.png

Table 3-9: Cadmium and inorganic Cd compounds – exposed workforce		
Sector	**Uses and/or activities**	**No of workers**
13 Other (ASA & consultation)	See table below for ASA (2014) sectors Also, welding & energy generation Glass	Adjustment: 2,000
Total (best estimate)		***10,000***
Note: *Data for consultation response(s) & not extrapolated. Source: consultation and literature review		

A sector breakdown from the Finnish ASA Register is provided below.

Table 3-10: Workers exposed in Finland in 2014 by sector (ASA Register)	
Sector	**No. of exposed workers**
Metal processing	509
Real estate and landscaping	304
Process workers in the metal industry	268
Office and institutional detergents etc.	213
Collection, treatment and disposal of waste; recycling of materials	185
Agricultural and industrial machinery installers and repairers	184
Laboratories	140
Waste incineration and water treatment plants process managers	107
Electrical, gas and heat supply, cooling business	91
Scientific research and development	76
Architectural and engineering services; technical testing and analysis	75
Public administration and defense, compulsory social insurance	72
Paper, paper and board products manufacturing	54
Electronics and automation equipment installers and repairers	52
Mining of mineral ores	51
Office cleaners in offices, hotels and other institutions	46
Pipe fitters	41
Paper pulp and paper and board manufacturing process workers	30
Insulators	26
Others	406
Notes: There is some double-counting in the ASA register; a single worker may be counted above in more than one sector. Source: ASA Register 2014, available at http://www.julkari.fi/bitstream/handle/10024/131073/ASA_2014.pdf?sequence=1	

3.4.4 Trends

Although the Finnish ASA and French SUMER data suggest an increase in the exposed workforce over time, it is unclear whether this can be treated as representative of the trend across the EU. The French data suggest an annual expansion of the exposed workforce of around 2.5% and Finnish data suggest an increase of more than 5% per year. However, given legislative developments (REACH and other legislation such as the EU Toy Safety Directive), it is possible that these increases may reflect improved reporting rather than actual increases in the exposed workforce.

In particular, it is interesting that the ASA register shows no increase in the exposed worforce in the 1990s and early 2000s but indicates a large increase after 2005.[53]

3.4.5 Exposed workers: conclusion

The data collected through consultation for this study provides evidence of around 6,000-8,000 workers currently exposed to cadmium and its inorganic compounds. However, only limited extrapolation from the responses received to some of the sectors has been possible and some indications of exposure could not be confirmed. In order to reduce the potential for this study to underestimate the exposed workforce, the core estimate taken forward for modelling is 10,000. This is complemented by an estimate of 30,000 considered within the framework of the sensitivity analysis.

Table 3-11: Exposed workforce: conclusion

Estimate	No of exposed workers
Highest estimate	300,000
Lowest estimate	6,000-8,000
Estimate taken forward for modelling	10,000
Alternative estimate for the sensitivity analysis	30,000
Annual rate of change taken forward for modelling	Past: -7% p.a. (exp. level & workers) Future: Expected slight decline or 0%

3.5 Exposure concentrations

3.5.1 Current exposure concentrations

Available data on 8-hr TWA concentrations of Cd in the breathing zone of the worker are summarised below. Unless stated otherwise, these data originate from the consultation exercise for this study and most are sourced from ICdA's annual Observatory of Occupational Cd AIR exposure (OCdAIR) survey. OCdAIR data are available for 2016 and 2017 and have been collected using the following approach:

- Monitoring data based on shoulder/waist apparatus should be used in preference to fixed measurements;
- Workers should be grouped by Same Exposure Groups (SEG) and assessment conducted for each SEG separately;
- A minimum of 3 samples per SEG should be used;
- A lognormal distribution hypothesises assumed (and tested); and

[53] See Kauppinen et al (2007): https://academic.oup.com/annweh/article-lookup/doi/10.1093/annhyg/mem030

- For each SEG, an arithmetic mean, geometric mean, and 95th percentile 70% CI on a lognormal distribution have been calculated (where there are too few measurements to construct a log normal distribution, the 95th percentile has been estimated using a multiplier derived from the average difference for all other SEGs).

All data from the OCdAIR in the table below are for 2017. These data have been complemented with data collected through questionnaires, interviews, site visits and literature review for sectors for which no OCdAIR data are available.

Table 3-12: Cadmium and inorganic Cd compounds – exposure concentrations (ALL VALUES RESPIRABLE UNLESS SPECIFIED OTHERWISE)						
Sector	**Activities**	**Arithmetic Mean (AM)**	**Geometric Mean (GM)**	**90th percentile**	**95th percentile 70% CI (prEN 689)**	**Max**
1: Zn & Cu smelting and Cd refining	Roasting, boiler, purification, floating, leaching operators, warehouse, maintenance, mechanics, etc.		Min-Max: 0.03-4.95 µg/m³ SEG avg: 0.77 µg/m³ Worker avg: 0.5 µg/m³	Min-Max: 0.07-20.92 µg/m³ SEG avg: 2.26 µg/m³ Worker avg: 1.88 µg/m³	Min-Max: 0.16-48.75 µg/m³ SEG avg: 5.26 µg/m³ Worker avg: 4.64 µg/m³	
	Copper production, all workers are exposed	< 2 µg/m³		< 10 µg/m³		
2: Speciality chemicals	Purification, reactor, recycling		Min-Max: 0.11-1.5 µg/m³ SEG avg: 0.68 µg/m³ Worker avg: 0.76 µg/m³	Min-Max: 0.27-4.27 µg/m³ SEG avg: 1.91 µg/m³ Worker avg: 2.16 µg/m³	Min-Max: 3.56-11.12 µg/m³ SEG avg: 5.63 µg/m³ Worker avg: 5.73 µg/m³	
3: Ni-Cd batteries	Various operator roles, e.g. electrode cutting, maintenance		Min-Max: 0.002-1.98 µg/m³ SEG avg: 0.36 µg/m³ Worker avg: 0.43 µg/m³	Min-Max: 0.01-5.72 µg/m³ SEG avg: 1.01 µg/m³ Worker avg: 1.08 µg/m³	Min-Max: 0.02-17.68 µg/m³ SEG avg: 3.82 µg/m³ Worker avg: 3.19 µg/m³	
4: Pigments	Operators, maintenance, laboratories		Min-Max: 0.98-4.46 µg/m³ SEG avg: 2.63 µg/m³ Worker avg: 2.71 µg/m³	Min-Max: 4.03-9.29 µg/m³ SEG avg: 5.82 µg/m³ Worker avg: 6.40 µg/m³	Min-Max: 5.11-13.87 µg/m³ SEG avg: 9.7 µg/m³ Worker avg: 10.84 µg/m³	
5a: Aerospace & defence – surface treatment	Operators		Min/Max/SEG avg/Worker avg: 1 µg/m³	Min/Max/SEG avg/Worker avg: 2.85 µg/m³	Min/Max/SEG avg/Worker avg: 3.9 µg/m³	

Table 3-12: Cadmium and inorganic Cd compounds – exposure concentrations (ALL VALUES RESPIRABLE UNLESS SPECIFIED OTHERWISE)						
Sector	**Activities**	**Arithmetic Mean (AM)**	**Geometric Mean (GM)**	**90th percentile**	**95th percentile 70% CI (prEN 689)**	**Max**
5b: Aerospace & defence – brazing alloys						
6: Surface treatment contractors	Electo plating contractors		Min/Max/SEG avg/Worker avg: 1 µg/m³	Min/Max/SEG avg/Worker avg: 2.85 µg/m³	Min/Max/SEG avg/Worker avg: 3.9 µg/m³	
7: Niche manufacturing	Laboratories, Office &On-site, Front end operations, Back end operations, Deposition, Finishing, Cutting, Rodaging, Charge preparation, Polishing		Min-Max: 0.1-15 µg/m³ SEG avg: 3.5 µg/m³ Worker avg: 1.27 µg/m³	Min-Max: 0.2-42.68 µg/m³ SEG avg: 9.89 µg/m³ Worker avg: 2.85 µg/m³	Min-Max: 0.77-111.24 µg/m³ SEG avg: 25.68 µg/m³ Worker avg: 8.81 µg/m³	
	Workers in thin film solar cell production[54]		Production: 0.006 µg/m³* Maintenance: 0.067 µg/m³ Laboratory tests: 11.2 µg/m³			Production: 0.76 µg/m³ Maintenance: 217.9 µg/m³ Laboratory tests: 11.2 µg/m³
8a: Recycling – post-industrial	Battery sorting, dismantling cutting, compacter – refiner, head of team, maintenance, warehouse, sorting, production, foundry, tankhouse /electrolysis, lead/tin department, sampling and quality, department, internal transport, reception raw materials		Min-Max: 0.06-0.86 µg/m³ SEG avg: 0.14 µg/m³ Worker avg: 0.05 µg/m³	Min-Max: 0.01-3.5 µg/m³ SEG avg: 0.47 µg/m³ Worker avg: 0.21 µg/m³	Min-Max: 0.02-6.38 µg/m³ SEG avg: 1.06 µg/m³ Worker avg: 0.52 µg/m³	

54 Spinazze et al (2015): Occupational Exposure to Arsenic and Cadmium in Thin-Film Solar Cell Production, available at https://academic.oup.com/annweh/article/59/5/572/2196099

Table 3-12: Cadmium and inorganic Cd compounds – exposure concentrations (ALL VALUES RESPIRABLE UNLESS SPECIFIED OTHERWISE)						
Sector	**Activities**	**Arithmetic Mean (AM)**	**Geometric Mean (GM)**	**90th percentile**	**95th percentile 70% CI (prEN 689)**	**Max**
8a: Recycling –WEEE	Shredding of electronic waste	*0.2 µg/m3*[55]			*0.4 µg/m3*[56]	
9: Mining	U/G mining, beneficiation, crushing, support services (tech, storage, supervision, env. department, administration, etc.	Group average: 0.02 µg/m³				
	Outside stacks, warehouse, processing, labs	SEG avg: 11 µg/m³**				
10 Metals fabrication	Sampling, internal logistics, smelting, concentration, furnace, refinery	*Min-Max: 0.01-1.29 µg/m³ Group avg: 0.34 µg/m³ Worker avg: 0.4 µg/m³*				
	Foundries	< 0.08 µg/m³				
11 Glass		< 0.1 µg/m³				
12 Cement	Cement & clinker production	Not measured				
Notes: *Entries italics assumed respirable*. *55% of samples below LoQ[57]. **Heavily skewed by laboratory work. Source: consultation for this study						

The data in the table above can be compared with the data given in REACH registration CSRs (most of which is measured long term inhalation exposure, although some CSRs provide data derived through modelling). These data suggest exposure concentrations several orders of magnitude greater than

55 Exposure data are calculated on the basis of average residues in dust, using a worst case scenario. A set of exposure estimates has been validated by actual measurements & corroborated by the environmental and labour inspectorates at the recycling facility which provided these data in the framework of consultation for this study.

56 Estimated data - see above. 95th percentile calculated on the basis of individual estimated exposure concentrations without the estimation of a log-normal distribution.

57 Limit of Quantification: the smallest concentration of a measurand that can be reliably measured by an analytical procedure (Armbruster and Pry, 2008, Limit of Blank, Limit of Detection and Limit of Quantitfication, *The Clincial Biochemist Reviews*.Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2556583/)

the data collected through consultation. The average concentration per REACH CSR in total inhalable is 7 **mg**/m³ and the average concentration per REACH CSR is 2.4 **mg**/m³.

3.5.2 Trends

In order to determine the current and future burden of disease, it is necessary to consider how exposure concentrations have changed over time and how they are likely to change in the future.

Altough data from OCdAir are available for several years, and the data for 2015 and 2016 are summarised below, the differences between the datasets most likely reflect increased reporting in 2016 rather than substantive changes. In addition, data for two consecutive years are unlikely to be an accurate representation of a long-term trend.

Table 3-13: Comparison of OCdAIR data for 2015 and 2016 (all values µg/m3 respirable fraction)

Year	No. of workers covered by data	SEG averages			Worker averages		
		GM	90th percentile	95th percentile 70% CI	GM	90th percentile	95th percentile 70% CI
2015	1,190	1.20	3.29	6.28	0.88	2.74	5.94
2016	2,249	0.87	2.46	6.19	0.54	1.62	4.01
Note: All values are in µg/m³ (respirable fraction). Source: ICdA OCdAIR							

An indication of historical trends is also provided by Symanski et al (1998), see below. Individual consultation responses have not identified any significant decreases over time.

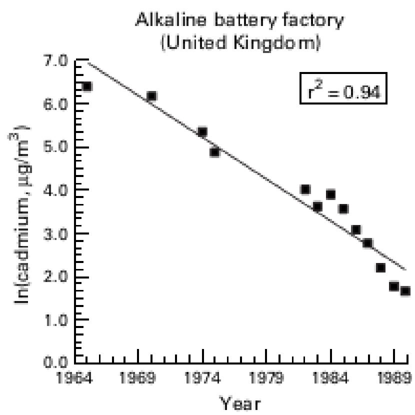


Figure 3-1: Exposure to Cd in an alkaline battery factory, Source: Symanski et al (1998)

For the purposes of modelling in this study, it is assumed that exposure concentrations have been declining on average by 3% per year. This is a generic value that generates a combined 7% decline in the exposed workforce and exposure concentrations; this value is consistent with previous Commission Impact Assessments. No further declines have been modelled for the future.

3.6 Current Risk Management Measures (RMMs)

A wide range of RMMs have been considered, reflecting the hierarchy of RMMs in the CMD, as set out in Table 3-14 below. Data on these have been collected both through literature review and consultation.

Table 3-14: Hierarchy of measures to be applied by the employers, as listed in the CMD

Type of measure	Measures specified in the CMD
Reducing the quantities of the chemical agents used (substitution and material reduction)	(a) limitation of the quantities of a carcinogen or mutagen at the place of work;
Reducing the number of workers exposed	(b) keeping as low as possible the number of workers exposed or likely to be exposed;
Reducing the concentration of the chemical agents at the workplace	(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;
	(d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
	(e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
	(f) application of suitable working procedures and methods;
Reducing the exposure of workers by protective measures	(g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
	(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
	(i) information for workers;
	(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;
	(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
Other measures	(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;

Data on the RMMs in place from the SUMER studies are reproduced below in Table 3-15, while data collected through consultation are summarised in Table 3-16.

Table 3-15: RMMs for workers exposed to Cd and its compounds in the SUMER surveys		
RMM	**SUMER 2010**	**SUMER 2003**
Collective measures		
None	34%	23%
Local Exhaust Ventilation (LEV)	28%	28%
Isolation		6%
General Dilution Ventilation (GDV)	9%	21%
No information	26%	22%
PPE		
Skin protection	56%	49%
Respiratory protection	49%	30%
Eye protection	56%	33%
None	30%	

Analysis of REACH registration CSRs for Cd metal, Cd oxide, and Cd carbonate suggests that all companies that are covered by the CSRs have in place the following measures:

- LEV;
- Process enclosures or semi-enclosures;
- Technical: Cyclones/filters (for minimizing dust emissions), efficiency: 70-90% (cyclones), 50-80% (dust filters), 85-95% (double stage, cassette filters); and
- Organisational personal and collective hygiene procedures, e.g. minimising the number of workers exposed or likely to be exposed as well as medical management system. Many more measures described, e.g. showers taken at end of shift, training etc.

Table 3-16: Current RMMs from consultation														
No & compound		Sector/ application	1 Substitute/reduce	2 Reduce workers	3 Reduce ambient concentration			4. Reduce worker exposure		Best practive				Possible to reduce further?
					3a Reduce concentration by process design	3b Reduce concentration by control equipment	3c. Reduce concentr.: detect problems	4a Collective	4b PPE	Comments	Lowest 8hr TWA achieved?	Which application did this apply to?	Which measures were used?	
1	Cd, CdO	Zinc smelting					Yes	Yes	Yes		*< 0.01 I < 0.002 R mg/m3*			
2	CdS	Pigment production, welding		Yes	Yes	Yes			Yes	Welding: on-tool extraction	*< 0.025 mg/m3*	Welding	Low conc. in consumables	No
3	CdO	Welding				Yes	Yes	Yes	Yes		*< 0.01 mg/m3*	Grinding		No
4	Cd, CdO	Smelting, mining, refining, WEEE treatment, waste handling, energy generation.			Yes	Yes		Yes	Yes		Below LoD	Mining, refinery, waste treatment etc.		Yes
5	CdS	Mining	No		Yes	Yes		Yes	Yes		*0.05 $\mu g/m3$*	Most stages		No
6		Copper production	No		Yes	Yes (LEV)	Yes	Yes	Yes	RPE in high exposure areas	AM: < 2 $\mu g/m^3$ 90P: < 10 $\mu g/m^3$			
7		Recycling/ metals	No	No	Yes (closed process as much as possible)	Yes (LEV)	Yes (targeted continuous measurements)	Yes (automatisation to avoid direct contact)	Yes (specific PPE)	Other: extensive worker training	AM: 0.2 $\mu g/m^3$ 95P: 0.4 $\mu g/m^3$			
8		Foundries				Yes (LEV)				Low Cd in casting alloys so possibly meet current OELs even without LEV				
9	$CdCO_3$	Glass	No	Yes (product rotation)	No	Yes (LEV)	No	Yes (natural ventilation)	Yes (assisted ventilation masks & glove,		<0.3 $\mu g/m^3$ inhalable = 0.1 $\mu g/m^3$ respirable			

Table 3-16: Current RMMs from consultation

No & compound		Sector/ application	1 Substitute/reduce	2 Reduce workers	3 Reduce ambient concentration			4. Reduce worker exposure		Best practive				Possible to reduce further?
					3a Reduce concentration by process design	3b Reduce concentration by control equipment	3c. Reduce concentr.: detect problems	4a Collective	4b PPE	Comments	Lowest 8hr TWA achieved?	Which application did this apply to?	Which measures were used?	
									shoes, workwear)					
10	CdS	Mining	No (Cd in ore)	No (not possible)	Yes	Yes (LEV, encapsulation, air filtering and closure of processes and places)	Yes (another element used as proxy)		Yes (ABEK P3 full mask, half masks with their own filters P3-level, protective equipment for the whole body, especially disposable protective overalls).		< 1 µg/m³ respirable except laboratory (<50 µg/m³)			
11	CdS	Mining	No	No	Yes	Yes	No	Yes	Yes		All < 0.05 µg/m³ respirable			
12		Cement			Yes (limit stoage, direct supply, closed conveyer belt)	Yes (filters, air-sealed cabins of tractors with filters)		Yes (wrapped & compressed RDF bales)	Yes (incl. single-use uniform and full face masks)					
13		Foundries				Yes (blown away with oxygen, dust extraction)			Yes (masks, clothing)					

Notes: *Italics, either not clear whether R or I or estimated on the basis of information in the consultation response*

3.7 Voluntary industry initiatives

The International Cadmium Association (ICdA) has a voluntary programme in place, built around a guidance document for its members as well as non-member companies (first issued 2006, revised 2013). The Guidance is linked to the following voluntary targets:

- 95% of European employees subject to medical surveillance and bio-monitoring as required by their occupational medical doctor and below the urinary cadmium level of 2 µg Cd/g creatinine by the end of 2017; and
- 98% of European employees subject to medical surveillance and bio-monitoring as required by their occupational medical doctor and below the urinary cadmium level of 2 µg Cd/g creatinine by the end of 2020.

The ICdA Guidance 2013 Revision comprises the following three pillars which are to be implemented concurrently:

- Plant cleanliness;
- Collective and individual hygiene procedures; and
- Medical surveillance of exposed workers, including bio-monitoring of both urinary cadmium and blood cadmium, as a safety net to detect any issue arising in pillars (1) and (2).

The key elements of the three pillars are summarised in Table 3-18. This table reproduces the key parts of the Eurometaux-ICdA guidance (some parts have been shortened). For the avoidance of misunderstanding, all sentences in italics are quotes from the ICdA guidance.

Table 3-17: Eurometaux – ICdA: Management of the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds (2013 Revision)

Elements	Details
	Pillar 1: Plant cleanliness
Eliminating cadmium deposits on all surfaces	This involves the requirement that floors, structures, machines, change rooms be kept tidy, so as to ensure that cadmium containing dust deposited onto surfaces cannot be remobilised by air movements into the working environment nor picked up by physical contact. In practical terms, adequate equipment and proper routines need to be set up. These routines should include, inter alia: • Choosing the floor coating colour which helps spotting any deposits (choose a floor coating colour which contrasts with the Cd compound being controlled); • Acquiring floor scrubbers, and putting in place the adequate cleaning routines (preferably involving water spraying to avoid remobilization of dust to air); • Setting up negative pressure piping with permanent/moveable click-on suction hoses; • Implementing regular routine addressing structure clean-up; • Include machine clean-up at the end of each shift in the shift ending procedure; and • Handling of contaminated defect equipment – cleaning or isolating before it is sent to the workshop.
Ensuring workplace air quality	**Selecting the workplace OEL:**

Table 3-17: Eurometaux – ICdA: Management of the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds (2013 Revision)	
Elements	**Details**
	"In 2010, SCOEL gave its view as to what the EU-wide health-based OEL should be. Although as of today, EU institutions have not yet acted on this by adopting a legislative instrument, the Cadmium consortium and lead registrants of Cd and compounds brought this proposed OEL forward as the DNEL in the REACH registration dossiers of these substances. *For this reason, this DNEL becomes legally binding on Producers and Downstream Users. The DNEL of the cadmium and compounds REACH registration dossiers is 4 µg/m3 (respirable)."* **Ensuring compliance:** In order to comply with this DNEL, equipment upgrade may be required and should include, inter alia, a combination of the following adjustments: o Installing plant wide piping, connected to negative pressure ventilation, along with adequate filtration before air is released to the outside atmosphere; o Placing machinery within negative pressure enclosures where feasible; o Installing, when and where appropriate, suction heads in places where cadmium releases occur (this should be preferred over ensuring a building-wide air circulation and replacement speed); o Conduct local adequate air flow studies before new equipment is installed so as to ensure adequate air speed is obtained at the opening of each suction head; and o Conduct section wide air flow studies when plant layout is modified. These should cover heating and ventilation issues so as to understand and control the air flow (along with related costs) with this equipment in mind. In cases, where it is impossible to maintain exposure at all times below the occupational exposure limit, or during intervention or particular maintenance work with risk of exposure respiratory protection devices with P3 efficiency level shall be worn (for efficiency levels see EN 143). It is recommended to provide blower supported devices. For tasks of up to 2 hours normal half or full masks can be used.
Pillar 2: Collective and personal hygiene procedures *Once the inhalation route is placed under control through compliance with workplace air quality requirements (see above), the ingestion route may become the predominant route of cadmium intake.*	
Collective level	• Conduct initial training on cadmium related risks: how to mitigate it and the importance of complying with rules and policies; • Conduct refresher training on these issue on a regular basis, preferably yearly; • Set up dual compartment change closets: preferentially with separate change rooms for the city clothes side and the work clothes side, separated by a shower section; and • Have employer supplied work clothes: with adequate frequency of clean clothes supply (from weekly to daily depending on the area), taking into account the differing requirements of male/female employees as well as the specific requirements for the different seasons of the year. This should also

Table 3-17: Eurometaux – ICdA: Management of the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds (2013 Revision)	
Elements	**Details**
	include company supplied laundry service, so that dirty clothes do not find their way into the home of employees.
Individual measures (requirements for employees)	• The requirement to comply with the above mentioned collective hygiene procedures; • The requirement to take a shower after the end of each shift: which requires that an adequate number of showers is made available, so as not to discourage employees from showering; • The requirement to only smoke, snack and drink in designated areas, these activities must not occur within work areas; • The requirement to wash one's hands before all meals, snacks and breaks; • An encouragement to stop smoking, biting nails and to avoid growing facial hair, these being habits which favor the accumulation and transfer of cadmium into the organism; and • The requirement to store all personal objects (keys, cell phone, cigarette packs...) in dedicated lockers outside of the work area.
Pillar 3: Medical surveillance	
Identification of employees covered	All employees under a risk of exposure to cadmium, whether on a permanent basis or occasional basis, throughout their work day, are to be identified by plant management and the occupational medical doctor. The medical monitoring of employees who have been exposed to cadmium and have been removed from exposure for medical reasons needs to be continued.
Exposure biomarkers[58] and their uses	• Cd-B (Cd concentration in blood) is a biomarker which is influenced both by total exposure (integrated over 20 years) and recent exposure (over the past 3 months), both from ingestion and inhalation. However the variation of Cd-B over two consecutive dates if less than a year apart reflects recent exposure, and its sensitivity to recent exposure, in both directions (up or down), is quite high. • Cd-B should therefore be used to detect an equipment dysfunction or a poor implementation of hygiene policies which happened over the past 3 months. • Cd-U (Cd concentration in urine) is a biomarker which reflects total exposure of the worker over a period of 20 years. It integrates both ingestion and inhalation. There is a direct proportion between urinary clearance of cadmium and cadmium load in the kidney, which above certain levels may induce tubular dysfunction. Cadmium half-life in the kidney is approximately 20 years. Therefore, this biomarker varies quite slowly over time. • Cd-U should therefore be used to assess whether an exposed worker total exposure brings them to a situation in which his risk to develop a tubular dysfunction is increased over a non-exposed worker. • To ensure good correction for urine dilution, and ensure this indicator is meaningful, this biomarker needs to be standardised by means of a creatinine measurement.

58 "Indicator signaling an event or condition in a biological system or sample and giving a measure of exposure, effect, or susceptibility." (IUPAC, Accessed Feb2018)

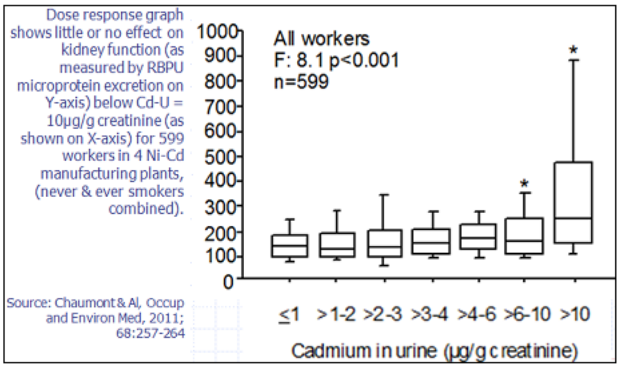
<table>
<tr><th colspan="2">Table 3-17: Eurometaux – ICdA: Management of the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds (2013 Revision)</th></tr>
<tr><th>Elements</th><th>Details</th></tr>
<tr><td></td><td>Figure 1. Urinary RPB as a function of Cd in urine (adapted from Chaumont et al 2011).


Figure 1 indicates that no degradation of the kidney tubular reabsorption (as measured by urinary RBP) function occurs if cadmium in urine is maintained below the 5 to 10 µg Cd / g creatinine level</td></tr>
<tr><td>Effect biomarkers and their uses</td><td>In order to measure the actual decrease in kidney functionality, and more specifically on tubular reabsorption, the urinary clearance of one amongst several proteins is measured.

The most commonly used proteins for this purpose are:

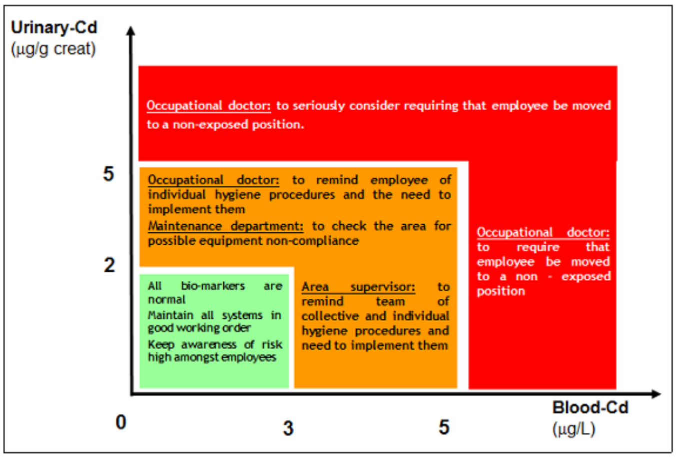
• Retinol binding protein (RBP)
• Alpha 1 microglobulin (α1 microglobulin also called protein HC)
• Beta 2 microglobulin (β2M)

In table 1 is the guideline given to interpret the results of microprotein excretion.

Table I. Interpretation of elevated values of urinary β_2-microglobulin (β_2-M) and retinol-binding protein (RBP) induced by occupational or environmental exposure to Cd
<table>
<tr><th>β_2-M or RBP in urine (µg/g creatinine)</th><th>Significance</th></tr>
<tr><td>< 300</td><td>Normal value</td></tr>
<tr><td>300 - 1,000</td><td>Incipient Cd tubulopathy (possibility of some reversal after removal of exposure if urinary Cd is not too high i.e. below 20 µg/g cr)</td></tr>
<tr><td>1,000-10,000</td><td>Irreversible tubular proteinuria that may accelerate the decline of glomerular filtration rate with age. At this stage glomerular filtration rate is normal or slightly impaired.</td></tr>
<tr><td>>10,000</td><td>Overt Cd nephropahy usually associated with a decreased glomerular filtration rate</td></tr>
</table>
Modified from Ref. 4

Source table I: Bernard A. Cadmium & its adverse effects on human health. Indian J Med Res. 2008; 128(4):557-64. Review.
Ref 4= Bernard A. Renal dysfunction induced by cadmium: biomarkers of critical effects. Biometals 2004; 17: 519-23.</td></tr>
<tr><td>Using exposure biomarkers to conduct adequate advanced medical surveillance (Cd-U)</td><td>• Cd-U =< 2 µg Cd/g creatinine, [2 µg Cd/g creatinine is a conservative threshold (and action level) based on general population studies (green zone, see the decision diagram below)]:
  ○ general medical follow-up is conducted along with regular measures of the exposure indicators Cd-U, Cd-B and the subclinical effect BI (urinary protein excretion measurement), no further special action is required beyond proper implementation of the general hygiene procedures and medical surveillance.

• 2 µg Cd /g creatinine < Cd-U =<5 µg Cd/g creatinine, [5 µg Cd/g creatinine is a 2nd threshold (and action level) based on studies at the workplace (orange zone, see the decision diagram below)]:
  ○ general medical follow-up is conducted along with regular measures of the exposure indicators Cd-U, Cd-B and the subclinical effect BI (urinary protein excretion measurement), and
  ○ a detailed analysis of the related workplace (by plant maintenance) along with an assessment of collective (by area supervisor) and individual hygiene procedures implementation, including training are conducted (by occupational doctor).</td></tr>
</table>

Table 3-17: Eurometaux – ICdA: Management of the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds (2013 Revision)	
Elements	**Details**
	• Above Cd-U > 5 µg Cd/g creatinine (red zone, see the decision diagram below): ○ worker is removed from cadmium exposure.
Using exposure biomarkers to conduct adequate advanced medical surveillance (Cd-B)	Cd-B is function of both the Cd body burden (and as such partially proportionate to Cd-U) and of recent exposure. Cd-B is used as a complementary biomarker, mainly to identify recent accumulation (approximately within the preceding 3 months). Cd-B is evaluated as follows: • A rapid increase of Cd-B towards 3 µg Cd/L or the exceedance of an action level of 3 µg Cd/L triggers a detailed analysis of the related workplace (by plant maintenance) along with an assessment of collective (by area supervisor) and individual hygiene procedures implementation, including training (by occupational doctor); and • A rapid increase of Cd-B towards 5 µg Cd/L or the exceedance of an action level of 5 µg Cd/L triggers the removal of the worker from exposure.
Decision diagram	Figure 2. Decision diagram: 
Using the effect biomarker (B2-M, RBP or protein HC)	In all situations, if the effect biomarker is exceeding the reference value or shows a consistent pattern of increase, which may lead to approaching the reference value (300 µg/g creatinine for beta-2 microglobulin (P2-MG) and retinol binding protein (RPB), or 700 [µg/mmol creatinine (=6200 [µg/g creatinine) for alpha-1 microglobulin (a1-microglobulin or protein HC), the worker is removed from cadmium exposure.
OCdBio: Observatory of Occupational Cadmium Biomarkers	Reporting of biomarkers to ICdA
Source: Eurometaux ICdA Guidance 2013 revision. http://www.cadmium.org/doc/menu_86/icda-guidance-document-2013-revision-final.pdf	

The ICdA Guidance is comprehensive and provides targets for companies to follow, both in terms of air concentrations (4 µg/m3 respirable fraction, which, using the conversion ration of 2.5, is taken as equivalent to 10 µg/m3 inhalable fraction for the purposes of this report) and Cd-U (cadmium in urine) and Cd-B (cadmium in blood). These targets broadly correspond to Approach 2 in ACSH Doc. 663/17 (see Section 2.1.2).

The current degree of compliance with these targets is summarised below, based on ICdA's reporting of Cd air concentrations (OCdAIR) and Cd-U (OCdBio).

Table 3-18: Compliance with the voluntary target of 4 µg/m3 respirable fraction

	% of workers in SEGs/companies that have achieved 4 µg/m3 respirable fraction			% SEGs that have achieved 4 µg/m3 respirable fraction		
Source	**Achieved**	**Not achieved**	**Inconclusive**	**Achieved**	**Not achieved**	**Inconclusive**
OCdAIR 2016	36%	18%	46%	27%	20%	54%
OCdAIR 2017	64%	13%	23%	48%	19%	33%
Est. all workers*	50%*	50%*	*	-	-	-

Notes:
*Indicative, 70% confidence test could not be carried out.
Using a conversion factor of 2.5, 4 µg/m3 respirable fraction converts into 10 µg/m3 inhalable fraction

The data for Cd-U is provided below.

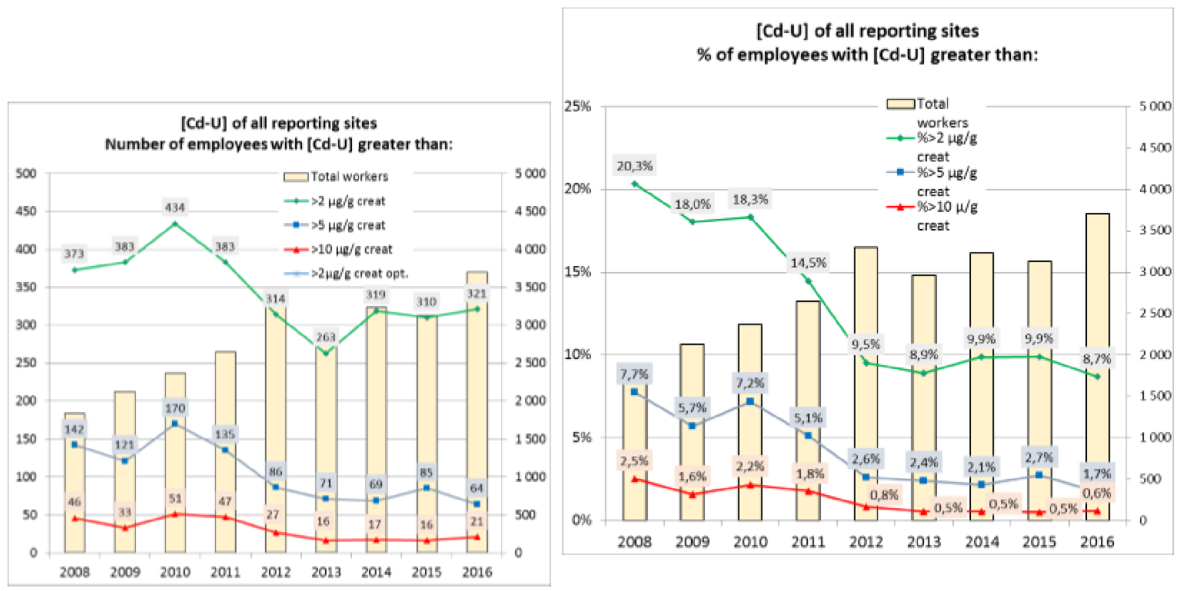


Figure 3-2: Cd-U in OCdBio 9 (2017), Source: ICdA

The data presented above suggest that between one half and two thirds of workers may be working in companies/SEGs that have already achieved compliance with 4 µg/m3 respirable fraction (based on P95 70% confidence). The proportion of workers that have achieved Cd-U below 2 µg Cd /g creatinine is even greater; OCdBio 9 (2017) suggests that this proportion is over 90%. Exposure in excess of the voluntary industry targets appears to be declining and it is expected to continue to decline in the future; data provided by the ICdA show that when only workers hired in or after 2000 are considered, the proportion of workers with Cd-U below Cd-U below 2 µg Cd /g creatinine is 97%, suggesting that Cd-U in excess of 2 µg Cd /g creatinine is mainly associated with workers that may have been exposed to high concentrations in the past.

Although reporting in OCdAIR and OCdBio does not cover some workers that are expected to be exposed to cadmium and its inorganic compounds, it appears that the proportion of workers that are at or below 4 µg/m3 respirable fraction appears to be broadly consistent between OCdAIR 2017 and companies that do not participate in this reporting scheme.

3.8 Best practice

3.8.1 Risk Management Measures

The study has tried to identify examples of best practice RMMs in addition to the measures set out in the ICdA Guidance. This has included identification of RMMs by:

- Application, where examples of best practices for the specific applications are listed; including a description of the combination of RMMs for the main processes and their efficiency; and

- Technology type, where examples of the good/best technologies and their efficiency are described across the different applications (for some technologies, e.g. for design of work processes for reducing releases of the chemical agents, the technologies are very application specific).

One such example identified through consultation is best practice at a WEEE recycling facility, as described below.

Table 3-19: RMMs at a WEEE recycling facility

Type of measure	Details
	Organisational
Internal occupational health & safety management system in place?	Yes, OHSAS 18001
Training management system in place (incl. documentation)?	Yes, use is made of an operational capability matrix; tasks that employees can perform are linked to the level of training, including OHS training. Toolbox trainings are given, special films are shown. In 2016 96 different OHS topics were addressed.
Regular cleaning of workplaces prescribed?	Yes, inside and outside
Washing/shower facilities available to workers?	Yes, both everyday showers and washing facilities and calamity showers and eye washers.
Job rotation?	Yes, but only for ergonomic purposes (in case of repetitive work)
Record keeping according to Article 15 CMD	Yes
	Technical
Prevention	Separation of high risk materials at source
Collective RMMs	Fogging and moistening of floors and waste; fume on waste material to make it sticky Spraying of outdoor space to prevent dry dust from whirling Closed system for thermo-mechanical recycling Local suction at source Roof ventilation
Individual RMMs	PPE (gloves, sleeves)
Source: consultation for this study	

3.9 Standard monitoring methods/tools

3.9.1 Analytical methods identified from desk research and consultation

Cadmium concentrations are generally measured although an example of a company that estimates Cd content in dust in the workplace on the basis of Cd content in waste has also been identified. Measurements can be either as inhalable or respirable fraction.

SCOEL (2017) lists two methods for measuring Cd in workplace air; these are summarised in the table below.

The UK-HSE MDHS91/2 method requires the use of either an inhalable or a respirable dust sampler upstream of the sampling on a filter, according to UK-MDHS14. This is in order to distinguish between inhalable and respirable particulates.

The DFG method is based on full digestion of the air sample on the filter and elemental analysis by (graphite) furnace atomic absorption spectroscopy (GFAAS or FAAS). The UK- HSE method is based on direct analysis of the loaded filter by X-ray fluorescence spectroscopy (XRFS).

Table 3-20: Analytical methods in SCOEL/OPIN/336

Method	Respirable (R) and/or Inhalable (I)	Stationary (S) and/or personal (P)	Analysis	Flow rate/sample volume/time	LoD*/LoQ**
UK-HSE MDHS91/2	R and I	S and P	XRFS	Long-term: max. 8 hours (960 L) Short-term: 15 minutes (60L) 2 L/min	LOD: 1 µg (Kα X-ray line) 0.005 µg (Lα X-ray line) LOQ: 4 µg (Kα X-ray line) 0.02 µg (Lα X-ray line)
DE-DFG	Not possible	S and P	GFAAS FAAS	420 L 45,000 L	LOQ 0.10 µg/m³ LOQ 0.17 µg/m³
Notes: *Limit of Detection, **Limit of Quantification Source: SCOEL/OPIN/336					

It is noted that both methods available have a problem, there is no separation into respirable fraction with the DE-DFG method or the LOQ is not low enough for the UK-HSE method).

A method used in Denmark and other methods identified through literature review and consultation are summarised below.

Table 3-21: Sample and analytical methods for Cd

	Data for Denmark	Spinazze et al (2015)[59]	Consultation
Sampling method	Active		
Sample media	Not weighted filter e.g. Teflon		
Flow rate (l/min)	1-4		

[59] Spinazze et al (2015): Occupational Exposure to Arsenic and Cadmium in Thin-Film Solar Cell Production, available at https://academic.oup.com/annweh/article/59/5/572/2196099

Table 3-21: Sample and analytical methods for Cd			
	Data for Denmark	Spinazze et al (2015)[59]	Consultation
Sample duration	5 h		
Recommended airflow	300 l		
Limit of quantification	0.002 µg/filter		
Limit of quantification (LoQ) µg/m^3	0.0035*	0.0017 (fixed); 0.0037 (personal) (assumed RESPIRABLE)	LoD** 0.1 (respirable)
Cost of analysis EUR incl sample media	185		
*Flowrate 1,9 l/min. Sample duration 5 h ** LoD (Limit of Detection)			

The LoQ appears to be between 0.0017 µg/m^3 and 0.0037 µg/m^3 (respirable) depending on whether fixed site measurements are taken or personal sampling devices are used.

GESTIS database

The 'GESTIS - Analytical methods' database 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 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.

The 'GESTIS - Analytical methods' database contains 16 methods for 'Cadmium and Cd compounds except CdO fume and CdS pigments (as Cd)'. Of these, 6 are assigned an 'A' ranking, 10 a 'B' ranking and none a 'C' ranking. The following table summarises the most important information for the four methods with an 'A' ranking.

Table 3-22: Analytical methods for cadmium and compounds ('A' ranking methods)					
Standard	**Year**	**Principle***	**Flow rate/recommended air volume**	**LoQ [µg/m³]**	**Validated working range**
ISO 11174	1996	InhSam ET-AAS F-AAS	Flow rate: Sampler–dependent Recommended sampling time: 15 min–8 h	0.8 4	30 L 30 L
ISO 15202	2004	InhSam ICP-AES	Flow rate: Sampler–dependent Recommended sampling time: 15 min–8 h	0.5	480 L
MDHS 10/2	1994	InhSam ET-AAS F-AAS	2 L/min 2 L/min	0.08 0.25	30 L 480 L
MDHS 91	1998	InhSam XRF	2 L/min, 60-960 L	4.2 0.33	960 L 60 L
BGI 505-54	1994	InhSam F-AAS ET-AAS	No data	No data 0.1	No data 420 L
INSHT MA-205	1992	37mm F-AAS	1-2 L/min, 200 L	0.1	480 L
Note: *InhSam: Inhalable sampler; 37mm: 37mm cassette filter holder					

On the basis of the information in the Gestis database, it can be concluded that:

- Lowest LoQ for methods with an indicative 'A' ranking: 0.1 µg/m³;
- Methods (MDHS 10/2, ET-AAS; BGI 505-54, ET-AAS; INSHT MA-205) cover range of OELs well below discussed OELV (LoQ ≥ 0.1 µg/m³); the LoQ of 0.08 µg/m³ is apparently recommended only for short-term monitoring;
- Method suggested in Germany for controlling most recent OEL: 7808 cadmium and inorganic compounds, Status: December 2013;
- There are some methods in the database with a lower LoQ of 0.05 µg/m³ (e.g. NIOSH 7048, F-AAS), but all of them only have a 'B' ranking; and
- No information on discrimination of suitability for different particle sizes (inhalable, respirable, total).

3.10 Relevance of REACH Restrictions and Authorisation

3.10.1Introduction

At the present time, neither cadmium nor any cadmium compounds have been included in Annex XIV of REACH, 'The Authorisation List'. However, a number of relevant compounds are at earlier stages of the process, which may lead to their eventual inclusion into Annex XIV. A brief description of these compounds and more details on their current status is given below.

3.10.2Cadmium Compounds on the Candidate List for Authorisation

Cadmium and several cadmium compounds are currently on ECHA's 'Candidate List' for Authorisation (see Table 3-24). From inclusion in the Candidate List, there is no set time under which a substance has to move to the Authorisation list. Instead, substances are prioritised based on the criteria set out in Article 58(3) of REACH (which states that priority shall normally be given to substances with persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties, or wide dispersive use, or high volumes). The purpose of the prioritisation is to recommend the substances on the Candidate List in such an order that the substances of most concern are included in Annex XIV before the substances of least (but still high) concern.

ECHA will submit recommendations to the Commission on what substances in the Candidate List should be prioritised for inclusion in Annex XIV. Before sending its recommendation to the European Commission, ECHA launches a public consultation which lasts for 90 days.

Once a substance is recommended by ECHA, the process to inclusion in Annex XIV is expected to take approximately 14 months. In reality, it can take substantially longer, as was the case with the 5th and 6th ECHA recommendations. The European Commission has the final say on the substances added to the Authorisation list, with this occurring via the 'comitology' procedure.

Despite their inclusion on the Candidate List, no cadmium compounds have been included in any of ECHA's formal or draft recommendations to date – including up to the draft 8th recommendation, published early in 2017. Therefore, as it stands, the date(s) on which cadmium and cadmium compounds could potentially be included in Annex XIV of REACH can be based only on purely speculative assumptions.

The next (draft) recommendation to be made public will be ECHA's 9th. Based on prior timescales, the earliest this is likely to happen is Q1 2018.

Table 3-23: Cadmium compounds on Candidate List of substances of very high concern for Authorisation[1]

Name	EC Number	CAS Number(s)	Registration tonnage band (tpa)	Date of entry to ECHA Candidate List
Cadmium	231-152-8	7440-43-9	1,000 – 10,000	20/6/2013
Cadmium chloride	233-296-7	10108-64-2	0 – 10	16/6/2014
Cadmium fluoride	232-222-0	7790-79-6	Not registered	17/12/2014
Cadmium oxide	215-146-2	1306-19-0	1,000 – 10,000	20/6/2013
Cadmium sulphate	233-331-6	10124-36-4, 31119-53-6	Int. use only	17/12/2014
Cadmium sulphide	215-147-8	1306-23-6	10 - 100	16/12/2013
Cadmium carbonate	208-168-9	513-78-0	10 - 100	Not yet on Candidate List but subject to SVHC proposals
Cadmium hydroxide	244-168-5	21041-95-2	1,000 – 10,000	
Cadmium nitrate	233-710-6	10325-94-7	0 – 10	

[1]See http://echa.europa.eu/web/guest/candidate-list-table

3.10.3Restriction

General REACH restriction

Under REACH Annex XVII (entry 23), there is a general restriction (weight restrictions apply)[60] on cadmium and its compounds in the following applications:

- Plastic materials;
- Paints;
- Cadmium plating metallic articles or components of the articles used in equipment and machinery for food production, agriculture, cooling and freezing, printing and book-binding and equipment and machinery for the production of household goods, furniture, sanitary ware, central heating and air conditioning plant;
- Cadmium-plated articles or components of such articles when used in equipment and machinery for the production of paper and board, textiles and clothing, industrial handling equipment and machinery, road and agricultural vehicles, rolling stock, and vessels;
- Brazing fillers; and
- Metal beads and other metal components for jewellery making, metal parts of jewellery and imitation jewellery articles and hair accessories.

A number of derogations have been established for (specific conditions may apply):

- Articles coloured with mixtures containing cadmium for safety reasons;
- Mixtures produced from PVC waste ('recovered PVC');
- Articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehi cles, rolling stock and vessels;
- Electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed; and
- Brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.

Derogation for brazing fillers in aerospace, defence and safety-relevant applications

The scope of the exemption is summarised below, together with information on the continued relevance of this exemption.

Table 3-24: Cadmium in brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons
The use of cadmium in brazing fillers is currently restricted under paragraph 8 of Entry 23 of Annex XVII of REACH, as follows: *'Cadmium shall not be used in brazing fillers in concentration equal to or greater than 0.01% by weight. Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.01% by weight. For the purpose of this paragraph brazing shall mean a joining technique using alloys and undertaken at temperature above 450°C.'* As noted in paragraph 9 of this entry, 'By way of derogation, paragraph 8 shall not apply to brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons.'

[60] See https://echa.europa.eu/documents/10162/3bfef8a3-8c97-4d85-ae0b-ac6827de49a9

Table 3-24: Cadmium in brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons
ECHA's consultation with Member States and industry has suggested that, although the use of cadmium had been declining for several years, a small number of continued uses of cadmium in brazing fillers still exist in the EU. These applications seem to relate to the need to achieve a specific operating temperature range at which, in the absence of cadmium, there would be a risk of explosion or catastrophic failure. ECHA received indication that other specialised, proprietary uses of cadmium in brazing fillers might exist but no further information to identify the existence and nature of these uses. These features imply that amending or removing the derogation concerning brazing fillers provided in paragraph 8 of Entry 23 could have significant costs for the industrial sectors concerned and/or occupational safety while the reduction in risks from cadmium if the derogation was removed would seem be very small as far as safety applications are concerned. It is concluded that the derogation on brazing fillers for safety applications is still relevant and applicable.
Source: https://echa.europa.eu/documents/10162/13641/cadmium_brazing_fillers_safety_reasons_201211_en.pdf/018a1d5e-c7f1-48b2-8a60-c61a82ac742e

It is expected that an OELV established under the CMD would apply to these sectors and would thus impact any remaining users of cadmium containing brazing fillers.

Although it cannot be ruled out that cadmium containing brazing fillers are still used in the aerospace sector, it is expected that any such use is limited, given the switch to cadmium free brazing fillers indicated by Johnson Matthey Metal Joining and supported by the availability of alternatives. Indeed, Johnson Matthey Metal Joining (2012)[61] notes that many aerospace companies and organisations made the switch to cadmium-free products several years before the ban on Cd in brazing fillers. The same source also notes that

> *"in the last 20 year,s Johnson Matthey Metal Joining has not come across any situation where a cadmium-free silver brazing filler metal could not be used as a suitable alternative to a cadmium bearing filler metal once the proper adjustments have been made to brazing practices."*

ECHA (2012) also lists multiple commercially available alternatives based on silver, copper and zinc alloys. Additional metals can be used to impart specific performance, including nickel, manganese, tin and silicon. Examples of cadmium free brazing alloys on offer for use in the aerospace sector include:

- Saldflux Ag 155 - presented as an alternative to cadmium based brazing alloys. It has a working temperature of 600-630°C and consists (by weight) of 55% silver, 21% copper, 22% zinc alloys and 2% silicon (Saldflux, undated)[62]; and
- Silver-flo® 55 – according to the producer, Johnson Matthey, it is their highest selling silver brazing alloy and it is used throughout the brazing industry, including aerospace. The producer also claims that with the right heating method and technique, adequate fluxing, correct joint gaps and set-up it can penetrate superbly well even on heavy and difficult to heat components (Johnson Matthey, undated)[63]. Johnson Matthey also highlight the product Silver-flo® 24 as a cadmium free silver brazing filler material that has been incorporated into

[61] http://www.jm-metaljoining.com/italian/pdfs-products/The%20Ban%20on%20Cadmium%20in%20Brazing%20-%20Some%20Questions%20Answered.pdf

[62] Saldflux. (undated). Let's start to braze without cadmium. Retrieved 2016 6, October, from http://www.saldflux.com/wp-content/uploads/2014/11/Cd-Free-Alloys1.pdf

[63] Johnson Matthey. (2012). Time for brazing to go cadmium free. Retrieved October 6, 2016, from http://www.jm-metaljoining.com/italian/pdfs-products/The%20Ban%20on%20Cadmium%20in%20Brazing%20-%20Some%20Questions%20Answered.pdf

aviation / aerospace industry standards and is consequently used in the manufacture of components for applications in this field.

Recent proposal

ECHA has recently launched consultation on a draft Commission Regulation that proposes to include within the scope of entries 28 to 30 of Annex XVII to Regulation (EC) No 1907/2006 cadmium carbonate; cadmium hydroxide; cadmium dihydroxide; cadmium nitrate and cadmium dinitrate, with the effect of restricting their placing on the market or use for supply to the general public as substances on their own, as constituents of other substances or in mixtures and to impose the requirement to mark packaging with the label "restricted to professional users". It is proposed that the restriction applies from 1 December 2018.

Ongoing role of the CMD

The introduction of OELVs under the CMD has the potential to play an important role in the reduction of worker exposure to cadmium compounds. However, it is also important to consider the REACH-related mechanisms that are in place and which may affect occupational exposure into the future (i.e. the pending authorisation status of several cadmium compounds with their inclusion on the Candidate List, as well as any future decisions that may be made with regard to ongoing proposed restrictions and restriction derogations).

3.11 Market analysis

The companies that have been identified and their location are summarised below. Note that this table includes only companies for which there are indications that workers may be exposed to cadmium and its inorganic compounds. The extended supply chain is more complex. For example, the use of cadmium and cadmium compounds within the aerospace industry (primarily alloys, brazing, batteries and plating) remains widespread and the wider supply chain is multi-tiered and complex.

Table 3-25: Cadmium and inorganic Cd compounds – number of companies

Sector	Uses and/or activities	No of companies/sites	Known sites (excl. confidential information)
1: Zn & Cu smelting and Cd refining	Extraction and refining of Cd	Companies: 7 Sites: Zn refining: 10-11 Cd refining: 5 of the 11 Zn refiners	Boliden - Kokkola FI Nyrstar - Auby FR Nyrstar - Balen BE Nyrstar - Overpelt BE Xstrata - San Juan SP Portovesme IT Boliden - Odda NO Nyrstar - Büdel NL Xstrata - Nordenham DE KCM - Plovdiv BU HCM - Miasteczko Slaskie PL
2: Speciality chemicals	Mechanical or chemical transformation of Cd metal into specialised compounds, mainly for the battery, PV panels	Companies: 4 Sites: 4	Flauréa - Ath BE Bochemie - Bohumín CZ 5N+ - Eisenhuttenstadt DE PPM Recyclex - Langelsheim DE

Table 3-25: Cadmium and inorganic Cd compounds – number of companies			
Sector	**Uses and/or activities**	**No of companies/sites**	**Known sites (excl. confidential information)**
	and pigments sectors		
3: Ni-Cd batteries	Production of Ni-Cd batteries	Companies: 4 Sites: 7	Saft - OSK SE Saft - RAS CZ Saft - NER FR Saft - BDX FR Hoppecke - Brilon DE Enersys/Gaz - Zwickau DE ARTS Energy - Nersac FR
4: Pigments	Production of pigments	Companies: 2 Sites: 2	Rockwood Pigments - Kidsgrove UK Huntsman - Fenton UK
5: Aerospace & defence	Parts[64], connectors and fasteners undergo Cd surface treatment	Companies: 13 Sites: 17 (Parts: 7 Connectors: 6 Fasteners: 4)	Dassault Safran Thales Ratier Airbus Souriau Amphenol Radiall TE/Deutsch LISI Alcoa Aurcad AHG ITT Cannon
	Brazing alloys	Estimated to be very few	
6: Surface treatment contractors	Subcontracted surface treatment for Sector 5, includes repair & maintenance[65]	Companies: 35	
7: Niche manufacturing	PV panels, low temperature infra-red detectors, high performance contact materials	Companies: 4 Sites: 4	Calyxo - Bitterfeld DE Sofradir - Veurey FR Umicore Thin Film - Hanau DE Lamifil - Heliksem BE
8: Recycling	Post-industrial waste, used batteries, treatment of ZnO dust captured in Zn smelters' bag houses, metals	Companies: 7 Sites: 8 (5 plants production waste, 2 plants ZnO, 1 other)	SNAM - Viviez FR Euro Dieuze Industrie - Dieuze FR Accurec - Mülheim DE ZM Silesia PL Nimetal - Lichoceves CZ Metallo - Bersee BE Metallo - Berango SP
	WEEE (shredding of electronic waste)	Companies: 20 (consultation response extrapolated over	Confidential

[64] Assumed to include landing gear.
[65] See http://dublinaerospace.com/landing-gear/

Table 3-25: Cadmium and inorganic Cd compounds – number of companies			
Sector	**Uses and/or activities**	**No of companies/sites**	**Known sites (excl. confidential information)**
		EU-28 on the basis of WEEE collection data)	
9: Mining of non-ferrous metal ores		At least 2	Confidential
10 Metals fabrication	Smelting (steel), foundries, refining	At least 1	Confidential
11 Glass	Production of frit	At least 1	Confidential
12 & 13 Other		Not known (estimated 5-50)	
Total		***100-150 companies***	
Source: consultation and literature review			

3.12 Alternatives

Given the recent regulatory restrictions on the use of cadmium, it is expected that its remaining uses are concentrated in sectors and applications where alternatives are not readily available and where its use is not easily substituted.

In some sectors, such as in metals fabrication and recycling, mining, and post-consumer recycling, substitution is not possible since Cd is present in the source material (post-industrial or post-consumer waste or ore).

3.13 Current disease burden (CDB)

The current burden of disease has been estimated using the data in the preceding sections and assuming that the numbers of workers in the relevant sectors and the exposure concentrations have been decreasing by a combined 7% per annum.

With regards to lung cancer, the ERR is applied an estimated workforce/concentrations halfway through a past assessment period of 40 years which is assumed to have expired 30 years ago (30 years is expected to be the average latency for lung cancer). The CBD is thus approximated on the basis of the estimated number of workers and exposure concentrations 50 years ago (1/2 of risk over 40 years and a latency period of 30 years).

For elevated proteinurea, the CBD is approximated with reference to the workforce and concentrations 20 years ago (halfway through the period to which the DRR applies).

Table 3-26: Current burden of disease due to past exposure	
Endpoint	**Cases per annum**
Lung cancer	11 new registrations each year
Increased proteinuria	Around 500 people living with increased proteinurea
Source: modelling by the study team	

The estimates presented above only relate to the sectors where exposure to Cd currently occurs and do not represent the total burden of past occupational exposure to cadmium and inorganic cadmium compounds. The total burden from all past occupational exposure to cadmium would require consideration of sectors where occupational exposure no longer takes place and which may not be relevant to the problem definition for this Impact Assessment.

In addition, it should be noted that recent regulatory developments (e.g. REACH Annex XVII entry 23 general restriction, the Toy Safety Directive, etc.) have resulted in a significant reduction in terms of the workforce exposed to cadmium and the associated exposure concentrations. This means that although the burden of historical exposure to cadmium may be relatively significant due to the large number of sectors where exposure occurred in the past and the long latency periods, the scope for further health benefits due to an OELV is limited to the sectors/uses where occupational exposure to Cd still occurs (these have been the focus of this study).

3.14 Future disease burden (FDB)

The number of cases of lung cancer and proteinuria expected to occur in the future is given below for a workforce of 10,000. These estimates are based on the assumption that the number of workers exposed to cadmium and its inorganic compounds and the associated exposure concentrations will remain unchanged.

The first set of estimates assumes a constant exposed workforce, while the second set takes into account staff "turnover" (i.e. the fact that some percentage of staff – 5% assumed here - will change occupations or leave work and be replaced in any given year; see also Section 4.2).

Table 3-27: Baseline burden of disease – constant workforce				
Endpoint	**Number of cases over 40 years**	**Number of cases over 60 years**	**Monetary value PV 60 years[66]**	
			Static discount rate	**Declining discount rate**
Lung cancer	3.4	5.8	€5 million	€5 million
Increased proteinuria	95	181	€9-42 million	€9-43 million

Table 3-28: Baseline burden of disease – staff turnover taken into account				
Endpoint	**Number of cases over 40 years**	**Number of cases over 60 years**	**Monetary value PV 60 years[67]**	
			Static discount rate	**Declining discount rate**
Lung cancer	3.4	5.8	Same as 'no turnover' scenario	
Increased proteinuria	190	280	€13-61 million	€13-63 million
Source: modelling by the study team				

66 Static discount rate: 4% per year. Declining discount rate: 4% per year for the first 20 years, 3% per year thereafter.

67 Static discount rate: 4% per year. Declining discount rate: 4% per year for the first 20 years, 3% per year thereafter.

3.15Summary of the baseline scenario

The table below provides a summary of the baseline scenario for this impact assessment.

Table 3-29: Cadmium – summary of the baseline scenario	
Carcinogen	***Cadmium and its inorganic compounds:*** Cadmium (CAS No. 7440-43-9) Cadmium oxide (CAS No. 1306-19-0) Cadmium sulphide (CAS No. 1306-23-6) Cadmium fluoride (CAS No. 7790-79-6) Cadmium chloride (CAS No. 10108-64-2, 35658-65-2) Cadmium sulphate (CAS No. 7790-84-3, 10124-36-4, 31119-53-6) Cadmium nitrate (CAS No. 10022-68-1, 10325-94-7) Cadmium hydroxide (CAS No. 21041-95-2) Cadmium carbonate (CAS No. 513-78-0) Cadmium sulfate hydrate (CAS No. 15244-35-6)
Classification	Carc. 1B
Key sectors used	Zn & Cu smelting and Cd refining, metals fabrication Speciality chemicals Ni-Cd batteries Pigments Aerospace & defence Surface treatment contractors Niche manufacturing Recycling Mining of non-ferrous metal ores
Types of cancer caused	Lung cancer
No. of exp. workers	10,000
Change exp. level	Past: -7% p.a. (exp. level & workers) Future: Expected slight decline or 0%
Change no. of exp. workers	Past: -7% p.a. (exp. level & workers) Future: Expected slight decline or 0%
Period for estimation	60 years (future)
Current disease burden (CDB) - no. of cancer cases	11 new registrations each year
Future disease burden (FDB) - no. of cancer cases	Additional to CDB: 0.1 p.a. (5.8 over 60 years)
CDB no. of other adverse health effects	Around 500 people living with elevated proteinurea
FDB no. of other adverse health effects	CDB + 180-280 workers with elevated proteinurea over 60 years
Exp. no. of deaths FDB cancer	CDB + additional 5 over 60 years
Exp. no. of deaths FDB other adverse health effects	CDB + additional 6-8 over 60 years
Monetary value FDB cancer	CDB + additional €5 million over 60 years
Monetary value FDB other adverse health effects	CDB + additional €9-63 million

Note that this assessment does not capture the full burden of disease (current and future) from historic exposures to cadmium and its inorganic compounds for the following reasons:

- Not all past uses of cadmium and its inorganic compounds 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; and
- Not all health endpoints could be quantified and monetised.

The implication of these factors is that the current burden of disease may be underestimated, as may the burden of disease related to CDB.

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 employers
- Section 4.6: Benefits to the public sector
- Section 4.7: Aggregated benefits & sensitivity analysis

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 Table 4-1 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[68]	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[69]: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY[70]: Mortality	
	Approach 2 DALY: Morbidity	

68 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.

69 Willingness to Pay: The maximum sum an individual is willing to pay for a service/goods in order to avoid loss, in this case, in terms of health treatment.

70 Disability Adjusted Life Year. DALY is whereby one year of health is lost. It is used to calculate the gap between current health status and the ideal health situation (WHO, accessed Feb 2018, Metrics: Disability-Adjusted Life Year (DALY)).

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. These are:

- **ExW-Constant:** This assumes that 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.

- **ExW-Turnover**: This 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 assimptions underpinning it are set out in the methodology report.

4.2.2 Relevant health endpoints for cadmium

For cadmium, the benefits (i.e. changes in the costs caused by ill health) have been quantified for two health endpoints:

- lung cancer; and
- elevated proteinurea.

Other relevant endpoints which have not been quantified include kidney and prostate cancer and osteotoxic (toxic to the bones) or respiratory effects.

With regard to elevated proteinurea, this endpoint covers a range of effects including:

- Elevated proteinuria, which is regarded as first sign of (tubular) kidney damage by SCOEL (and others);
- Chronic Kidney Disease (CKD), which is defined as abnormalities of kidney structure or function, present for 43 months, with implications for health; CKD is classified based on cause, Glomerular Filtration Rate (GFR[71]) category, and albuminuria category (CGA)[72]; and
- End stage renal disease (ESRD) is the last stage of CKD and may require dialysis or a kidney transplant.

Chronic Kidney Disease (CKD) is characterised by a gradual loss of renal function, and its severe levels in which the kidney is unable to provide its essential functions are referred to as End Stage Renal Disease or End Stage Kidney Disease (ESRD or ESKD). Treatment for ESRD involves regular dialysis or kidney transplant.

The relationship between these terms is depicted in the figure below. However, please note that, in a worst-case scenario, all cases of elevated proteinurea could develop into CKD and ESRD.

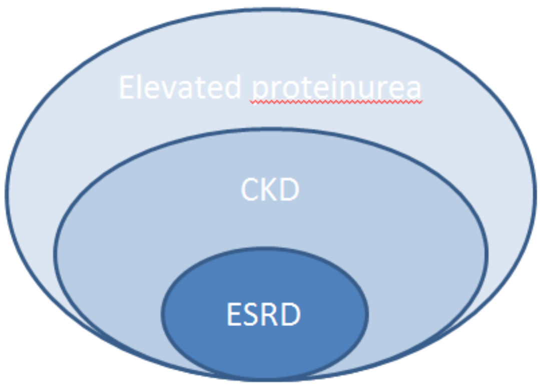


Figure 4-1: Elevated proteinurea, CKD, ESRD

[71] "Volume of ultrafiltrate formed in the kidney tubules from the blood passing through the glomerular capillaries divided by time of filtration" (IUPAC, Feb 2018)

[72] Source: http://www.kdigo.org/clinical_practice_guidelines/pdf/CKD/KDIGO_2012_CKD_GL.pdf

4.2.3 Summary of the key assumptions for cadmium

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 lung cancer and elevated proteinurea are summarised below.

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

Endpoint	MinEx (years)	MaxEx (years)
Lung cancer	2	40
Renal disease	1	20

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

For lung cancer, 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, i.e. 0% of the excess risk arises in year 2 and 100% of the excess risk arises by year 40.

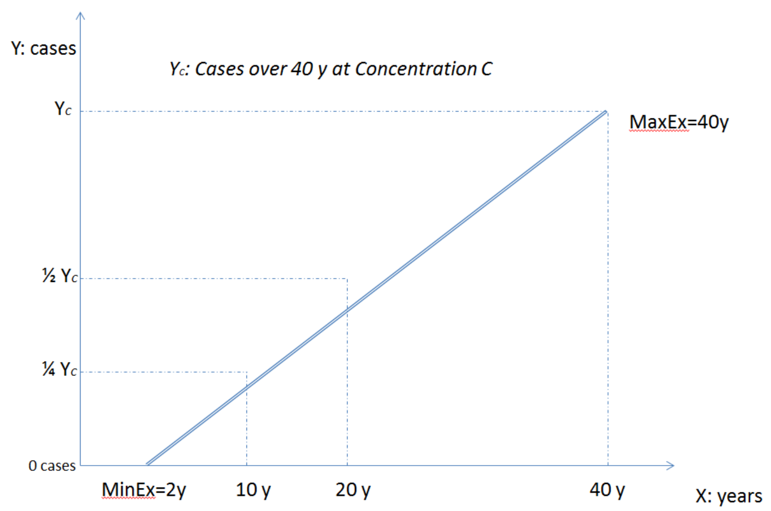


Figure 4-2: Lung cancer risk – distribution over time
Source: study team assumptions

The time typically needed for renal damage is assumed to be relatively long, e.g. 20 years. The distribution is expected to be largely linear [affected fraction (for 10 years of exposure) = affected fraction (for 40 years of exposure) x (10/20)].

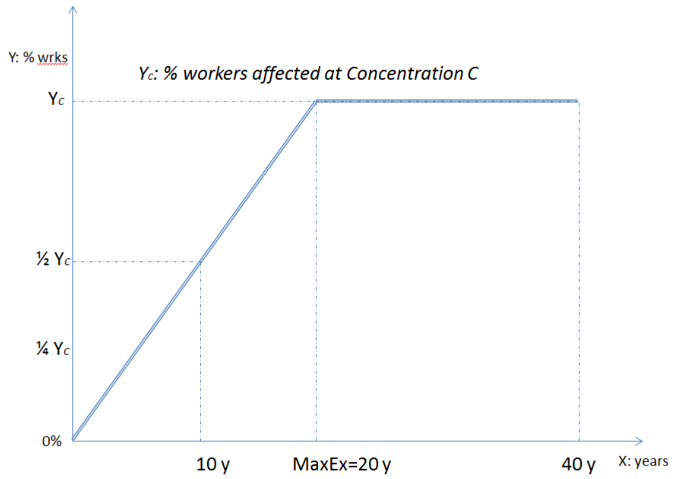


Figure 4-3: Kidney disease – fraction affected over time
Source: study team assumptions

For lung cancer, a latency period of 10 years is used in this study. Although longer latency periods are often estimated for lung cancer, a short latency period is used to be protective of workers and ensure that relevant cancer cases are assessed within the 60 year assessment period for this study.

The estimated latency period for renal disease in this study is 0 years.

The effects of the disease

The key assumptions used for the modelling of the benefits from reduced exposure to cadmium 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 fatal and non-fatal cancer and elevated proteinurea; 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)**
Cancer	5
Renal disease	30
Source: study team assumptions	

Mortality rate

The mortality rates used in the model are given below.

Table 4-5: Fatality rates (MoR)	
Endpoint	**MoR (years)**
Cancer - lung	80%
End-stage renal disease (ESRD)	40%[73]
Elevated proteinurea	2.5%*
Note: *Assumes 6% of cases of elevanted proteinurea develop into ESRD. This is estimated by applying the ESRD estimate in Annex 3 of this report to the total number of cases of elevated proteinurea. Source: study team assumptions	

Cost of treatment

The average of the UK NHS Reference costs 2015/16 for CKD and general renal disorders have been used, see below.

Table 4-6: NHS UK reference costs for CKD	
Description	**Unit cost**
Chronic Kidney Disease with Interventions, with CC Score 6+	€8,239
Chronic Kidney Disease with Interventions, with CC Score 3-5	€5,626
Chronic Kidney Disease with Interventions, with CC Score 0-2	€4,338
Chronic Kidney Disease without Interventions, with CC Score 11+	€3,766
Chronic Kidney Disease without Interventions, with CC Score 8-10	€3,183
Chronic Kidney Disease without Interventions, with CC Score 5-7	€2,444
Chronic Kidney Disease without Interventions, with CC Score 3-4	€1,814
Chronic Kidney Disease without Interventions, with CC Score 0-2	€1,202
General Renal Disorders with Interventions, with CC Score 6+	€7,294
General Renal Disorders with Interventions, with CC Score 3-5	€5,012
General Renal Disorders with Interventions, with CC Score 0-2	€3,534
General Renal Disorders without Interventions, with CC Score 9+	€3,242
General Renal Disorders without Interventions, with CC Score 6-8	€2,436
General Renal Disorders without Interventions, with CC Score 3-5	€1,670
General Renal Disorders without Interventions, with CC Score 0-2	€937
Average	***€3,600***
Source: Department of Health (2016). Reference costs 2016. https://www.gov.uk/government/publications/nhs-reference-costs-2015-to-2016	

Willingness to Pay (WTP) values

The WTP values for a case of fatal and non-fatal cancer are €4,100,000 and €420,000 respectively; this is in line with the approach taken across all the reports produced under this contract, see the methodology report for details.

The WTP value for a case of non-fatal elevated proteinurea has been estimated at €2,000. This is based on the following sources:

---

73 Average for dialysis and transplant patients, see http://www.lkdn.org/dialysis_life_expectancy/KidneyDialysisLifeExpectancy.pdf

- ECHA (2016) - Valuing Selected Health Impacts of Chemicals[74]: The value of avoiding CKD, requiring a four-hour hospital visit three times a week for the rest of a person's life was valued at an apparently low €2,761. However, ECHA (2016) concludes that this value is too low for the condition that it is supposed to represent and its use for monetisation of CKD should be avoided.
- Herold (2010) - Patient Willingness to Pay for a Kidney for Transplantation[75]: The study described end-stage renal disease (ESRD) patient willingness to pay for a kidney. The data in Herold (2010) allows the inference that the WTP for a kidney transplant is around €13,000 in 2017.

Based on these sources, a WTP value for a non-fatal case of elevated proteinurea has been estimated at €2,000, see below.

Table 4-7: WTP for a non-fatal case of proteinurea		
Endpoint	**WTP**	**% of elevated proteinurea**
Elevated proteinurea (not CKD, not ESRD)	Unknown but assumed lower than CKD/ESRD, e.g. €1,000	Unknown
CKD (not ESRD)	€3,000*	Unknown
ESRD	€13,000	6% or 3%**
Elevated proteinurea (including CKD & ESRD)	***€2,000***	100%
*Since this was judged too low for ESRD in ECHA (2016~), this value is used in this table as a proxy for WTP for non-ESRD case of CKD, although the description of the treatment avoided by a potential payment of this sum in ECHA (2016) suggests ESRD. ** Estimated based on the estimate of future ESRD cases – see Annex 3. Two estimates are available 3% and 6%, with the 6% estimate being more relevant to the current data and the 3% estimate being more relevant to the future situation.		

Although several of the parameters that have a bearing on the WTP for elevated proteinurea are unknown, varying these parameters converges on an estimate around €2,000 for the WTP to avoid an average case of elevated proteinurea, which includes non-CKD cases, CKD, and ESRD.

Disability weights

The disability weights used are summarised below.

Table 4-8: Disability weights		
Type of cancer	**Stage of disease**	**Disability Weight**
Lung	Disseminated	0.515[76]
Elevated proteinuria	-	0.15[77]

[74] ECHA, 2016, Valuing Selected Health Impacts of Chemicals: Summary of the Results and a Critical Review of the ECHA study. European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf

[75] Herold, D.K., 2010. Patient Willingness to pay for a Kidney for Transplantation. American Journal of Transplantation, 10(6), pp.1394-1400. Accessed here via a university VPN: https://www.ncbi.nlm.nih.gov/pubmed/20486915

[76] European Burden of Disease study (2015)

[77] Rounded from 0.169. Saloman, J.A., *et al.* 2015. Disability weights for the Global Burden of Disease 2013 study. Lancet Glob Health, 3: e712–23.

The disability weight for proteinuria is based on the assumption that those with a diagnosis of proteinuria will go on to develop, as a worst-case scenario: ESRD on dialysis, 10%; CKD stage V, 10%; CKD stage IV, 10%; CKD stage III, 10%. The remaining 60% will develop CKD stage II or below, and this is assumed equivalent to living with a diagnosis of diabetes. The resulting value (0.169) has been rounded down to 0.15. It is recognised that this may still be an overestimate (particularly should the estimate of the cases that develop into ESRD be based on the lower estimate in Table 4-8) and the calculations based on monetised DALYs should thus be treated as overestimates.

Summary

Table 4-9: Unit costs

Category	Cost	Lung cancer	Elevated proteinurea
Direct	Healthcare	€7,000 /year	CKD: €3,600 /year
	Informal care	€3,000 /year	€1,500 /year*
	Cost for employers	€12,000 /case	
Indirect	Mortality – productivity loss	€5,000 /year	
	Morbidity – lost working days	€1,000 /year	€ 500 /year**
Intangible	Approach 1 WTP: Mortality	€4,100,000 /case	
	Approach 1 WTP: Morbidity	€420,000 /case	€2,000 /case
	Approach 2 DALY: Morbidity	Value of a DALY: €100,000	

* 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 (cancer and non-cancer)

Since average exposure concentrations (Geometric Mean GM or Arithmetic Mean AM of samples)[78] are used to calculate the incidence of ill health but an OELV would most likely be implemented with reference to a 95th percentile 70% confidence (hereinafter P95-70C) (prEN689:2016), compliance with reference OELVs has to be tested against P95-70C for which a corresponding AM/GM figure has to be established.

For the companies/SEGs for which this study has collected both a P95-70C and a GM value, the relevant conversion ratio has been used (this includes SEGs reported by the ICdA OCdAir 2017 which use a generic ratio of 7). For the companies/SEGs workers for which one of the two values is not available, a conversion ratio of 5 has been used in order to ensure a degree of consistency across the different reports for this study.

The avoided cases of ill health at the reference OELV levels are summarised below. These estimates have been used as reference points to plot the number of cases as continuous functions.

78 OCdAIR provides a Geometric Mean and 95th percentile for SEGs. Some consultation responses from companies not reporting through OCdAIR provide an Arithmetic Mean. All conversions between average exposure and the 95th percentile have been made on the basis of a Geometric Mean-95th percentile ratio. No special allowance has been made to correct an Arithmetic Mean to a Geometric Mean.

Table 4-10: Cases of lung cancer and elevated proteinurea for each reference OELV				
Reference point (inhalable fraction)	Lung cancer		Elevated proteinurea	
	40 years	60 years	40 years	60 years
Baseline	3.4	5.8	95	181
1 µg/m³	0	0	0	0
4 µg/m³	0.1	0.1	3	5
5 µg/m³	0.6	1.1	12	22
10 µg/m³	1.1	1.9	47	89
25 µg/m³	2.9	4.9	86	164

Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
Source: Modelling by the study team

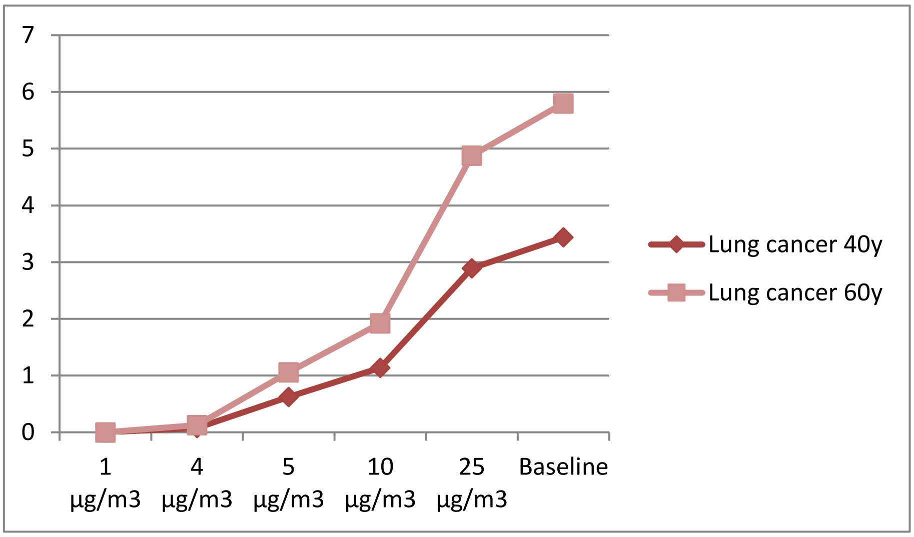


Figure 4-4: Lung cancer cases due to occupational exposure to cadmium in relation to different OELV levels
Source: Modelling by the study team

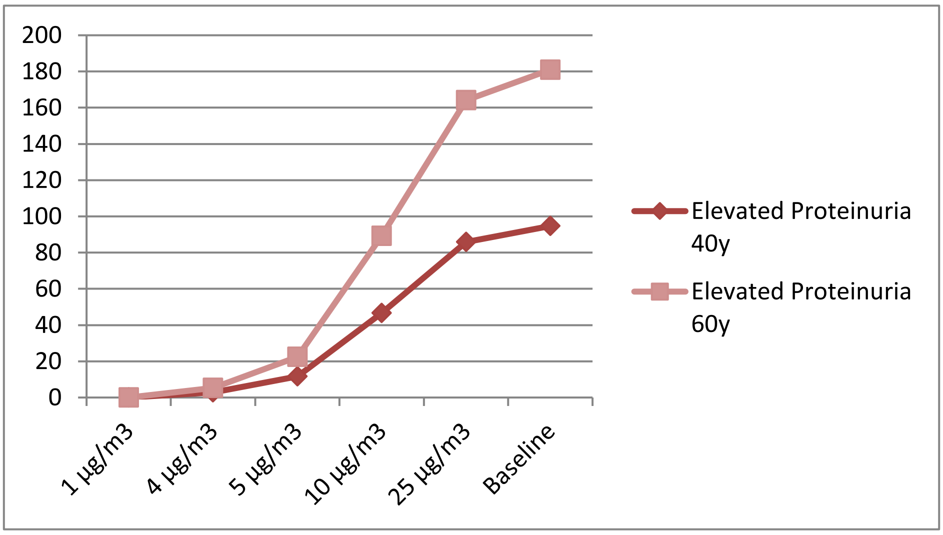


Figure 4-5: Cases of elevated proteinurea in relation to different OELV levels
Source: Modelling by the study team

The number of cases over 60 years shown as a percentage reduction over 60 years vis-à-vis the baseline is shown below.

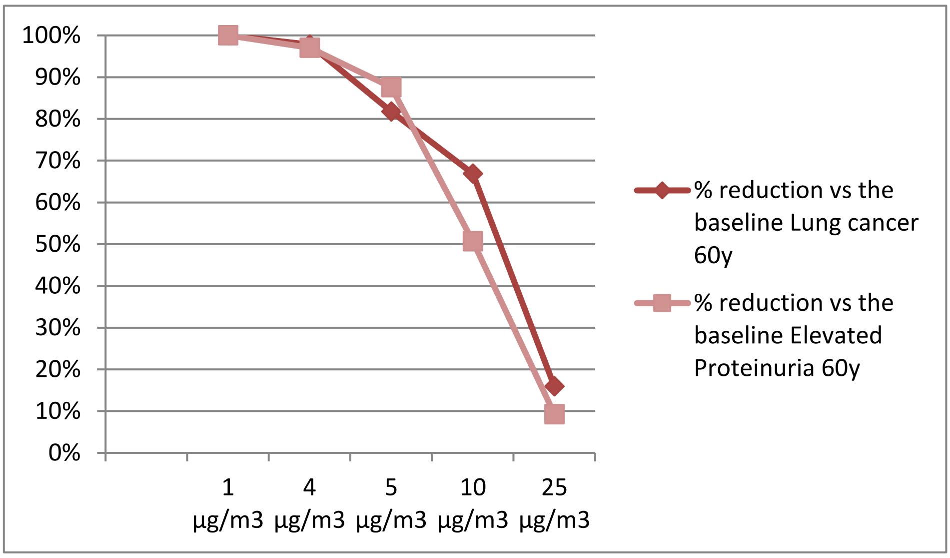


Figure 4-6: Cases of elevated proteinurea in relation to different OELV levels
Source: Modelling by the study team

4.4 Benefits to workers & families

The benefits (avoided costs of ill health relative to the baseline) 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)

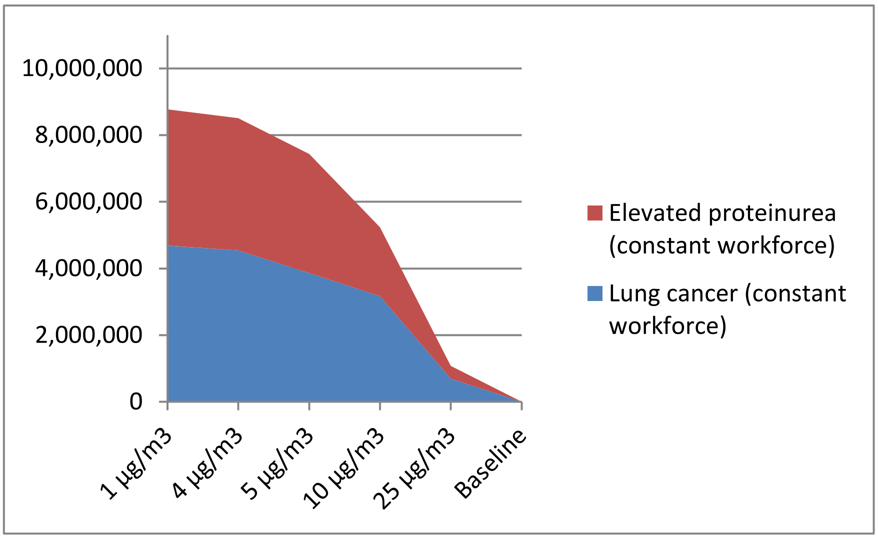
Stakeholder group	Costs	Method of summation
Workers/family	Ci, Cl, Cvsl, Cvcm, Cdaly	Method 1: *CtotalWorker&Family=Ci+Cvsl+Cvcm* Method 2: *CtotalWorker&Family=Ci+Cl+Cdaly*

The benefits of each reference OELV (relative to the baseline) are summarised below. Method 1 relies on WTP values for morbidity, with the resulting estimates given in Table 4-12 and Figure 4-7.

Table 4-12: METHOD 1: benefits to WORKERS & FAMILIES (relative to the baseline)

Reference (inhalable)	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
			Constant workforce			
Lung cancer	4,684,000	4,546,000	3,857,000	3,169,000	689,000	0
Elevated proteinurea	4,089,000	3,960,000	3,573,000	2,066,000	388,000	0
Total	8,772,000	8,505,000	7,429,000	5,234,000	1,076,000	0

Table 4-12: METHOD 1: benefits to WORKERS & FAMILIES (relative to the baseline)						
Reference (inhalable)	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Workforce turnover 5% per year (cancer same as above[79])						
Elevated proteinurea	5,685,000	5,505,000	4,967,000	2,872,000	538,000	0
Total	10,369,000	10,052,000	8,824,000	6,041,000	1,227,000	0
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team						



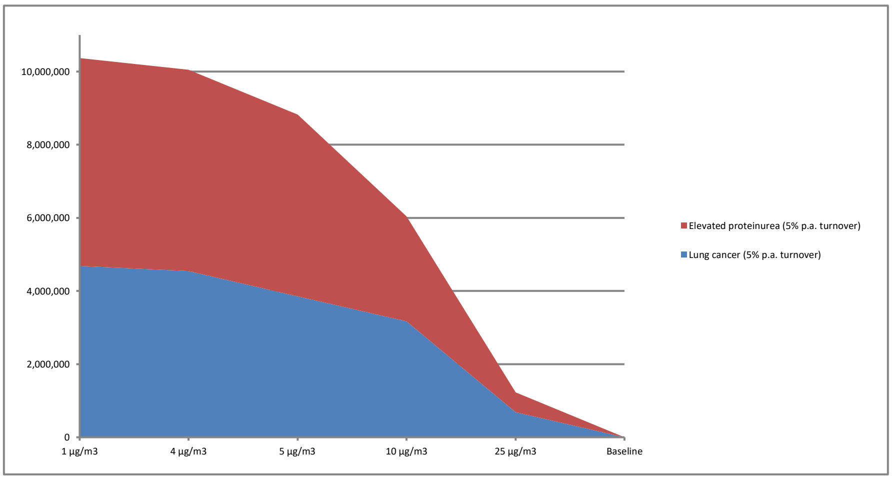
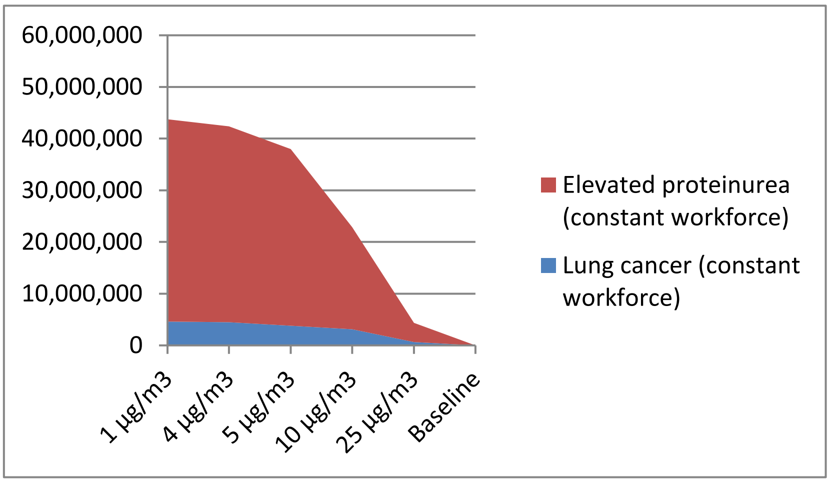


Figure 4-7: METHOD 1: benefits to WORKERS & FAMILIES (reference OELVs, relative to the baseline)
Source: Modelling by the study team

Method 2 relies on monetised DALYs, with the estimates given in table 4-13 and depicted in Figure 4-8.

[79] Due to the cumulative nature of cancer risk (as modelled in this study), the two scenarios (no turnover/staff turnover) provide identical results.

Table 4-13: METHOD 2: benefits to WORKERS & FAMILIES (reference OELVs, relative to the baseline)						
Reference point (inhalable)	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Constant workforce						
Lung cancer	4,356,000	4,228,000	3,587,000	2,947,000	641,000	0
Elevated proteinurea	38,114,000	36,910,000	33,300,000	19,258,000	3,611,000	0
Total	42,470,000	41,138,000	36,887,000	22,204,000	4,251,000	0
Workforce turnover 5% per year (cancer same as above)						
Elevated proteinurea	54,168,000	52,457,000	47,326,000	27,369,000	5,132,000	0
Total	58,524,000	56,685,000	50,913,000	30,316,000	5,772,000	0
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team						



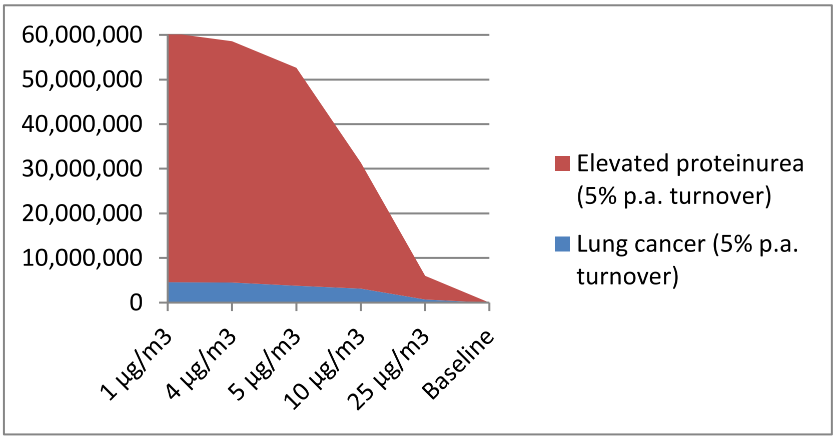


Figure 4-8: METHOD 2: benefits to WORKERS & FAMILIES (reference OELVs, relative to the baseline)
Source: Modelling by the study team

4.5 Benefits to the public sector

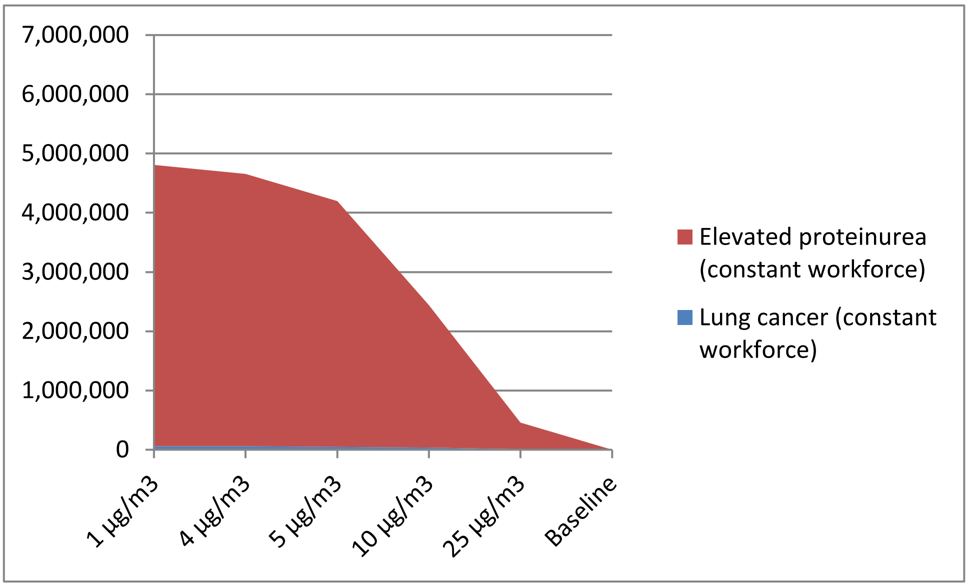
The benefits (avoided costs of ill health, relative to the baseline) for the public secor are calculated using the method summarised below.

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)*[80]

The benefits of each reference OELV (relative to the baseline) are summarised below and depicted in Figure 4-9.

Table 4-15: Benefits to the PUBLIC SECTOR (reference OELV, relative to the baseline)						
Reference point (inhalable)	**1 µg/m3**	**4 µg/m3**	***5 µg/m3***	***10 µg/m3***	***25 µg/m3***	**Baseline**
Constant workforce						
Lung cancer	55,000	53,000	45,000	37,000	8,000	0
Elevated proteinurea	4,600,000	4,455,000	4,019,000	2,324,000	436,000	0
Total	4,654,000	4,507,000	4,063,000	2,361,000	443,000	0
Workforce turnover 5% per year (cancer same as above)						
Elevated proteinurea	6,664,000	6,454,000	5,822,000	3,367,000	631,000	0
Total	6,719,000	6,507,000	5,868,000	3,404,000	640,000	0
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team						

80 Assumes 20% tax.



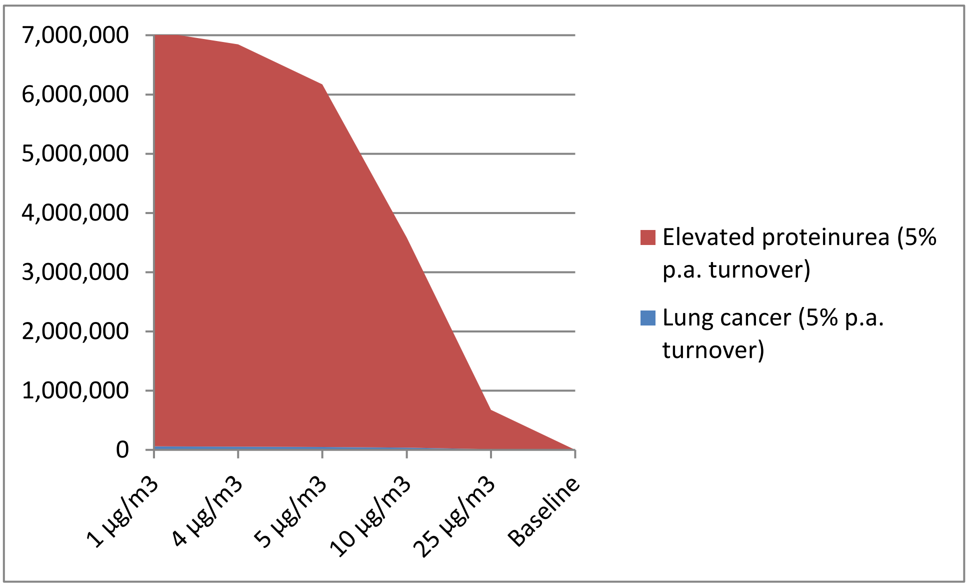


Figure 4-9: Benefits to the PUBLIC SECTOR (reference OELVs, relative to the baseline)
Source: Modelling by the study team

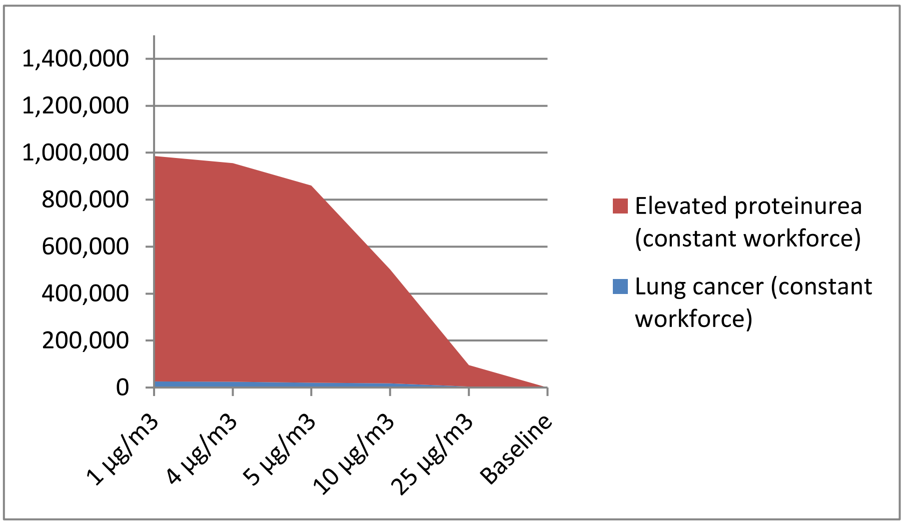
4.6 Benefits to employers

The benefits (avoided costs of ill health relative to the baseline) 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, and depicted in Figure 4-10.

Table 4-17: Benefits to EMPLOYERS (reference OELVs, relative to the baseline)						
Reference point (inhalable)	**1 µg/m3**	**4 µg/m3**	***5 µg/m3***	***10 µg/m3***	***25 µg/m3***	**Baseline**
			Constant workforce			
Lung cancer	24,000	23,000	20,000	16,000	3,000	0
Elevated proteinurea	937,000	907,000	819,000	474,000	89,000	0
Total	961,000	931,000	838,000	490,000	92,000	0
			Workforce turnover 5% per year (cancer same as above)			
Elevated proteinurea	1,332,000	1,290,000	1,164,000	673,000	126,000	0
Total	1,357,000	1,314,000	1,184,000	690,000	130,000	0
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team						



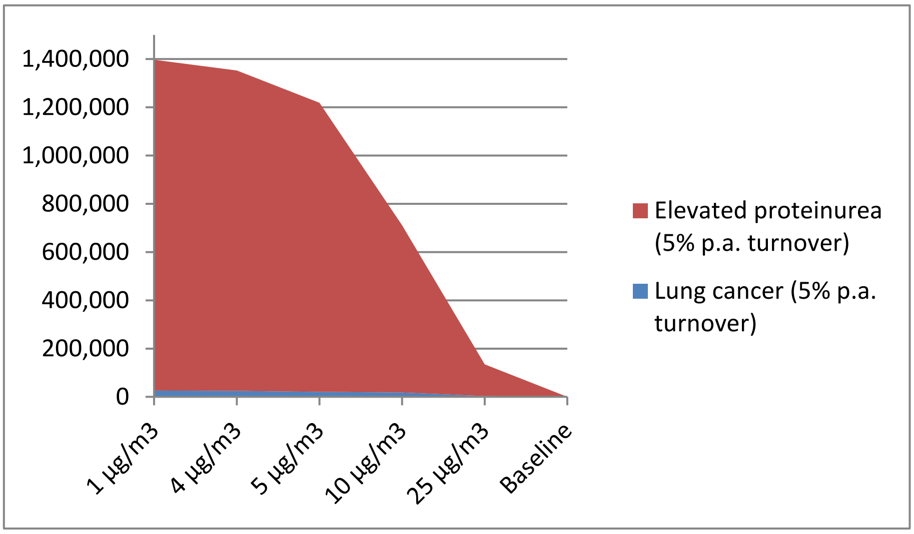


Figure 4-10: Benefits to EMPLOYERS (reference OELVs, relative to the baseline)
Source: Modelling by the study team

4.7 Aggregated benefits

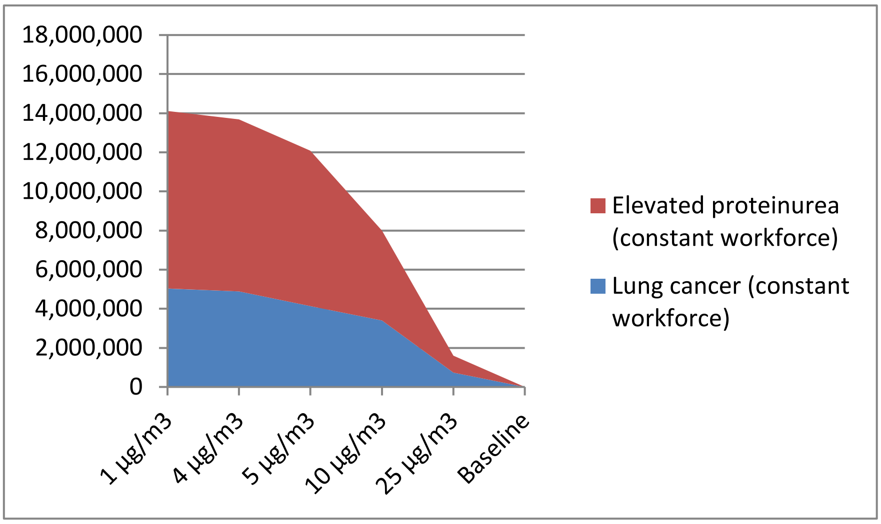
The benefits of each reference OELV (relative to the baseline) are summarised below. These equal the cost of ill health under the baseline scenario minus the cost of ill health following the introduction of an OELV, i.e. they represent the net benefits from introducing an OELV.

Method 1 relies on WTP values for morbidity. The benefits calculated on the basis of Method 1 are given in Table 4-18 and depicted in Figure 4-11.

Table 4-18: METHOD 1: benefits from avoided ill health (reference OELVs, relative to the baseline)

Reference point (inhalable)	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Constant workforce						
Lung cancer	4,743,000	4,604,000	3,906,000	3,209,000	698,000	0
Elevated proteinurea	8,689,000	8,415,000	7,592,000	4,390,000	824,000	0
Total	**13,431,000**	**13,017,000**	**11,497,000**	**7,598,000**	**1,520,000**	0
Workforce turnover 5% per year						
Lung cancer	Same as above					0
Elevated proteinurea	12,350,000	11,960,000	10,790,000	6,240,000	1,170,000	0
Total	**17,092,000**	**16,563,000**	**14,695,000**	**9,448,000**	**1,867,000**	0

Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
Source: Modelling by the study team



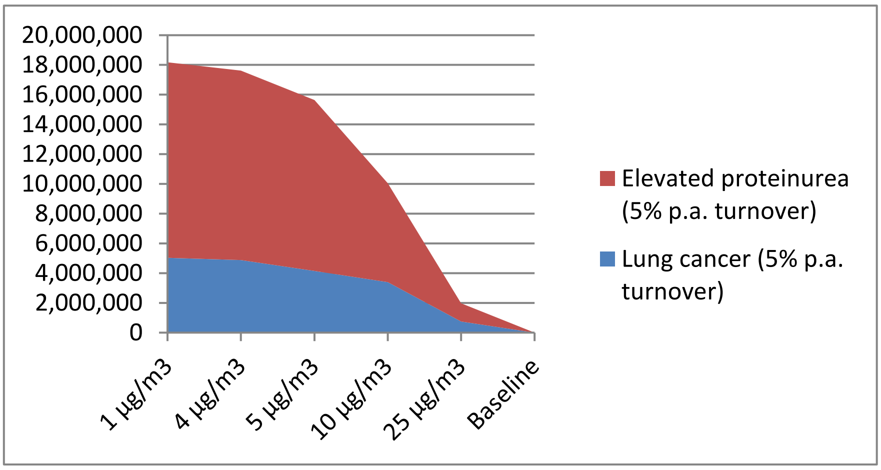


Figure 4-11: METHOD 1: benefits from avoided ill health (reference OELVs, relative to the baseline)
Source: Modelling by the study team

Method 2 relies on monetised DALYs, with the results presented in Table 4-19 below. The total net benefits calculated on the basis of Method 2 are depicted in Figure 4-12.

Table 4-19: METHOD 2: benefits from avoided ill health (reference OELVs, relative to the baseline)

Reference point (inhalable)	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
			Constant workforce			
Lung cancer	4,415,000	4,285,000	3,636,000	2,987,000	649,000	0
Elevated proteinurea	42,714,000	41,365,000	37,319,000	21,582,000	4,046,000	0
Total	**47,129,000**	**45,650,000**	**40,954,000**	**24,568,000**	**4,696,000**	**0**
			Workforce turnover 5% per year			
Lung cancer	Same as above			0		
Elevated proteinurea	60,832,000	58,911,000	53,148,000	30,736,000	5,763,000	0
Total	**65,247,000**	**63,196,000**	**56,784,000**	**33,723,000**	**6,412,000**	**0**

Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
Source: Modelling by the study team

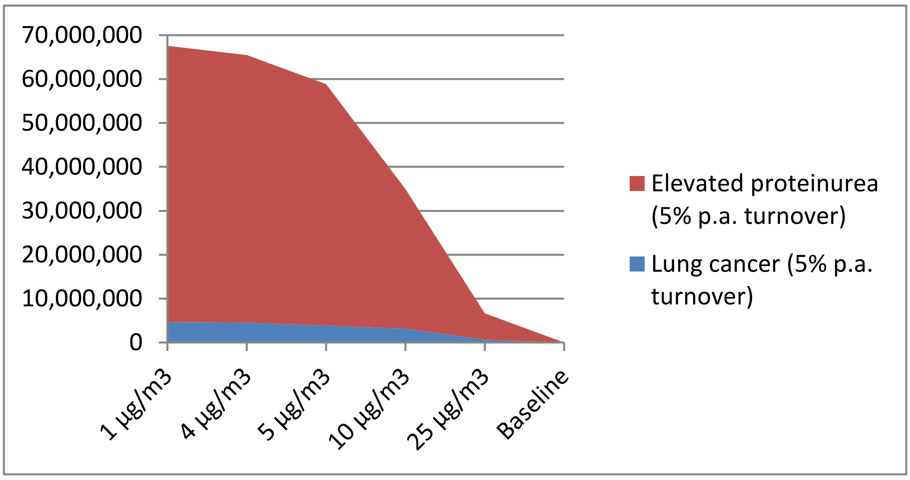


Figure 4-12: METHOD 2: benefits from avoided ill health (reference OELVs, relative to the baseline)
Source: Modelling by the study team

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 costs for companies
- Section 5.4: OELVs – indirect costs for companies
- Section 5.5: OELVs – costs for public authorities
- Section 5.6: Aggregated costs

5.2 The cost framework

5.2.1 Summary of the cost assessment framework

The first step in estimating the economic impacts of introducing a new OELV for cadmium and its inorganic compounds was the development of a cost framework describing the different cost components (direct, indirect and intangible; one-off versus recurring) and the determination of the assessment period.

In line with the more general IA requirements of BR Tool #19, this first involved determining which of the potentially relevant impacts are expected to be significant and should thus be subject to a detailed cost assessment.

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

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

The table below summarises the impact categories that could be significant and that are thus assessed in this report, together with the relevant questions considered in this section (costs for companies and public authorities) and the next section (impacts on competitiveness, etc.).

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

Impact category	Key impacts
Operating costs and conduct of business	Will it impose additional adjustment, compliance or transaction costs on businesses? Does it impact on the investment cycle? Will it entail the withdrawal of certain products from the market? Will it lead to new or the closing down of businesses? Are some products or businesses treated differently from others in a comparable situation?

Table 5-1: Assessment of the most significant economic impact categories	
Impact category	**Key impacts**
Administrative burdens on businesses	Does it affect the nature of information obligations placed on businesses?
Trade and investment flows	How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? How will investment flows be affected and the trade in services? Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered?
Public authorities	Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? Does it bring additional governmental administrative burden? Does the option require the creation of new or restructuring of existing public authorities?
Consumers and households	Does the option affect the prices consumers pay for goods and services? Does it have an impact on the quality or safety of the goods/services consumers receive? Does it affect consumer choice, trust or protection? Does it have an impact on the availability or sustainability of consumer goods and services?
Specific regions or sectors	Does the option have significant effects on certain sectors? Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? Is there a single Member State, region or sector which is disproportionately affected (so-called “outlier” impact)?
Source: BR Tool #19	

The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are presented below.

Table 5-2: Cost impacts on different stakeholders						
Type of cost		**Citizens**	**Consumers**	**Workers**	**Enterprises**	**Public authorities**
Direct	Compliance costs				✓	✓
Indirect	Product choice/price		✓*		✓	
Enforcement	Measurements & inspections				✓	✓
Notes: *Considered in Section 6 Market effects.						

These costs are assessed below qualitatively and, whenever possible, quantitatively.

A continuous cost function has been developed by means of estimating the costs for the reference OELVs and other significant tipping points, and subsequently integrating these to estimate the costs for the intervening OELV values.

5.3 OELVs – compliance costs for companies

5.3.1 Introduction

Compliance costs are defined as the additional costs of complying with an OELV, i.e. the costs incurred by companies in bringing down their exposure to levels below the OELV. The total compliance cost of the introduction of an OELV depends on the number of companies above the OELV and the cost for each company of reducing the exposure concentration to a level below the OELV. The costs for each company depend on the size of the relevant activities (e.g. number of moulding machines; number of workers, etc.) and the gap between the actual exposure and the OELV, as well as the type of RMM needed to bridge the gap.

Three methods have been used to estimate the compliance costs for companies:

a) Application of the model developed for this study (see the methodology report for a detailed description of the model);
b) Application of the model developed for this study but adjusted on the basis of additional input from industry stakeholders ("rock bottom" estimate of RMMs) to mitigate the potential underestimation resulting from the generic estimation model (see below for explanation); and
c) Use of data estimated in Cap Ingelec (2017) for member companies of ICdA and the extrapolation of these data to non-ICdA members.

The key difference between them are summarised below. It is advised that the final cost-benefit conclusions take all the three methods into account, bearing in mind the advantages and disadvantages of each of them. For this reason, all these methods are presented in this report, including in the conclusions section.

Table 5-3: Methods for the estimation of the compliance costs – advantages and disadvantages

Method	Reasons for underestimation of the costs	Reasons for overestimation of the costs	Conclusion
RPA model, unadjusted	Generic model, developed for any chemical agent but Cd-companies typically have a large number of workers exposed and the costs are thus higher The costs of process redesign and highly uncertain	Does not consider the limitations placed by some Member States on PPE use	The estimate is most likely an underestimate but it is used as an an indication of a 'low' estimate since all of the methods reflect a static baseline whilst further reductions may also be achieved by companies under the baseline.
RPA model, adjusted	As above but mitigated by upward adjustment informed by consultation	Does not consider the limitations placed by some Member States on PPE use	Estimate used in this study
Extrapolation from Cap Ingelec (2017)	Does not consider process/machine redesign or substitution which would increase the overall costs (some processes are indicated as 'not feasible' and not costed)	Does not consider the possibility of using PPE to reduce exposure	Estimate used in this study

Extrapolation from Cap Ingelec (2017)

The Cap Ingelec (2017) study estimates the cost of compliance with four OEL levels for the 3,000 workers in eight industrial segments identified as relevant by the ICdA. Only the costs of additional ventilation and hygiene measures have been estimated. Machinery redesign, process changes or PPE are outside the scope of the Cap Ingelec (2017) study.

The following control systems have been considered in Cap Ingelec (2017):

- **Block A: Capture at source systems**, such as LEV, encompassing different enclosure types and sometimes including compensation air delivery systems; estimated lifetime 15 years
- **Block C: General plant cleanliness**, i.e. equipment and procedures[81] to reduce deposition of Cd dust, thus reducing the amount of airborne Cd; estimated lifetime 10 years;
- **Block D: Collective hygiene procedures**, equipment and procedures to reduce dust generation and mobilisation and contain cadmium and its inorganic compounds within the plant (lock-room enhancements)[82]; estimated lifetime 15 years;
- **Block E: Individual hygiene procedures**, i.e. procedures followed by individual workers[83], such as mandatory showers, PPE, procedures, and monitoring; estimated lifetime 10 years.

Blocks C, D, and E follow the structure of the ICdA Guidance Document on the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds.

A detailed overview of the study is provided in Annex 2. The costs estimated in Cap Ingelec (2017) have been extrapolated to the companies that are not members of ICdA but are considered as relevant in this study on the basis of the numbers of exposed workers, taking the average of the industrial in Cap Ingelec (2017) as the basis for extrapolation.

Estimation using the cost model developed for this study (unadjusted)

A model has been developed to estimate the compliance costs of the measures assessed in the six reports under this contract. In summary, the characteristics of the relevant sectors, the RMMs in place, and the sizes of the companies, and the required reduction in exposure, are used to propose suitable RMMs for each company. The model subsequently selects the cheapest of the suitable options. The results are summed up across all companies and sectors. A detailed description of the model is provided in the methodology report.

This model has been applied to all companies that are considered relevant including member companies of the ICdA.

---

81 These include floor coating colour that allows detection of Cd dust deposits, floor cleaning equipment and related cleaning procedures, on-the-spot vacuuming equipment incl. negative pressure inlets and flexible piping, procedures for regular cleaning of the building structure and production equipment, and machine clean-up as part of end-of-shift procedures.

82 These include: training for new workers, a mentoring programme for new workers, annual refresher course on risk management practices, double compartment lockers, three areas in the locker room (non-work clothes, shower, work clothes), work clothes supplied with adequate frequency, laundry service by a specialised contractor.

83 These include mandatory showers, smoking and drinking in designated areas, washing hands and removing jacket before entering the eating area, encouragement to stop smoking, biting nails and growing facial hair, storage of personal objects in dedicated lockers outside the work area, PPE including testing and handling procedures, biomonitoring and air monitoring.

Estimation using the cost model developed for this study (adjusted)

The model developed for this study is a generic one that covers a range of chemical agents and it is not Cd-specific. It draws on a set of unit cost assumptions that relate to the cost of controlling exposure to any chemical agent in typical small, medium, and large companies. However, the companies that are relevant to cadmium and its inorganic compounds often have a larger exposed workforce that the average assumed in the model. This suggests that the model could be underestimating the compliance costs.

For this reason, this model has been adjusted using a "rock bottom" ventilation estimate provided by the ICdA in the framework of the consultation for this study. This adjustment increases the costs by around €30 million (PV over 60 years) at 10 µg/m3 (inhalable) and around €40 million (PV over 60 years) at 4 and 5 µg/m3 (inhalable). The estimates used for the adjustment are summarised in the box below; these include €6 million measurement costs which have not been included in the adjustment. No adjustment has been carried out for the level of 1 µg/m3 (inhalable) where the costs estimated using the model and the costs estimated in Cap Ingelec (2017) are of a similar order of magnitude.

Box 5-1: Estimated "Rock Bottom" Costs for compliance over 60 years from ICdA
The costs estimated for compliance are: **10 µg/m^3: €50 million (phase 1); 5 µg/m^3: €72 million (10 µg/m^3 to 5 µg/m^3: phase 2) and €122 million (from current OELV to 5 µg/m$^{3:}$ phase 3)** **Assumptions**: For an OELV of 10 µg/m^3 (phase 1): There are 100 facilities with exposed workers with 50% in compliance and the other 50% need additional measures to comply with the OELV. In the facilities where additional measures are required, it is assumed that 20% of workers are exposed to levels above 10 µg/m^3 From 10 µg/m^3 to 5 µg/m^3 (phase 2): For the 50% of facilities requiring additional measures under phase 1, it is assumed 10% of workers would require to be further protected and 10% if workers currently between 5-10 µg/m^3 would require ventilation. 50% of the facilities not considered under phase 1, half of these facilities would require ventilation systems for 10% of workers. **Cost breakdown**: Phase 1: Discounted ventilation: €29 million; discounted soil planting: €5 million; discounted air monitoring: €6 million; and maintenance: €9 million Phase 2: Additional costs are for 50% of facilities in Phase 1: €44 million (ventilation); for 50% of facilities not considered under Phase 1: €22 million; and €6 million for compensation air systems Phase 3: Costs of phase 1 and 2 combined **Limitations:** Unable to ascertain if the air systems used in Phase 1 (10 µg/m^3) will allow compliance to 5 µg/m^3
Source: consultation for this study

5.3.2 Current exposure levels

The key input parameters for the cost and benefit estimation models developed for this study is the distribution of the actual exposure levels across companies or facilities and workers. Whilst the distribution function for the benefit model focuses on the distribution of the workforce over different exposure concentrations, the key parameter for the cost function is the distribution of companies across different exposure levels. Although the ideal parameter would be the number of SEGs, factory lines or facilities/sites operated by the different companies, such data are not available for many of the chemical agents considered under this contract and the number of companies together with their distribution across the different size bands has been taken as a proxy in the cost model. The highest concentration in a company is thus taken in the cost model as the value that determines the scale of the costs. It is, however, recognised that this approach may lead to some overestimation of the costs.

The cadmium exposure data collected through questionnaires and communication with industry has been collected for three different reference groups:

- SEGs[84] in individual companies;
- self-defined group of workers (process/activity or department/unit or similar); and
- the whole company.

Although exposure data are also available from the CSRs for REACH descriptors[85], the exposure concentrations in the CSRs are order of magnitude greater than those reported by other sources and, as a result, it has been assumed that the data in the CSR are outdated.

The Cd compliance cost model always relies on data for the most detailed reference point. Where data were available for individual SEGs, these are taken as the basis for modelling. Where SEG data are not available, data for units within individual companies were taken, and where such data were not available, company-level data were used. The reference points for cost modelling are summarised below.

Table 5-4: Cost model inputs – numbers of SEGs, other intra-company reference points, companies, etc.

Group	SEGs	Other intra-company category*	Companies	% of exposed workforce
Group 1 (SEGs)	162		27	22%
Group 2 (other intra-company groups)		12	2	16%
Group 3: Companies			32 (4+ est. 28)	24%
Group 4 (extrapolation)			Est. 40-90 (extrapolation)	38%

Notes: Shaded cells show data that were used for modelling. * process/activity or department/unit

The relevant reference points have been assigned to the different size bands on the basis of the numbers of exposed workers.

Table 5-5: Size bands of SEGs and companies for which data were collected through consultation

Size band	Number of companies, intra-company units, or SEGs
Large (average 75 exposed workers)	127
Medium (average 27 exposed workers)	29
Small (average 2 exposed workers)	49

84 A Similar Exposure Group (SEG) is a group of workers having the same general exposure profile for the chemical agent(s) being studied because of the similarity and frequency of the tasks they perform, the materials and processes with which they work and the similarity of the way they perform those tasks. A SEG can be constituted by one worker.

85 The descriptors used under REACH include the Sector of Use (SU) which describes in which sector of the economy exposure occurs (e.g. rubber manufacturing sector, glass manufacturing sector, etc.) and the process categories (PROCs) which describe the tasks, application techniques or process types defined from the occupational perspective.

The distribution of the relevant units (companies, SEGs or other units) over exposure concentrations is summarised below.

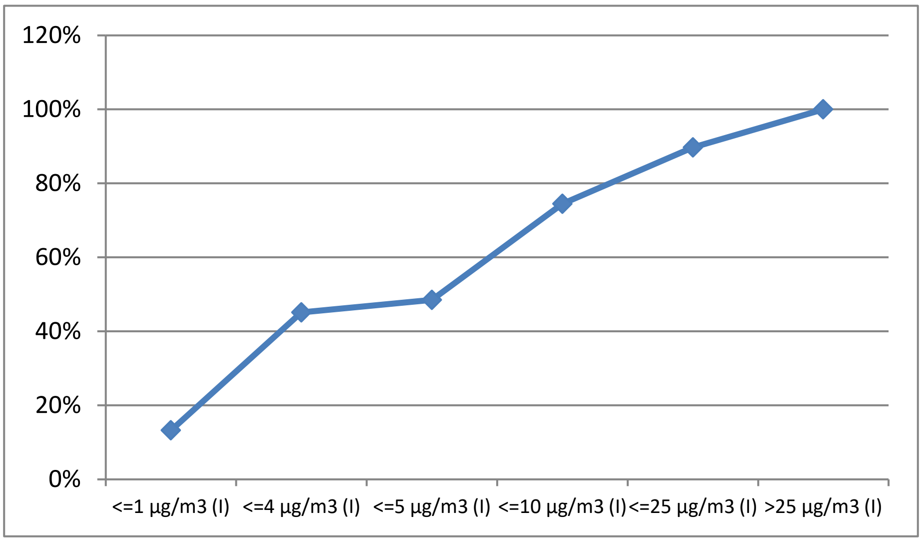


Figure 5-1: Proportion of companies, SEGs, other groups in the modelling input data that have achieved different concentrations (95th percentile 70% confidence of all measurements)
Source: consultation for this study

The distribution in the figure above, together with information on current RMMs collected through consultation (see, for example, Section 3.6), has been used to estimate the broad distribution of current RMMs by company or SEG size.

Table 5-6: Percentage breakdown of RMMs currently used by enterprises

Type of RMM	% of large enterprises currently with this type of RMM	% of medium enterprises currently with this type of RMM	% of small enterprises currently with this type of RMM
Full enclosure LEV	0%	0%	0%
Partial enclosure LEV	30%	20%	10%
Open hood LEV	10%	10%	10%
Pressurised or sealed cabin	0%	0%	0%
Simple enclosed cab	5%	5%	5%
Breathing apparatus	0%	0%	0%
Mask with a HEPA filter	10%	10%	10%
Simple mask	0%	0%	0%
Organisational measures	20%	20%	20%
General dilution ventilation	5%	5%	5%
Nothing	20%	30%	40%
Source: estimates/assumptions of the study team based on all the information collected			

5.3.3 Sector/use-specific cost curves

Extrapolation from Cap Ingelec (2017)

The detailed assessment in Cap Ingelec (2017) focuses on the two largest segments in terms of the workforce exposed to Cd (Zn/Cd refining and industrial battery manufacturing; these two segments represent over 50% of the exposed workforce in companies that belong to the ICdA. The costs to the other segments have been extrapolated from the costs estimated for the industrial battery segment. The same approach is followed in this study and the remaining sectors have been grouped in this report for the purposes of the extrapolation. Cost data are thus estimated for the following sectors/uses:

- Zn/Cd refining;
- industrial battery production;
- other ICdA member companies; and
- other (not members of the ICdA).

The cost estimates (incremental to the baseline) reported in Cap Ingelec (2017) are summarised below (see Annex 2 for more detailed cost estimates).

Table 5-7: Summary of the costs for ICdA members (additional to the baseline)

Sector	Type of cost	10 μg/m³ (R)	4 μg/m³ (R)	*1.6 μg/m³ (R*)*	*0.4 μg/m³ (R*)*
		25 μg/m3 (I)*	*10 μg/m3 (I*)*	4 μg/m3 (I)	1 μg/m3 (I)
Industrial batteries	CAPEX (€2017)	45,000	12,769,000	25,340,000**	*25,932,000****
	OPEX (annual in €2017)	56,000	2,459,000	2,825,000**	*2,826,000****
Zn smelting/ Cd refining	CAPEX (€2017)	2,301,000	*2,307,000****	*4,873,000****	*6,485,000****
	OPEX (annual in €2017)	2,339,000	*2,699,000****	*2,750,000****	*2,797,000****
Other	CAPEX (€2017)	90,000	9,281,000	17,127,000**	*18,497,000****
	OPEX (annual in €2017)	323,000	2,664,000	2,942,000**	*3,000,000****
Total (3,700 workers estimated by ICdA)	CAPEX (€2017)	2,436,000	*24,357,000****	*47,340,000****	*50,913,000****
	OPEX (annual in €2017)	2,718,000	*7,821,000****	*8,517,000****	*8,624,000****

Source: Cap Ingelec (2017)

Notes:
All values supplied are VAT free.
*Asterisked values in italics denote calculations by the study team using a Respirable -> Inhalable conversion factor of 2.5.
**Uncertain for some process stages.
***According to Cap Ingelec (2017), it is not feasible for key process stages in the relevant sector to achieve the target concentration by means of additional ventilation. In such instances, the concentration of Cd in air could be further reduced by machinery redesign, process changes or PPE but such measures were not considered in Cap Ingelec (2017).
Values in yellow and italics denote partial quantifications, i.e. estimates for those process stages where the reduction is feasible.

The total compliance costs over 60 years are set out below, extrapolated to all relevant companies (both members of the ICdA as well as non-member companies).

Table 5-8: RMM costs over 60 years based on extrapolation from Cap Ingelec (2017), PV 60 years, additional to the baseline					
Sector	**1 µg/m3**	**4 µg/m3**	***10 µg/m3***	***25 µg/m3***	**Static baseline**
CAPEX (€)	225,000,000	209,000,000	108,000,000	11,000,000	0
OPEX (€)	532,000,000	526,000,000	483,000,000	168,000,000	0
Total (€)	***758,000,000***	***735,000,000***	***591,000,000***	***179,000,000***	0

Note:
All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
*Extrapolation of the Cap Ingelec (2017) data over time entails a potential for overestimation or underestimation due to the fact that these data do not consider the potential for companies to comply with the OELVs by means of PPE or process redesign. Also, the costs of substitution or business discontinuation have not been considered; this is particularly significant since Cap Ingelec (2017) notes that reductions in some process stages cannot be achieved by means of LEV and hygiene measures.
Source: study team extrapolations from Cap Ingelec (2017)

Estimation using the cost model developed for this study (unadjusted)

Model inputs

The sectors identified in Section 3 have been assigned to three groups for which characteristics of cadmium exposure have been estimated:

- Smelting, refining, foundries, and similar activities;
- Mining; and
- Industrial batteries and other sectors.

There are certain characteristics about each sector and the kind of work during which exposure to cadmium and its inorganic compounds occurs within the sector. This information helps to determine the type of RMMs that are suitable. The kind of work characteristics split into three groups:

- Duration of exposure over a day;
- Form of cadmium and its inorganic compounds to which workers are exposed; and
- Extent to which cadmium and its inorganic compounds disperse or spread when emitted.

The amount of exposure is split into work where the worker is exposed to cadmium and its inorganic compounds for less than an hour a day and for more than an hour a day. This also equates to exposure for more or less than 2.5 days/month. Many production activities only occasionally use cadmium and its inorganic compounds. 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 cause exposure to workers beyond the area where the cadmium and its inorganic compounds is being worked. This means that administrators, managers and sales staff may be exposed.

In the table below, the percentage split between each form of substance used in the analysis is given for each sector. These values were built into the cost model.

Table 5-9: Cadmium and its inorganic compounds: amount of exposure, form of cadmium and extent of spread by sector

Sector	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
Smelting, refining, foundries, and similar activities	20%	80%	100%	0%	50%	50%	0%
Mining	0%	100%	100%	0%	45%	45%	10%
Industrial batteries & other sectors	20%	80%	90%	10%	50%	0%	50%

Note: Dust = dust and fibres, Gas = vapour, fumes, gas, mist and aerosol
Source: Study team estimates

<u>Model outputs for the three sectors</u>

The compliance costs over 60 years (CAPEX and OPEX) that are incremental to the baseline estimated for the three sectors are summarised below.

Table 5-10: Compliance costs for the reference OELVs by sector (PV CAPEX and OPEX over 60 years, additional to the baseline) excluding measurement costs

Sector	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Smelting, refining, foundries, and similar activities	101,600,000	10,500,000	8,000,000	2,900,000	700,000	0
Mining	38,500,000	2,100,000	2,100,000	1,400,000	800,000	0
Industrial batteries & other sectors	166,000,000	39,100,000	36,100,000	4,700,000	800,000	0
Extrapolation to companies for which no data are available*	140,806,000	23,782,000	21,252,000	4,140,000	1,058,000	0
Total for all sectors/companies	447,000,000	75,000,000	67,000,000	13,000,000	3,000,000	0

Notes:
All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
*These companies may be in any of the three sectors.
Source: Modelling by the study team, RPA model (unadjusted)

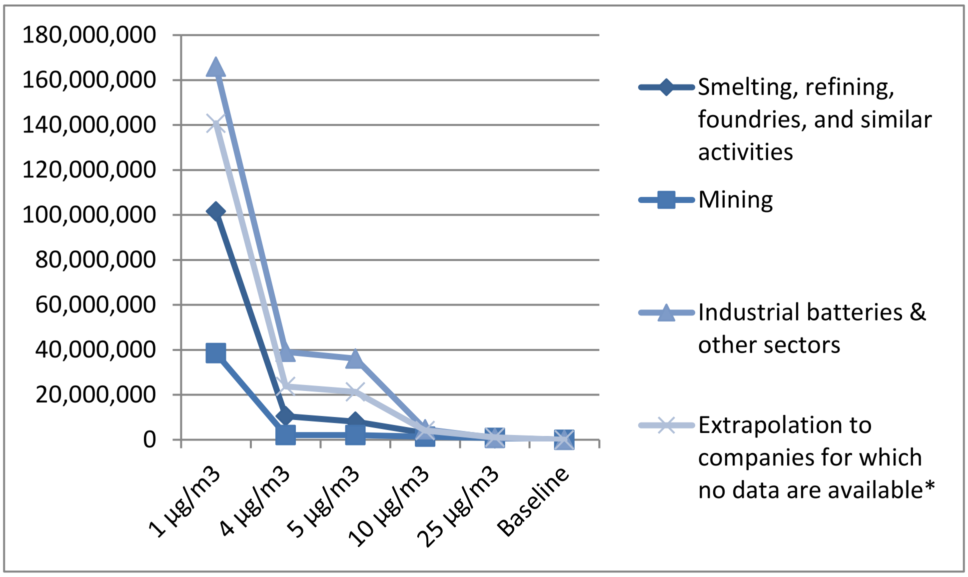


Figure 5-2: Additional compliance costs for the reference OELVs by sector (PV CAPEX and OPEX over 60 years, additional to the baseline) excluding measurement costs
Notes: Exposure concentrations expressed as inhalable fraction. *Any of the other three sectors
Source: Modelling by the study team, RPA model (unadjusted)

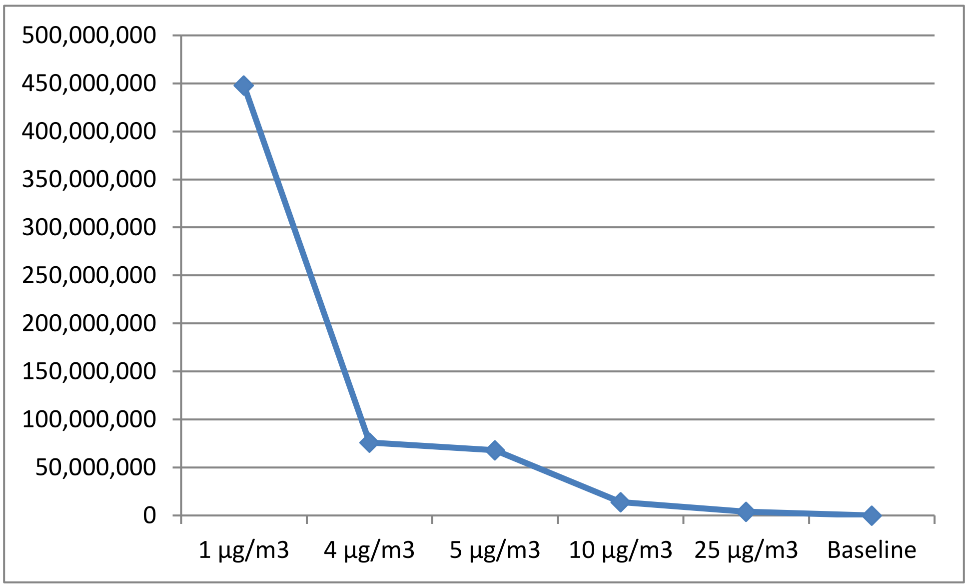


Figure 5-3: Total additional compliance costs for the reference OELVs across all sectors (PV CAPEX and OPEX over 60 years, additional to the baseline) excluding measurement costs
Note: Exposure concentrations expressed as inhalable fraction. Source: Modelling by the study team, RPA model (unadjusted)

Estimation using the cost model developed for this study (adjusted)

The compliance costs over 60 years (CAPEX and OPEX) that are incremental to the baseline estimated after the adjustment are summarised below.

Table 5-11: Compliance costs for the reference OELVs by sector (PV CAPEX and OPEX over 60 years, additional to the baseline) excluding measurement costs, RPA model (adjusted)						
Sector	**1 µg/m3**	**4 µg/m3**	***5 µg/m3***	***10 µg/m3***	***25 µg/m3***	**Baseline**
Total for all sectors/companies	447,000,000	116,000,000	116,000,000	44,000,000	4,000,000	0
Notes: All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team and consultation for this study						

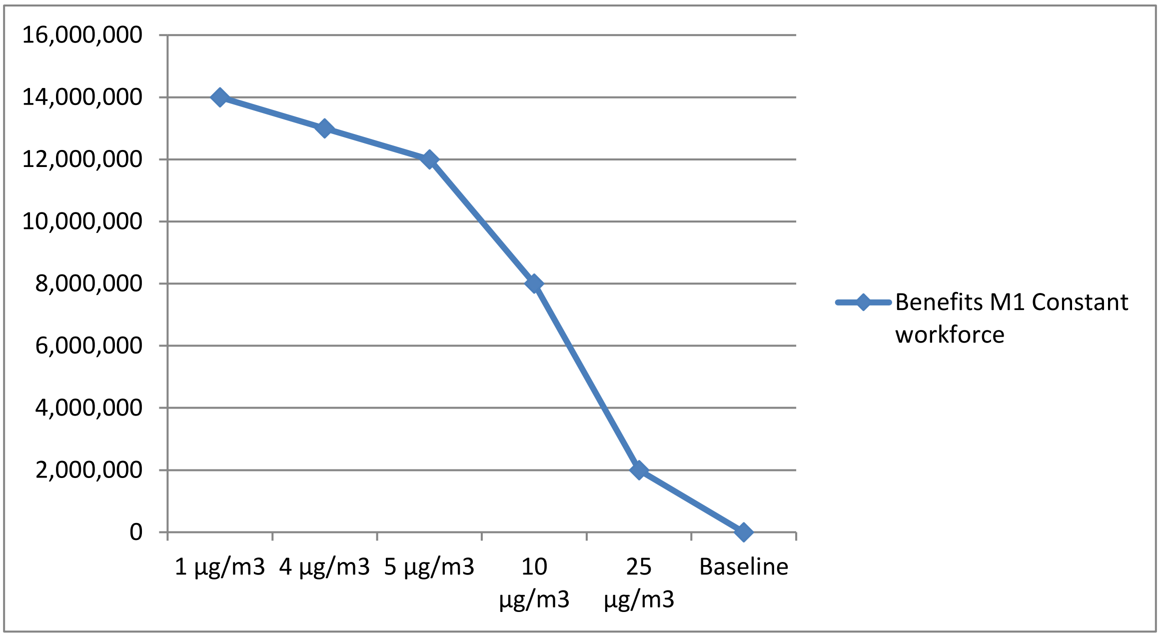


Figure 5-4: Total additional compliance costs for the reference OELVs across all sectors (PV CAPEX and OPEX over 60 years, additional to the baseline) excluding measurement costs
Note: Exposure concentrations expressed as inhalable fraction. Source: Modelling by the study team, RPA model (adjusted)

5.3.4 Measurement costs

It is expected that all companies that would have to reduce exposure would need to re-measure to demonstrate compliance with the new OELV. The table below estimates the numbers of companies that would have to pay for air sampling and analysis.

Table 5-12: Estimated proportion of companies that would have to remeasure	
Reference OELV	**%**
25 µg/m3	10%
10 µg/m3	25%
5 µg/m3	51%
4 µg/m3	55%
1 µg/m3	At least 87%
Note: Exposure concentrations expressed as inhalable fraction. Source: Modelling by the study team	

Estimates of the costs of monitoring air concentrations of the six substances subject to this contract (As, Be, Cd, CrVI, CH_2O, and MOCA) have been developed for a number of EU Member States; see the methodology report for detailed and itemised estimates. The resulting costs for cadmium are summarised below.

Table 5-13: Estimated cost of a monitoring campaign (additional to the baseline)	
Member State	**Cost per company**
Denmark	€12,000
Greece	€6,000
Lithuania	€4,000
Poland	€5,000
Slovenia	€6,000
UK	€10,000
Average of DK, EL, PL, UK	€8,000
Source: Modelling by the study team	

These estimates are somewhat lower than previously estimated in RPA (2017[86]).[87] However, it is expected that only some workers would be monitored in each company and the two sets of cost estimates are seen as broadly consistent. The cost of carrying out additional measurements is estimated below.

Table 5-14: Cost of air sampling and analysis (additional to the baseline)		
Reference OELV	**Number of companies**	**Cost**
25 µg/m3	10	€80,000
10 µg/m3	25	€200,000
5 µg/m3	51	€410,000
4 µg/m3	55	€440,000
1 µg/m3	87	€700,000
Note: Exposure concentrations expressed as inhalable fraction. Source: Modelling by the study team		

[86] RPA (2017): Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC

[87] The cost of monitoring can be in the range of €1,000-€3,000 per worker which includes the cost of equipment, monitoring by an occupational technician (one of which is required to monitor 3-5 people at a cost of €800-1,200 per day) and sample analysis (the cost of analysis per sample has been estimated to range between €50-€100). The frequency of sampling depends on the requirements of specific national authorities but, in general, repeat monitoring may not be neccessary if the production process does not change.

5.4 OELVs – indirect costs for companies

Indirect costs could include possible ripple effects through value chain and the potential for costs to be passed on to users further down the value chain or consumers.[88]

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.

The figures below set out a range of potential scenarios covering likely indirect impacts along the supply chain resulting from the introduction of harmonised OELs. In the most severe case (in the event that a number of companies using cadmium and its inorganic compounds 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 cadmium and its inorganic compounds, it is most likely that companies would obtain supplies of components from outside the EU where the EU OEL restrictions would not apply. Under this scenario, jobs and profits would be lost to the EU, being taken up by workers and competitors in third countries.

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 cadmium and its inorganic compounds pass on the additional costs of meeting the OELs to their customers. For certain final products (such as planes and defence equipment), the contribution of cadmium and its inorganic compounds 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, such as those using NiCd batteries, the price of the component requiring the use of cadmium and its inorganic compounds 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.

88 Impacts on consumers are considered in Section 6 (Market effects).

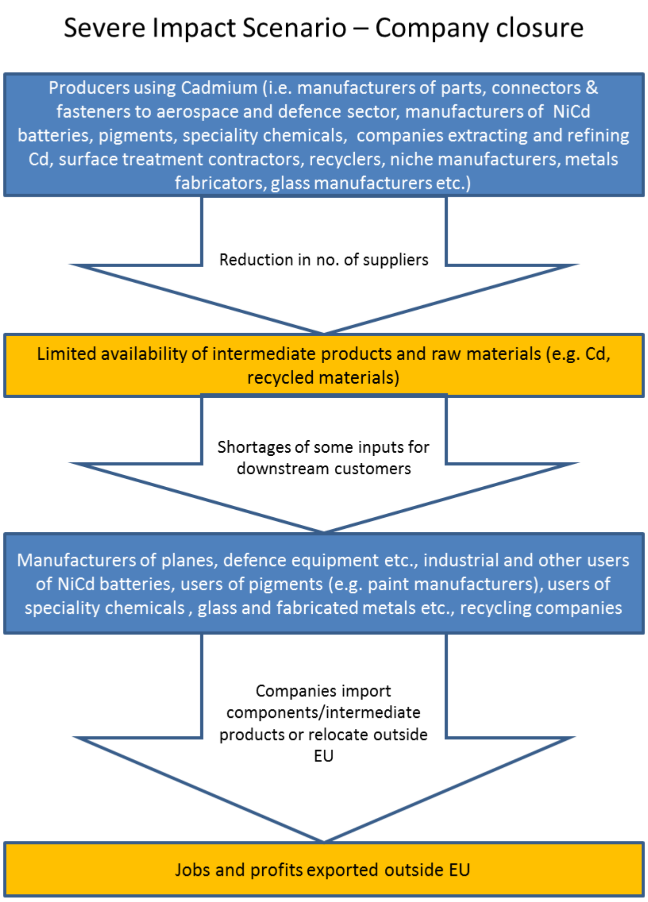


Figure 5-5: Indirect costs – severe impact scenario

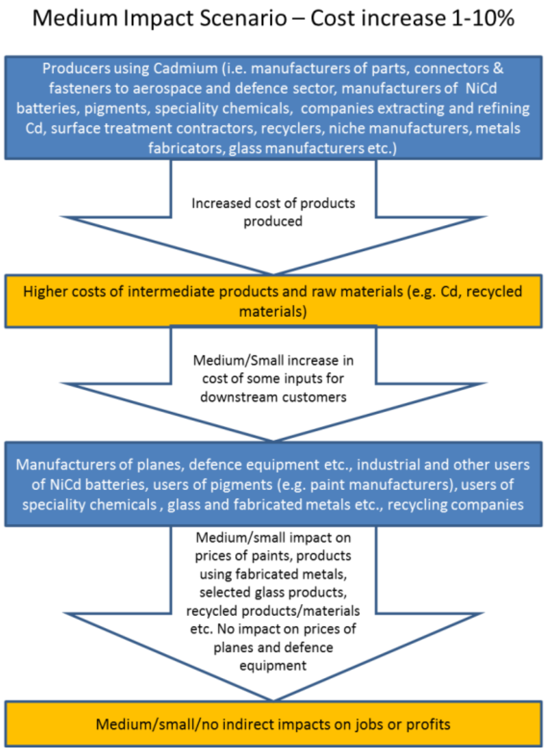


Figure 5-6: Indirect costs – medium impact scenario

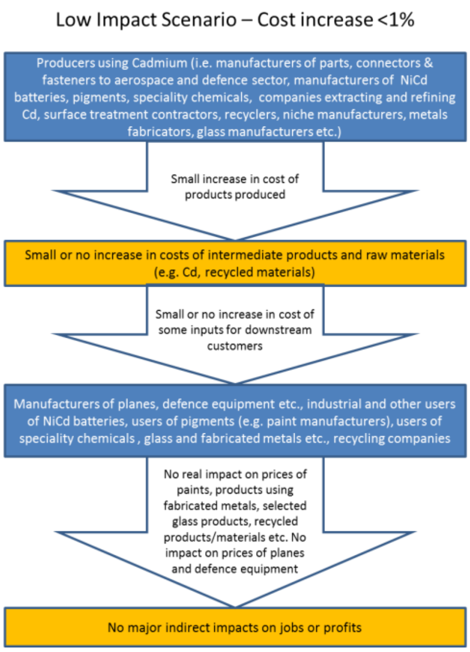


Figure 5-7: Indirect costs – low impact scenario

5.5 OELVs – costs for public authorities

The impacts on public authorities, mainly at the national level but in some Member States also at the regional level, are expected to relate to:

- The cost of adapting national legislation and procedures to the new OELV (where the Member State is above the OELV); and
- The enforcement of the new OEL.

It is not expected that there would be a significant cost to national authorities in the Member States which already have an OEL for Cd.[89] Member States where this is not the case may incur a one-off cost for changing their legislation and a recurring cost of increased enforcement. Thus, although the specific OELV level will determine whether a Member State needs to revise legislation, the transposition and implementation costs are unlikely to depend on the specific values so there will only be a cost difference between the baseline scenario and scenarios where a new OEL is introduced in a Member State.

In addition, the cost of legislative change will only be incurred once, regardless of whether one or several chemical agents are covered, and whether an OELV or also a STEL and/or skin notation is introduced.

5.5.1 Costs of transposition

Should Option A3 be implemented, EU Member States would incur costs arising from the need to transpose the relevant changes into national legislation. In practice, the exact costs would depend on the specific changes agreed in the final version of the Directive and the regulatory model used in each country to implement the Directive (i.e. the number of departments involved in transposition or implementing the Directive). These costs are therefore likely to vary significantly between Member States (for example, Sweden is obliged to carry out an impact assessment on new EU legislation; it is expected that this may not be the case in some Member States).

Of the 28 EU Member States, research carried out for this study has confirmed that 22 have an OEL(s) for cadmium and (at least some of) its inorganic compounds. There is no information with regard to a Cd OEL for the following Member States and this study thus assumes that they do not have an OEL for cadmium and (at least some of) its inorganic compounds: Italy, Luxembourg, Malta, Portugal, Romania, and Slovakia. It is thus assumed that these six Member States would incur costs for transposing an OELV introduced under the CMD.

Specific data on the costs of transposition of EU legislation by Member States and their relevant departments/ministries are not readily available. As noted in RPA (2012)[90], one UK impact assessment states that *"the costs of amending current regulations to implement a Directive are thought to be around £700,000"* (around €900,000 in €2017). Although no details are given on the basis for this calculation, it is expected that these costs relate to a rather substantial legislative change and would include those costs of making (e.g. preparing an impact assessment, drafting a substantial bill and presenting the legislation before parliament), printing and publishing the legislation. This estimate is

---

89 Some Member States may carry out Impact Assessments on the transposition of EU legislation but this cost is not considered here.

90 RPA (2012): Ex-Post Evaluation and Impact Assessment Study on Enhancing the Implementation of the Internal Market Legislation Relating to Motor Vehicles, http://www.rpaltd.co.uk/documents/J746_MotorVehicleLegislation_FinalReport_publ.pdf

significantly higher than the cost estimated in UK Department for Transport (2011) which notes that *"a combination of legal and technical resources as well as policy advisors are usually required to implement such a change, costing approximately £15,687 per amendment"* (approximately €20,000 in €2017).

Considering that all Member States have transposed the CMD which already contains a number of OELVs, it appears more likely that the cost of transposing an additional OELV would be closer to the low-end estimate. However, it is also appears that there has been a general trend towards increased impact assessment in the Member States (see, for example, RPA 2015[91]), which suggests that the costs would likely be higher than €20,000. This study thus takes €50,000 per Member State as an approximation of the general order of magnitude of the applicable transposition costs.

Table 5-15: Transposition costs		
Member States with no OEL	**Transposition cost per Member State**	**Total cost across the EU**
6 Member States: Italy, Luxembourg, Malta, Portugal, Romania, and Slovakia	€50,000	€300,000

It is assumed that for Member States that already have an OEL for cadmium and its inorganic compounds, the change to a different value (in case the OEL were to be higher than the OELV) would entail no significant costs.

5.5.2 Enforcement costs

The enforcement costs depend on the number of companies that will be covered by the OELV. In principle, national authorities are supposed to inspect companies already as they have the general obligation to protect workers. However, there could be an additional cost due to the need to ensure compliance with the new rules. Such enforcement costs depend on the inspection regime in each country and they are not estimated in this study.

5.6 Aggregated costs

5.6.1 Extrapolation from Cap Ingelec (2017)

The total compliance costs over 60 years (additional to the baseline) are set out below, extrapolated to all relevant companies (both members of the ICdA as well as non-member companies).

Table 5-16: RMM costs over 60 years based on extrapolation from Cap Ingelec (2017), additional to the baseline					
Sector	**1 µg/m3**	**4 µg/m3**	***10 µg/m3***	***25 µg/m3***	**Static baseline**
Total (€)	***758,000,000***	***735,000,000***	***591,000,000***	***179,000,000***	***0***
Note: All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Study team extrapolation from Cap Ingelec (2017)					

[91] RPA (2015): Study on the potential of impact assessments to support environmental goals in the context of the European Semester, available at http://ec.europa.eu/environment/integration/green_semester/pdf/J856.pdf

5.6.2 Cost data estimated by the model developed for this study (unadjusted)

The total compliance costs that are additional to the baseline are shown below as estimated by the cost model developed for this study. These costs exclude the distress costs from employment changes (see Section 6).

Table 5-17: Sum of all costs for the reference OELVs (PV CAPEX and OPEX over 60 years, incremental to the baseline)

Cost	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Total across all sectors /companies /stakeholders	***448,000,000***	***76,000,000***	***68,000,000***	***13,000,000***	***4,000,000***	***0***

Notes: All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Totals may not sum due to rounding. Source: Modelling by the study team (unadjusted model)

5.6.3 Cost data estimated by the model developed for this study (adjusted)

The total compliance costs that are additional to the baseline are shown below as estimated by the cost model developed for this study. These costs exclude the distress costs from employment changes (see Section 6).

Table 5-18: Sum of all costs for the reference OELVs (PV CAPEX and OPEX over 60 years, incremental to the baseline)

Cost	1 µg/m3	4 µg/m3	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Total across all sectors /companies /stakeholders	***448,000,000***	***116,000,000***	***116,000,000***	***44,000,000***	***4,000,000***	***0***

Notes: All values expressed as inhalable fraction. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Totals may not sum due to rounding. Source: Modelling by the study team (unadjusted model)

5.6.4 Comparison of the three cost estimates

There is a large difference between the compliance costs estimated by the model developed for this study (both unadjusted and adjusted) and the costs estimated in Cap Ingelec (2017). The three sets of cost estimates are also compared below. The greatest difference between the sources is at OELVs of 10 µg/m^3 (inhalable) and 25 µg/m^3 (inhalable).

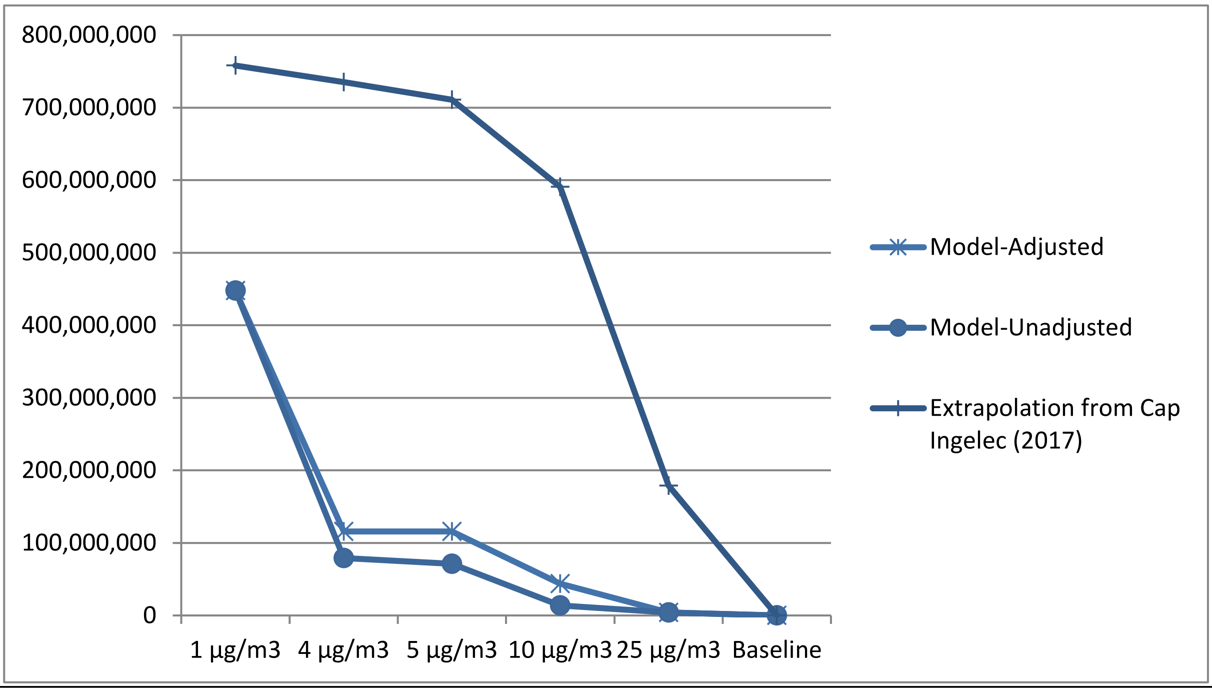


Figure 5-8: Costs estimated in the model developed for this study and estimated in Cap Ingelec (2017), PV 60 years € (additional to the baseline)

The CAPEX and OPEX estimated in the study model (unadjusted) and Cap Ingelec (2017) are set out below.

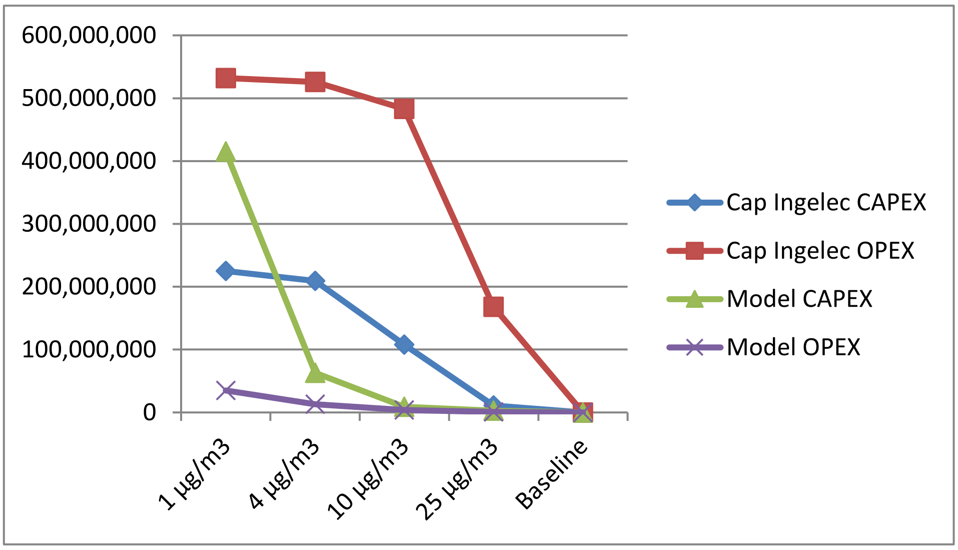


Figure 5-9: CAPEX and OPEX estimated in the model developed for this study(unadjusted) and estimated in Cap Ingelec (2017), PV 60 years € (additional to the baseline)

Although the differences stem from both CAPEX and OPEX, the greatest difference relates to OPEX. The OPEX estimated in Cap Ingelec (2017) is significantly greater than the OPEX estimated in the model developed for this study. It should be remembered that the model developed for this study is a generic one that covers a range of chemical agents and it is not Cd-specific, whilst the Cap Ingelec (2017) study is specific to Cd. As a result, it is possible that the model developed for this study underestimates the OPEX required to comply with the different OELVs.

In addition, the model developed for this study draws on a set of generic unit cost assumptions that relate to the cost of controlling exposure to any chemical agent in typical small, medium, and large companies. However, the companies that are relevant to cadmium and (at least some of) its inorganic compounds often have a larger exposed workforce that the average assumed in the model. This suggests that the model could be underestimating the compliance costs.

5.6.5 Conclusion

The aggregated costs are presented below. The two figures presented are for the model estimates (unadjusted or adjusted) and the figure in brackets is the value extrapolated from Cap Ingelec (2017).

Table 5-19: Summary of monetised costs and benefits (static discount rate)	
Reference OELV	**PV costs over 60 years (€2017 million)**
25 µg/m3 (inhalable fraction)	4 (179)
10 µg/m3 (inhalable fraction)	14 or 44 (591)
5 µg/m3 (inhalable fraction)	71 or 116 (711)
4 µg/m3 (inhalable fraction)	79 or 116 (735)
1 µg/m3 (inhalable fraction)	448 (758)
Monetised costs and benefits	RMMs Discontinuation of business Transposition costs Measurements
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.	

It is also not certain whether the lower limits are technically achievable – the analysis in Cap Ingelec (2017) suggests that process/machine redesign or PPE would be required in some operations for OELVs at or below 10 µg/m3 (inhalable fraction). It is of note that the data collected for this study shows that, with a few exceptions, companies in Europe are currently not achieving 1 µg/m^3 inhalable. Although this may not always take into account the possibility to use PPE to reduce air intake of cadmium and its inorganic compounds, national regulations may prevent companies from using PPE as the default RMM in cases where exposure occurs over prolonged periods of time.

It should be further noted that, although Germany currently has a tolerable limit for cadmium and inorganic cadmium compounds of 1 µg/m^3 (inhalable fraction), it is not clear whether German companies are actually achieving this level (in fact, there is evidence to suggest that there may be companies that have not achieved this level). The TRGS 561[92] lists general RMMs, which appear to be taken as a presumption of compliance with the legal requirements, regardless of the air concentration actually achieved. Consultation for this study also suggests that the German system is based on a 'pragmatic approach' that requires companies being required to implement measures that are technically achievable, with exceedance of the OEL not necessarily triggering discontinuation of operations. The second lowest national inhalable OEL in the EU is 10 µg/m^3. There are respirable OELs at around 2 µg/m^3 which could convert into inhalable OELs between 5 µg/m^3 (conservative assumption of a conversion ratio of 2.5) and over 10 µg/m^3 (using a conversion factor of 5 or 6). This illustrates the scale of the reductions required, even in well performing Member States.

[92] https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-561.pdf;jsessionid=638AD23E1DC9886BAE03C051EB4E006C.s1t1?__blob=publicationFile&v=2

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
- Section 6.5: Impact on employment.

6.1 Overall impact

Overall, market impacts (in terms of the effect on R&D, the single market, competitiveness of EU businesses and employment) will be strongly influenced by the extent to which costs are incurred to comply with the OELVs and by the feasibility of meeting the required air concentrations. In extreme cases, companies will be forced out of business if they are unable to meet the OELVs. The model developed for this study estimates the following distribution of companies or business units, broken down by sector, that would discontinue Cd-related activities, potentially leading to them ceasing trading.

Table 6-1: Estimates of companies or business units that will cease trading under different OELs (feasibility issues)

Sector	OEL µg/m³ (inhalable fraction)				
	1	4	5	10	25
Smelting, refining, foundries, and similar activities	2	0	0	0	0
Mining	0	0	0	0	0
Industrial batteries & other sectors	2	0	0	0	0
Total	***6***	***1***	***1***	***0***	***0***

Note: Totals may not be the sum of all sectors due to rounding.
Source: Modelling by the study team

The impacts shown in the table above relate to the fact that the reductions required to meet the different OELVs are greater than those permitted by the cost model used for this study (see the methodological note for the effectiveness and suitability of RMMs). In addition, companies may go out of business when they cannot pass the additional costs on to customers and/or consumers. However, such impacts are not modelled here.

The table below[93] provides estimates of the costs that are estimated to be incurred on a per company basis (discounted at 4% over 60 years). These costs are based on the study model. It should be noted that when the Cap Ingelec (2017) estimates are considered, the costs per company are between €9 million and €19 million. The subsequent table then provides estimates of these costs as a % of the average turnover.

[93] As noted above, some companies will cease trading as a result of the fact that they will be unable to meet the OELs required. As such, these companies are not considered when it comes to calculating the average costs for firms implementing RMMs.

Table 6-2: Costs per business and numbers of businesses implementing RMMs, additional to the baseline					
Item	OEL µg/m^3 (inhalable fraction)				
	1	4	5	10	25
Cost per business/€m	5	1.2-1.7	1.1-1.6	0.5 or 1.4	0.3
% of businesses affected	83%	62%	59%	29%	12%
No. businesses affected	85	64	61	30	12
Source: Modelling by the study team. The costs per businesses are model estimates (unadjusted or adjusted).					

The vast majority of businesses operating with workers exposed to cadmium are large ones and the estimates below have been calculated on the basis of average turnover for large companies (estimated at just over €350 million based on annual average turnover, arising from cadmium-related operations of €15 million per annum) over the 60-year assessment period (PV, discounted at 4%).

Costs (additional to the baseline) as a percentage of turnover are provided for both the low and high ends of the cost ranges indicated in Table 6-2 above. These estimates are based on the cost model outputs. When compliance cost estimates are extrapolated from Cap Ingelec (2017 are considered), the percentage of turnover increases manifold.

Table 6-3: Costs (additional to the baseline) for businesses implementing RMMs as a % of turnover					
Item	OEL µg/m^3 (inhalable fraction)				
	1	4	5	10	25
Cost as % turnover (low)	1.42%	0.34%	0.31%	0.14%	0.09%
Cost as % turnover (high)	1.42%	0.48%	0.45%	0.40%	0.09%
Source: Modelling by the study team					

Alternatively, higher costs for implementing RMMs (based on CAPEX and OPEX expenditures, additional to the baseline) have been estimated by industry stakeholders during consultation for this study and these indicate that costs as a percentage of turnover could range from 2.5% to 6% of turnover under the different OELs, indicating a significantly higher burden on companies and potential threat to profit margins.

Overall, Section 3 earlier in the report estimates that approximately 100–150 enterprises in the EU are potentially involved in working with cadmium and its inorganic compounds across the sectors. The market effects of the introduction of OELVs at different levels will, therefore, 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 (R&D) are key activities in an industry's capacity to develop new products and produce existing ones more efficiently and sustainably, 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.

The table below provides examples of sector-wide R&D expenditures in 2015 in a selection of MS using cadmium and its inorganic compounds.

Table 6-4: R&D expenditure at national level per manufacturing sector involving cadmium (in €)					
Member state	Sector				
	C20: Chemicals and chemical products	C24: Basic precious and other non-ferrous metals	C25: Fabricated metal products, except machinery and equipment	C27: Electrical equipment	C33: Repair and installation of machinery and equipment
CZ	42,749,000	4,100,000	44,247,000	122,848,000	26,118,000
DE	3,786,000,000	238,000,000	824,000,000	2,249,000,000	1,275,000,000
IT	417,600,000	29,200,000	358,600,000	505,400,000	67,500,000
PL	60,754,000	13,288,000	78,918,000	83,889,000	26,720,000
UK	429,871,000	11,987,000	658,997,000	261,505,000	217,829,000
Source: Modelling by the study team					

R&D expenditures in sectors such as chemicals and chemical products and electrical equipment are clearly significant (although it is noted that these figures cover the entire sector and not just R&D in production using cadmium and its inorganic compounds).

Better Regulation Tool #21 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 be becoming stricter, and companies may be doubtful about the future of cadmium and its inorganic compounds as an input in their production process. Even if the final OELVs implemented were at the higher end of the range, the perception that other more stricter limits might be imposed in the future could well emerge, 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.

6.3 Single market

6.3.1 Competition

The table 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 6-5: 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

Table 6-5: Screening of competition impacts		
Impacts	**Key questions**	**Yes/No**
		Capital and on-going (see costs as % of turnover in the tables 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, e.g. aerospace
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
	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.

Existing firms

Section 6.1 indicates that whilst the absolute number of firms likely to exit the market in the sectors identified as using cadmium and its inorganic compounds is relatively small, the six companies anticipated to leave the market (in the event of an OEL of 1 µg/m^3 being adopted) represent 6% of the total number of companies. Depending on market share, this could potentially have a significant effect on competition.

Section 6.1 estimated that no companies are likely to cease trading at OELVs of 25 and 10 µg/m^3 (inhalable fraction) and only a single company or a business unit is likely to cease trading at 5 or 4 µg/m^3 (inhalable fraction). Any effects on overall levels of competition would be more limited therefore at these higher OELs.

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 OELVs 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 OELV. Whilst the 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 one would represent a significant proportion of a company's turnover, especially for smaller companies. This high initial outlay requirement may result in additional companies being unable to continue operations, particularly where they are unable to secure finance for the investment (e.g. for necessary LEV equipment).

As indicated previously, costs would be incurred by companies through expenditures on additional RMMs in order to ensure compliance with the different OELs. As set out in Table 6-3, these costs are calculated as amounting to approximately 0.1% of company turnover at the 25 µg/m^3 OEL over the 60-year assessment period and as much as 1.4% at the 1 µg/m^3 OEL. Higher industry cost estimates ranging from 2.5% to 6% of turnover across the OELs, if they materialised, would put significant pressure on companies' profit margins. It is noted that regarding the modelled impacts, the 1.4% figure is an average across all companies implementing RMMs and some companies will actually incur higher costs than others.

Moreover, it is likely to be the case that greater pressure on costs will be felt in those MS which currently have the highest national OELs, requiring a greater shift in exposure levels where businesses are operating at levels close to these. Section 8.6 below provides greater detail on the potential impacts at different OELs and identifies Austria, Bulgaria, Croatia, Cyprus, Czech Republic, France, Hungary, Ireland, Lithuania, Slovenia, Sweden and United Kingdom as potentially having the highest (or no) national OELs, and where companies might therefore be operating currently at higher levels.

New entrants

The significant capital expenditures required in order to ensure that exposure to cadmium and its inorganic compounds is within OELs represents a barrier to trade for potential new entrants to the market.

6.3.2 Consumers

The information presented above suggests that no companies using cadmium would be forced to exit the market at harmonised OELS of 10 and 25 µg/m^3, implying that no monopolistic markets are likely to emerge as a result of the introduction of OELs at these levels. Those companies continuing operation will incur additional capital and operating costs, and this may be 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. Cost increases resulting from the requirement to implement additional RMMs for some businesses may be as much as 1.4% of average turnover at the 1 µg/m^3 level, and even higher based on industry estimates (up to 6%). This suggests that some increases in price would be likely, particularly as some companies would be likely to exit the market under the stricter OELs, in markets where there are limited numbers of companies across the EU. At less strict OELs, the cost increases arising from the implementation of RMMs represent a much lower proportion of turnover, particularly at the 10 µg/m^3 and 25 µg/m^3 levels and any impact on prices would likely be less significant at these levels as a result.

In addition, most of the sectors in which occupational exposure to cadmium occurs do not serve consumers directly but supply components to other industrial sectors. The companies that incur additional capital and operating costs may attempt to pass these costs further down the value chain but it is not expected that this would lead to a significant increase in overall prices paid by consumers.

6.3.3 Internal market

All the reference OELVs would have a positive impact on the simplification of the existing rules and the creation of a more level playing field in the internal market. All policy options are expected to significantly reduce the diversity of national OELs (see the table below).

Table 6-6: Simplification / level playing field

Reference OELV*	% of MS currently above the OELV**
1 µg/m³	80%
4 µg/m³	75%
5 µg/m³	70%
10 µg/m³	55%
25 µg/m³	45%

Notes:
*Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
**This does not include MSs for which no information or incomplete information is available. For example, the proportion of SMEs > 1 µg/m³ is most likely higher than 80%, probably as high as 95%.
Source: Table 3-1 in Section 3

A wide range of OELs are currently in place in the different MS. For example, France does not have a binding limit for cadmium and relies on an indicative limit of 50 µg/m³ (inhalable). On the other hand, there are several MS that have a binding inhalable limit of 10 µg/m³. Furthermore, Germany has a tolerable limit of 1 µg/m³ (inhalable), although it is not clear whether companies are currently achieving this level.

The differences should be considered in conjunction with the fact that there are companies that have several production facilities in different states and could potentially benefit from further implication. All identified companies and sites are listed in Table 3-26 in Section 3.11. A summary of the companies that are known to have several production facilities in different MSs is provided below.

Table 6-7: Companies active in several Member States

Segment	Company	Location of sites	Range of OELs µg/m3
Zn smelting and Cd refining	Nyrstar	Belgium, France, the Netherlands	BE: 10 (I), 2 (R) FR: 50(I) Indicative NL: 5 (R)
	Xstrata	Germany, Spain	DE: 1 (I) tolerable level ES: 10 (I), 2 (R)
Industrial batteries	Saft	Czech Republic, France, Sweden	CZ: 50 FR: 50(I) Indicative SE: 20 (T), 2 (R)

Source: consultation for this study

Introducing a harmonised OEL would reduce the need to research OEL requirements across the EU for companies wishing to operate in more than one MS, saving on both research costs as well as design costs relating to having to design facilities to meet with different OEL requirements.

However, it should also be noted that enforcement criteria and procedures may differ between Member States and an EU OELV does not necessarily guarantee a level playing field across the EU. In this regard, it is of note that although Germany currently has a tolerable limit for cadmium and inorganic cadmium compounds classified as Carc. 1A or Carc. 1B of 1 µg/m^3 (inhalable fraction), it is not clear whether German companies are actually achieving this level (in fact, there is evidence to suggest that this level is not universally achieved). The TRGS 561[94] lists general RMMs, which appear to be taken as a presumption of compliance with the legal requirements, regardless of the air concentration actually achieved. This suggests that, in some MS, companies may be required to do what is 'technically achievable' but would not have to discontinue operations because they cannot achieve the OELV, whilst in other MS it is possible that a company would be required to discontinue operations if they exceed the OELV. In addition, there appear to be differences in terms of the maximum length of time for which MS allow workers to wear PPE. These issues are particularly significant when it comes to the lowest reference OELVs, for which it is not clear whether they are achievable using generic RMMs such as LEV. This may put some companies at a competitive advantage compared to others.

6.4 Competitiveness of EU businesses

6.4.1 Cost competitiveness

The introduction of harmonised OELs will have an impact on companies' cost competitiveness, but will be more significant the stricter the OEL. As indicated previously, the increase in costs due to having to implement more or better RMMs are calculated to represent in the region of 1.4% of average turnover at the 1 µg/m^3 OEL. This would make those companies incurring these costs less competitive where they are competing with companies not using cadmium and its inorganic compounds and with any companies already compliant at this level. It is noted that the 1.4% figure represents an average across all companies with workers exposed to cadmium and its inorganic compounds, and for some companies, this proportion may be somewhat higher, implying a more significant impact on their cost competitiveness.

Consultation with industry suggests that very few companies are already meeting this level, and as a result, the majority of companies would be required to undertake some measures. Those companies already operating closer to the OEL will be affected less than those with higher exposure levels, providing them with a competitive advantage resulting from the introduction of a harmonised OEL. Companies operating in MS where there are lower OELs already in force, such as in Germany (see Table 3-1 in Section 3), might improve cost competitiveness as a result in this respect.

It is also of note that additional costs for Ni-Cd battery manufacturers would be incurred at a time when efforts are underway at the EU level to stimulate battery manufacturing in Europe (see the box below).

94 https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-561.pdf;jsessionid=638AD23E1DC9886BAE03C051EB4E006C.s1t1?__blob=publicationFile&v=2

Box 6-1: EU efforts to stimulate battery production
The recent 'industrial revolution' of batteries within the global market has highlighted the lack of and competitive disadvantage of the EU battery industry. In addition to this, companies producing cadmium and other battery types suffer from additional burdens of increased cost (between €46 and €918 million[95]) due to the introduction of OELs. Despite this, the EU has shown support for the battery industry and aims to establish a competitive market, a successful manufacturing chain, capture sizable markets and boost jobs within the industry[96]. The 'EU Batteries Alliance' has extended a budget of €100 million to finance new topics on batteries to be included in the Horizon 2020 Work Programme for 2019 and 2020[97]. This financial proposal in itself shows a form of acknowledgement from the EU that financial support to the battery industry is needed. The €100 million issued is designed to offer advice to help companies grow internally and self-sustain. Interestingly, the EU may have the potential to support the initiative with up to €2.2 billion, providing a larger scope for battery companies to benefit from[98]. In addition to this, in early 2018, the European Commission DG Research and Innovation organised the successful 'European Battery Cell R&I Workshop' which aimed to encourage next generation battery research. By involving relevant stakeholders within the workshop (including cell manufacturers, research organisations, material suppliers, OEMs, battery pack/module suppliers and national organisations), it offered an opportunity to develop a plan for an advanced future EU battery industry. Although the introduction of new OELs is likely to incur significant costs on industry, the support from the EU is likely to compensate for these addition costs. For example, the recent popularity of battery run cars creates such a huge market for the EU to operate in that the initial costs of revised OELs will naturally become less significant.

6.4.2 Capacity to innovate

Potential impacts on companies' capacity to innovate have been outlined in Section 6.2 above. Primarily, the diversion of costs away from R&D may occur due to overall cost impacts of having to invest in RMMs in order to meet the prescribed OELs.

6.4.3 International competitiveness

In the event that EU companies are required to comply with stricter OELs than those in effect in third countries, they will be at a disadvantage when compared to their competitors from third countries with higher OELs who will be able to operate without incurring large capital and operating costs necessary to meet stricter OELs. In certain cases, in particular where they have existing plants in third countries, EU companies working with cadmium and its inorganic compounds might have the incentive to shift EU operations away from the EU.

Table 6-5 below draws on information provided in Table 3-1 in Section 3 to highlight the OELs existing in a range of third countries, converting limits from mg/m^3 to $\mu g/m^3$ for ease of comparison with the OELs being considered under the different options. Where OELs are given as "Respirable", these have

95 European Parliament, 2017, Limits on Exposure to Carcinogens and Mutagens at Work: Second Proposal. Available at: http://www.europarl.europa.eu/RegData/etudes/BRIE/2017/603931/EPRS_BRI(2017)603931_EN.pdf

96 Europa, 2017, Statement by Vice-President for Energy Union Maroš Šefčovic following the high-level meeting on battery development and production in Europe. Available at: http://europa.eu/rapid/press-release_STATEMENT-17-3861_en.htm

97 Europa, 2018, European Battery Cell R&I Workshop. Available at: http://ec.europa.eu/research/index.cfm?pg=events&eventcode=230DABFD-90AB-8F7D-083EF5BD909DD025

98 EuroActive, 2017, European Battery Alliance Launched in Brussels. Available at: https://www.euractiv.com/section/electric-cars/news/european-battery-alliance-launched-in-brussels/

been converted to “Inhalable”, again, for ease of comparison with the options being considered for harmonised OELs. Regarding OELs expressed as “Total”, it has not been possible to convert these (with the exception of USA), due to the diverse ways in which the term is defined in different countries. It is noted that, in a number of cases, it has not been possible to determine the precise nature of the OEL (whether it is “Inhalable”, “Respirable” or “Total”).

Table 6-8: OELs in selected non-EU countries					
Country	OEL µg/m³				
	Unknown	Inhalable	Respirable	Total	Inhalable (or inhalable equivalent)
Australia	10				
Canada Ontario		10			10
Canada Ontario			2		5
Canada Quebec	25				
China	10				
India	50				
Japan	50				
South Korea				10	
South Korea			2		5
USA ACGIH		10			10
USA ACGIH			2		5
USA OSHA				5	5-10
Note: Respirable limits have been converted to Inhalable using a conversion factor of 2.5 Source: Table 3-1 in Section 3					

As can be seen from the table (ignoring those countries where the specific nature of the OEL is unknown), in the event that harmonised OELs of 25 µg/m^3 or 10 µg/m^3, competitors to EU companies would not generally appear to have specific advantages when it comes to having to comply with less strict OELs in the countries identified. For example, competitors in USA, South Korea and Canada would appear to have to comply with OELs of 10 µg/m^3 or stricter. However, in the event that harmonised OELs of 5 or lower were introduced for EU companies, their competitors would most likely be facing less strict OELs, putting them at a competitive advantage as they would be able to incur lower costs to meet with compliance requirements.

Less strict OELs in other countries would provide an incentive to EU companies to relocate operations outside of the EU, in particular where they already have facilities in other countries. A significant number of the companies using cadmium and its inorganic compounds are large multi-national corporations operating in more than one country and might be in a position to relocate.

6.5 Employment

As estimated previously, it is anticipated that up to eight companies or business units might close down at the strictest OELV proposed of 1 µg/m^3 (inhalable fraction). As a result, all employees working in these activities 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)[99] and adapted from Haveman and Weimer (2015)[100] and Dubourg (2016)[101]. The impacts include the following components:

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

Analysis carried out earlier in this report has indicated that up to six companies are working with cadmium and its inorganic compounds and have employees potentially exposed to cadmium and its inorganic compounds. In the event that an enterprise is unable to meet the prescribed OELs for those workers, they would be forced to close down specific operations using cadmium and its inorganic compounds and these workers would lose their jobs. The table below summarises the numbers of jobs of potentially exposed workers that would be lost at differing OELVs.

Table 6-9: Numbers of firms and exposed workers

µg/m³ (inhalable fraction)	Total no. of firms working with cadmium	No. firms or business units that would have to discontinue or substitute	Total no. workers affected by cadmium	Total workers in firms or units discontinuing or substituting	Total social cost (based on annual salary of €30,000)
1	100–150	8	10,000	280	€23 million
4		1		35	€3 million
5		1		35	€3 million

Note: Assumed 35 workers per firm or business units. This is the average per SEG or company in the data input into the model. Source: Modelling by the study team.

Based on a ratio of social cost per job loss over annual pre-displacement wage of 2.72 for EU28, as proposed by Dubourg (2016), the overall social costs of almost 600 job losses (at an OEL of 1 µg/m³ inhalable fraction) would be close to €23 million per annum based on an average annual wage of €30,000[102]. Equivalent figure for OELs at 4 or 5 µg/m³ inhalable fraction would be around €3,000,000.

99 "The social cost of unemployment", *32nd Meeting of the Committee for Socio-economic Analysis*, available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

100 Haveman R, H. and Weimer, D., L, 2015, "Public Policy Induced Changes in Employment", *Journal of Benefit-Cost Analysis*, 6, pp. 112-153

101 Valuing the social costs of job losses in applications for authorisation, Richard Duborg, The Economics Interface Limited, September 2016

102 This figure assumes that wage rate does not include employer taxes

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

It is not clear whether an OELV would have an impact on environmental releases of cadmium. It can be expected that, unless an OELV were to force companies to substitute cadmium for another metal or discontinue production in the EU, such impacts would be minimal.

In order to provide an indication of the significance of any such impacts, the environmental properties of cadmium are summarised below.

7.1 PBT screening

Cadmium is **very toxic to environmental organisms** (H400, H410). There is a wealth of data available, such that PNEC values were derived by species sensitivity distributions implying very low assessment factors. The aquatic and terrestrial PNEC were derived to 190 ng/L (assessment factor 2) and 0.90 mg/kg soil dry weight (assessment factor 1), respectively (ECHA Dissemination, 2017, as of November 2017).

The ecotoxicologically active species is Cd2+ which is stable in the environment. While some Cd compounds are highly insoluble (e.g. sulphide, carbonate, oxide), these can be transformed to more soluble forms under environmental conditions. Further, adsorption to sediment and soil is often strong (depending on composition) but (re)mobilisation is possible, e.g. due to acidification (WHO, 1992). Given the very high ecotoxic potential already low bioavailable concentrations may be sufficient for ecotoxicological effects. Further, sediment and soil dwelling organisms incorporating solid matter may also be affected by the particle bound faction. In conclusion, cadmium must be regarded as **persistent in the environment**.

While there are data demonstrating very high bioconcentration factors for e.g. algae and molluscs, bioconcentration factors for fish are much lower and obviously there is no biomagnification across trophic levels (ECHA Dissemination, 2017; WHO, 1992). Therefore, **cadmium is not regarded as bioaccumulative** (ECHA Dissemination, 2017).

Within the Annex XV reports on cadmium and compounds, the PBT and vPvB assessment was not considered, because it is not relevant for inorganic substances (ECHA Dissemination, 2017).

7.2 Current environmental levels in relation to hazard data

For cadmium, it is difficult to judge if current levels in water and soil are already close to or even above the respective PNECs: soil background levels are governed to a large extent by the geological characteristics and vary for agricultural soils between 0.25 mg/kg soil dry weight and somewhat above 0.9 mg/kg soil dry weight when extracted using aqua regina (Schmidt and Giese, 2009). Background concentrations are much lower, however, if extraction is performed using ammonium nitrate as a means to estimate the fraction bioavailable to plants. Without closer analysis of how the bioavailability issue was tackled in the relevant ecotoxicological data used for derivation of the PNEC, it is hard to draw firm conclusions here.

On the other hand, cadmium toxicity decreases with increasing water hardness. Therefore, DIRECTIVE 2008/105/EC defines 5 different environmental quality standard (EQS) classes for cadmium dependent on water hardness (from 0.08 µg/L up to 0.25 µg/L). Further, due to the high adsorption potential of Cd2+ to particulate matter, aquatic organisms may be affected by sediment borne Cd either during development (spawning to sediment layer) or due to remobilisation from sediment as a consequence of flood events.

Accordingly, the EU Risk Assessment Report on Cadmium Metal (ECB, 2007) states considerable y, especially with regard to the environmental risk to aquatic organisms in very soft waters. Generally, 90th percentiles for concentrations in water and soil are very close to relevant PNECs and sometimes somewhat in excess. However, analytical data were often of insufficient quality (not sensitive enough), such that only a small fraction of the data actually could be evaluated. Further, bioavailability in water depends on the extent of adsorption, which again was difficult to predict.

7.3 Current environmental exposure – sources and impact

For Germany, deposition of cadmium from air is actually much more relevant compared to direct industrial emissions into surface waters. The latter were estimated to be around 0.2 tonnes per year, being equal to the input into surface waters from atmospheric deposition. Rather, diffuse sources make up the major share of total input into surface waters (ca. 6.8 t/a) (2012 to 2014; UBA, 2016). In turn, many of these diffuse sources for Cd in surface waters will have their input from atmospheric emissions: total emission to air for the same period of time amounted to ca. 6.7 t/a (UBA, 2017).

Most recent data for 2015 (UBA, 20172) demonstrate that:

- Total emissions amount to ca. 6.57 t/a (100%);
- 57% of emissions are due to combustion of fuels including transport;
- 43% of emissions are due to industrial production processes, especially mineral and metals industry.

According to the EMEP-Report for Germany (EMEP, 2014):

- Yearly atmospheric Cd-depositions amount, on average, to 36 g/km^2;
- Only approximately 39% thereof are estimated to be anthropogenic;
- Approximately 61% are due to global, natural and historical emissions.

In consequence, atmospheric emissions for Germany due to current anthropogenic sources amount to ca. 14 g/km^2 per year. The fraction due to chemical industry emission (excluding combustion processes) amounts to ca. 6 g/km^2 per year. In comparison, cadmium input on agricultural fields due to application of mineral fertilisers are estimated to be ca. 220 g/km^2 per year (50th percentile; Schmidt and Giese, 2009). As such, from a total of around 226 g/km^2 cadmium input per year on agricultural soils in Germany, only ca. 2.7% are due to emissions from the chemical industry.

Due to data availability, this comparative data analysis was performed for Germany. According to EMEP data for 2015, total emissions to air for Germany (6.57 t/a) correspond to the 90th percentile over 24 countries of the EU. Considering that currently there are no EU wide thresholds for Cd in fertilisers, while in Germany these do exist, relative contribution to cadmium input per year on agricultural soils from chemical industry emissions will be lower in the majority of countries.

Given that a stricter OEL for cadmium would lead to higher environmental emissions, upper emissions would still be limited by human health based "emission limit values" (e.g. according to TA Luft for Germany (BMU, 2002): cadmium deposition must not exceed a yearly average deposition of 2 µg/(m2*d)). Assuming a worst case doubling of current emissions, this would lead to an estimated increase of total cadmium input onto agricultural soil of around 2.7% for Germany. While this is a relevant figure, compared to other factors the impact would be moderate. As outlined above, similar or lower figures are to be expected for most other countries of the EU.

7.3.1 Cadmium in food

Cadmium is an important food contaminant, and estimated quantities consumed through the diet are close to regulatory limits for certain population groups (Schwarz et al., 2014). Food group cereals and vegetables have been identified as relevant contributors to total cadmium intake, which is due to the accumulation of cadmium from agricultural soil by certain plant species.

Cadmium levels on agricultural soils therefore must not increase. However, currently there are no EU wide thresholds for Cd in fertilisers. In Germany, a limit concentration of 1.5 mg Cd/kg fertiliser dry weight or 50 mg/kg P_2O_5 is in place, as well as limits for Cd in biological wastes or sewage sludge spread on fields.

7.3.2 Potential impacts from relocation of industries

It is possible that relocation of some of the relevant industries to locations outside the EU (e.g. the production of Ni-Cd batteries) would lead to increased transport distances and, consequently, to increased CO_2 emissions.

Table 7-1: Data in g CO_2 per metric ton of freight and per KM of transportation

Type of Transportation	CO_2 g/km
Airplane (air cargo)	560 g
Modern truck/lorry	45 g
Modern train	18 g
Modern ship (Maersk Line, Triple E)	3 g

Source: UNEP DTU Partnership, 2017, CO_2 Emissions from International Maritime Shipping, Working Paper Series 2017: 4. Available at: http://www.unepdtu.org/-/media/Sites/Uneprisoe/Working%20Papers/2017/Working-Paper-4_Emissions-from-Shipping.ashx?la=da

The above table outlines the most basic data on CO_2 emissions via each mode of transport. In addition to these figures, it is important to consider the amount of freight that can be transported per mode of transport. In regards to Nickel Cadmium batteries, it can be assumed that they are mostly transported via boat.

Using the above figures, the following comparison between shipping from China to Finland and Spain to Finland has been made.

Table 7-2: Cargo capacity of different transportation modes				
Mode of transport	China to Finland Emissions (g)	Time required	Spain to Finland Emissions (g)	Time required
Air	4,530,912.2	7 days	1,707,672.1	7 hours
Boat	148,738.38	28 days	41,418.78	11 days
Train	134,577.72	14 days	67,326.84	7 days
Truck	336,444.3	7 days	168,317.1	3 days
https://www.searates.com/reference/portdistance/?K=ChIJ39UebIqp0EcRgI4tMyWV4fQ&A=ChIJkbeSa_BfYzARphNChaFPjNc&B=3015&I=470&shipment=4&wagon=FW&product=0&weight=1&volume=1&weight_unit=MT&volume_unit=CBM&container-type=20st&mode=& *All data was manipulated from the SeaRates website (above link) and data in Table 1-1.*				

When comparing the above statistics, it is clear that transporting batteries from China to Finland (for example) will produce more grams of CO_2 than transporting from within the EU (Spain to Finland). However, per day, a truck travelling from China to Finland emits 48,063.5 grams of CO_2, whereas transporting via truck from Spain per day equates to 56,105.7 grams. The only mode of transport that proved significantly more efficient and environmentally friendly was a boat, whereby shipping from Spain to Finland would emit 3,765.35 grams of CO_2 in comparison to 5,312.1 grams from China to Finland (per day). Although the distance from Spain to Finland is far less, this does not necessarily mean it is more efficient. In addition, due to the short transportation times, shipping within the EU can encourage shipping of products; for every 1 journey made from China to Finland by air, 24 of the same journey could be made from Spain to Finland within the same amount of time. Although this is beneficial in terms of supporting the economy, CO_2 emissions for all 24 journeys would amount to 40,984,130 grams of CO_2. Similarly, for a single truck journey from China to Finland, a truck travelling to Finland from Spain could make 2.3 as many journeys within the same 7 days.

Table 7-3: Cargo capacity of different transportation modes	
Mode of transport	Tons of cargo
One barge (ship)	1,500 tons
One rail car	100 tons
100-car train unit	10,000 tons
Large semi-trailer truck	26 tons
http://business.tenntom.org/why-use-the-waterway/shipping-comparisons/	

Table 7-4: Energy efficiency of shipping methods	
Mode of transport	Number of miles/gallon carrying one ton of cargo
One barge (ship)	514 miles/gallon
100-car train unit	202 miles/gallon
Large semi-trailer truck	59 miles/gallon
http://business.tenntom.org/why-use-the-waterway/shipping-comparisons/	

Table 7-5: Environmental quality of shipping methods			
Mode of transport	Hydrocarbons emitted (lbs/ton-mile)	Carbon monoxide emitted (lbs/ton-mile)	Nitrous oxide emitted (lbs/ton-mile)
One barge (ship)	0.0009	0.0020	0.0053
100-car train unit	0.0046	0.0064	0.0183

Table 7-5: Environmental quality of shipping methods			
Mode of transport	Hydrocarbons emitted (lbs/ton-mile)	Carbon monoxide emitted (lbs/ton-mile)	Nitrous oxide emitted (lbs/ton-mile)
Large semi-trailer truck	0.0063	0.0190	0.1017
http://business.tenntom.org/why-use-the-waterway/shipping-comparisons/			

7.4 Conclusion

Considering the following:

- the PT (not B) properties of cadmium;
- The uncertainty regarding environmental exposure/PNEC ratio; and
- The low contribution of industrial air emissions to the total emission;

the environmental impact of cadmium is regarded as 'significant' but not 'substantial'. Consequently, it is expected that these impacts would be minor and do not change the overall conclusions of the cost-benefit assessment. However, should any of the OELVs result in companies relocating production outside the EU, it is possible that this would result in increased CO_2 emissions due to more distant supply chains.

No alternatives to cadmium and its inorganic compounds can be easily identified. Due to past regulatory actions targeting cadmium, it is expected that most sectors where cadmium can be easily substituted have already switched to alternatives.

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 costs and benefits for businesses (relative to the baseline) are summarised below for the different reference OELVs. The two business compliance costs presented below are the model estimates (unadjusted or adjusted) and the figure in brackets is the value extrapolated from Cap Ingelec (2017).

Table 8-1: Costs and benefits to EMPLOYERS (PV over 60 years, reference OELVs relative to the baseline)

Reference point (inhalable)	1 µg/m³	4 µg/m³	*5 µg/m³*	*10 µg/m³*	*25 µg/m³*	Baseline
Benefits (avoided disruption)	€1–1.4 million	€0.9–1.3 million	€0.8–1.2 million	€0.5–0.7 million	€0.1 million	0
Compliance costs	€447 million (€758 million)	€79 or 116 million (€735 million)	€71 or 116 million (€711 million)	€14 or 44 million (€591 million)	€4 million (€179 million)	0
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team, consultation input, Cap Ingelec (2017)						

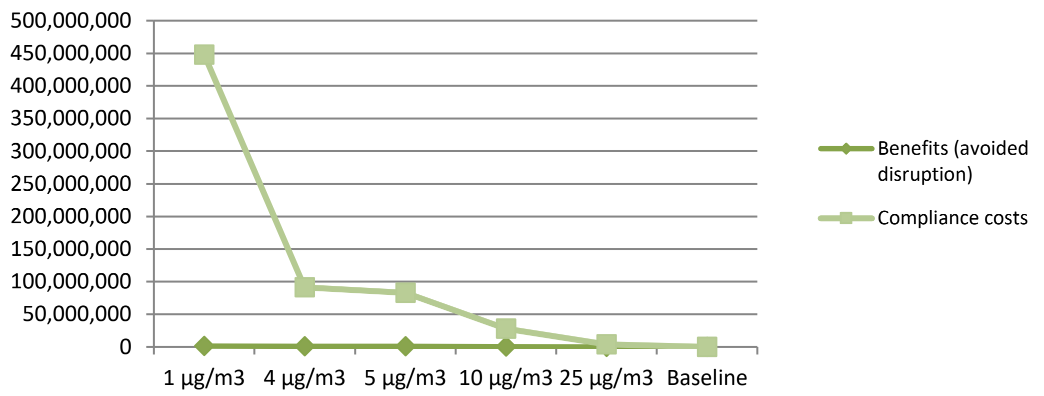


Figure 8-1: Comparison of the costs and benefits to EMPLOYERS (PV 60 yrs, € relative to the baseline), average of the ranges used for the benefit and cost curves. Source: modelling by the study team, only costs estimated using the unadjusted model outputs shown

8.2 SMEs

As noted in Tool #22 The SME test in the Better Regulation toolbox, SMEs generally tend to *"find it more difficult to access capital, and their cost of capital is often higher than for larger businesses."* In addition, the regulatory climate surrounding cadmium means that the long-term future of companies using it may be perceived by finance companies as being inherently more risky than other investment opportunities, thereby increasing the difficulty that SMEs might face in securing any finance, or at least having a premium placed on it with the potential threat of further regulation in the future.

An overview of the identified presence of SMEs is provided below. Where a company is a part of a larger company or a group of companies, it is not included among SMEs even where it would (on its own) comply with thresholds in the EU SME definition.

Table 8-2: Cadmium and inorganic Cd compounds – SMEs

Sector	No of companies	Proportion of SMEs
1: Zn & Cu smelting and Cd refining	Companies: 7	None
2: Speciality chemicals	Companies: 4	None: all companies that could comply with the SME thresholds are a part of larger companies
3: Ni-Cd batteries	Companies: 4	None
4: Pigments	Companies: 2	None: both companies are a part of larger companies
5: Aerospace & defence, including brazing alloys	Companies: 13+	None or very few (almost all confirmed not SMEs)
6: Surface treatment contractors	Companies: 35	Possibly SMEs
7: Niche manufacturing	Companies: 4	1* of 4, another company that could comply with SME criteria is part of a larger company

Table 8-2: Cadmium and inorganic Cd compounds – SMEs		
Sector	**No of companies**	**Proportion of SMEs**
8: Recycling	Cd recycling-Companies: 7	2* of the 7 companies are SMEs
	WEEE recycling - Companies: 20	Possibly SMEs
9: Mining of non-ferrous metal ores	At least 2	No indication of SMEs that would be affected
10: Metals fabrication	At least 1	No indication of SMEs that would be affected
11: Glass	At least 1	Not known**
12 & 13: Other & adjustment	Up to 50	Includes cement: number not known but could be SMEs
Notes: *Two of these 3 SMEs are in Germany where the tolerable limit is already 1 µg/m^3 inhalable so no impacts from any of the reference OELVs can be expected. ** No impacts from the reference OELVs expected in this sector in any case. Source: consultation for this study and study team estimates		

The table above suggests that SMEs could be active in the following sectors:

- **Surface treatment contractors** that supply the aerospace sector: there are an estimated 35 companies in this sector that use cadmium or its inorganic compounds and, whilst the proportion of SMEs is not known, consultation for this study suggests that a significant proportion could be SMEs. No data on exposure concentrations is known and the costs of RMMs have therefore been estimated on the basis of average exposure concentrations across all sectors.

- **Recycling – WEEE:** there are an estimated 20 companies in which workers may be exposed to cadmium and its inorganic compounds. However, the exposure concentrations are relatively low (est. 95th percentile 2.5 µg/m^3 inhalable) and are expected to further decline in the future, since the source of Cd exposure appears to be very old TV sets or incorrect handling of end-of-life batteries. It is therefore expected that the cost impacts on this sector would not be significant and, as a result, no significant impacts on SMEs are expected.

- **Recycling – Cd:** two SMEs are active in this sector. However, one of them is based in a MS where no impacts from any of the reference OELVs considered in this report are expected. The average 95th percentile of measured exposure concentrations in four companies in this sector is 1 µg/m^3 respirable fraction (range: 0.02–6.4 µg/m^3). Applying a conversion factor of 2.5, the average concentration is 2.5 µg/m^3 inhalable (range: 0.05–16 µg/m^3). This suggests that there could be some impacts from the policy options on the one SME in this sector. The exposure data were provided to the consultants in an anonymised format and it is therefore not possible to determine whether this SME would be affected by the reference OELVs considered in this study.

- **Niche manufacturing:** one SME is expected to be active in this sector but it is based in a MS where no impacts from any of the reference OELVs considered in this report are expected.

- **Other unknown sectors & adjustment** – no information available but some companies could be SMEs.

In conclusion, the key sector where impacts on SMEs could occur is the surface treatment sector supplying the aerospace industry. Although the number of SMEs has not been confirmed, it is possible that many (or all) of the 35 companies that provide Cd surface treatment are SMEs.

8.3 Workers

The costs and benefits for workers and their families (relative to the baseline) are summarised below for the different reference OELVs. The benefits are the avoided costs of ill health and the costs are the distress burden of unemployment.

Table 8-3: Comparison of the costs and benefits to WORKERS & THEIR FAMILIES (PV over 60 years, reference OELVs, relative to the baseline)

Reference point (inhalable)	1 µg/m³	4 µg/m³	*5 µg/m³*	*10 µg/m³*	*25 µg/m³*	Baseline
Benefits-low (avoided ill health)	€9 million	€9 million	€7 million	€5 million	€1 million	0
Benefits-high (avoided ill health)	€59 million	€57 million	€51 million	€30 million	€6 million	0
Costs (unemployment distress)	€23 million	€3 million	€3 million	0	0	0

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. Source: Modelling by the study team.

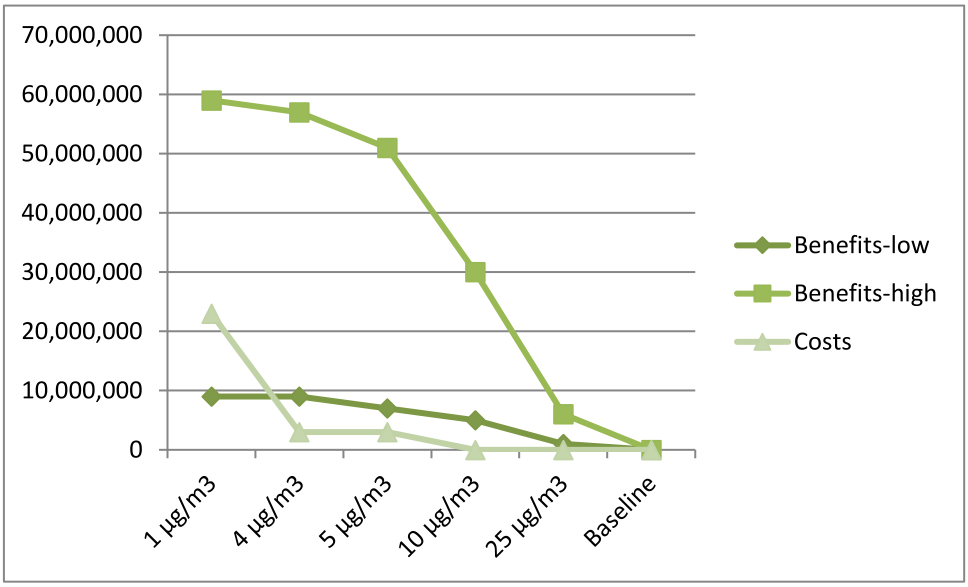


Figure 8-2: Costs and benefits to WORKERS & THEIR FAMILIES (PV 60 yrs, € relative to the baseline) Source: modelling by the study team

8.4 Consumers

No significant impacts on consumers have been identified. In case of significant impacts on EU-based companies, it is expected that the consumer market would be able to source the relevant products from outside the EU.

8.5 Taxpayers/public authorities

The costs and benefits for the public sector (relative to the baseline) are summarised below for the different reference OELVs.

Table 8-4: Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 60 years, reference OELVs relative to the baseline)

Reference point (inhalable)	1 µg/m³	4 µg/m³	*5 µg/m³*	*10 µg/m³*	*25 µg/m³*	Baseline
Avoided costs of healthcare and avoided loss of tax revenue	€4.6–€6.7 million	€4.5–€6.5 million	€4.1–€5.9 million	€2.4–€3.4 million	€0.4–€0.6 million	0
Transposition costs	€1.2 million	€1.1 million	€1 million	750,000	600,000	0

Notes: Only additional costs and benefits (i.e. relative to the baseline) are presented in this table. Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.
Source: Modelling by the study team.

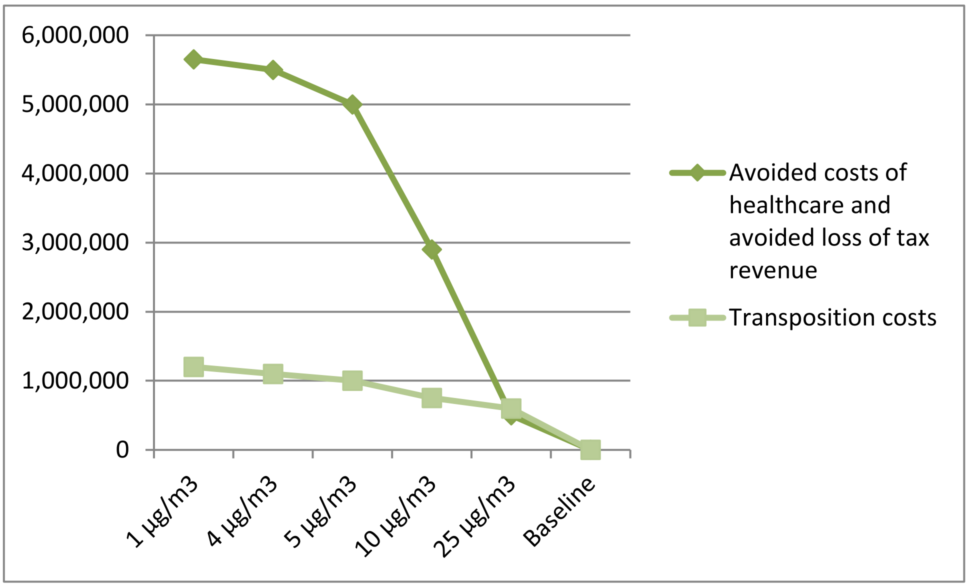


Figure 8-3: Comparison of the costs and benefits for the public sector (PV 60 years, relative to the baseline), average of the range for avoided costs of healthcare taken as the basis of the benefit (avoided cost) curve. Source: modelling by the study team

8.6 Specific Member States/regions

MS national limits

OELs already exist in the vast majority of MSs[103] but these differ from MS to MS. Table 3-1 in Section 3 of this report sets out the OELs in force in the MS and it can be seen that a number of MS would

[103] Where these are known. The study team has been unable to identify values for IT, LU, MT, PT, RO and SK

already have equivalent or lower OELs in place than those being proposed. The table below lists those MS at each proposed OEL that currently have a higher limit, indicating which MS would incur transposition costs due to the introduction of each specific OEL.

Table 8-5: MS with OELs higher than proposed levels			
OEL µg/m³	**MSs where current limits are higher**	**% of MSs above reference OELV**	**Notes regarding national limits**
1	AT, BE, BG, HR, CY, CZ, DE, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	80%	DE: Excess cancer risk (I): 2.5×10^{-3} (1.6 µg/m³; "tolerable risk")
4	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL?, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	75%	BE: 5 µg/m³ but not clear for what. EL: limit of 2.5 µg/m³ but unclear if (I) or (R). If R, equiv. I is 6.25 µg/m³
5	AT, BE, BG, HR, CY, CZ, DK?, FI, FR, EL?, HU, IE, LV, LT, NL, PL?, SI, ES?, SE, UK	70%	DK: limit of 5 µg/m³ but unclear if (I) or (R). If R, equiv. I is 12.5 µg/m³ EL: As above PL: 10 µg/m³ based on (I) value and 5 µg/m³ based on (R) value ES: 10 µg/m³ based on (I) value and 5 µg/m³ based on (R) value
10	AT, BG, HR, CY, CZ, DK?, FR, HU, IE, LV, LT, NL, SI, SE, UK	55%	AT: 15 µg/m³ for welding of Cd containing alloys, other uses DK: as above FI: 10 µg/m³ limit is indicative LV: limit of 10 µg/m³ but unclear if (I) or (R). If R, equiv. I is 25 µg/m³
25	AT, BG, HR, CY, CZ, FR, HU?, IE, LT?, SI, SE, UK?	45%	AT: 30 µg/m³ for manufacture of batteries, thermic extraction of zinc, lead and copper HR: 75 µg/m³ for CdS and pigments (indicative). Limit of 25 µg/m³ covers Cd F, Cd O, Cd Cl HU: limit of 15 µg/m³ but unclear if (I) or (R). If R, equiv. I is 37.5 µg/m³ IE: limit of 62.5 µg/m³ for "except CdO fume and CdS pigments". Other limits at 25 and 5 µg/m³ LT: 50 µg/m³ based on (I) value and 25 µg/m³ based on (R) value UK: limits of 25 µg/m³ and 30 µg/m³ but unclear if (I) or (R). If R, equiv. I values are 62.5 µg/m³ and 75 µg/m³
(I) = inhalable, (R) = respirable (T) = total dust CY has limit of 50 µg/m³ (T) Included in all OEL categories EE also has limit of 50 µg/m³ (T) Included in all OEL categories SE also has limit of 5 µg/m³ (T) Already included for (I) values Source: Table 3-1 in Section 3			

In this regard, it is of note that although Germany currently has a tolerable limit for cadmium and inorganic cadmium compounds classified as Carc. 1A or Carc. 1B of 1 µg/m³ (inhalable fraction), it is not clear whether German companies are actually achieving this level (in fact, there is evidence to suggest that this level is not universally achieved). The TRGS 561[104] lists general RMMs, which appear to be taken as a presumption of compliance with the legal requirements regardless of the air concentration actually achieved. The second lowest national inhalable OEL in the EU is 10 µg/m^3. There are respirable OELs at around 2 µg/m^3 which could convert into inhalable OELs between 5 µg/m^3 (conservative assumption of a conversion ratio of 2.5) and over 10 µg/m^3 (using a conversion factor of 5 or 6).

It is thus essential to consider the national enforcement regimes to appreciate the impacts that would be experienced in the different Member States. If an OELV of 1 µg/m^3 (inhalable fraction) were introduced into the CMD, it is conceivable that this may not have any cost impacts in Germany, whilst other Member States where enforcement regimes are based on non-exceedance of measured air values may experience more significant impacts.

Numbers of companies affected in different MS

Estimates have been made in Section 3 of this report of the number of companies operating with cadmium and its inorganic compounds across the EU28 MS. The MS with several relevant companies are (in alphabetical order) the Czech Republic, Italy, Germany, France, the Netherland, Poland and the UK.

8.7 Different timeframes for costs and benefits

The effect of the long latency period for lung cancer (10–50 years, midpoint: 30 years) on the Present Value of the burden of disease is mitigated by applying a conservative latency period of 10 years for the purposes of the modelling exercise. Although the effect of latency on the monetised benefits is reduced in this way, the cumulative nature of cancer risk over time which results in monetised benefits being assigned to later years than the costs means that the benefits are still discounted more heavily than the costs.

The monetisation of the cases of elevated proteinuria is characterised by a similar issue, although it is less pronounced than in the case of cancer since the 'fraction of workers affected by elevated proteinuria' relates to a 20-year exposure period, whilst the risk of developing cancer accumulates over the whole working life.

[104] https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/TRGS-561.pdf;jsessionid=638AD23E1DC9886BAE03C051EB4E006C.s1t1?__blob=publicationFile&v=2

9 Limitations & sensitivity analysis

9.1 Overview of limitations and uncertainties

This section sets out the key limitations and uncertainties and considers their potential impact on the conclusions. Whilst some of these uncertainties have been internalised into the assessment by means of the different cost and benefit scenarios, significant uncertainties remain. These are summarised below and their significance for the results of this study are assessed. A more detailed assessment of some of these limitations and uncertainties is provided in the second part of this section.

Table 9-1: Overview of the key limitations/uncertainties and their significance

Limitation or uncertainty	Explanation	Estimates in this study are U (underestimates) or O (overestimates)	
		Costs	Benefits
Conversion factor between respirable & inhalable fraction	The conversion factor used is 2.5 (Respirable x 2.5 = Inhalable). This is a conservative estimate which has been chosen to ensure that the assessment is protective of the workers. However, the real-life conversion factor can be highly variable. Some stakeholders believe that the generic conversion factor should be 5 or 6.	Significant U	O
Exposed workforce	Exposed workforce: the original model was further developed to account for the fact that large exposed populations have been estimated by SUMER and ASA. A greater workforce would increase both the costs and the benefits.	U	U
Additional health endpoints	A number of health endpoints could not be quantified. The impact of this is (to an unknown degree) mitigated by adopting highly conservative assumptions for the estimation of the cases of elevated proteinurea and their monetisation.	Not relevant	U
Slope of ERRs/DRRs	There are uncertainties in the evidence available to develop the ERR and DRR.	Not relevant	Could be either U or O
Cd-AIR vs Cd-U	Due to the uncertainty in linking air exposure and elevated proteinurea, a DRR for Cd-U has also been derived. The use of a Cd-U DRR results in a lower estimate of the cases of elevated proteinurea.	Not relevant	O
The latency period for cancer	In order to avoid underestimating the benefits from an OELV, an extremely conservative latency period of 10 years has been used for the estimation of future cancer cases. Lung cancer has a latency period of 10–50 years (average: 30).	Not relevant	O
Future trends	Exposed workforce and concentrations are assumed to remain unchanged.	O	O
Discount rate	The estimates in this report have all been modelled using a static discount rate. A declining discount rate would reduce both the costs and the benefits.	U	U
PPE in exposure data	Some of the input data have been corrected for PPE use. However, there is insufficient information to determine which data precisely have been corrected. Should PPE currently be worn, then both the costs and benefits would be overestimated.	O	O

Table 9-1: Overview of the key limitations/uncertainties and their significance			
Limitation or uncertainty	Explanation	Estimates in this study are U (underestimates) or O (overestimates)	
		Costs	Benefits
Constant exposure concentrations for the ERRs/DRRs	Influence of the fact that some workers have had higher concentrations in the past and reduction is only over a part of the period.	Not relevant	U
'Positive bias' in reported data	It is possible that there has been some self-selection among companies that provided the data collected through consultation for this study, with worse-performing companies less likely to report their exposure concentrations.	U	U
RMMs in place	The assumptions about RMMs in place impact on the costs since it is costlier for a company that already has RMMs in place to make improvements. To mitigate a potential positive bias in the reported data, the model inputs assume lower proportions of companies with RMMs than the data reported through consultation.	U	Not relevant
P95 70% Confidence/GM ratio	Generic average used for stakeholders which did not report both values: 5. Should this ratio be too low, then the costs would be underestimated and the benefits would be overestimated.	U	O
Assessment period	The reference period of 60 years for this study was selected both to be consistent with previous Commission IAs but also to ensure that the long latency period for cancer does not mean that the benefits are not counted. The cumulative nature of cancer risk and the fact that 20 years are sufficient to develop the full risk of elevated proteinurea mean that the impact of extending the assessment period would most likely to be significant.	U	U
Elevated proteinurea	The proportion of cases of elevated proteinurea that develop into End-Stage Renal Disease (ESRD) are based on assumptions that relate to the current biomonitoring values.	Not relevant	U

9.2 Key limitations and uncertainties

9.2.1 Conversion factor between respirable and inhalable

The conversion factor used is 2.5 (Respirable x 2.5 = Inhalable). This is a conservative estimate which has been chosen to ensure that the assessment is protective of the workers. However, the real-life conversion factor can be highly variable. Some stakeholders believe that the generic conversion factor should be 5 or 6.

Most of the exposure data collected for this study is expressed as 'respirable fraction'. A conversion factor of 2.5 could therefore significantly underestimate the costs. The ICdA Industry Guidance Document refers to the REACH DNEL of 4 $\mu g/m^3$ respirable which is taken in this study as corresponding to 10 $\mu g/m^3$ inhalable (conversion factor: 2.5). However, when conversion factors of 5 or 6 are used, 4 $\mu g/m^3$ respirable corresponds to 20 $\mu g/m^3$ or 25 $\mu g/m^3$ inhalable.

The reference OELVs of 1 µg/m^3 and 4 µg/m^3 are expressed as inhalable fraction and have not been converted from respirable fraction values. The reductions calculated on the basis of a conversion factor of 2.5 could thus underestimate the costs in case.

If a conversion factor of 5 or 6 were to be used, this would adjust the costs by a factor of up to 2 or 2.4. At the same time, where the ERRs/DRRs rely on epidemiological or toxicological data derived on the basis of respirable concentrations, the use of a higher conversion factor would result in lower benefits of regulatory action.

9.2.2 Exposed workforce greater than 10,000

The core estimations were further developed to account for the fact that large exposed populations have been estimated by the SUMER and ASA datasets (see Section 3).

A larger exposed workforce results in an increase to both the costs and benefits. Their extent (as well as the relative magnitudes of the cost and benefit increases) depends on the assumptions made about the concentrations to which the additional workers are exposed.

The magnitude of these increases can be very large. For example, estimating that the total workforce is 30,000 has the potential to increase the PV of the costs over 60 years to € hundreds of millions for OELs between 10 and 4 µg/m^3 (inhalable fraction) and € billions for 1 µg/m^3 (inhalable fraction). The precise magnitude of the cost increases depends on the assumptions about the exposure concentrations that apply to these 20,000 additional workers.

The additional modelling still supports the conclusion that the lowest reference OELV at which the monetised benefits may exceed the costs is 10 µg/m^3 (inhalable fraction), i.e. 4 µg/m^3 (respirable fraction).

9.2.3 Additional ill-health endpoints

The costs and benefits of the OELVs for cadmium and inorganic compounds depend on the toxicological parameters (ERR, DRR, threshold), as derived in Section 2 of this report. However, those parameters include some uncertainties, including the completeness of endpoints (Are all relevant tumour locations addressed? Are all relevant non-cancer endpoints covered?). Due to uncertainties about whether sufficient evidence is available and whether these risks are additive, only the most sensitive endpoints for which SCOEL decided that there was sufficient evidence have been quantified in this study.

The health endpoints that could not be quantified include kidney and prostate cancer (IARC, 2016[105]; Rushton et al 2012[106]; Boffetta et al 2011[107]) and respiratory and bone toxicity fractions (ECHA, 2013a; KEMI, 2011; SCOEL, 2017).

[105] IARC (2016): List of classifications by cancer sites with sufficient or limited evidence in humans, available at https://monographs.iarc.fr/ENG/Classification/Table4.pdf

[106] Rushton et al (2012): Occupational cancer in the UK – overview report, available at http://www.hse.gov.uk/research/rrpdf/rr931.pdf

[107] Boffetta P et al (2011): Occupational exposure to arsenic, cadmium, chromium, lead and nickel, and renal cell carcinoma: a case-control study from Central and Eastern Europe, available at http://www.ncbi.nlm.nih.gov/pubmed/21217163

The impact of this is (to an unknown degree) mitigated by adopting highly conservative assumptions for the estimation of the cases of elevated proteinurea and their monetisation.

9.2.4 ERRs/DRRs

Another uncertainty is the slope of the ERR or DRR (effects and severity in higher doses compared to lower doses).

For cadmium, SCOEL assumes that the suggested OEL (1 µg/m³, inhalable fraction) is a "practical" threshold for cancer effects.[108] This threshold was adopted in this analysis to derive an ERR. However, SCOEL does not provide further data to establish the ERR and the Committee assumed a practical threshold for local respiratory effects (possibly including cancer) at 4 µg/m^3 (respirable fraction) in an earlier assessment.[109] Therefore, the selected starting point ("practical threshold") for lung cancer is uncertain. In addition, SCOEL reports various unit risk quantifications for lung cancer from animal studies and from epidemiological evidence, without discussing the reliability and quality of either of those two risk quantifications. Those two estimates differ by more than one order of magnitude.[110] The more conservative estimate from animal studies was used to establish an ERR. However, if the assumption of a "practical threshold" were not to be taken forward, the animal data on lung cancer risk would result in a different ERR, with more cancer cases in the low exposure range. Therefore, the German assessment on cadmium provided an ERR with an acceptable risk level (excess risk of 4:10,000), well below the cancer threshold selected in this report.

SCOEL also states that "positive associations have been observed between exposure to cadmium and cadmium compounds and cancer of the kidney and of the prostate, whilst there is also sufficient evidence in experimental animals for the carcinogenicity of cadmium compounds" for various tumour sites. Because of those uncertainties, no conclusions in the shift of the slope for the ERR (all cancer sites vs. most significant cancer site) can be provided in this sensitivity analysis. Moreover, there exists no adequate methodology to discriminate the occurrence of multiple cancers in identical persons or the additive occurrence of cancers in different persons (hence, additional cancer cases, if more cancer sites are considered). Therefore, a quantitative sensitivity analysis is not feasible, but it may be concluded that the reference to only lung cancers and the assumption of a "practical threshold" tends to underestimate the total number of cancer cases to be expected after occupational exposure to inorganic cadmium compounds. On the other hand, the use of animal data to establish the ERR may be conservative (tends to overestimate the "true" excess risk, if just one cancer site (the lung) is covered).

[108] SCOEL, Scientific Committee for Occupational Exposure Limits (2017), Cadmium and its inorganic compounds. SCOEL/OPIN/336. Adopted 8th of February 2017, European Commission, Directorate-General for Employment, Social Affairs and Inclusion. Directorate B - Employment. Unit B.3 - Health and safety

[109] SCOEL, Scientific Committee for Occupational Exposure Limits (2010), Recommendation from the Scientific Committee on Occupational Exposure Limits for cadmium and its inorganic compounds. SCOEL/SUM/136. February 2010, European Commission; Employment, Social Affairs and Inclusion

[110] Haney, J. (2016), Development of an inhalation unit risk factor for cadmium; Regulatory Toxicology and Pharmacology, 77, 175-183,(epidemiological assessment); Takenaka, S.; Oldiges, H.; König, H.; Hochrainer, D.; Oberdörster, G. (1983), Carcinogenicity of cadmium chloride aerosols in wistar rats, Journal of the National Cancer Institute, 70, 367-373 (assessment based on animal data)

Regarding non-cancer effects, the exposure concentration corresponding to a threshold for proteinuria is discussed in the literature. There are significant uncertainties with regards to:

- the slope of the DRR for proteinuria, because more recent assessments indicate a non-linear slope with a steeper upwards slope only at 10 µg/m³ (inhalable) or above (Chaumont et al., 2011)[111]; and
- the cut-off concentration of proteins in urine indicative of renal tubular damage and causally linked to cadmium exposure is a controversial discussion, with some assessments still assuming significant risk for renal damage at or close to the SCOEL threshold level, where others assume reversible and non-adverse minor changes at exposure concentrations well above the suggested OEL by SCOEL.

It should also be noted that there is an ongoing discussion about the concenpt of a practical threshold.[112]

9.2.5 Air concentrations vs Cd-U

The numbers of cases of ill health have been estimated using the DRR based on the correlation between air concentrations (µg/m³) and elevated proteinuria incidence (fraction affected). However, it is acknowledged that this correlation is uncertain. It can also be argued that the concentration of cadmium in urine [CdU in µg cd/L urine or µg Cd/ g creatinine] has the potential to provide a more reliable indication of proteinuria than Cd concentration in air (Cd-Air). The two DRR approaches (DRR based on Cd-Air vs. DRR based on CdU) have been derived using different methods and the Cd-Air DRR can be regarded as a more conservative estimate compared to CdU. However, the slope of the CdU DRR is also highly uncertain. As indicated above (Section 2.3.4) some assessments find a LOAEL for proteinuria at lower levels than 2 µg Cd/g creatinine and others assume that more severe kidney damage would occur at slightly elevated CdU values.

Moreover, other non-cancer health effects are expected at low CdU levels and at current typical occupational exposure levels of cadmium. Most importantly, bone toxicity is expected at low exposures and respiratory effects are to be considered from inhalation exposure to cadmium. In addition, cadmium is discussed to be an endocrine disrupting chemical with high uncertainties on the dose response and reliability of this potential toxicological endpoint. Since those non-cancer endpoints have not been selected for OEL derivation by SCOEL, because the studies often do not provide a dose response relationship validated for the occupational exposure scenario and because those studies are not equally analysed for reliability, a quantitative sensitivity analysis is not feasible. For the reasons mentioned, the reference to proteinuria and Cd-Air in correlation does not necessarily overestimate the total number of non-cancer cases to be expected after occupational exposure to cadmium or inorganic cadmium compounds at elevated exposure levels.

Nevertheless, the number of workers developing elevated proteinurea is estimated below, using the Cd-U DRR and compared with the results presented in Section 4.

---

111 Chaumont, A.; De Winter, F.; Dumont, X.; Haufroid, V.; Bernard, A. (2011), The threshold level of urinary cadmium associated with increased urinary excretion of retinol-binding protein and beta 2-microglobulin: a re-assessment in a large cohort of nickel-cadmium battery workers, Occupational and Environmental Medicine, 68, 257-264

112 See https://echa.europa.eu/documents/10162/13579/rac_joint_scoel_opinion_en.pdf/58265b74-7177-caf7-2937-c7c520768216

Table 9-2: Modelling on the basis of Cd-U DRR (all for exposed workforce of 10,000)			
Scenario	**Details**	**Workers with proteinurea (% of baseline, no staff turnover)**	
		40 years	**60 years**
Workers employed in or after 2000, average of ranges*	OCdBIO average % of workers 2014–2016, only workers employed 2000 or later, average of ranges µg Cd/ g creatinine and range CdU above 10 µg Cd/ g creatinine represented by 15 µg Cd/ g creatinine	15 (16%)	30 (16%)
Workers employed in or after 2000, higher value in range*	OCdBIO average % of workers 2014–2016, only workers employed 2000 or later, higher value in range used and range CdU above 10 µg Cd/ g creatinine represented by 15 µg Cd/ g creatinine	25 (26%)	50 (26%)
All workers in OCdBIO, average of ranges*	OCdBIO average % of workers 2014–2016, average of ranges µg Cd/ g creatinine and range CdU above 10 µg Cd/ g creatinine represented by 15 µg Cd/ g creatinine	46 (48%)	92 (48%)
All workers in OCdBIO, higher value in range*	OCdBIO average % of workers 2014–2016, higher value in range used and range CdU above 10 µg Cd/ g creatinine represented by 15 µg Cd/ g creatinine	73 (77%)	146 (77%)
*% of workers with a Cd-U level in OCdBIO are reported for the following ranges: < µg Cd/ g creatinine, 2–5 µg Cd/ g creatinine, 5–10 µg Cd/ g creatinine, and > µg Cd/ g creatinine			

The monetised benefits estimated under the different scenarios are compared below.

Table 9-3: Modelling on the basis of Cd-U DRR (all for exposed workforce of 10,000), €million PV over 60 years							
Scenario code	**Scenario description**	**1 µg/m^3**	**4 µg/m^3**	***5 µg/m^3***	***10 µg/m^3***	***25 µg/m^3***	**Baseline**
Benefits-C-M1-C	Benefits - Core Scenario - Method 1 - Constant Workforce	14	13	12	8	2	0
Benefits-C-M2-T	Benefits - Core Scenario - Method 2 - Workforce 5% p.a. turnover	66	64	58	34	6	0
Benefits-S-M1-C-Cd-U DRR A2000 M	Benefits - Sensitivity - Method 1 - Constant Workforce - Cd-U DRR workers after 2000, middle of range values	6	6	5	4	0.8	0
Benefits-S-M2-C-Cd-U DRR All T	Benefits - Sensitivity - Method 2 - Workforce 5% turnover - Cd-U DRR, all workers, top of range values	54	52	46	28	5	0
Note: Values in italics converted from respirable to inhalable using a conversion ratio of 2.5.							

9.2.6 Future trends

It should be noted that the industry is working towards voluntary targets which involve a reduction of Cd exposure. It is therefore likely that the exposure concentrations will reduce in the future even under the baseline. In this regard, it is of note that the ICdA Industry Guidance refers to the REACH DNEL of 4 µg/m^3 respirable (using a conversion factor of 2.5, this corresponds to 10 µg/m^3 inhalable). The data on measured concentrations provided by industry stakeholders for this study shows that further reductions are needed before this level is achieved across the whole industry. It is therefore likely that further reductions would take place even in the absence of an OELV being introduced under the CMD.

9.2.7 Discount rate

The static discount rate is 4%: this is taken over the whole 60-year period. A dynamic discount rate would increase both the value of the benefits and the costs but the value of the benefits would increase by a comparatively greater rate than the costs. The costs per company and the benefits per case: cancer value increase 12–13%, elevated proteinurea 5–10% and costs by max. 6%.

9.2.8 Use of AM/GM vs P95 in the case of a threshold substance

Across all the substances subject to this study, the mean of available exposure measurements[113] has been used for the estimation of the benefits, whilst the 95th percentile (P95) has been used as the determinant of compliance with an OEL.

At the company level, measuring exposure concentrations typically involves taking a number of samples. Due to the costs involved, companies strive to minimise the number of samples taken and sent for analysis. However, the exposure concentrations can differ substantially between samples, even within a single SEG[114]. Although a small number of Member States may accept the average of several samples as the basis for determining compliance with an OEL, the most common method of determining compliance is with reference to the EN689 standard (currently under revision[115]). By way of simplification, it is assumed that samples are log-normally distributed and companies are required to ensure that the 95th percentile of all samples is expected not to exceed the OEL.

Since the ERR and DRR for cadmium relates to lifetime exposure, average exposure concentrations are expected to be the most appropriate method for estimating the health effects.

This approach has been used across all the substances but its effect is most pronounced in the case of threshold carcinogens, for which some of the reduction in exposure would occur at levels below the threshold. Since a GM or AM is lower than P95, it is more likely that some part of the reduction will fall below the threshold when average values are used than when P95 values are used. This explains some of the differences between the costs and the benefits for cadmium and its inorganic compounds, which is expected to have threshold of ≤1 µg/m^3 (inhalable fraction) for both lung cancer and elevated proteinurea. Approximately 40% of the companies, SEGs or other units used in the assessment of the costs or benefits are characterised by an average concentration below the threshold but a P95

[113] Geometric Mean (GM) or Arithmetic Mean (AM)

[114] SEG: Similar Exposure Group (SEG), i.e. a group of workers that undertake similar tasks in a similar way and which should thus be exposed to very similar exposure concentrations

[115] Most recent draft available: prEN689:2016, which is broadly equivalent to the French national method for determining OEL compliance

concentration above the threshold – these SEGs/companies/other units would incur costs for all of the reference points above 1 µg/m³ (inhalable fraction) but would accrue no benefits. Almost 60% of the SEGs/companies/other units used for the calculation of the costs and benefits have average concentrations ≤1 µg/m³ (inhalable fraction).

A graphical explanation of this issue is provided below.

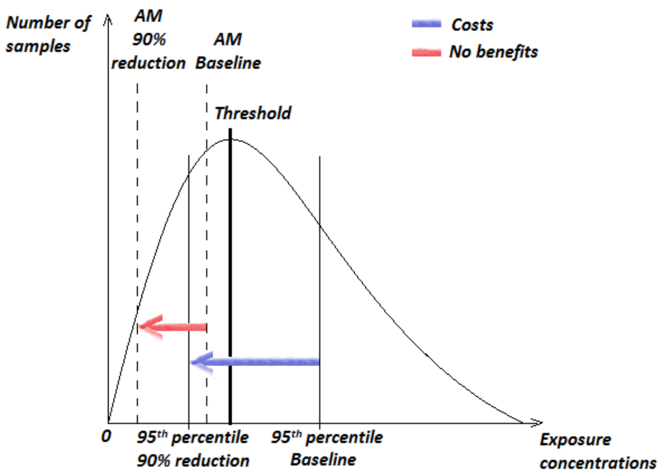


Figure 9-1: A case with costs but no benefits

9.2.9 Assessing the effects of elevated proteinurea

The endpoint 'elevated proteinurea' covers a range of effects ranging from subclinical effects to Chronic Kidney Disease (CKD) to End Stage Renal Disease (ESRD). There is significant uncertainty about the exposure concentrations required for elevated proteinurea to develop into CKD or ESRD. The data used for the estimation in this report suggest that only a small proportion of the cases of proteinurea expected to occur over the coming 60 years (under the scenario which estimates the highest number of proteinurea cases) will develop into ESRD, for which the most significant costs (per case) can be expected. These estimates have been developed on the basis of the current biomonitoring data (see Annex 3). Should the exposure concentrations in companies where no biomonitoring takes place be higher, the proportion of ESRD cases in the total number of cases of elevated proteinurea could be higher. The potential for underestimation has been mitigated by means of using the conservative assumptions for the derivation of the estimates of ESRD in this report.

10 Conclusions

This section summarises the estimates presented in the previous sections by means of a Cost-benefit (CBA) and Multi-criteria (MCA) analyses. All the costs and benefits presented in this section are PV over 60 years and additional to the baseline scenario.

However, it should be noted that, due to the large number of uncertainties surrounding the estimates, the costs and benefits in the CBA and MCA should only be taken as an indication of the order of magnitude of the potential impacts of the OELVs. Therefore, the final conclusion should go beyond a simple comparison of the costs and the benefits that could be monetised in this study and should take into account all the information presented in this report, including the impacts that could not be monetised and the limitations and uncertainties in the preceding section. In order to mitigate the uncertainty surrounding the estimates, the costs estimated using all three cost estimation methods are presented below and the benefits estimated in the core model are complemented with those estimated using the Cd-U DRR (see Section 9 – limitations and sensitivity analysis).

10.1 Cost-benefit assessment (CBA)

10.1.1 Overview of the benefits for the reference OELVs

The costs and benefits (relative to the baseline) estimated in this report for the different reference OELVs are summarised in the tables below. For the purposes of this report, all benefits that accrue from reduced ill health are treated as direct benefits.

Table 10-1: Overview of the benefits (relative to the baseline)		
Description	**PV over 60 years, static discount rate, relative to the baseline**	**Comments**
	Direct benefits	
Direct benefits – cancer	*25 $\mu g/m^3$:* €0.7 million *10 $\mu g/m^3$:* €3 million *5 $\mu g/m^3$:* €4 million 4 $\mu g/m^3$: €5 million 1 $\mu g/m^3$: €5 million	Healthcare, informal care, productivity loss, lost wages, employers, intangible benefits
Direct benefits – elevated proteinurea	*25 $\mu g/m^3$:* €0.9–6 million *10 $\mu g/m^3$:* €5–32 million *5 $\mu g/m^3$:* €8–55 million 4 $\mu g/m^3$: €9–61 million 1 $\mu g/m^3$: €9–63 million ***Lower if Cd-U used:*** *25 $\mu g/m^3$:* €0.1–5 million *10 $\mu g/m^3$:* €0.8–25 million *5 $\mu g/m^3$:* €1–42 million 4 $\mu g/m^3$: €1–47 million 1 $\mu g/m^3$: €1–49 million	
	Indirect benefits	
	None quantified	
Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.		

10.1.2 Overview of the costs for the reference OELVs

As noted in Section 5, there are large differences between the compliance costs (additional to the baseline) estimated by the model developed for this study (unadjusted and adjusted) and the costs estimated in Cap Ingelec (2017). The two business compliance costs presented below are the core model estimates (unadjusted or adjusted) and the figure in brackets is the value extrapolated from Cap Ingelec (2017).

Table 10-2: Overview of the costs (incremental to the baseline, PV over 60 years)

Reference OELV	Cost type	Workers		Businesses		Administrations	
		One-off PV 60y €m	Recurring PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m	CAPEX PV 60y €m	OPEX PV 60y €m
25 µg/m³ (inhalable fraction)	Direct	0	0	3 (11)	1 (168)	0.3	N/A
	Indirect	0	0	N/A	N/A	N/A	N/A
10 µg/m³ (inhalable fraction)	Direct	0	0	9 or 30 (108)	4 or 14 (483)	0.3	N/A
	Indirect	0	0	N/A	N/A	N/A	N/A
5 µg/m³ (inhalable fraction)	Direct	3	0	59 or 100	9 or 15	0.3	N/A
	Indirect	0	0	N/A	N/A	N/A	N/A
4 µg/m³ (inhalable fraction)	Direct	3	0	63 or 100 (209)	13 or 16 (526)	0.3	N/A
	Indirect	0	0	N/A	N/A	N/A	N/A
1 µg/m³ (inhalable fraction)	Direct	23	0	412 (225)	35 (532)	0.3	N/A
	Indirect	0	0	N/A	N/A	N/A	N/A

Note: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5.

10.1.3 CBA for the reference OELVs

The overall costs and benefits of establishing an OELV at the different reference levels are shown in Figure 10-1 and Table 10-4. The scenarios presented in Figure 10-1 are summarised below.

Table 10-3: Description of the scenarios in Figure 10-1

Scenario code	Description
Benefits-C-M1-C	Benefits - Core Scenario - Method 1 - Constant Workforce
Benefits-C-M2-T	Benefits - Core Scenario - Method 2 - Workforce 5% p.a. turnover
Benefits-S-M1-C-Cd-U DRR A2000 M	Benefits - Sensitivity - Method 1 - Constant Workforce - Cd-U DRR workers after 2000, middle of range values
Benefits-S-M2-C-Cd-U DRR All T	Benefits - Sensitivity - Method 2 - Workforce 5% turnover - Cd-U DRR, all workers, top of range values
Costs-C-Mod-Ad	Costs - Core Scenario - RPA Model - Adjusted based on additional ICdA data
Costs-C-Mod-N	Costs - Core Scenario - RPA Model - Not adjusted (underestimate)
Costs-C-Cap Ingelec 2017	Costs - Core - Extrapolation from Cap Ingelec (2017)

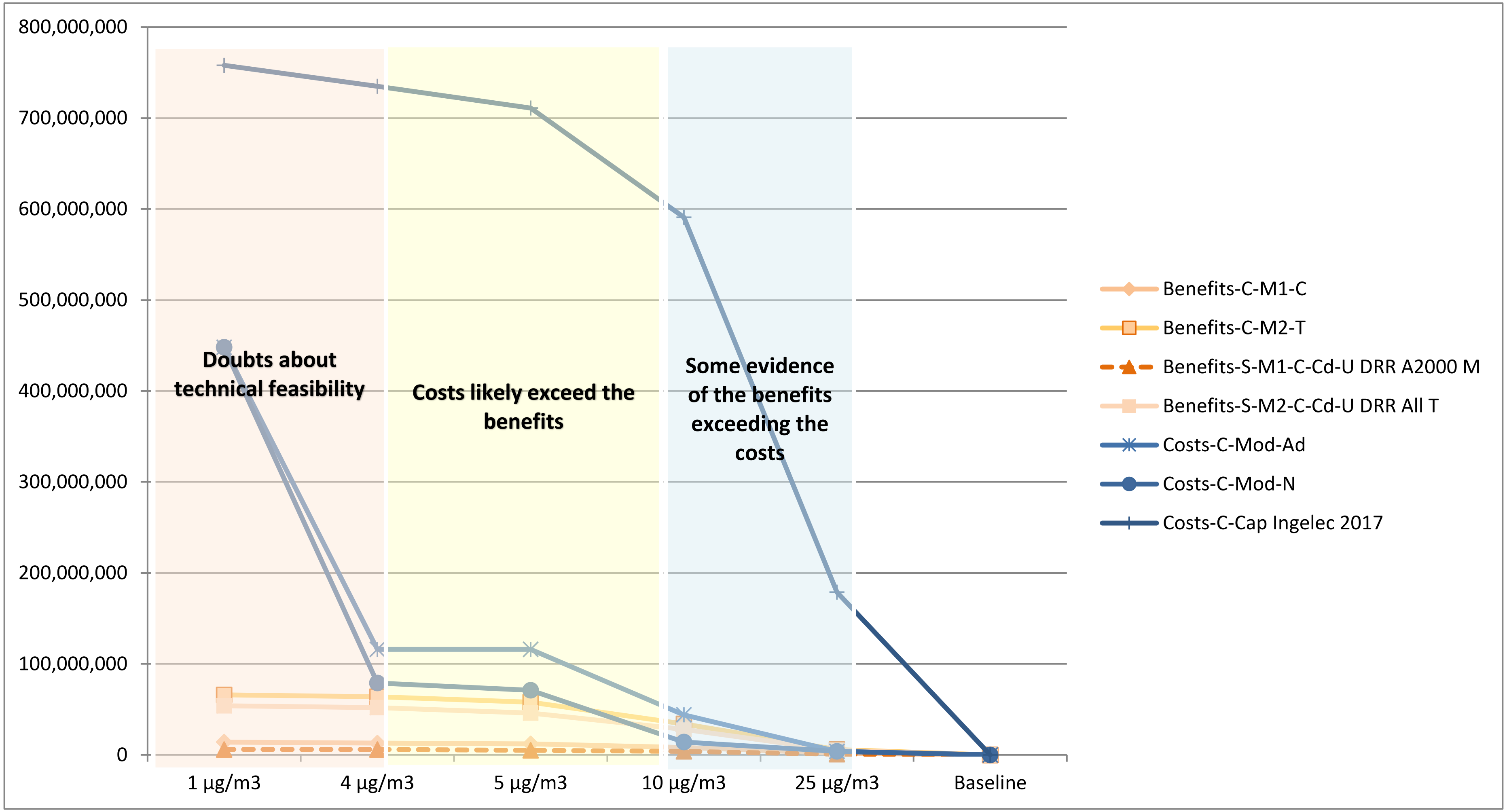


Figure 10-1: Comparison of the costs and the benefits estimated using the different methods

The costs and benefits that could be monetised are also summarised below.

Table 10-4: Summary of monetised costs and benefits (static discount rate, additional to the baseline)		
Reference OELV	**PV benefits* over 60 years (€2017 million)**	**PV costs over 60 years (€2017 million)**
25 µg/m³ (inhalable fraction)	(0.9-) 2–6	4 (179)
10 µg/m³ (inhalable fraction)	(4-) 8–34	14 or 44 (591)
5 µg/m³ (inhalable fraction)	(5-) 12–58	71 or 116 (711)
4 µg/m³ (inhalable fraction)	(6-) 13–64	79 or 116 (735)
1 µg/m³ (inhalable fraction)	(7-) 14–66	448 (758)
Monetised costs and benefits	Avoided lung cancer and elevated proteinurea cases vis-à-vis the baseline	RMMs Discontinuation of business** Transposition costs Measurements
Significant non-monetised costs and benefits	Simplification of rules for companies operating in several Member States	
Notes: Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. *Values in brackets relate to sensitivity analysis using Cd-U DRR, lowest value of all scenarios. **Some methods (e.g. extrapolation from Cap Ingelec (2017) do not include these costs).		

Bearing in mind that the benefits could not be monetised for some health endpoints, it can be concluded that the lowest reference OELV at which the monetised benefits are likely to exceed the costs is around 10 µg/m³ (inhalable fraction), i.e. 4 µg/m³ (respirable fraction) – see shaded rectangles in Figure 10-1. Please note that these rectangles are for illustrative purposes only, e.g. there is no precise concentration at which feasibility issues are expected to start occurring.[116]

10.2 Multi-criteria analysis (MCA)

The table below summarises both the monetised and qualitative impacts.

Table 10-5: Multi-criteria analysis (cadmium and its inorganic compounds) (all impacts over 60 years and additional to the baseline)						
Impact	**Stakeholders affected**	**1 µg/m³**	**4 µg/m³**	***5 µg/m³****	***10 µg/m³****	***25 µg/m³****
Economic impacts						
Compliance costs**	Companies	€447 million (€758 million)	€79 or 116 million (€735 million)	€71 or 116 million (€711 million)	€14 or 44 million (€591 million)	€4 million (€179 million)
Transposition costs	Public sector	€1.2 million	€1.1 million	€1 million	750,000	600,000
Benefits from reduced ill health (values in brackets relate to sensitivity analysis using Cd-U	Reduction in cases (lung cancer)	6	6	5	4	1
	Reduction in cases	(30-)181	(28-)176	(25-)159	(15-)92	(3-)17

[116] The analysis in Cap Ingelec (2017) suggests that process/machine redesign or PPE would be required in some operations for OELVs at or below 10 µg/m3 (inhalable fraction).

Table 10-5: Multi-criteria analysis (cadmium and its inorganic compounds) (all impacts over 60 years and additional to the baseline)						
Impact	**Stakeholders affected**	**1 µg/m³**	**4 µg/m³**	***5 µg/m³****	***10 µg/m³****	***25 µg/m³****
DRR – lowest value of all scenarios)	(elevated proteinurea)					
	Reduction in DALYs	(310-) 1,600–2,800	(300-) 1,600–2,800	(260-) 1,400–2,400	(180-) 800–1,500	(40-) 150–300
	Employers (avoided costs)	(€0.2-) €1–1.4 million	(€0.2-) €0.9–1.3 million	(€0.2-) €0.8–1.2 million	(€0.1-) €0.5–0.7 million	(€0.02-) €0.1 million
	Public sector (avoided costs)	(€0.9-) €4.6–€6.7 million	(€0.8-) €4.5–€6.5 million	(€0.8-) €4.1–€5.9 million	(€0.4-) €2.4–€3.4 million	(€0.1-) €0.4–€0.6 million
Single market: competition	No. of company closures	8 companies or business units close or substitute	1 company or business unit closes or substitutes	1 company or business unit closes or substitutes	0 closures	0 closures
Single-market: consumers	Consumers	Limited impacts expected				
Single market: internal market*****	Companies	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 'no difference'	Reduction of highest OEL/lowest OEL ratio from 5 to 2
International competitiveness	Companies	Significant negative impact	Significant negative impact	Significant negative impact	Moderate impact	Limited impact
Specific MSs/regions	MSs that would have to change OELs	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, EL?, HU, IE, LV, LT, NL, PL, SI, ES, SE, UK	AT, BE, BG, HR, CY, CZ, DK?, FI, FR, EL?, HU, IE, LV, LT, NL, PL?, SI, ES?, SE, UK	AT, BG, HR, CY, CZ, DK?, FR, HU, IE, LV, LT, NL, SI, SE, UK	AT, BG, HR, CY, CZ, FR, HU?, IE, LT?, SI, SE, UK?
Social impacts						
Ill health avoided, incl. intangible costs (values in brackets relate to sensitivity analysis using Cd-U DRR, lowest value of all scenarios)	Workers & families	(€6m-) €9m–€59m	(€5m-) €9m–€57m	(€5m-) €7m–€51m	(€4m-) €5m–€30m	(€0.8m-) €1m–€6m
Employment	Jobs lost*****	280	35******	35******	0	0
	Social cost*****	€23 million	€3 million	€3 million	€0	€0

Table 10-5: Multi-criteria analysis (cadmium and its inorganic compounds) (all impacts over 60 years and additional to the baseline)						
Impact	**Stakeholders affected**	**1 µg/m³**	**4 µg/m³**	***5 µg/m³****	***10 µg/m³****	***25 µg/m³****
Environmental impacts						
Environmental releases	Environment	No impact/limited impact				
Recycling – loss of business	Recycling companies	Negative impact	No impact/limited impact			
Notes: All costs/benefits are incremental to the baseline (PV over 60 years). *Values in italics denote Respirable->Inhalable conversions on the basis of a factor of 2.5. **The two business compliance costs presented are the model estimates (unadjusted or adjusted) and the figure in brackets is the value extrapolated from Cap Ingelec (2017). ***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). *****Illustrative only: significant uncertainties about national OELs remain. Many OELs also apply only to specific sectors and have a specific role within the national enforcement system. *****Worst-case, does not take into account the possibility of substitution. Not included in the totals in the CBA. ****** Average per input data (SEG or company).						

11 References

ACGIH, American Conference of Governmental Industrial Hygienists (1986): Documentation of the Threshold Limit Values and Biological Exposure Indices Cincinnati OH

ACGIH, American Conference of Governmental Industrial Hygienists (2001): *Cadmium and Compounds* In: **Documentation of the Threshold Limit Values and Biological Exposure Indices**, 7th Ed., 2011, Cincinnati, OH, 4p

ACGIH, American Conference of Governmental Industrial Hygienists (2016): TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices Cincinnati, OH

ACSH WPC (2017): Opinion on an EU Occupational Exposure Limit value for Cadmium and its inorganic compounds under Directive 2004/37/EC (CMD) Doc. 663/17, available at https://circabc.europa.eu/sd/a/937cca1a-c6ff-4a17-9d8a-6c7aa00107a9/Doc.663-17-EN_WPC%20Opinion%20Cadmium_Adopted%2031.05.2017%20.pdf

AGS, Ausschuss für Gefahrstoffe (2013): Leitfaden zur Quantifizierung stoffspezifischer Expositions-Risiko-Beziehungen und von Risikokonzentrationen bei Exposition gegenüber krebserzeugenden Gefahrstoffen am Arbeitsplatz, (Anlage 3 zu TRGS 910). Version N10, Stand: 15.09.2013
Ausarbeitung durch den Arbeitskreis Risikoableitung im UA III des AGS. http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-910.html

AGS, Ausschuss für Gefahrstoffe (2014): Begründung zu Expositions-Risiko-Beziehung für Cadmium in TRGS 910. Ausgabe: Oktober 2014. Stand: Mai 2014
http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/Begruendungen-910.html

Åkesson A *et al* (2014): *Non-renal effects and the risk assessment of environmental cadmium exposure* Environmental Health Perspectives, 122, 431-438

Bay BH (2006): *Metallothionein as a prognostic biomarker in breast cancer* Experimental Biology and Medicine, 231, 1516-1521

Benbrahim-Tallaa L (2009): *Cadmium malignantly transforms normal human breast epithelial cells into a basal-like phenotype* Environmental Health Perspectives, 117, 1847-1852

Bernard A (2016): *Confusion about cadmium risks: the unrecognized limitations of an extrapolated paradigm* Environmental Health Perspectives, 125, 1-5

BMU, Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (2002): Erste Allgemeine Verwaltungsvorschrift zum Bundes-Immissionsschutzgesetz (Technische Anleitung zur Reinhaltung der Luft – TA Luft) vom 24. Juli 2002 Gemeinsames Ministerialblatt, 25-29, 511-605

Buchet JP (1990): *Renal effects of cadmium body burden of the general population* The Lancet, 336, 699-702

Buha A *et al* (2016): *Cadmium and bone disorders-current state of knowledge* Austin Journal of Environmental Toxicology, 2(1): 1012, 2pp

Butz M (2012): Beruflich verursachte Krebserkrankungen: Eine Darstellung der im Zeitraum 1978 bis 2010 anerkannten Berufskrankheiten 10. überarb. u. erg. Aufl., HVBG, Hauptverband der gewerblichen Berufsgenossenschaften, Sankt Augustin. http://publikationen.dguv.de/dguv/pdf/10002/berufl_krebs-07-14-06.pdf

Byber K *et al* (2017): Response to letter to the editor from Elinder and Nordberg concerning Byber et al. 2016. Cadmium or cadmium compounds and chronic kidney disease in workers and the general population: a systematic review, Critical Reviews in Toxicology 46(3):191–240. DOI: 0.3109/10408444.2015.1076375 Critical Reviews in Toxicology, 47, 902-903

Byber K *et al* (2016): *Cadmium or cadmium compounds and chronic kidney disease in workers and the general population: a systematic review* Critical Reviews in Toxicology, 46, 191-240

Byrne C *et al* (2013): *Metals and breast cancer* Journal of Mammary Gland Biology and Neoplasia, 18, 63-73

Byrne C *et al* (2009): *Cadmium - a metallohormone?* Toxicology and Applied Pharmacology, 238, 266-271

Cannino G *et al* (2009): *Cadmium and mitochondria* Mitochondrion, 9, 377-384

Cap Ingelec (2017): Cadmium Industrial Users - Creation of a model to estimate the costs of exposed people protection upgrade, Report for the International Cadmium Association (ICdA), I-IM17014-11DD, 22 December 2017

Chaumont A *et al* (2013): *Associations of urinary cadmium with age and urinary proteins: further evidence of physiological variations unrelated to metal accumulation and toxicity* Environmental Health Perspectives, 121, 1047-1053

Chaumont A *et al* (2011): *The threshold level of urinary cadmium associated with increased urinary excretion of retinol-binding protein and beta 2-microglobulin: a re-assessment in a large cohort of nickel-cadmium battery workers* Occupational and Environmental Medicine, 68, 257-264

Cortona G (1992): *Occupational exposure to cadmium and lung function* In: Nordberg, G.F.; Herber, R.F.M.; Alessio, L., IARC Scientific Publication No. 118. **Cadmium in the Human Environment: Toxicity and Carcinogenicity**, IARC International Agency for Research on Cancer Lyon, 205-210

ECB, European Chemicals Bureau (2007): European Union Risk Assessment Report: CADMIUM METAL, European Commission. Joint Research Centre. https://echa.europa.eu/documents/10162/4ea8883d-bd43-45fb-86a3-14fa6fa9e6f3

ECHA Dissemination (2017): Information on Chemicals - Registered Substances, European Chemicals Agency. Online: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

EMEP (2014): Transboundary Pollution by Heavy Metals and Persistent Organic Pollutants in 2014. Germany http://www.msceast.org/reports/country_reports/Germany_2014.pdf

EFSA, European Food Safety Authority (2009): Meta-analysis of Dose-Effect Relationship of Cadmium for Benchmark Dose Evaluation. Prepared by the Assessment Methodology Unit (Question No EFSA-Q- 2009-00472). Issued on 20 March 2009.

EFSA Scientific Report 254: http://www.efsa.europa.eu/en/efsajournal/pub/254r.htm

ECHA, European Chemicals Agency (2017): Information on Chemicals - Classification & Labelling Inventory Online: http://echa.europa.eu/information-on-chemicals/cl-inventory, Disclaimer: http://echa.europa.eu/web/guest/legal-notice

ECHA, European Chemicals Agency (2013a): Annex XV dossier: Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Cadmium submitted by: Swedish Competent Authority (Swedish Chemicals Agency). https://echa.europa.eu/documents/10162/13638/annex_xv_svhc_ec_231-152-8_cadmium_en.pdf

ECHA, European Chemicals Agency (2013b): Annex XV dossier: Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Cadmium oxide submitted by: Swedish Competent Authority (Swedish Chemicals Agency). https://echa.europa.eu/documents/10162/13638/annex_xv_svhc_ec_215-146-2_cadmium_oxide_en.pdf

ECHA, European Chemicals Agency (2013c): Inclusion of Substances of Very High Concern in the Candidate List (Decision of European Chemicals Agency). Doc: ED/69/2013 https://echa.europa.eu/documents/10162/49a335ae-1ec4-40e5-88fb-3b08702da95c. Assessed Dec 9, 2017

ECHA, European Chemicals Agency (2013d): Support Document for Identification of Cadmium as a Substance of Very High Concern Because of its CMR1 Properties and because of its Adverse Effects on Kidney and Bone Tissues after Prolonged Exposure, which Cause Robable Serious Effects to Human Health which Give Rise to an Equivalent Level of Concern to Those of CMR and PBT/vPvB2 Substances. Adopted on 12 June 2013
https://echa.europa.eu/documents/10162/a048359b-de39-4b7e-8602-51272a55aeae

ECHA, European Chemicals Agency (2011): The Operation of REACH and CLP Helsinki, Finland. http://echa.europa.eu/

ECHA C&L Inventory (2017): Information on Chemicals - Classification & Labelling Inventory
European Chemicals Agency. Online: http://echa.europa.eu/information-on-chemicals/cl-inventory, Disclaimer: http://echa.europa.eu/web/guest/legal-notice

EFSA, Panel on Contaminants in the Food Chain (CONTAM) (2011): *Scientific Opinion on tolerable weekly intake for cadmium* The EFSA Journal, 9, 1975, http://www.efsa.europa.eu/en/efsajournal/pub/1975.htm

Elinder CG (1985): *β2-Microglobulinuria among workers previously exposed to cadmium: follow-up and dose-response analyses* American Journal of Industrial Medicine, 8, 553-564

Engström A (2009): *Cadmium-induced bone effect is not mediated via low serum 1,25-dihydroxy vitamin D* Environmental Research, 109, 188-192

Eom S-Y *et al* (2017): *Low-level environmental cadmium exposure induces kidney tubule damage in the general population of Korean adults* Archives of Environmental Contamination and Toxicology, 73, 401-409

EPA, Environmental Protection Agency (1998): Integrated Risk Information System (IRIS). Arsenic, inorganic; CASRN 7440-38-2 (04/10/1998) http://www.epa.gov/iris/subst/0278.htm

Fischer BM *et al* (2016): *Use of high-throughput RT-qPCR to assess modulations of gene expression profiles related to genomic stability and interactions by cadmium* Archives of Toxicology, 90, 2745-2761

Forni A (1992): *Chromosomal effects of cadmium exposure in humans* In: Nordberg GF, Herber RFM, Alessio L, IARC Scientific Publication No. 118. **Cadmium in the Human Environment: Toxicity and Carcinogenicity**, IARC, International Agency for Research on Cancer, Lyon 377-383

Glaser U *et al* (1990): *Carcinogenicity and toxicity of four cadmium compounds inhaled by rats* Toxicological and Environmental Chemistry, 27, 153-162

Hambach, R *et al* (2013): *Adverse effects of low occupational cadmium exposure on renal and oxidative stress biomarkers in solderers* Occupational and Environmental Medicine, 70, 108-113

Haney J (2016*): Development of an inhalation unit risk factor for cadmium* Regulatory Toxicology and Pharmacology, 77, 175-183

Hartwig A (2013): *Cadmium and Cancer* In: Sigel, A.; Sigel, H.; Sigel, R.K.O., **Cadmium: From Toxicity to Essentiality. Metal Ions in Life Sciences** Vol. 11, Springer Netherlands, 491-507

Heinrich U *et al* (1989): *Investigation on the carcinogenic effects of various cadmium compounds after inhalation exposure in hamsters and mice* Experimental Pathology, 37, 253-258

IARC, International Agency for Research on Cancer (2012): *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Vol. 100C. A Review of Human Carcinogens. Arsenic, Metals, Fibres, and Dusts WHO, World Health Organization, Lyon, France

IFA, Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (2017): GESTIS - Internationale Grenzwerte für chemische Substanzen
http://www.dguv.de/ifa/GESTIS/GESTIS-Internationale-Grenzwerte-für-chemische-Substanzen-limit-values-for-chemical-agents/index.jsp

IIAC, Industrial Injuries Advisory Council (2009): Review of Occupational Exposure to Cadmium and Genito-urinary Cancer. Position Paper No 24
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328543/iiac-pp24.pdf

INRS, Institut National de Recherche et de Sécurité (2016): Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984, Octobre 2016
http://www.inrs.fr/media.html?refINRS=ED%20984. Assessed December 09, 2017

Jakubowski M (2012): Kadm i jego związki nieorganiczne – w przeliczniu na Cd Podstawy i Metody Oceny Srodowiska Pracy, 2(72), 111-146

Järup L *et al* (2009): *Current status of cadmium as an environmental health problem* Toxicology and Applied Pharmacology, 238, 201-208

Järup L *et al* (2004*): Low level cadmium exposure, renal and bone effects* - the OSCAR study Biometals, 17, 505-509

Järup L *et al* (1993): *Renal function impairment in workers previously exposed to cadmium* Nephron*, 64, 75-81*

Jin T *et al* (2002): *Cadmium biomonitoring and renal dysfunction among a population environmentally exposed to cadmium from smelting in China (ChinaCad)* Biometals, 15, 397-410

Kauppinen T *et al* (2007): *Evaluation of a National Register on Occupational Exposure to Carcinogens: Effectiveness in the prevention of occupational cancer, and cancer risks among the exposed workers* The Annals of occupational hygiene, 51, 463-470

KEMI, Kemikalieinspektionen (2011): Kadmiumhalten måste minska – för folkhälsans skull En riskbedömning av kadmium med mineralgödsel i fokus
https://www.kemi.se/global/rapporter/2011/rapport-1-11.pdf

Kjellström T *et al* (1977): *Dose-response analysis of cadmium-induced tubular proteinuria: A study of urinary b2-microglobulin excretion among workers in a battery factory* Environmental Research, 13, 303-317

Klaassen CD *et al* (2009): *Metallothionein protection of cadmium toxicity* Toxicology and Applied Pharmacology, 238, 215-220

Lappano R *et al* (2017): *Recent advances on the stimulatory effects of metals in breast cancer* Molecular and Cellular Endocrinology, 457, 49-56

Mason HJ (1988): *Relations between liver cadmium, cumulative exposure and renal function in cadmium alloy workers* British Journal of Industrial Medicine, 45, 793-802

Nagata C *et al* (2013): *Cadmium exposure and the risk of breast cancer in Japanese women* Breast Cancer Research and Treatment, 138, 235-239

NLM, U.S. National Library of Medicine (2017): ChemIDplus Lite online: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp

Oldiges H *et al* (1989): *Long term inhalation study with Wistar rats and four cadmium compounds* Toxicological and Environmental Chemistry, 19, 217-222

Pacini S *et al* (2009): *A paradox of cadmium: a carcinogen that impairs the capability of human breast cancer cells to induce angiogenesis* Journal of Environmental Pathology, Toxicology and Oncology, 28, 85-88

Park RM *et al* (2012): *Cadmium and lung cancer mortality accounting for simultaneous arsenic exposure* Occupational and Environmental Medicine, 69, 303-309

Rahim F *et al* (2013): *Breast cancer frequency and exposure to cadmium: a meta-analysis and systematic review* Asian Pacific Journal of Cancer Prevention, 14, 4283-4287

Roels H (1993): *Markers of early renal changes induced by industrial pollutants. III. Application to workers exposed to cadmium* British Journal of Industrial Medicine, 50, 37-48

Rushton L (2012): *Occupational cancer burden in Great Britain* British Journal of Cancer, 107, Suppl. 1, S3-7

Schwerdtle T *et al* (2010): *Genotoxicity of soluble and particulate cadmium compounds: impact on oxidative DNA damage and nucleotide excision repair* Chemical Research in Toxicology, 23, 432-442

Schmidt S *et al* (2009): Cadmium im Boden – Deposition und Gehalte, In: BfR, Bundesinstitut für Risikobewertung, BfR-Statusseminar „Cadmium - Neue Herausforderungen für die Lebensmittelsicherheit“, http://www.bfr.bund.de/de/uebersicht_der_praesentationen_zum_bfr_statusseminar__cadmium___neue_herausforderungen_fuer_die_lebensmittelsicherheit_-30412.html

SCOEL (2017): SCOEL/OPIN.336 Cadmium and its inorganic compounds, available at https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

Schwarz M *et al* (2014): Cadmium exposure from food: the German LExUKon project, Food Additives and Contaminants. Part A: Chemistry, Analysis, Control, Exposure & Risk Assessment, 31, 1038-1051

SCOEL, Scientific Committee for Occupational Exposure Limits (2017): Cadmium and its inorganic compounds. SCOEL/OPIN/336. Adopted 8th of February 2017 European Commission, Directorate-General for Employment, Social Affairs and Inclusion. Directorate B - Employment. Unit B.3 - Health and safety

SCOEL, Scientific Committee for Occupational Exposure Limits (2010): Recommendation from the Scientific Committee on Occupational Exposure Limits for cadmium and its inorganic compounds. SCOEL/SUM/136. February 2010 European Commission; Employment, Social Affairs and Inclusion

Suwazono Y *et al* (2010): *Benchmark dose for cadmium-induced osteoporosis in women* Toxicology Letters, 197, 123-127

Symanski et al 1998*: Comprehensive evaluation of long term trends in occupational exposure: part 1*. Description of the database, In: Occup Environ Med 1998;55:300–309

Takenaka S *et al* (1983): *Carcinogenicity of cadmium chloride aerosols in wistar rats* Journal of the National Cancer Institute, 70, 367-373

Thun MJ *e al* (1991*): Scientific basis for an occupational standard for cadmium* American Journal of Industrial Medicine, 20, 629-642

Thun MJ *et al* (1985): *Mortality among a cohort of U.S. cadmium production workers - an update* Journal of the National Cancer Institute, 74, 325-333

Wallin M *et al* (2016): *Low-level cadmium exposure is associated with decreased bone mineral density and increased risk of incident fractures in elderly men: The MrOS Sweden Study* Journal of Bone and Mineral Research, 31, 732-741

WHO World Health Organization (2000): Air Quality Guidelines for Europe WHO Regional Publications, European Series, No. 91, 2nd ed., Regional Office for Europe, Copenhagen

WHO World Health Organization (1992): Environmental Health Criteria 135, Cadmium - Environmental Aspects, IPCS International Programme on Chemical Safety; World Health Organization Geneva

Woo HD *et al* (2015): Benchmark dose for urinary cadmium based on a marker of renal dysfunction: a meta-analysis PLoS One, 10, e0126680

Annex 1 Summary of Consultation

The number of consultation responses for cadmium is summarised below.

Table 11-1: Number of responses relevant to cadmium	
Questionnaire responses	11
Interviews	10
Site visits	3
Total	**24**

There were a relatively larger number of questionnaire responses, interviews and site visits for cadmium due to its widespread use in a number of key sectors (e.g. aerospace, metal processing, glass, cement, recycling, etc.).

Two face-to-face meetings were also held with the International Cadmium Association (ICdA); one in Paris and one in London. More than 10 conference calls have also been carried out with the ICdA.

Annex 2 Summary of the Cap Ingelec (2017) study

A2.1 Introduction

A2.1.1 Scope of the study

The Cap Ingelec (2017) study estimates the cost of compliance with four OEL levels for the 3,000 workers in eight industrial segments identified as relevant by the ICdA. Only the costs of additional ventilation and hygiene measures have been estimated. Machinery redesign, process changes or PPE are outside the scope of the Cap Ingelec (2017) study.

The following control systems have been considered in Cap Ingelec (2017):

- **Block A: Capture at source systems**, such as LEV, encompassing different enclosure types and sometimes including compensation air delivery systems; estimated lifetime 15 years
- **Block C: General plant cleanliness**, i.e. equipment and procedures[117] to reduce deposition of Cd dust, thus reducing the amount of airborne Cd; estimated lifetime 10 years;
- **Block D: Collective hygiene procedures**, equipment and procedures to reduce dust generation and mobilisation and contain cadmium within the plant (lock-room enhancements)[118]; estimated lifetime 15 years;
- **Block E: Individual hygiene procedures**, i.e. procedures followed by individual workers[119], such as mandatory showers, PPE, procedures, and monitoring; estimated lifetime 10 years.

Blocks C, D, and E follow the structure of the ICdA Guidance Document on the Risks Related to Chronic Occupational Exposure to Cadmium and its Compounds.

The detailed assessment in Cap Ingelec (2017) focuses on the two largest segments in terms of the workforce exposed to Cd (Zn/Cd refining) and industrial battery manufacturing; these two segments represent over 50% of the exposed workforce in companies that belong to the ICdA. The costs to the other segments have been extrapolated from the costs estimated for the industrial battery segment.

A2.1.2 Summary of the methodology

The approach in Cap Ingelec (2017) is based on establishing correlations between air concentrations that have been achieved in each Similar Exposure Group (SEG) and the RMMs in place in each SEG, and carrying out a gap analysis for the SEGs that are above a given OEL target. These relationships are used to predict the measures that would have to be implemented to achieve the different OEL levels. The subsequent estimation of the CAPEX and OPEX takes into account the plant size. This has been

117 These include floor coating colour that allows detection of Cd dust deposits, floor cleaning equipment and related cleaning procedures, on-the-spot vacuuming equipment incl. negative pressure inlets and flexible piping, procedures for regular cleaning of the building structure and production equipment, and machine clean-up as part of end-of-shift procedures.

118 These include: training for new workers, a mentoring programme for new workers, annual refresher course on risk management practices, double compartment lockers, three areas in the locker room (non-work clothes, shower, work-clothes), work clothes supplied with adequate frequency, laundry service by a specialised contractor.

119 These include mandatory showers, smoking and drinking in designated areas, washing hands and removing jacket before entering the eating area, encouragement to stop smoking, biting nails and growing facial hair, storage of personal objects in dedicated lockers outside the work area, PPE including testing and handling procedures, biomonitoring and air monitoring.

complemented with expert knowledge of Cap Ingelec in terms of potential measures that could be implemented in addition to those already in place.

The data sources used in Cap Ingelec (2017) are summarised below.

Table 11-2: Summary of approach in Cap Ingelec (2017)		
Data	**Source/method**	**Details**
Air concentrations	ICdA's annual Observatory of Occupational Cd AIR exposure (OCdAIR) survey.	Data available by SEG, data for 2017 used. Individual samples are reported and compliance against a target OEL is tested as a Geometric Mean (GM), 90th percentile, and 95th percentile with a 70% Confidence Interval (CI). For SEGs where less than six samples are available, a 95th percentile/70% CI is estimated using an average ration 95thP/GM across all SEGs for which these two values are available. Air concentrations mostly cleared of PPE.
RMMs in place	ICdA Cap Ingelec questionnaire of ICdA members, 24 plants reporting in 2017 (covering 2,103 workers)	Both equipment and procedures recorded by SEG, by process stage for Zn/Cd refining[120] and industrial batteries[121] and by SEG type[122] for other segments. Size of the plant recorded.
RMM unit costs	Cap Ingelec's experience, supplier queries, data provided by individual plants	Data exclude VAT.

The methods used to estimate the costs in the specific segments are summarised below.

A2.2 Methods for specific sectors

A2.2.1 Industrial battery production

The following process stages in the industrial battery segment are considered in Cap Ingelec (2017).

Table 11-3: Industrial battery production – process stages and the exposed workforce		
Process stage (PS)	**PS description**	**No. of workers exposed to Cd**
PS1: Active material	Reception and preparation of active material	45
PS2: Foils coating	Charging of foils with active material	129
PS3: Electrode production	Manufacturing of electrodes and assemblies	284
PS4: Electrode insertion	Electrode insertion and cell closing	108
Total		***566***

120 Process stages in the Zn/Cd refining segment: 1) Concentrate reception and preparation, 2) Roaster and boiler, 3) Leaching and purification, 4) Electrolysis and casting

121 Process stages in the Industrial Battery manufacturing segment: 1) Reception and preparation of active material, 2) Charging of foils with active material, 3) Manufacturing of electrodes and assemblies, 4) Electrode insertion and cell closing

122 SEG types considered: mechanical operations, diffuse contamination operations with set workplaces, diffuse contamination operations without set workplaces, peripheral work with set workplaces, peripheral work without set workplaces.

Table 11-3: Industrial battery production – process stages and the exposed workforce		
Process stage (PS)	PS description	No. of workers exposed to Cd
Source: Cap Ingelec (2017)		

The following RMMs are considered in establishing a relationship between RMMs and air concentrations. A score has been assigned to each RMM level (hereinafter referred to as 'Maturity Level' or M) and the total SEG scores have been correlated with the air concentrations.

Table 11-4: Industrial battery production – RMMs considered in Cap Ingelec (2017)		
Type of measure	Maturity (M) levels	Score
Plant cleanliness	M1 = dust accumulation cleared at less than 24 hours interval M2 = dust accumulation cleared within 12 to 24 hours M3 = dust accumulation cleared more frequently than 12 hours	M1: -0.3 M2: 0 M3: +0.3
Capture at source	M1 = no Local Exhaust Ventilation (LEV) is present M2 = added-on open LEV: presence of a simple ventilation hood (compensation air is taken in the workshop volume) M3 = integrated LEV: presence of a simple flow ventilation system integrated to the machine. The machine is partially enclosed M4 = machine in a box: presence of a specific exhaust system close to each possible position of the workers. It is a double flow ventilation (compensation air supply near the workstation)	M1: 1 M2: 2 M3: 3 M4: 4
Source: Cap Ingelec (2017) Note: M stands for maturity level.		

The resulting correlations are shown in the figure below.

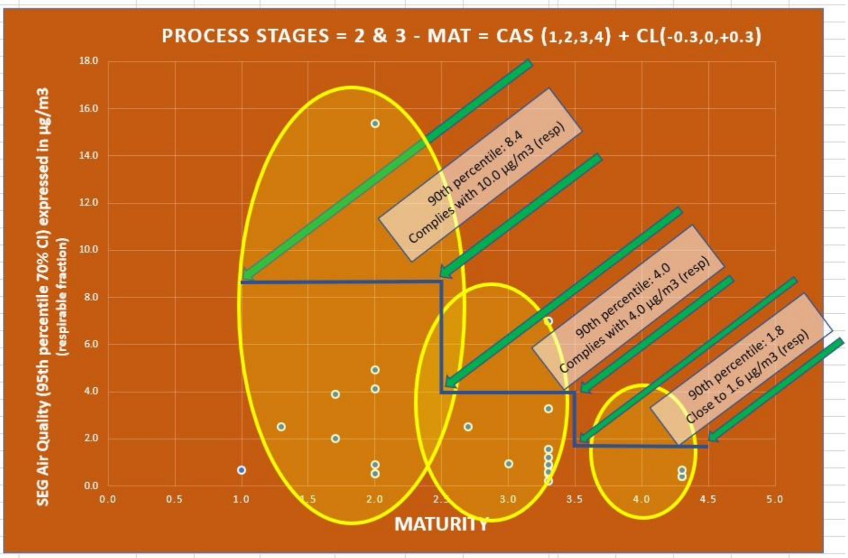


Figure 11-1: Relationship between RMMs in place and air concentrations – industrial battery production
Source: Cap Ingelec (2017)
Notes: Yellow circles show groups of SEGs with a similar maturity level. The horizontal line shows the 90th percentile of the air values in each group. CAS=Capture at source, CL=Plant cleanliness.

No relationship has been developed for PS1 (too few SEGs) and the costs have been extrapolated from PS2&3. No relationship could be developed for PS4 and average data for PS2&3 have been applied at SEG level. No relationship has been developed for potential OELs at or below 0.4 µg/m3 (R) since this level is seen as unattainable using local ventilation or plant cleanliness.

The resulting relationships are summarised in the table below.

Table 11-5: Industrial battery production – Maturity levels required to achieve air concentrations		
Maturity (M) score	**Air concentration achieved**	**Details**
M=2	10 µg/m3 (R) 25 µg/m3 (I*)	Good level of confidence about this relationship. All SEGs already comply.
M=3.3	4 µg/m3 (R) 10 µg/m3 (I*)	Good level of confidence about this relationship.
M=4.3	1.6 µg/m3 (R*) 4 µg/m3 (I)	Based on the expertise of Cap Ingelec (2017) but a definitive answer would require detailed plant specific studies.
Not feasible	0.4 µg/m3 (R*) 1 µg/m3 (I)	Not possible to reach with existing processes and current production equipment.
Source: Cap Ingelec (2017) Note: *Asterisked values denote calculations by the study team using a Respirable -> Inhalable conversion factor of 2.5.		

The types of measures that are costed are given below.

Table 11-6: Additional costs of reducing air concentration to a lower level		
Air concentration	**CAPEX**	**OPEX**
4 µg/m3 (R) 10 µg/m3 (I*)	Types of costs considered: • A1 = cost at the workplace, which include: Extraction points, Light enclosures, Cost of connection of extraction points to the "workstation duct". • A2 = costs at the workstation level, which includes the "workstation duct" which connects the workstation to a "main duct". • A3 = costs of ducts shared at the SEG level, these cover the cost of main ducts to the ventilation station. • A4 = costs of equipment at the SEG level, these cover: Ventilation station, Filtration of exhaust air, All necessary works including electrical, including possibly structural reinforcement. Costs A1, A2, A3, and A4 have been estimated based on a typical installation, composed of 4 workstations (WS) and each workstation consists of 4 workplaces (WP). Thus, a total of 16 workplaces is connected to 1 extraction and filtration unit. ***The average cost per workplace have been estimated to be €31,000.***	OPEX includes mandatory air speed control, servicing and maintenance, energy costs, consumables (filters), and heating. **The estimated cost per extraction unit per year is €51,000.**
1.6 µg/m3 (R*) 4 µg/m3 (I)	As above, plus: A5: improvement of existing ducts (corresponding to above A2 and A3 costs) due to air flow changes and tightness enhancement. A6 incorporates: Compensation air blowers, Compensation air ducts, Heating systems, A7 covers enhanced machine enclosure. ***The average cost per workplace (additional to the cost above) is €14,000.***	**The additional energy costs have been estimated to be €4,500 per extraction unit per year.**

A2.2.2 Zn/Cd refining

The following process stages in Zn/Cd refining segment are considered in Cap Ingelec (2017).

Table 11-7: Zn/Cd refining – production stages and the exposed workforce	
Process stage (PS)	**No. of workers exposed to Cd**
PS1: Concentrate reception & preparation	136
PS2: Roasting & boiler	339
PS3: Leaching & purification	414
PS4: Electrolysis & casting	21
Total	***910***
Source: Cap Ingelec(2017)	

PS1: Zn/Cd refining Process Stage (PS) 1: Concentrate reception & preparation

No RMM-air concentration relationship has been developed for PS 1 in the Zn/Cd sector. However, the RMMs that can be used to reduce exposure include:

- Building of a closed area (for the receiving step) (CAPEX €120,000)
- Capture at source around the wagon (CAPEX €63,000)
- Industrial vacuum cleaner installation (CAPEX €8,000)
- Pressurisation of a cabin (CAPEX €4,000)
- Servicing and maintenance, energy costs, consumables (OPEX €11,000)

These measures are expected to ensure compliance with 4 µg/m3 (R)/10 µg/m3 (I). Further reductions are not attainable without process changes, machinery redesign or PPE.

PS2: Zn/Cd refining Process Stage (PS) 2: Roasting & boiling

The following measures have been considered in the estimation of an RMM-exposure concentration correlation in PS 2 in the Zn/Cd sector. A score has been assigned to each RMM level (hereinafter referred to as 'Maturity Level' or M) and the total SEG scores have been correlated with the air concentrations.

Table 11-8: Zn/Cd refining PS2		
Type of measure	**Maturity (M) levels**	**Score**
Plant cleanliness	M1 = dust accumulation cleared at less than 24 hours interval, M2 = dust accumulation cleared within 12 to 24 hours, M3 = dust accumulation cleared more frequently than 12 hours.	M1: -0.3 M2: 0 M3: +0.3
Capture at source	M1 = none M2 = work area is partially isolated M3 = work area is completely isolated M4 = work area is completely isolated and depressurised	M1: 1 M2: 2 M3: 3 M4: 4
Source: Cap Ingelec (2017)		

The resulting relationships for PS2 are shown in the figure below.

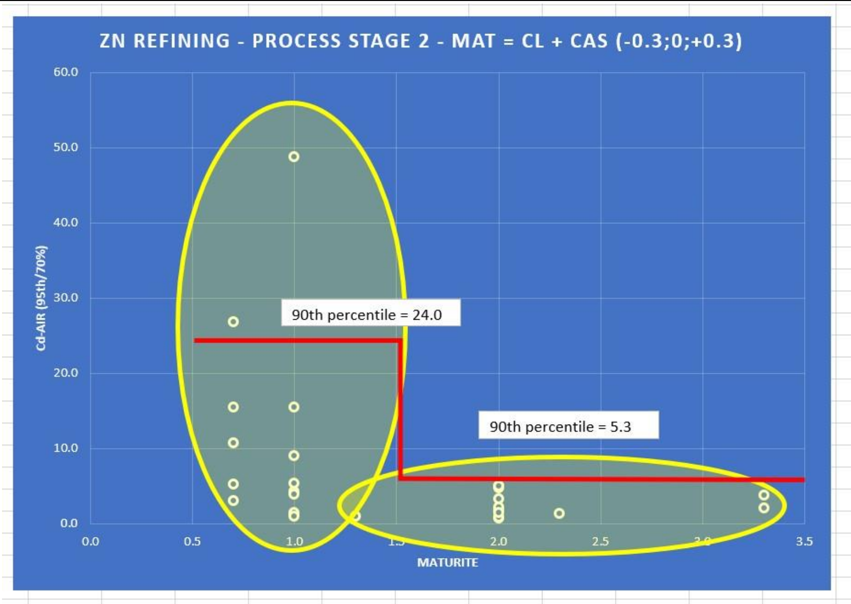


Figure 11-2: Relationship between the controls in place and air concentrations achieved – Zn/Cd refining Process Stage 2 Roasting & boiler
Source: Cap Ingelec (2017)
Notes: Yellow circles show groups of SEGs with a similar maturity level. The horizontal line shows the 90th percentile of the air values in each group. CAS=Capture at source, CL=Plant cleanliness.

The figure above shows that M=2 is sufficient to achieve 10 µg/m3 (R)/25 µg/m3 (I). No relationships have been developed for 4 µg/m3 (R)/10 µg/m3 (I) and below since these levels are seen as unattainable without process changes, machinery redesign or PPE.

The types of measures costed to reach 10 µg/m3 (R)/25 µg/m3 (I) are given below.

Table 11-9: Additional costs of reducing air concentration to a lower level (PS 2 Zn/Cd refining)

Air concentration	CAPEX	OPEX
4 µg/m3 (R) 10 µg/m3 (I*)	Industrial vacuum cleaner installation at a cost of €84,000 per SEG.	Servicing & maintenance (machine change every 5 years), energy costs, consumables, cleaning at a cost of €74,000.

PS3: Zn/Cd refining Process Stage (PS) 3: Leaching & purification

The following measures have been considered to establish an RMM-exposure concentration correlation in PS 3 in the Zn/Cd sector.

Table 11-10: Zn/Cd refining PS3		
Type of measure	**Maturity (M) levels**	**Score**
Plant cleanliness	M1 = dust accumulation cleared at less than 24 hours interval, M2 = dust accumulation cleared within 12 to 24 hours, M3 = dust accumulation cleared more frequently than 12 hours.	M1: 1 M2: 2 M3: 3
Capture at source	M1 = none M2 = work area is partially isolated M3 = work area is completely isolated M4 = work area is completely isolated and depressurised	M1: 1 M2: 2 M3: 3 M4: 4
Source: Cap Ingelec (2017)		

The resulting relationships for PS3 are shown in the figure below.

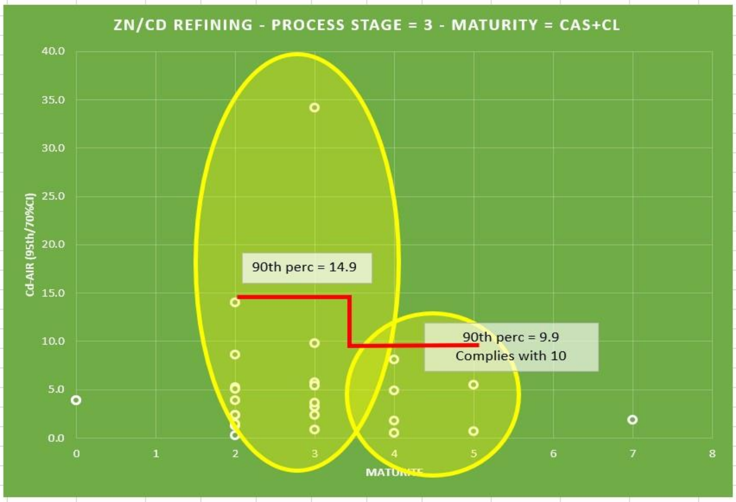


Figure 11-3: Relationship between the controls in place and air concentrations achieved – Zn/Cd refining Process Stage 3: Leaching & purification
Source: Cap Ingelec (2017)
Notes: Yellow circles show groups of SEGs with a similar maturity level. The horizontal line shows the 90th percentile of the air values in each group. CAS=Capture at source, CL=Plant cleanliness.

The figure above shows that M=4 or 5 is sufficient to achieve 10 µg/m3 (R)/25 µg/m3 (I). No relationships have been developed for 4 µg/m3 (R)/10 µg/m3 (I) and below since these levels are seen as unattainable without process changes, machinery redesign or PPE.

The types of measures costed to reach 10 µg/m3 (R)/25 µg/m3 (I) are given below.

Table 11-11: Additional costs of reducing air concentration to a lower level (PS 3 Zn/Cd refining)		
Air concentratio n	**CAPEX**	**OPEX**
4 µg/m3 (R) 10 µg/m3 (I*)	Automated LEV in purification units (automatically captures polluted air before opening) at a cost of €41,000	Servicing & maintenance, energy costs, consumables, cleaning at a cost of €27,000 or €17,000 depending on CL M already achieved

PS4: Zn/Cd refining Process Stage (PS) 4: Electrolysis & casting

Not assessed due to the low number of workers exposed.

A2.2.3 Other segments

No RMM-exposure concentration correlations have been developed and the costs have been extrapolated from data for the industrial battery segment on the basis of the numbers of workers exposed. It is expected that the other segments are similar to industrial batteries in terms of facilities layout (plants operate within closed industrial buildings) and processes (a combination of mechanical and chemical processes). As shown below, the distributions of 95th/70%CI values amongst the SEGs which belong to segments Others is broadly similar the distribution of the 95th/70%CI values of the SEGs which belong to the Batteries segment.

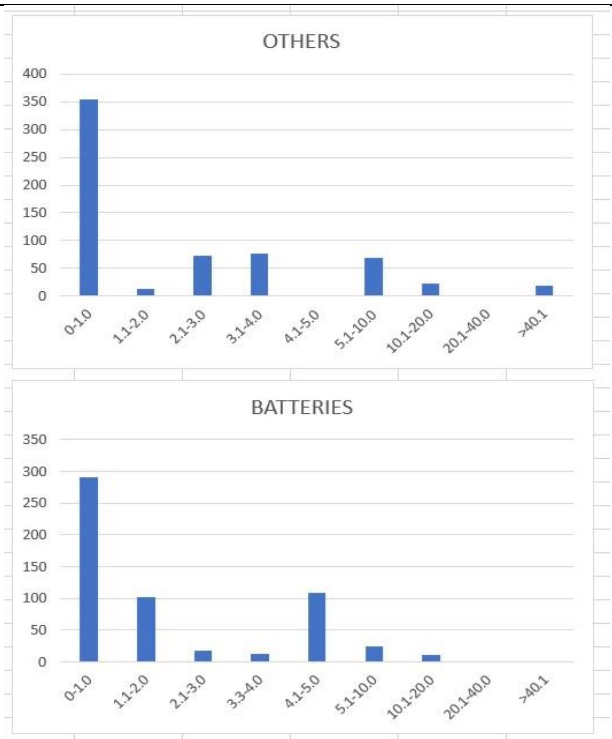


Figure 11-4: SEGs in each exposure concentration band in the Industrial Battery segment and other segments
Source: Cap Ingelec (2017)

The conclusions for the Industrial Battery sector also apply to the other sectors:

- site specific studies would be required to determine whether 1.6 µg/m3 (R)/4 µg/m3 (I) is attainable; and
- 0.4 µg/m3 (R)/1 µg/m3 (I) is not considered feasible.

A2.3 Overall results

The results are summarised below. These do not take into account machinery redesign, process change or PPE.

Table 11-12: Summary of the costs for ICdA members

Sector	Type of cost	10 µg/m³ (R) *25 µg/m3 (I*)*	4 µg/m³ (R) *10 µg/m3 (I*)*	*1.6 µg/m³ (R*)* 4 µg/m3 (I)	*0.4 µg/m³ (R*)* 1 µg/m3 (I)
Industrial batteries	CAPEX (€2017)	45,000	12,769,000	25,340,000**	*25,932,000****
	OPEX (annual in €2017)	56,000	2,459,000	2,825,000**	*2,826,000****
Zn smelting/ Cd refining	CAPEX (€2017)	2,301,000	*2,307,000****	*4,873,000****	*6,485,000****
	OPEX (annual in €2017)	2,339,000	*2,699,000****	*2,750,000****	*2,797,000****
Other	CAPEX (€2017)	90,000	9,281,000	17,127,000**	*18,497,000****
	OPEX (annual in €2017)	323,000	2,664,000	2,942,000**	*3,000,000****
Total	CAPEX (€2017)	2,436,000	*24,357,000****	*47,340,000****	*50,913,000****
	OPEX (annual in €2017)	2,718,000	*7,821,000****	*8,517,000****	*8,624,000****

Source: Cap Ingelec (2017)

Notes:
All values supplied are VAT free.

*Asterisked values in italics denote calculations by the study team using a Respirable -> Inhalable conversion factor of 2.5.
**Uncertain for some process stages.
***According to Cap Ingelec (2017), it is not feasible for key process stages in the relevant sector to achieve the target concentration by means of additional ventilation. In such instances, the concentration of Cd in air could be further reduced by machinery redesign, process changes or PPE but such measures were not considered in Cap Ingelec (2017).
Values in yellow and italics denote partial quantifications, i.e. estimates for those process stages where the reduction is feasible.

A more detailed overview of the results is provided below.

Table 11-13: Detailed results of the Cap Ingelec (2017) study

CAPEX		10 µg/m3	4 µg/m3	1.6 µg/m3	0.4 µg/m3
Industrial Batteries		**45 000**	**12 769 177**	**25 340 390**	**n/a**
	partial sum			*uncertain for PS2 and 3*	***25 932 060***
	A	*0*	*12 724 177*	*20 593 240*	*not possible for PS2 and 3*
	C	*45 000*	*45 000*	*4 618 000*	*4 722 950*
	D	*0*	*0*	*0*	*452 000*
	E	*0*	*0*	*129 150*	*163 870*
Zn/Cd Refining		**2 301 000**	**n/a**	**n/a**	**n/a**
	partial sum		***2 307 000***	***4 872 900***	***6 484 700***
	A	*2 211 000*	*not possible for PS2 and 3*	*not possible for PS2 and 3*	*not possible for PS2 and 3*
	C	*90 000*	*90 000*	*2 490 000*	*3 140 000*
	D	*0*	*3 000*	*3 000*	*868 000*
	E	*0*	*3 000*	*168 900*	*265 700*
Others		**90 000**	**9 280 828**	**17 127 135**	**n/a**
	partial sum				***18 496 555***
	A	*0*	*9 169 928*	*14 748 685*	*not within reach*
	C	*90 000*	*90 000*	*2 290 000*	*3 268 300*
	D	*0*	*20 100*	*20 100*	*293 100*
	E	*0*	*800*	*68 350*	*186 470*
TOTAL		**2 436 000**	**n/a**	**n/a**	**n/a**
	partial sum		***24 357 005***	***47 340 425***	***50 913 315***
	A	*2 211 000*	*n/a*	*n/a*	*n/a*
	C	*225 000*	*225 000*	*9 398 000*	*11 131 250*
	D	*0*	*23 100*	*23 100*	*1 613 100*
	E	*0*	*3 800*	*366 400*	*616 040*

Source: Cap Ingelec (2017)

Annex 3 Estimates of ESRD Cases

The analysis in this annex is based on input from the ICdA.

Chronic Kidney Disease (CKD) is characterised by a gradual loss of renal function and its severe levels in which the kidney is unable to provide its essential functions are referred to as End Stage Renal Disease or End Stage Kidney Disease (ESRD or ESKD). Treatment for ESRD involves regular dialysis or kidney transplant.

The EU RAR (2007) for cadmium provides the following stratification of elevated urinary low molecular weight proteins (U-LMWPs) based on Bernard et al (1997).

Table 11-14: Significance of elevated urinary low molecular weight proteins (U-LMWPs) in urine

B2M and RBP µg/g creatinine	Interpretation
< 300 µg/g creatinine	Normal values
300-1,000 µg/g creatinine	Incipient cadmium tubulopathy with possibility of reversibility after removal from exposure. No change in Glomerular Filtration Rate (GFR).
1,000-10,000 µg/g creatinine	Irreversible tubular proteinuria which may lad to accelerated decline of the GFR with age. GFR normal or slightly altered.
>10,000 µg/g creatinine	Overt Cd nephropathy usually associated with decreased GFR
Source: Bernard (1997) cited in EU RAR (2007) p. 335, available at http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/5172/1/cadmiummetalhhreport303.pdf	

The Glomerular Filtration Rate (GFR) measures the volume of liquid a kidney can process per minute (with a correction by a surface-equivalent of the filter which is linked to a person's height). A reduced GFR is one of the key indicators (along with elevated albuminuria[123]) of the severity and prognosis of CKD, as shown below.

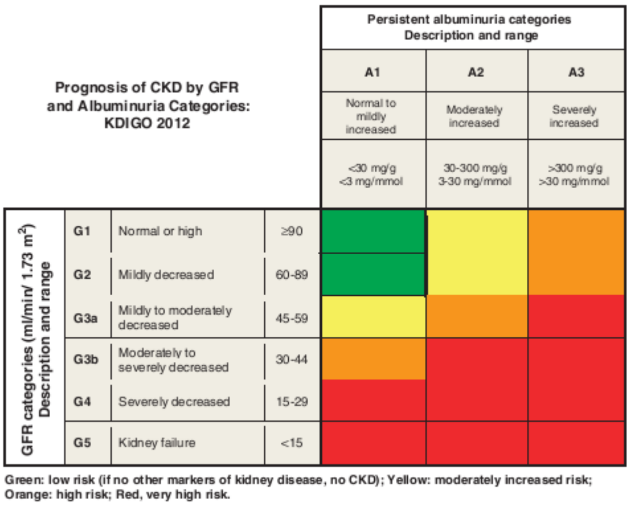


Figure 11-5: Prognosis of CKD by GFR and albuminuria categories
Source: GDIGO (2012), available at http://www.kdigo.org/clinical_practice_guidelines/pdf/CKD/KDIGO_2012_CKD_GL.pdf

[123] See https://www.kidney.org/atoz/content/albuminuria

Considering Bernard et al (1997) and GDIGO (2012) together suggests that increased risk of CKD mainly occurs at decreased GFR which can be associated with U-LMWP levels above 1,000 µg/g creatinine, and which is occurs as a result of >10,000 µg/g creatinine.

As a precautionary approach, the number of cases of elevated proteinuria above 1,000 µg/g creatinine has been estimated from Cd-U data in OCdBIO.

Chaumont et al (2009)[124] provide an indication of the relationship between elevated U-LMWP (U-RBP, i.e. retinol binding protein) and Cd-U.

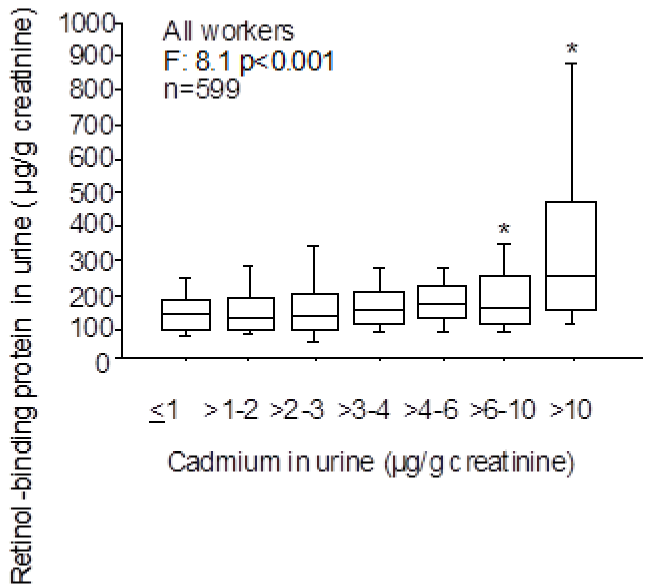


Figure 11-6: Relationship between U-LMWP and Cd-U µg/g creatinine
Note: Levels shown in the boxplots are 10th, 25th, 50th, 75th, and 90th percentiles of U-RBP values
Source: Chaumont et al (2009), available at http://oem.bmj.com/content/68/4/257

The figure above suggests that in the group where Cd-U>10, the fraction of U-RBP > 1,000 is approx. 10% (100-90). In the Cd-U 6-10 group, the fraction is lower than 10% (e.g. 5%). In the groups CdU <6, the fraction with U-RBP > 1,000 is insignificant.

Applying these fractions to the Cd-U distribution supplied by ICdA (OCdBIO-2016) results in the following estimates of workers with U-LMWP >1,000.

[124] Chaumont et al (2009): The threshold level of urinary cadmium associated with increased urinary excretion of retinol-binding protein and β2-microglobulin: a re-assessment in a large cohort of nickel-cadmium battery workers, available at http://oem.bmj.com/content/68/4/257

Urine (µg/g creat.)	2008	2009	2010	2011	2012	2013	2014	2015	2016
0.00 - 1.00	1204	1442	1599	1906	2629	2422	2536	2439	2568
1.01 - 2.00	258	300	337	360	353	271	376	371	330
2.01- 3.00	113	135	146	119	112	104	147	135	138
3.01 - 5.00	118	127	118	129	116	88	103	90	77
5.01 - 7.00	56	50	59	46	28	35	32	41	19
7.01 - 10.00	40	38	60	42	31	20	20	28	19
>10	46	33	51	47	27	16	17	16	6
Total workers	1 835	2 125	2 370	2 649	3 296	2 956	3 231	3 120	3 157
				264		159	172	175	121
>2 µg/g creat	373	383	434	383	314	263	319	310	259
>5 µg/g creat	142	121	170	135	86	71	69	85	44
>10 µg/g creat	46	33	51	47	27	16	17	16	6
%>2 µg/g creat	20.33%	18.02%	18.31%	14.46%	9.53%	8.90%	9.87%	9.94%	8.20%
%>5 µg/g creat	7.74%	5.69%	7.17%	5.10%	2.61%	2.40%	2.14%	2.72%	1.39%
%>10 µ/g creat	2.51%	1.55%	2.15%	1.77%	0.82%	0.54%	0.53%	0.51%	0.19%

Figure 11-7: OCdBIO 2016
Source: ICdA

Taking into account the above and the trends in Cd-U among workers employed by companies reporting to OCdBIO, the number of ESRD cases can be estimated based on the following assumptions:

The fraction of bio-monitored workers with a CdU > 2 will plateau at 3% (as reported in OCdBIO)

- 25% of bio-monitored workers with CdU > 2 have a CdU > 5 (based on 2014-2017)
- 75% with a Cd-U between 2 and 5
- 5% of all workers with a Cd-U > 5 will reach a U-LMWP greater than 1,000
- 1% of all workers with a Cd-U between 2 and 5 will reach a U-LMWP greater than 1,000
- U-LMWP > 1,000 always triggers a decrease in GFR
- GFR always evolves into ESRD

Based on a Cd exposed headcount of 7,000:

- 3% = 210 will exceed CdU=2
- 25% = 52 will exceed CdU = 5
- 75% = 158 will have CdU >2 but <5
- 5% of 52 = 2.5 will exceed U-LMWP = 1,000
- 1% of 158 = 1.6 will exceed U-LMWP = 1,000
- These 1.6 + 2.5 = 4 workers will encounter a decrease in GFR
- These 4 workers will see this decrease in GFR evolve into ESRD.

This can be extrapolated over the exposed workforce of 10,000, resulting in 6 cases of ESRD.

Alternatively, when only those workers in OCdBIO that have been hired in 2000 or later are taken as the basis for this estimation, it can be estimated that **a total of 3 cases of ESRD could occur among an exposed workforce of 10,000.**

Getting in touch with the EU

In person

All over the European Union there are hundreds of Europe Direct Information Centres. You can find the address of the centre nearest you at: http://europa.eu/contact

On the phone or by e-mail

Europe Direct is a service that answers your questions about the European Union. You can contact this service

– by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),

– at the following standard number: +32 22999696 or

– by electronic mail via: http://europa.eu/contact

Finding information about the EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website at: http://europa.eu

EU Publications

You can download or order free and priced EU publications from EU Bookshop at: http://bookshop.europa.eu. Multiple copies of free publications may be obtained by contacting Europe Direct or your local information centre (see http://europa.eu/contact)

EU law and related documents

For access to legal information from the EU, including all EU law since 1951 in all the official language versions, go to EUR-Lex at: http://eur-lex.europa.eu

Open data from the EU

The EU Open Data Portal (http://data.europa.eu/euodp/en/data) provides access to datasets from the EU. Data can be downloaded and reused for free, both for commercial and non-commercial purposes.

Publications Office
of the European Union