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

(Ref: VC/2017/0011)

Final Report for inorganic arsenic compounds incl. arsenic acid and its salts

February – 2018

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

Inorganic arsenic compounds incl. arsenic acid and its salts

8 February 2018

Final Report

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List of acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ACEA	The European Automobile Manufacturers Association
ACSH	Advisory Committee on Safety and Health at Work
AfA	Application for authorisation
AFEMS	Association of European Manufacturers of Sporting Ammunition
AM	Arithmetic mean
As	Arsenic
ASA	Finnish Register of Employees Exposed to Carcinogens
BAR	German Biological Reference Value
BAT	Best available technique
BEI	Biological Exposure Index
BGV	Biological guidance value
BLV	Biological limit value
BLW	German Biological Guidance Value
CAPEX	Capital expenditure
CAREX	CARcinogen EXposure
CBA	Cost-benefit assessment
CBD	Current disease burden
CCA	Chromated copper arsenate (wood preservative)
CEFIC	European Chemical Industry Council
CI	Confidence interval
C&L	Classification and Labelling
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging (Regulation)
CMD	The Carcinogens and Mutagens Directive
CNC	Computer numerical control
CN8	Combined Nomenclature with 8 digits
CSR	Chemical safety report
CuAl	Copper-aluminium (alloy)
CuAs	Copper-arsenic (alloy)
DALY	Disability adjusted life years
DECOS	The Dutch Expert Committee on Occupational Safety
DMA	Dimethylarsinic acid
DNA	Deoxyribonucleic acid
DRR	Dose response relationship
EAF	European Foundry Association
ECGA	European Special Glass Association
ECHA	European Chemicals Agency
ECI	European Copper Institute
EFMA	European Fertilizer Manufacturers' Association
ERR	Exposure-risk relationship
E-PRTR	European Pollutant Releases and Transfer Register
ESA	European Sulphuric Acid Association
ESIA	European Semiconductor Industry Association
EU	European Union
EURIMA	European Insulation Manufacturers Association
EUROBAT	Association of European Automotive and Industrial Battery Manufacturers
Europacable	European Cable and Wire Association
Eurometaux	European Non-Ferrous Metal Association
FBD	Future disease burden

GaAs	Gallium arsenide
GAE	GlassAlliance Europe
GGBS	Ground granulated blast furnace slag
GHS	The Globally Harmonized System of Classification and Labelling of Chemicals
GM	Geometric mean
GSD	Geometric standard deviation
HEPA	High efficiency particulate air
IA	Impact assessment
iAs	Inorganic arsenic
IARC	International Agency for Research on Cancer
IFA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety of the German Social Accident Insurance)
ILA	International Lead Association
IOM	Institute of Occupational Medicine
ISO	The International Organization for Standardization
IZA	International Zinc Association
JRC	Joint Research Centre
LED	Light emitting diode
LEV	Local exhaust ventilation
LOAEC	Lowest Observable Adverse Effect Concentration
LOD	Level of detection
LOQ	Limit of quantification
miRNA	Micro ribonucleic acid
MAG	Metal Active Gas welding
MEGA	IFA's workplace exposure database
MMAD	Mean mass aerodynamic diameter
MMA	Monomethylarsonic acid
TIG	Tungsten inert gas welding
MoA	Mode of Action
MS	Member State
NIOSH	National Institute for Occupational Safety and Health
NOAEC	No Observed Adverse Effect Concentration
OEL	Occupational exposure limit
OELV	Occupational exposure limit value
OPEX	Operating Expenses
OSH	Occupational health and safety
OSHA	Occupational Safety and Health Administration
PEL	The permissible exposure limit
PBT	Persistent, Bioaccumulative and Toxic
PIC	Prior Informed Consent (Regulation)
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
ppm	parts per million
PROC	Process categories
PV	Present value
R&D	Research and development
RAC	Risk Assessment Committee
RAR	Risk assessment report
RMM	Risk management measure
RNA	Ribonucleic acid
RPE	Respiratory protective equipment
SCOEL	Scientific Committee on Occupational Exposure Limits
SME	Small and medium-sized enterprise
SMR	Standardised Mortality Ratio

STEL	Short-term Exposure Limit
TLV	Threshold Limit Value
TRA	Targeted risk assessment
TWA	Time weighted average
UK	United Kingdom
VSL	Value of a statistical life
VSM	Value of statistical morbidity
WCS	Worker contributing scenario
WEEE	Waste electrical and electronic equipment
WIG	Wolfram Inert Gas welding
WVM	German WirtschaftsVereinigung Metalle
WHO	World Health Organization
WTP	Willingness to pay

Executive summary

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereinafter the CMD, protects workers from exposure to carcinogens or mutagens at work. The aim of this study is to support the European Commission's Impact Assessment of a potential Occupational Exposure Limit Value (OELV) for inorganic arsenic compounds including arsenic acid and its salts.

Assessed OELVs - The study assesses the impacts of an OELV at three levels: 10, 20 and 50 µg/m^3.

ACSH recommendation - The Advisory Committee on Safety and Health at Work (ACSH) recommends in its opinion an OELV at 10 µg/m^3. The ACHS notes that *"after a preliminary assessment for one specific sector, copper smelting, it is currently not technically achievable to comply with this OELV. In addition, the ACSH notes that the Commission Impact Assessment may identify other sectors which are in a similar situation."*

Overall exposure sources

Occupational exposure to inorganic arsenic compounds including arsenic acid and its salts may take place by a number of processes:

- **Intentional use -** The two substances used intentionally in the highest quantities are arsenic acid and diarsenic trioxide with a registered import/production in the 100-1000 t/y range. Other substances are registered in quantities below 10 t/y. The main areas of intentional use of arsenic compounds are glass production, electrowinning of zinc and production of electronic components.

- **Use or production of arsenic metal and arsenic substances beyond the scope** - The main uses of arsenic metal is in alloys of copper (various articles of zinc) and lead (batteries, ammunition and others). Inorganic arsenic compounds may be formed when the arsenic metal is heated e.g. by production of the alloys. Inorganic arsenic compounds may furthermore be formed by the production and use of gallium arsenide wafers outside the scope of this study.

- **Arsenic present as unintentional impurity** - Arsenic is naturally present as impurity in ores, fossil fuels, soil, plant material, etc. and may be released to the air by thermal processing/combustion of these materials. Furthermore, arsenic compounds would be present in dust formed by the processes. The main areas are copper production (due to high arsenic content of copper concentrates), copper mining (production of concentrate), other non-ferrous metal production and mining, combustion of coal and oil shale, ferrous basic metal production and production of sulphuric acid from pyrite. Workers may in particular be exposed directly to arsenic compounds in the workplace air from smelting processes and to dust from raw materials and flue gas cleaning residues by cleaning and maintenance work.

- **Management of articles with arsenic compounds** - Inorganic arsenic compounds were formerly used in chromated copper arsenate (CCA) wood preservatives. Recycling of CCA preserved wood is restricted, but occupational exposure may take place by some exempted applications and waste disposal.

Exposed workforce - A challenge of the study has been to fill a gap between the large number reported in previous surveys such as the CAREX survey from 1993/97 and the number of workers represented by the available exposure concentrations. For this assessment, the estimated number of workers exposed to inorganic arsenic compounds including arsenic acid and its salts is divided into two groups.

- Workers exposed at higher levels as demonstrated by measurements, modelling or from comparison to similar processes, with reference to the reported exposure concentrations. The total number of workers in this group is estimated at 7,900-15,300 (midrange: 11,600). For the majority of workers in this group, exposure levels are based on actual data from stakeholder consultations, from applications for authorisation, from Chemical Safety Reports from REACH registration dossiers or from the German MEGA[1] database. For a minor part, where data on actual exposure levels are not available, exposure data reported in the literature is applied.

- Other workers which may potentially be occupationally exposed. The latter group either works in sectors and with processes where arsenic may be present in raw materials at relatively low levels, or they work in high-exposure sectors (as the copper sector), but are not routinely working with the high-exposure processes covered by the monitoring of workplace concentrations. The total number of workers in this group is estimated at 18,000-102,000 (midrange: 60,000). For this group, an average exposure level of 1 µg/m^3 has been estimated for the baseline assessment.

Sectors impacted - The main sector impacted is the copper sector which represent nearly half of the workers in group of 11,600 assessed. No other sectors have provided specific information demonstrating that they would be impacted if an OELV at the assessed level is established. For the intentional use of arsenic information has been received for all uses except the possible use in domestic glass. The major use of diarsenic trioxide in the domestic glass sector took place in Northern Italy and has been prohibited in recent years, but it cannot be excluded that some activities take place in some Member States and in this case these activities would likely be affected. For two other sectors no actual data have been obtained but based on literature data, it is estimated that some exposure to inorganic arsenic compounds in flue gas cleaning residues may take place by cleaning and maintenance activities. These sectors are ferrous basic metal production and coal and oils shale power plants using raw materials/fuels with high arsenic content. Furthermore, a few companies in other non-ferrous metal sector may be impacted, but the available data indicates that the majority of companies involved in base metal production og zinc, lead and cadmium as well as companies producing or using arsenic-lead alloys would not be affected.

Cost-benefit assessment (CBA)

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

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[1] MEGA: The workplace exposure database of Institute for Occupational Safety of the German Social Accident Insurance.

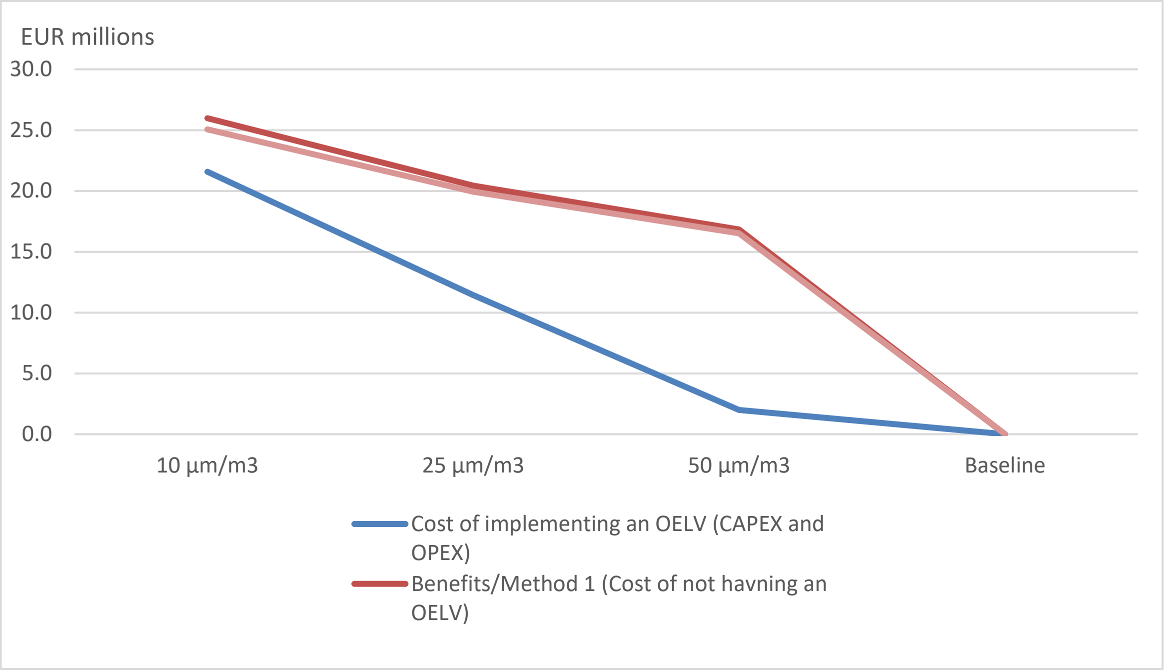

Figure 0-1: Costs/benefits of establishing an OELV for inorganic arsenic compounds including arsenic acid and its salts for all sectors in the EU. Estimated costs (CAPEX AND OPEX) for 60 year and benefits (costs of not having an OELV) for a static baseline with a static discount rate.

The table overleaf summarises both the monetised impacts as well as those that are assessed qualitatively.

Uncertainty on benefits assessment - The benefits assessment consists of an estimate of the benefits of avoided cases of lung cancer and an estimate of avoided cases of peripheral neuropathy, where the benefits of avoided cases of peripheral neuropathy account for the major part. The benefits assessment is consequently very sensitive to the uncertainty on the quantification of the benefits of avoided cases of peripheral neuropathy which is based on a limited dataset. Furthermore, it may be concluded that the reference to only lung cancers and peripheral neurotoxicity tends to underestimate the total number of cases to be expected after occupational exposure to inorganic arsenic compounds.

Uncertain benefits costs assessment - Within the copper sector, a primary smelter in Bulgaria, and two secondary smelters in Slovakia and Austria, respectively, will be affected by establishing an OELV at the assessed levels (the smelter in Bulgaria would not be affected by an OELV at 50 µg/m^3). The costs have been estimated on the basis of knowledge on the RMMs implemented in other smelters in order to comply with an OELV of 10 µg/m^3. The highest uncertainty is linked to the estimated investment for better LEV (local exhaust ventilation). For other non-ferrous metal production than copper, domestic glass production, power plants and ferrous basic metal production it cannot be excluded that a few companies could be impacted, but the total costs for each sector are considered to be small compared to the costs to the copper sector.

With the uncertainties on the costs and benefits it cannot be estimated whether the costs are higher than the benefits at the OELVs of 5 and 10 µg/m^3.

Table 0-1: Inorganic arsenic compounds. Multi-criteria analysis

Impact	Stakeholders affected	Reference OELV A: 10 $\mu g/m^3$	Reference OELV B: 25 $\mu g/m^3$	Reference OELV C: 50 $\mu g/m^3$
Economic impacts				
Compliance costs	Companies exposing their workers	€ 21.2 million	€11 million	€1.6 million
Transposition costs	Public sector	€0.4 million	€0.4 million	€0.4 million
Benefits from reduced ill health	Reduction in number of cancer cases	3	2	1
	Reduction in numbers of non-cancer cases	574	468	393
	Employers avoided costs	€2.8 million	€2.3 million	€1.9 million
	Public sector avoided costs	€1.3 million	€1.1million	€0.9 million
Single-market: competition		Limited impact - no closures expected		
Single-market: consumers		No impact	No impact	No impact
Single-market: internal market	Companies. Positive impact: level playing field	Reduction of highest OEL/lowest OEL ratio from 71 to 4	Reduction of highest OEL/lowest OEL ratio from 71 to 9	Reduction of highest OEL/lowest OEL ratio from 71 to 18
International competitiveness		No impact	No impact	No impact
SMEs		No or very limited impact	No impact	No impact
Specific MS/regions	MS that would have to change OELs Companies that might be impacted	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, HR, CZ, FR, EL, HU, IT, LU, MT, PT, SK, SI, UK
Social impacts				
Ill health avoided – lung cancer and peripheral neuropathy (incl. intangible costs)	Workers & families	€9 to €34 million	€7 to €28 million	€ 5to €23 million
Other health points	Workers & families	Additional ill-health from other types of cancer and non-cancer endpoints not included in the assessment (expected to be lower than the assessed endpoints)		
Employment	Workers	No impact	No impact	No impact
Environmental impacts				
Environmental releases		No impact (expected that ventilation air is cleaned before released to the environment)		
Recycling – loss of business	Recycling companies	No impact		
Recycling – durability of consumer goods, etc.		No impact		

1 Introduction

1.1 Background

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereinafter the CMD, aims to protect workers against health and safety risks from exposure to carcinogens or mutagens at work. To this end, it sets out the minimum requirements for protecting workers that are exposed to carcinogens and mutagens, including the so-called Binding Occupational Exposure Limit Values (OELVs)[2]. 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 (OELVs) and, where appropriate, a Short-Term Exposure Limits (STELs) and a skin notation.

The specific objective of this report is to assess the impacts of introducing an OELV and/or a STEL for inorganic arsenic compounds incl. arsenic acid and its salts.

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[2] 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/RAC, ACSH documents) and the scope of the assessment for inorganic arsenic compounds incl. arsenic acid and its salts;
- Section 3 sets out the baseline;
- Section 4 sets out the benefits of the relevant measures;
- Section 5 sets out the costs of the relevant measures;
- Section 6 summarises the market effects;
- Section 7 describes the environmental impacts;
- Section 8 describes the distribution of any impacts;
- Section 9 provides the conclusions;
- Section 10 sets out the sensitivity analysis; and
- Section 11 Key discusses issues for the outcome of the CBA

2 Background and scope of the assessment

This section comprises the following subsections:

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

2.1 Background

2.1.1 The RAC opinion of 29 May 2017

The RAC opinion of 29 May 2017 evaluates the OELs for **arsenic acids and its inorganic salts**. However, RAC notes that "*the toxicological and exposure data in particular, often do not discriminate between different arsenic species. In addition, taking into account the carcinogenicity and mutagenicity data on different inorganic arsenic compounds and mechanistic data, the carcinogenicity of inorganic arsenic is not limited only to arsenic acid and its salts. Therefore this evaluation also applies to arsenic and its inorganic compounds in general.*" (RAC 2017)

Some of the key conclusions of the evaluation are (extracted from the evaluation, partly citation):

- The critical endpoint for establishing an OEL is carcinogenicity;
- Health-based OELs cannot be established for arsenic acid and its salts because the available data do not allow the identification of a threshold for the genotoxic and carcinogenic effects of arsenic; [Author's comment: RAC does not draw the conclusion for the entire group of inorganic arsenic compounds, but the available data indicates that this would apply to the group of substances within the scope of the current report.]
- The broader group arsenic, and inorganic arsenic compounds are considered to be human carcinogens (Group 1) by the International Agency for Research on Cancer (IARC);
- Arsenic acid and its salts are classified as Carcinogen 1A under the CLP; [Author's comments: as shown below the majority of the inorganic arsenic compounds have similar classification]
- According to the SCOEL Classification scheme 6, arsenic acid and its inorganic salts would most likely be classified as "*Group B: Genotoxic carcinogens, for which the existence of a threshold cannot be sufficiently supported at present. In these cases the LNT model may be used as a default assumption, based on the scientific uncertainty*";
- Inhalation is the primary route of occupational exposure for arsenic while non-occupational exposure occurs mainly through food and through the drinking water in areas with high levels of arsenic in drinking water resources;

- Epidemiological studies of populations occupationally exposed to arsenic consistently demonstrate an excess lung cancer risk. In addition, epidemiological studies in the general population also show that the oral exposure to arsenic via drinking water increases the risk of skin and urinary bladder cancer;

- Absorption by the dermal route is considered to be low compared to the other routes thus a skin notation is not warranted.

2.1.2 Classification

The harmonised classification of arsenic and inorganic arsenic compounds (except arsine) are shown in Table 2-1. Most of the specifically listed substances are classified Carc. 1A. Gallium arsenide, outside the scope of this assessment, is classified Carc. 1B.

Arsenic metal (elemental arsenic) is not classified carcinogenic and the same is the situation for 'Arsenic compounds with the exception of those specified elsewhere in the annex'. This means that complex arsenic compounds which are not salts of arsenic acid are not classified carcinogenic.

Table 2-1: Harmonised classification of arsenic and inorganic arsenic compounds including arsenic acid and its salts (except arsine)

Index No	International Chemical Identification	EC No	Hazard Class and Category Code(s)	Hazard statement Code(s)
028-038-00-3	Trinickel bis(arsenate); nickel(II) arsenate	236-771-7	**Carc. 1A** STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H372** H317 H400 H410
028-042-00-5	Trinickel bis(arsenite)	CAS: 74646-29-0 [no EC number]	**Carc. 1A** STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H372** H317 H400 H410
028-051-00-4	Nickel diarsenide; [1] nickel arsenide [2]	235-103-1 [1] 248-169-1 [2]	**Carc. 1A** STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H372** H317 H400 H410
031-001-00-4	Gallium arsenide	215-114-8	Repr. 1B **Carc. 1B** STOT RE 1	H360F H350 H372 (respiratory and haematopoietic systems)
033-001-00-X	Arsenic	231-148-6	Acute Tox. 3 * Acute Tox. 3 * Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H400 H410

Table 2-1: Harmonised classification of arsenic and inorganic arsenic compounds including arsenic acid and its salts (except arsine)

Index No	International Chemical Identification	EC No	Hazard Class and Category Code(s)	Hazard statement Code(s)
033-002-00-5	Arsenic compounds, with the exception of those specified elsewhere in this Annex		Acute Tox. 3 * Acute Tox. 3 * Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H400 H410
033-003-00-0	Diarsenic trioxide; arsenic trioxide	215-481-4	**Carc. 1A** Acute Tox. 2* Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H300 H314 H400 H410
033-004-00-6	Diarsenic pentaoxide; arsenic pentaoxide; arsenic oxide	215-116-9	**Carc. 1A** Acute Tox. 3* Acute Tox. 3* Aquatic Acute 1 Aquatic Chronic 1	H350 H331 H301 H400 H410
033-005-00-1	Arsenic acid and its salt with the exception of those specified elsewhere in this Annex	-	**Carc. 1A** Acute Tox. 3* Acute Tox. 3* Aquatic Acute 1 Aquatic Chronic 1	H350 H331 H301 H400 H410
082-011-00-0	Lead hydrogen arsenate	232-064-2	**Carc. 1A** Repr. 1A Acute Tox. 3* Acute Tox. 2* STOT RE 2* Aquatic Acute 1 Aquatic Chronic 1	H350 H360Df H331 H301 H373** H400 H410

Source: Table 3.1 in Annex VI to the CLP Regulation (1272/2008)

Inorganic arsenic compounds, driver of carcinogenic potency or the mode of action

The mechanism of carcinogenicity is not yet clarified. Inorganic arsenic compounds do not affect DNA (deoxyribonucleic acid) directly in the form of DNA-adducts or DNA-protein crosslinks (point mutations). However, they can act as a co-mutagen, enhancing mutagenicity of other agents. Clastogenic[3] damage was observed in human and animal studies *in vivo* and *in vitro*. Reactivity of arsenicals with thiol-groups in proteins has been attributed with the inhibition of DNA repair enzymes. There is growing body of evidence that epigenetic[4] modifications play a role: arsenic induces them both at a genome-wide level and at gene promoter regions, and is also able to induce histone modifications (methylation, acetylation, and phosphorylation of histone tails), changing the expression of several genes. Furthermore, several findings demonstrated that the exposure to arsenic induces gene-specific

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[3] Clastogenic: Giving rise to or inducing disruption or breakages of chromosomes that result in the gain, loss, or rearrangements of chromosomal segments.

[4] Epigenetic: Heritable alterations that are not due to changes in DNA sequence.

alteration of miRNA[5] expression likely resulting in an impaired expression of all the genes regulated by those miRNAs. Furthermore, arsenic induces oxidative stress, not by itself, but inhibition of scavenging[6] systems of reactive oxygen species (AGS, 2011; IARC, 2012; Martinez et al., 2011).

Unintentional formation

The arsenic compounds within the scope of this assessment may in addition to intentional uses, unintentionally be formed by thermal processes from arsenic metal or arsenic compounds (inorganic and organic) present in coal, ores, and other raw materials. The unintentional formation accounts for a major part of the total occupational exposure to the compounds within the scope.

2.1.3 Presence in articles

In none of the present day use of the inorganic arsenic compounds in the EU, the compounds within the scope of this assessment would be present in the final articles.

Arsenic compounds within the scope would mainly be present in recycled articles from the former use of wood preservatives.

2.2 Study scope

This report assesses the impacts of establishing an OELV for inorganic arsenic compounds including arsenic acid and its salts.

2.2.1 Selection of the relevant compounds

The following screening criteria have been applied to select the arsenic compounds that will be prioritised in the study:

a) Is there a harmonised classification as Carc. 1A or 1B for the compound? We have assumed that in line with the 'arsenic acid and its salts not listed elsewhere in this annex' all arsenic acid salts are CLH Carc. 1A but have checked this for all the other arsenic compounds.
b) If the compound only has a self-classification as Carc. 1A or 1B, is the compound also registered? We have assumed that more reliable data/information will be available for registered compounds.
c) Does the compound fit the definitions 'arsenic acid and its salts' or 'inorganic arsenic compound?
d) Where compounds also contain another carcinogen element: Is As the component driving carcinogenic potency or Mode of Action (MoA)?[7]

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[5] A microRNA (abbreviated miRNA) is a small non-coding RNA (ribonucleic acid) molecule that functions in RNA silencing and post-transcriptional regulation of gene expression

[6] Scavenging systems serves to remove or de-activate unwanted reaction products.

[7] The compounds that will be considered are those where arsenic is clearly the driver of the carcinogenic potency or the "mode of action" (MoA). Existing OEL and cancer risk quantifications from SCOEL/RAC do not cover arsenic compounds with other MoA and potency. Therefore, the impact assessment is preferably to be linked to this demarcation criterion.

e) Is there any another reason for excluding any of the compounds? For example, we have excluded salts from arsine (because they are not classified Carc. 1A) or complex compounds (because they are not classified carcinogenic).

The relevant substances that remain within the scope of the study following the screening process are summarised below.

Table 2-2: Inorganic arsenic compounds – screening process

Step	Number of compounds
Total number of As compounds	164
Of which, compounds with harmonised classification as Carc. 1A or self-classified as Carc. 1A and registered	11+46
Of which, inorganic arsenic compounds	53
Of which, As is driver of carcinogenic potency or the mode of action	31

Source: RPA/COWI

The relevant compounds to be assessed in the study are summarised below.

The title of the study specifies that the inorganic arsenic compounds includes arsenic acid and its salts. Throughout the report the term "Inorganic arsenic compounds including arsenic acid and its salts" is used for the group of compounds listed in the table below which are under the scope of the CMD.

Excluded substances - Excluded inorganic arsenic compounds with registered uses are mainly arsine, gallium arsenide and diarsenic triselenide.

Table 2-3: Inorganic arsenic compounds – final selection

Compound	CAS No.
Diarsenic pentaoxide	1303-28-2, 12044-50-7
Diarsenic trioxide	1327-53-3, 7440-38-2
Arsenic acid, sodium salt	7631-89-2
Arsenic acid	7778-39-4
Disodium hydrogenarsenate	7778-43-0
Calcium arsenate	7778-44-1
Arsenic trichloride	7784-34-1
Potassium dihydrogenarsenate	7784-41-0
Diammonium hydrogenarsenate	7784-44-3
Sodium dioxoarsenate	7784-46-5
Iron arsenate	10102-49-5
Iron bis(arsenate)	10102-50-8
Arsenic acid, magnesium salt	10103-50-1
Arsenic acid, copper salt	10103-61-4
Arsenic acid, calcium salt	10103-62-5
Ammonium dihydrogenarsenate	13462-93-6
Trisodium arsenate	13464-38-5
Zinc arsenate	13464-44-3
Sodium metaarsenate	15120-17-9
Triammonium arsenate	24719-13-9
3-methyl-4-(pyrrolidin-1-yl)benzenediazonium hexafluoroarsenate	27569-09-1

Table 2-3: Inorganic arsenic compounds – final selection

Compound	CAS No.
Arsenic acid, copper(2+) salt	29871-13-4
Vanadium(4+) diarsenate (1:1)	99035-51-5
Sodium hexafluoroarsenate(V)	12005-86-6
Calcium hydrogen arsenate	15195-00-3
Sodium arsenate dibasic heptahydrate	10048-95-0
Source: RPA/COWI	

2.3 Background information on exposure sources of inorganic arsenic compounds including arsenic acid and its salts

Occupational exposure to inorganic arsenic compounds including arsenic acid and its salts may take place by a number of processes:

1. Production and intentional use of the substances within the scope;
2. Formation of the substances by processes involving arsenic metal, alloys with arsenic or arsenic compounds not within the scope;
3. Formation of the substances by thermal processes where arsenic is present as unintentional impurity in raw materials;
4. Management of articles with arsenic compounds due to former use of the substances in articles.

This division is followed initially in order to systematically identify the different sources of exposure.

The sources are subsequently grouped by sector for a sector-specific assessment. This section provides the overall description of the applications. More details on the various working processes is provided in the section on exposure concentrations (Section 3.3.12).

1) Production and intentional use of the substances within the scope

Data on registered tonnage and identified intentional uses of inorganic arsenic compounds including arsenic acid and its salts is summarised in the table below. Only four substances are registered with an indicated tonnage band: arsenic acid (100-1000 t/year), diarsenic triselenide (1-10 t/year), diarsenic trioxide (100-1,000 t/year) and gallium arsenide (10-100 t/year). Sectors where the compounds are used are the electronics sector, glass sector, chemical sector, and basic metal and alloys sector. The use is further described in separate sections for each sector.

Diarsenic triselenide is not within the scope of the study and not further investigated. The compound is a salt from arsine (As^{3-}). The substance is not classified as carcinogenic according to CLP criteria and the use is not subject to authorisation. To the extent that other arsenic compounds may be formed by the manufacture of the diarsenic triselenide, the exposure to these is included in manufacture of arsenic compounds.

Gallium arsenide is not within the scope of the study, but the possible exposure to inorganic arsenic substances by manufacture and use of that substance has been assessed.

Table 2-4: Potentially relevant sectors and uses – registered substances				
Compounds	**EC Number**	**Registered tonnage (t/year)**	**Uses**	**Source of information on use**
Arsenic acid	231-901-9	100-1,000 (Authorisations dossier 3.2 t)	Treatment of copper foil used in the manufacture of printed circuit boards	Authorisation dossier
			Remove gas bubbles from glass melt (fining agent) (exempt from authorisation)	ECHA, 2012b
Calcium arsenate	231-904-5	Intermediate Use Only	Manufacture of basic metals and alloys Used to precipitate nickel from the molten metal and to manufacture diarsenic trioxide	Registration dossier ECHA/PR/11/26
Trilead diarsenate	222-979-5	Intermediate Use Only	Intermediate use in the manufacture of basic metals, including alloys	Registration dossiers
Diarsenic triselenide - substance not within the scope	215-119-5	1-10	Add thin film into coating and assemble into a lens assembly; Glass shaping: grinding, polishing, moulding and DTP	Registration dossier
Diarsenic trioxide	215-481-4	100-1,000	Purification of metal impurities from the leaching solution in the zinc electrowinning process; Processing aid in gold electroplating; Absorption and desorption of carbon dioxide by potassium carbonate	Authorisation dossier
			Production of glass and enamel (exempt from authorisation)	ECHA, 2016
Gallium arsenide - substance not within the scope	215-114-8	10-100	Production of gallium arsenide wafers	Registration dossiers - substance not within the scope

2) Formation of the substances by processes involving arsenic metal and alloys with arsenic

Metal arsenic is not within the scope of the assessed OELV but inorganic arsenic compounds may be formed by processes involving arsenic metal and alloys with arsenic. Furthermore, inorganic arsenic compounds within the scope may be formed by processing arsenic compounds outside the scope.

Arsenic metal is mainly used intentionally in the production of copper alloys and lead alloys.

Arsenic metal is not registered, and consequently no detailed information from registrations has been available. Arsenic is included in the substances managed by the Arsenic Consortium, and arsenic metal is planned to be registered before the 1-100 tonne deadline of 31 May 2018.

Arsenic metal is used in ultrapure grade to produce gallium arsenide wafers described in Section 3.3.3. The raw materials for the manufacture of ultrapure arsenic metal originate from the EU.

Other applications of arsenic metal are mainly in various alloys. The arsenic used in the manufacture of alloys is mainly imported from countries outside the EU.

The reported import of arsenic (CN8[8]: 2804 8000) in 2015 and 2016 was 441 t/year and 380 t/year, respectively, while the export the same years were 33 t/year and 36 t/year. About 90% was imported from China while about 10% was imported from Japan. No data on the import/export of arsenic alloys are available from statistics as these alloys do not have separate CN8 commodity codes.

According to the obtained information, lead alloys (described in Section 3.3.7) and copper alloys (described in Section 3.3.5) account for the major part of the use of arsenic. Based on information from industry the import of approximately 400 t/year arsenic metal is distributed by 100 t/year for lead alloys and 300 t/year for copper alloys. In addition to this, some arsenic containing alloys may be imported, but no data have been available.

3) Formation of the substances by processes where arsenic is present as unintentional impurity in raw materials

Arsenic is naturally present as impurity in ores, fossil fuels, soil, plant material, etc. and may be released to the air by thermal processing/combustion of these materials. Furthermore, arsenic compounds would be present in dust formed by the processes.

The significance of the various processes can be indicated by the emission of As to the air from the various processes (even only minor part of the input of arsenic to the processes is emitted to the air). The E-PRTR (European Pollutants Releases and Transfer Register) database includes for 2015 data from 192 facilities reporting on emission of arsenic to air. The E-PRTR contains data reported annually by some 30,000 industrial facilities above the threshold for reporting. Data for industrial emissions from industrial facilities above the reporting threshold in the EU are shown below.

The major sectors included in the database, where arsenic occurs as unintentional impurity are energy sector (thermal power stations and other combustion installations), nonferrous metal production, non-ferrous crude metals from ore production and production of pig iron or steel.

Besides these processes, information on exposure to arsenic in pyrite by manufacture of sulphuric acid is available from the literature.

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[8] CN8 = Combined Nomenclature with 8 coding digits. Commodity codes used in external trade statistics.

Table 2-5: Emission of As from industrial facilities in the EU, 2015; Facilities above the E-PRTR reporting threshold

Sectors			Major subsectors		
Sector	Number of facilities (air emission)	Emission to air, t/year		Number of facilities	Emission to air, t/year
Energy sector	100	17.1	Thermal power stations and other combustion installations	93	16.4
Production and processing of metals	46	4.50	Production of non-ferrous crude metals from ore, concentrates or secondary raw materials	27	2.9
			Production of pig iron or steel including continuous casting	15	1.4
Mineral industry	32	1.73	Manufacture of glass, including glass fibre	25	1.5
Chemical industry	1	0.024			
Waste and waste water management	7	0.5			
Paper and wood production processing	6	0.2			

Source: E-PRTR at http://prtr.ec.europa.eu

Use of abrasive materials for sanding or sandblasting e.g. copper slags with unintentional content of arsenic have in the literature been reported to lead to high levels of arsenic in dust in the workplace.

4) Management of articles with arsenic compounds due to former use of the substances in articles

Historically, the main occupational exposure to arsenic in articles has been exposure to dust when working with arsenic-containing pressure-preserved wood in the construction and building sector (see section 3.5. The possible exposure by handling pressure-preserved wood will be discussed in the section with "other sectors".

Summary

Based on the available information, activities in which workers are likely to be exposed to inorganic arsenic compounds including arsenic acid and its salts as a result of their work are summarised in the table below.

Table 2-6: Relevant sectors and uses – inorganic As compounds

Sector	Intentional use of substances	Use or activity
1) Intentional use of inorganic arsenic compounds including arsenic acid and its salts within the scope		
Metal industry	Diarsenic trioxide, calcium arsenate, trilead diarsenate, arsenic metal	Purification of metal in zinc electrowinning process Manufacture of arsenic metal
Electronics sector	Diarsenic trioxide, arsenic acid,	Processing aid in gold electroplating Manufacture of semiconductors Manufacture of copper foil for printed circuit boards Manufacture of semiconductors Recycling of electronic equipment
Glass industry (incl. recycling for manufacture of glass fibre insulation)	Arsenic acid, diarsenic trioxide	Use as fining agent in the manufacture of glass Recycling of glass
Chemical industry	Diarsenic trioxide, various compounds	Manufacture of arsenic compounds Absorption and desorption of carbon dioxide in production of ammonia
Zinc industry	Diarsenic trioxide	Use in the electrowinning process
Laboratories	Various	Various uses as analytical standards
2) Formation of the substances by processes involving arsenic metal and arsenic substances outside the scope		
Metal industry	Metallic arsenic	Manufacture of arsenic alloys Use of arsenic alloys to produce batteries, ammunition, articles of brass, etc.
Recycling sector	Arsenic alloys	Recycling of articles made from arsenic alloys Welding, thermal cutting, soldering, etc.
Electronics sector	Gallium arsenide	Manufacture and use of electronics components of gallium arsenide
3) Arsenic unintentionally occurring as constituent of raw materials		
Non-ferrous metal production	Unintentional	Copper, nickel, zinc, lead, precious metal smelters Manufacture of concentrates (mining)
Coal and oil shale power plants	Unintentional	Maintenance of equipment for flue gas treatment
Chemical industry	Unintentional	Manufacture of sulphuric acid from pyrites and residues from non-ferrous production
Blasting and sanding abrasives	Unintentional	Sanding, sand blasting
4) Exposure due to former use of arsenic compounds		
Construction sector and recycling sector	Various arsenic compounds	Maintenance and recycling of wood treated with arsenic compounds
Source: RPA/COWI		

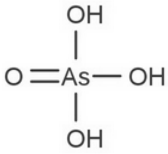
The number of exposed workforce is further described in section 3.5 but in the description of the sectors in this section, a more detailed description will be provided for sectors with the highest number of exposed workforce or the highest exposure levels (described in Section 3.3.12).

2.4 Summary of epidemiological and experimental data

2.4.1 Identity and classification

The harmonised classification of all inorganic compounds are listed in Table 2-1. The table below focuses on arsenic acid. The inorganic arsenic compounds included in the assessment are listed in Table 2-3.

Table 2-7: Identity and classification of arsenic acid

Chemical Substance	Arsenic acid
CAS-Number	7778-39-4
EC-Number	231-901-9
Sum Formula	H_3AsO_4
Synonyms	Orthoarsenic acid
Chemical Structure	
Classification (ECHA C&L Inventory, 2017)	For the index-number: 033-005-00-1 (Arsenic acid and its salt with the exception of those specified elsewhere in this Annex): Acute Tox. 3* (H301), Acute Tox. 3* (H331), Carc. 1A (H350), Aquatic Acute 1 (H400); Aquatic Chronic 1 (H410) (harmonized)
Unit Transformation	-

Sources: Data from ECHA (2017b); NLM (2017); CLP Regulation

Arsenic compounds are included in Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles).

Arsenic acid, diarsenic trioxide and diarsenic pentaoxide are included in Annex XIV of REACH ("Authorisation List").

Calcium arsenate is included in the Candidate list of Substances of Very High Concern for Authorisation. This document covers the toxicological properties of inorganic compounds of arsenic including arsenic acid and its salts, but not those of metallic arsenic. The following table summarises the chemical compounds of concern. All arsenic compounds covered are to be regarded as carcinogens. However, there may be differences with respect to carcinogenic potency as well as differences in non-cancer effect potency, which are not discriminated within the framework of this assessment. Effect concentrations are expressed in terms of As (ECHA C&L Inventory, 2017).

2.4.2 General toxicity profile, critical endpoints and mode of action

There are about 40 salts of arsenic acid, the sodium, calcium and iron salts are the most relevant.

The most common of the arsenic minerals is arsenopyrite (FeAsS), and arsenic is found associated with many types of mineral deposits, especially those including sulphide mineralisation. It has been estimated that about one-third of the atmospheric flux of arsenic is of natural origin, volcanic action being the most important natural source.

Occupational exposure mostly results from working places in mining and non-ferrous metal smelters processing arsenic-containing ores with exposure to a mixture of inorganic arsenic compounds. Arsenic exposure has also been relevant for pesticide manufacturers and operators.

The most critical endpoint of inhalation is lung cancer, and smoking had a synergistic effect. Excess cancer risk estimates have been derived from several studies on copper smelters. Several animal carcinogenicity studies on arsenic have been carried out, but limitations such as limited time of exposure and limited number of animals make these data inconclusive. Relevant non-carcinogenic endpoints of occupational exposure are neurotoxicity and cardiovascular effects. Immunotoxicity, reproductive and developmental effects have been observed in animal studies with inhalation exposure, but to date there is no evidence for such endpoints in humans exposed by inhalation.

Arsenic-bearing minerals can undergo oxidation and release arsenic to water. The primary route of arsenic exposure for the general population is via the ingestion of contaminated food or water. This exposure route is causally related to increased risks of cancer in the skin, liver, lungs, bladder and kidney, as well as other skin changes such as hyperkeratosis (a thickening of the outer layer of the skin) and pigmentation changes, as well as blackfoot disease, a severe form of peripheral vascular disease, leading to gangrenous changes[9].

In the human body, inorganic arsenic compounds are converted to As(III) and As(V). As(V) is rapidly converted to As(III) species, which are more toxic and bioactive than As(V), both because of a greater chemical reactivity and an enhanced ability to enter cells.

The mechanism of carcinogenicity is not yet clarified. Inorganic arsenic compounds do not affect DNA directly in the form of DNA-adducts or DNA-protein crosslinks (point mutations). However, they can act as a co-mutagen, enhancing mutagenicity of other agents. Clastogenic damage was observed in human and animal studies *in vivo* and *in vitro*. Reactivity of arsenicals with thiol-groups in proteins has been attributed with the inhibition of DNA repair enzymes. There is growing body of evidence that epigenetic modifications play a role: arsenic induces them both at a genome-wide level and at gene promoter regions, and is also able to induce histone modifications (methylation, acetylation, and phosphorylation of histone tails), changing the expression of several genes. Furthermore, several findings demonstrated that the exposure to arsenic induces gene-specific alteration of miRNA expression likely resulting in an impaired expression of all the genes regulated by those miRNA. Furthermore, arsenic induces oxidative stress, not by itself, but inhibition of scavenging systems of reactive oxygen species (AGS, 2011; IARC, 2012; Martinez et al., 2011).

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[9] Gangrene is a condition that occurs when body tissue dies

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

The most reliable exposure-response relationship data originated from the Anaconda smelter (Montana, USA). Lubin et al. (2000) examined 8014 white males who were employed at least 12 months before 1957 (starting from 1938) through 1957. Measurements of airborne arsenic were categorised in light, medium and heavy areas with time weighted average airborne arsenic concentrations. The mortality due to respiratory cancer was reported, including larynx and trachea tumours, but the authors stated that this may cause a deviation of only < 4% compared to lung cancer rates. 446 cases of respiratory cancer were examined. SMRs (Standardized Mortality Ratios) of 1.58 (all cases) and 1.91 (restricted data) were reported. To describe the dose-risk relationships both a power model and a linear model were applied. The linear model described the exposure risk ratio as Relative Risk = 1+0.19 x cumulative exposure. The authors calculated an excess relative risk of 0.21 per mg/m^3 x year with a 95% confidence interval of 0.10-0.46. The resulting exposure-risk relationships are reported in Section 2.5.1.

According to HCN (2012), the cohort study by Lubin et al. (2000) was evaluated as strongest study with fewest limitations and it was also used by ECHA (2017a) as key study for quantitative risk assessment. The update by Lubin et al. (2008) resulted in a similar SMR of 1.87 at a mean cumulative exposure to 5.4 mg/m^3 x years. The authors used an exposure reduction factor of 10 in the higher exposure categories to account for the use of personal protection equipment. This is an arbitrary value and it is not common practice in risk calculations. Therefore, this study was not further considered for risk assessment by HCN (2012) and others. However, the resulting risks were similar compared to the study by Lubin et al. (2000) and have been used by AGS (2011) to derive an exposure risk correlation.

There are further in-depth examinations of other smelters with exposure to arsenic. The Tacoma cohort with 2,802 workers was examined by e.g. Enterline et al. (1995), who found an overall SMR for bronchus, trachea and lung cancer of 214.1, for exposures ≥ 20 years it was 217.1. The authors calculated a regression equation of SMR = 100 + 10 x 5 (cumulative exposure)$^{0.279}$. The Rönnskär smelter cohort included 3,916 smelter workers and was examined by Järup et al. (1989). An overall SMR for lung cancer of 372 (304-450, 95% confidence interval) was calculated. An overview of further case-control and cohort studies is provided in e.g. IARC (2012). Studies on human effects of oral exposure to arsenic, e.g. via drinking water, are not considered here.

No studies were located regarding cancer in animals after inhalation exposure to inorganic arsenicals, although several intratracheal instillation[10] studies in hamsters have provided evidence that both arsenite and arsenate can increase the incidence of lung adenomas and/or carcinomas. Oral administration of sodium arsenate and dimethylarsinic acid (DMA) induced lung tumours in mice. Calcium arsenate induced lung tumours in hamsters by oral and intratracheal administration. Pre- and postnatal exposure in mice to arsenic trioxide, through subcutaneous injections (maternal and postnatal), induced lung tumours in the offspring. Transplacental exposure via maternal oral exposure in mice to sodium arsenite during gestation induced lung, liver, ovary and adrenal tumours in the offspring in several studies, and the uterus in one study. Chronic oral exposure of mice to 500 µg As(V)/l in drinking caused lung, liver, gastrointestinal tract and skin cancer (HCN, 2012; IARC, 2012).

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[10] Intratracheal instillation is the introduction of a substance directly into the trachea (tube about 4 inches long that begins just under the larynx (voice box) and runs down behind the breastbone.

Latency

Long term exposure (years) to inorganic arsenic compounds may be needed for carcinogenic outcome. Reported latency time is at least 10 years (Järup et al., 1989) or 37.6 years (Butz, 2012). For different cancer sites different latency periods are provided. The estimate of a peak latency of solid tumours at 35 years (Hutchings und Rushton, 2012) appears to be adequate for lung cancer. In this document animal data have not been assessed regarding latency, as Arsenic is classified Carc. Cat. 1A.

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

Relevant non-carcinogenic toxicological endpoints of inhalation exposure are peripheral neuropathy, cardiovascular effects and immunotoxicity. Irritating effects were documented only at higher concentrations (AGS, 2011).

Peripheral neuropathy and cardiovascular effects have been examined in workers of the Rönnskar smelter. A case-control study on 47 workers (exposed to 50 µg As/m^3 in the last 7 years before data collection, and up to 500 µg As/m^3 in former years, a total of 13-45 years) and 50 age-matched controls showed reduced nerve conduction velocity of peripheral nerves as consequence of exposure to arsenic (Blom et al., 1985). A follow-up by Lagerkvist und Zetterlund (1994) confirmed the observed effects in 43 examined workers, compared to 46 controls, showing a progression with increasing exposure duration and additionally sensoric neuropathy: the tibial motor nerve and the sural sensory nerve conduction velocities were both significantly reduced (3.0 and 3.5 m/sec compared to 1.9 and 0.9 m/sec in Blom et al. (1985), respectively. The incidences of reduced nerve conduction velocities are not reported, but symptoms possibly related to neuropathy were reported in 6/43 (joint/muscle pain) and 4/43 (numbness/paraesthesia/leg cramps) of the exposed workers compared to 0 and 1 cases in controls, respectively. A significant exposure to lead was excluded in both studies. The results of the follow-up indicate that the effects may not only be caused by the former, high exposures and point to an effect concentration of 50 µg As/m^3 (AGS, 2011). ATSDR (2001) and HCN (2012) averaged the different exposure levels and reported the results as a LOAEC[11] of 310 µg/m^3.

Another study on 70 Slovakian power plant employees exposed to 4.6-142.7 µg As/m^3 for an average of 22 years basically confirmed these results. 13 workers had symptoms of sensory and motoric polyneuropathy, 10 a pseudo-neurasthenic syndrome and 6 suffered from encephalopathy. The affected individuals showed also other symptoms of intoxication by arsenic (Buchancova et al., 1998).

Neuropathic effects of arsenic have also been reported by Sińczuk-Walczak et al. (2010). 21 workers (employed for 5-33 years as refiners of non-ferrous metals, copper electrolysers and crane operators) were exposed to current concentrations of 10 µg/m^3 in average (range 4-30 µg/m^3) at the time of examination. 16 non-exposed workers served as age-matched controls. Significant responses to motor fibre stimulation included reduced response amplitudes in the medial and peroneal nerves and a reduced conduction velocity only in the left peroneal nerve. Significant effects on sensory fibre stimulation were evident in the sensory potential amplitude of the medial, but not the sural nerves, whereas the nerve conduction velocity was significantly reduced in the sural, but not the medial nerve. The examination of the relationship between the effects and exposure parameters (duration, arsenic in air and urine) showed that only the sensory potential amplitude was significantly correlated to the arsenic concentration in air (but not urine), and the medial nerve conduction velocity to the exposure duration. The other parameters were neither correlated to internal nor external exposure, and also not to exposure duration. Therefore it can be assumed that the observed effects might be caused by former,

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[11] LOAEC: Lowest Observable Adverse Effect Concentration

higher exposures. As these are not reported in the publication, the effect exposure level is unclear. Additionally, lead as a possible confounding factor was not addressed in Sińczuk-Walczak et al. (2010).

Similar results have been obtained in a further study on this collective by Sińczuk-Walczak et al. (2014), where symptoms of neuropathy (fatigue and pain of the extremities, paraesthesia of lower extremities) were increased in the exposed workers. The workplace concentration ranged from 0.7-92.3 µg/m^3 (mean 25.2 µg/m^3), exceeding the Polish OEL of 10 µg/m^3 in 12 of the 21 examined workers. The lead burden of the workers (mean of 254.1 µg/L blood) was below the Polish Biological Exposure Index of 500 µg/L. However, the maximum burden was 469 µg/L, which is well above the German BLW of 400 µg/L (Drexler und Greim, 2006) and higher than the blood levels of < 160 µg/L reported by Lagerkvist und Zetterlund (1994). The electroneurographic results were more pronounced compared to Sińczuk-Walczak et al. (2010), showing significant results for reduced conduction velocity of left and right peroneal and sural right nerve, reduced response amplitudes for these and additionally the medial right nerve, and a standardised distal latency for all motoric nerves examined. Again, no definitely convincing correlations were found for these parameters to internal or external arsenic exposure.

Neurotoxic effects were also observed after oral exposure of rats to 0.05, 0.5 and 50 mg As/L drinking water as sodium arsenite for one year. There was hypoactivity and increases in the striatal dopamine content at the highest dose. The lower doses produced altered expression of several genes and an increased arsenic level in brain (Rodríguez et al., 2010).

The Rönnskär smelter workers (exposure conditions see above) also revealed hypotension in peripheral blood vessels and an increased prevalence to Raynaud's phenomenon. A decrease of the severity of effects after exposure reduction indicated partial reversibility (Lagerkvist et al., 1986; 1988) and was interpreted as indication of the lower exposures in the more recent years of occupation as effect concentration (AGS, 2011).

The immunotoxicity of arsenic trioxide was examined by Aranyi et al. (1985) in mice after 3 h/d inhalation exposures of 125-1000 µg As/m^3 (single, 5 days and 20 days). A reduced resistance to streptococcus infection was observed at 270 µg As/m^3 (NOAEC [12]125 µg As/m^3) after the single exposure, but only at higher concentrations after repeated exposures (LOAEC 500 µg As/m^3, NOAEC 250 µg As/m^3). The results therefore lack a progression with increasing exposure duration.

Another immunotoxicity study by Burchiel et al. (2009; 2010) exposed mice on 3 h/d for 14 days to 50 or 1000 µg As_2O_3/m^3 (MMAD[13] 2,3-2,5 µm, 19 or 379 µg As/m^3). Ex vivo cultures of splenic cells revealed a significant and dose-related suppression of the immune response to sheep erythrocytes (70% reduction compared to controls). Other parameters of immune function were not altered. The ex vivo stimulation is an unusual experimental design and therefore the results have been considered as equivocal (AGS, 2011).

With regard to the flaws of the immunotoxicity studies, they are not suitable for quantitative risk assessment (AGS, 2011).

A reduced foetal weight was observed after 4 h/d inhalation exposure of mice on gestation days 9-12 to 2200 µg/m^3 arsenic as arsenic trioxide; 21600 µg/m^3 caused increased foetal deaths, skeletal malformations and retarded growth. The NOAEC of this study was 200 µg/m^3 (Nagymajtényi et al., 1985). Due to limited documentation (e.g. lack of reporting of maternal effects) this study is less reliable. A one generation rat study could not observe developmental effects at concentrations up to 8000 µg As /m^3 as arsenic trioxide with signs of maternal toxicity (ATSDR, 2007).

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[12] NOAEC: No Observed Adverse Effect Concentration; LOAEC:

[13] MMAD: Mean mass aerodynamic diameter

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

For some of the sources of exposure to inorganic arsenic compounds, e.g. in the copper sector or by maintenance operations in other sectors, compliance to the national OELs can currently only be obtained by use of respiratory protective equipment (RPE). In this situation, it is common to use biomonitoring of inorganic arsenic compounds to assess to what extent workers are exposed to unacceptable levels of inorganic arsenic compounds. For this reason, some information on biomonitoring is added in the following.

Arsenic can be quantified in hair, nail, blood or urine samples. Total arsenic levels in hair, fingernails or toenails are used as indicators of past exposures. Because of its rapid clearing and metabolism, arsenic in blood and urine as well as urine arsenic metabolites (inorganic arsenic, monomethylarsonic acid (MMA) and dimethylarsinic acid (DMAV)) are typical indicators of more recent exposures.

The concentration of metabolites of inorganic arsenic in urine generally ranges from 5–20 µg/L, but may exceed 1000 µg/L. Occupational exposure to airborne arsenic trioxide is significantly correlated with inorganic arsenic metabolites in urine collected after a shift or just before the next shift. For example, at an airborne concentration of 50 µg/m^3, the mean concentration of arsenic derived from the sum of the three inorganic arsenic metabolites in a post-shift urine sample was 55 µg/g of creatinine. In non-occupationally exposed subjects, the sum of the concentration of the three metabolites in urine is usually less than 10 µg/g of creatinine (IARC, 2012).

The Biological Exposure Index (BEI) derived by ACGIH (2001; 2016) is 35 µg/L urine for the sum of inorganic arsenic and its methylated main metabolites methylarsonic acid and dimethylarsinic acid. This elimination is expected at exposures to about 0.01 µg/m^3, the ACGIH-TLV.

Lehnert and Greim (2003) derived a German Biological Guidance Value (BLW) of 50 µg/L urine for the sum of inorganic arsenic and its methylated metabolites. This value was orientated at the Technical Guidance Value (TRK) of 0.1 (meanwhile withdrawn), which would lead to an elimination of 130 µg/L. The TRK was not toxicologically based and was not protective to carcinogenic effects of arsenic. Non-carcinogenic effects of arsenic are not expected to occur below the BLW level. In an earlier German assessment, air concentrations of 10, 50 and 100 µg/m^3 were correlated to arsenic urine concentrations of 50, 90 and 130 µg/L, respectively (Greim und Lehnert, 1994).

A Biological Reference Value (BAR) of 15 µg/L urine for the sum of inorganic arsenic and its methylated metabolites was derived by Hartwig (2011) for Germany. This value represents the upper 95th percentile of the background burden of the general population (without fish and sea food consumption 48 h prior to sampling) from the “Umwelt-Survey” (Becker et al., 2002).

2.4.6 Different toxicological properties for various inorganic arsenic compounds

The arsenic compounds of concern may differ in their classification, but within the scope of this project there is no discrimination with regard to possible minor differences in carcinogenic and non-carcinogenic potency.

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

2.5.1 Inorganic arsenic compounds including arsenic acid and its salts

There is no derived OEL, based on carcinogenicity, to be used as a starting by either SCOEL or ECHA/RAC. However, ECHA (2017a) provides a linear risk estimate in the range of 0.01 µg/m^3 (risk of 1.4 x 10^{-6}) to 10 µg/m^3 (risk of 1.4 x 10^{-3}) for inhalable dust.

For non-cancer effects no OEL has been derived. However, ECHA (2017a) refer a peripheral neuropathy as a relevant toxicological endpoint. From the assessment by AGS (2011) a respective Lowest Observable Adverse Effect Concentration (LOAEC) of 50 µg/m^3 is adapted and used as a starting point to quantify a DRR for neuropathic effects.

No STEL is derived by ECHA (2017a). No "skin notation" is assigned.

No Biological Limit Value (BLV) is derived, but a Biological Guidance Value (BGV) of 10 µg As/L is reported.

Discussion

Unanimously carcinogenicity is regarded as critical endpoint for inorganic arsenic compounds including arsenic acid and its salts. Although primary genotoxicity is not a major mode of action for carcinogenicity of inorganic arsenic compounds, a linear ERR is generally assumed in existing assessments. For further discussion on the respective exposure response relationship (ERR) see Section 2.5.2.

Because of the high potency of this effect non-cancer endpoints are not usually discussed quantitatively. Therefore, in this assessment, the potency of non-cancer effects had to be assessed with no starting point from existing OEL-data. For further discussion on the respective dose response relationship (DRR) see Section 2.5.3.

2.5.2 Carcinogenic effects

Approach

ECHA (2017a) provides an excess risk for lung cancer from occupational lifetime exposure (40 years) to inorganic arsenic compounds of **1.4 x 10^{-4} per µg As/m^3 (**which is adapted in this assessment as exposure risk relationship (ERR). This ERR is associated with exposures to the inhalable particle fraction.

Table 2-8: The derived ERR	
Excess risk (entire range, inhalable)	**y=0.00014x [µg/m^3]**

The ERR is presented graphically in Figure 2-1:

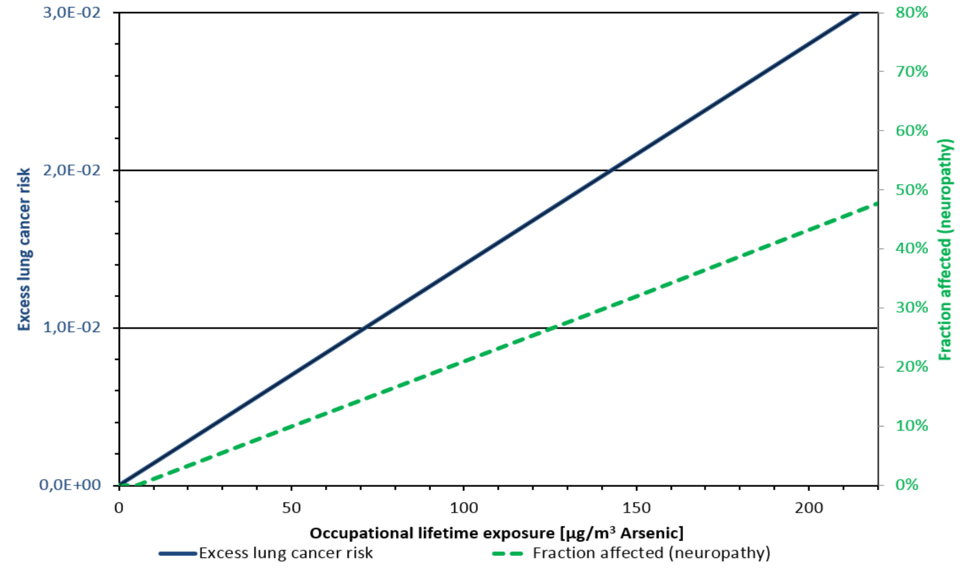

Figure 2-1: Exposure Risk Relationship (ERR) for lung cancer (left y-axis) and Dose Response Relationship (DRR) for non-cancer effects (right y-axis) from occupational exposure to inorganic arsenic compounds (inhalable fraction)

Discussion

Available mechanistic data suggest a non-stochastic mechanism for the carcinogenicity of arsenic. Therefore, an occupational exposure limit could be derived in principle, but the epidemiological and experimental studies, which are available to date, do not allow the derivation of a numerical threshold value (dose or concentration). Thus, according to ECHA (2017a) and other organisations, a linear extrapolation procedure is used.

The derived ERR as well as the risk assessments reported in Section 3.2.1 refer to an exposure to inhalable dust. However, some national OELs are linked to exposure quantifications as “total dust”. This indicates that possibly sampling in various epidemiological studies on arsenic exposure was performed with filters, which underestimated the “inhalable” fraction. However, no transformation factor is available and assessments by committees knowledgeable in OEL assessment have quantified the ERR linked to the inhalable fraction. Therefore, this approach is adapted in this assessment.

It is evident from Table 3-1 that the domain of inorganic arsenic compounds including arsenic acid and its salts covered by the respective OELs or risk quantifications varies (e.g. arsenic acid and its salts *or* arsenic and compounds, except arsine).

2.5.3 Non-carcinogenic effects

The starting point for the consideration of non-carcinogenic endpoints is a LOAEC of 50 µg/m^3 in occupational exposure for neurotoxic effects. This LOAEL is based on the study by Lagerkvist und Zetterlund (1994) as discussed by AGS (2011). From this a threshold is estimated considering usual extrapolation procedures (ECHA, 2012a; ECHA, 2012). No qualified data exist to quantify the slope for an increase in the affected fraction above 50 µg/m^3. Therefore, a linear increase was assumed to be supported by scarce and uncertain effect data reported at higher concentrations. Overall the following DRR is established:

Table 2-9: Derived DRR	
Concentration [µg As/m³]	**DRR-equation (fraction affected, neurotoxicity)**
5	Threshold, zero effect
50	10% affected fraction
[5- 300]	**y [% affected] = 0,222x - 1,111** **y [fraction affected] = 0.00222x – 0.0111** e.g., at 150 µg/m³ = ca. 32%

The DRR presented graphically in Figure 2-1 (above).

Discussion

As indicated, the LOAEC for neurotoxicity was adapted from Lagerkvist und Zetterlund (1994) as discussed by AGS (2011). At the LOAEC of 50 µg/m³ the fraction of the exposed experiencing neurotoxic effects is assumed to be about 10%. However, in the original study and in many other assessments a higher LOAEC (310 µg/m³) is reported because of earlier much higher exposures in respective workers (Blom et al., 1985). However, in more recent studies (Sińczuk-Walczak et al., 2014; Sińczuk-Walczak et al., 2010), as reported by ECHA (2017a), at even lower concentrations of about 25 µg/m³ occupational exposure neurotoxicity is reported. This lower concentration was not regarded suitable to establish a lower LOAEC (because of potential mixture effects from lead exposure), but is supportive of the LOAEC of 50 µg/m³.

Because of the uncertainties with a possible higher LOAEC at 310 µg/m³ and the indications of effects at lower concentrations, we applied a reduced factor of 2 (instead of a default of 3) to estimate the NOAEC for the exposed group. In order to protect sensitive individuals an intraspecies variability factor of 5 was applied according to ECHA (2012). Therefore, we derived a threshold (potential OEL for non-cancer effects) of 5 µg/m³ based on neurotoxic effects at 50 µg/m³.

In the study by Buchancova et al. (1998) at long term exposures to < 150 µg/m³ a significant fraction (29 of 70 workers) experienced different neuropathological diseases. Because of the large range of exposures, because of possible influence of peak exposures and because of different neurologic endpoints, this fraction of about 40% at or below 150 µg/m³ may not directly be used to establish a DRR. However, these observations support a linear extrapolation to higher concentrations from the low exposure range as applied in this assessment.

No DRR is proposed for exposure concentrations above >300 µg/m³ because of crucial uncertainties at extreme long term exposure levels.

It is obvious that the estimation of a DRR up to 300 µg/m³ also implicates uncertainties, but further endpoints (cardiovascular effects and immunotoxicity, not quantitatively considered within this report) were evident at comparable or slightly higher concentrations (AGS, 2011).

2.5.4 Skin Notation

No skin notation for inorganic arsenic compounds including arsenic acid and its salts is assigned, as there is no concern of a relevant dermal absorption, (AGS, 2011; ECHA, 2017; HCN, 2012).

2.5.5 Short-term limit value (STEL)

No STEL was derived by ECHA (ECHA, 2017). Some countries have different OEL and/or STEL for differing arsenic compounds, e.g. in Denmark for generic arsenic and compounds, except arsine (OEL: 0.01 mg/m^3, STEL: 0.02 mg/m^3) and calcium arsenate (OEL: 1 mg/m^3, STEL 2 mg/m^3). Hungary differentiates 3 STELs, and the Netherlands between soluble and insoluble salts of arsenic acid (for details, see Table 3-1. Within the scope of this project, no STEL was derived; a dose response relationship for peak exposures is not assessed.

2.5.6 Biomonitoring values

For this impact assessment, no dose response with regard to biological monitoring data for cancer or non-cancer effects has been derived. However, several national OEL-systems provide BLV or similar reference values; ECHA (2017a) provides a Biological Guidance Value (BGV).

2.6 Reference OELVs

SCOEL - The Scientific Committee on Occupational Exposure Limits (SCOEL) is still in the process of drafting a recommendation for arsenic and its compounds (planned as SCOEL recommendation No 193).

ACSH - The Advisory Committee on Safety and Health at Work concludes in its opinion (ACSH, 2017):

- "*The three interests groups agreed on the need for an EU OEL for arsenic acid and its salts as well as inorganic arsenic compounds under the scope of the CMD of 10 µg/m^3 (TWA 8 hrs measured as arsenic) inhalable fraction. However after a preliminary assessment for one specific sector, copper smelting, it is currently not technically achievable to comply with.*

- *In addition the Commission Impact Assessment may identify other sectors which are in a similar situation. For all these sectors a prolonged transitional period may be necessary.* "

Furthermore, it is indicated that the ACSH strongly recommends the Commission to adopt as soon as possible binding occupational exposure limit values for this substance under Directive 2004/37/EC.

The objective of the study is to provide a comparison of the costs and benefits for a range of potential OELVs.

Specific values have, however, been established for the purposes of the consultation exercise to provide reference points to the consultees who may otherwise find it impossible to provide data on the costs of the measures being considered. The reference points for inorganic arsenic compounds including arsenic acid and its salts are summarised below.

Assessed OELV - The study assesses the impacts of an OELV for inorganic arsenic compounds including arsenic acids and its salts at three levels:

- OELV at the level suggested by the ACSH: 10 µg/m^3

- OELV at close to the average of the OELs in the EU MS: 50 µg/m^3

- An OELV in between at 25 µg/m^3.

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: Exposure concentrations
- Section 3.5: Exposed workforce
- 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 authorisations or restrictions
- Section 3.11: Market analysis
- Section 3.12: Alternatives
- Section 3.13: Current and future burden of disease

3.2 Existing national limits

3.2.1 OELs

Current OELs for inorganic arsenic compounds including arsenic acid and its salts were established in the range of 2.8 and 200 µg/m^3 measured as As (Table 3-1), with an outlier of 1,000 µg/m^3 (Denmark for a single arsenic compound, calcium arsenate, only). However, beyond fixed OELs some authorities provide excess cancer risk quantifications associated with exposure levels. If only small risks are tolerated within the regulatory framework of a country, such a "risk based" OEL could possibly be associated with exposure concentrations of less than 2.8 µg/m^3 (see discussion below). For example, ECHA did not fix a risk level, but only describe excess risk associated with different exposure concentrations.

The background of most OELs is not known, as only a few background documents could be traced within the framework of this analysis. Moreover, many countries do not establish their own OEL, but adapt an OEL from other countries and therefore would not be in the position to provide background documents. However, most – if not all – of the existing OELs apparently find carcinogenicity of arsenic compounds being the most critical health endpoint and, accordingly, link their OEL to cancer risk.

This argument is predicated on early established OELs, which are in the same range (in mg/m^3) as most of the current OELs for this group of compounds. Already in 1986, the American Conference of Governmental Industrial Hygienists derived an OEL of 200 µg/m^3 for "arsenic and soluble compounds" (ACGIH, 1986). The U.S. OSHA (Occupational Safety and Health Administration) reported an OEL of 10 µg/m^3 for "arsenic and all inorganic compounds containing arsenic except arsine" in 1998 (probably derived much earlier)[14], which still remains the current OEL in USA. Both values, which reflect the

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[14] https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10024

current interval of OELs for arsenic compounds, were derived to reduce cancer risk from occupational exposure to this group of compounds.

Sometimes, the range of arsenic compounds covered by the OELs differs between countries and, in single instances, arsenic compounds are grouped according to their water solubility. However, no apparent and unambiguous discrimination of OELs can be observed with regard to the critical target organs, toxicological endpoints or potency.

ECHA, the Netherlands, Germany and Japan provided ranges of concentrations associated with differing cancer risk levels, which may be linked to an OEL, or to a "tolerable" or "acceptable" risk level, or just provide potency information. For example, in the Netherlands the Social and Economic Council of the Netherlands (SER) fixed an OEL of 2.8 µg/m^3 (corresponding to a cancer risk of 4 x 10^{-4})[15] in 2014/2015, considering socio-economic and acceptability criteria. This OEL is based on the range of risk estimates provided by HCN (2012) with a range of 0.28 to 28 µg/m^3 associated with risk levels of 4 x 10^{-3} and 4 x 10^{-5}, respectively.

For a direct comparison, the risk estimates are expressed as excess risk per 1 µg As/m^3 of occupational lifetime exposure:

The Netherlands/ECHA (RAC):	1.4 x 10^{-4}
Japan:	3.3 x 10^{-4}
Germany:	4.8 x 10^{-4}.

The background for these risk estimates is provided below. All quantitative cancer risk estimates were derived from epidemiological studies and indicate similar potency assessments. No systematic difference between the OELs and cancer risk estimates in Europe or in the competitor countries is observed.

Existing OELs are either linked to the inhalable fraction of particles or to total dusts, with no apparent consequence for the potency estimate.

As far as background documents are available, the data and methods used to derive an OEL or a risk estimate may be described in more detail.

AGS (2011)

AGS (2011) estimated excess risks of cancer risk of 4 x 10^{-3} and 4 x 10^{-4} for a 40 years exposure to arsenic at 8.3 and 0.83 µg/m^3, respectively (corresponding to a risk of 4.8 x 10^{-4} for a 40 years exposure to 1 µg/m^3). This estimate was based on the study by Lubin et al. (2008), see also Section 2.4.3. The overall risk based on the total of 446 lung cancer cases was 1.56 (1.4-1.7) at a mean exposure to 3,700 µg/m^3 x years. Based on 261 lung cancer cases with a more precise exposure definition, a SMR of 1.87 (95% confidence interval 1.7-2.1) for a mean cumulative exposure to 5,400 µg/m^3 x years resulted. The latter value was used by AGS (2011) for the risk estimate. The SMR is close to that of 1.58 (all data) - 1.91 (better defined cases) reported by Lubin et al. (2000). Lubin et al. (2008) used an exposure reduction factor of 10 in the higher exposure categories to account for the use of personal protection equipment. HCN (2012) and ECHA (2017a) considered this an arbitrary value, not used in common practice in risk calculations.

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[15] https://www.ser.nl/en/grenswaarden/arseentrioxide%20%20als%20as.aspx

https://www.ser.nl/en/grenswaarden/arseenpentoxide%20%20als%20as.aspx

https://www.ser.nl/en/grenswaarden/arseenzuur%20%20wateronoplosbare%20zouten%20%20als%20as.aspx

accessed December 2017

HCN (2012)/ECHA (2017a) and an earlier assessment by RIVM (2001)

ECHA (2017a) adopted the risk assessment by HCN (2012), which used the results of the study by Lubin et al. (2000), see also Section 2.4.3. The update (Lubin et al., 2008) was not considered for risk assessment due to reasons mentioned above. Based on the function Relative Risk = 1+0.19 x cumulative exposure HCN (2012) calculated excess risks of 4 x 10^{-3} and 4 x 10^{-5} for 40 years of occupational exposure to 28 µg/m^3 and 0.28 µg/m^3, respectively. The Social and Economic Council of the Netherlands (SER) fixed an OEL of 2.8 µg/m^3 (corresponding to a cancer risk of 4 x 10^{-4}) in 2014/2015, considering socio-economic and acceptability criteria.

In an earlier Dutch risk assessment RIVM evaluated arsenic 1999 as threshold carcinogen and derived a tolerable concentration in air of 1 µg/m^3, based on the lowest concentration of 10 µg/m^3 for a significant increase in SMR (Standardised Mortality Ratio) for lung cancers (Baars et al., 2001).

USA, ACGIH

ACGIH (2001; 2016) derived a TLV (Threshold Limit Value) based on the results from the Tacoma smelter (Enterline, 1987). According to the authors the lowest human carcinogenic level (SMR of 213) was 0.2 µg/m^3, and "to allow some measure of safety", the TLV of 0.01 µg/m^3 (as arsenic) was derived (factor of 20). It can be assumed that no exposure-risk relationship was established.

The basis for the OEL (for which background documents are available) is the endpoint carcinogenicity.

Limit values of all relevant arsenic compounds are presented in Table 3-1.

3.2.2 STELs

There are no reliable data with regard to effect levels of short-term effects in occupational exposure. The STELs (if derived) are higher than the 8 h TWA (time weighted average) OELs by a factor of 2 to 8, see Table 3 1. No detailed comparative analysis is performed, because respective justifications are mostly not publicly available. The value of 66 µg/m^3 (inhalable fraction) as a STEL in Germany, listed in IFA (2017a) was not confirmed in the substance specific documentation (AGS, 2011).[16]

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[16] A more recent version of this assessment is documented: https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/910/910-arsenverbindungen.pdf?__blob=publicationFile&v=2, assessed December 2017

Table 3-1: OELs for inorganic arsenic compounds including arsenic acid and its salts for EU Member States and selected non-EU countries

Country	Value [mg/m^3] (I) inhalable; (T) total particulate; (R) respirable	Specification of value‡ (year)	OEL definition	Study details	STEL [mg/m^3]	Specification of STEL‡
Austria	0.1 (I)		SE/T	Not known or not reported	0.4 (I)	
Belgium	0.01 (I)		SE/T		-	n.a.
Bulgaria	0.05		SE/T		-	n.a.
Croatia**	0.1	-SKIN notation only for AsO_3 and As_2O_3	SE/T		-	n.a.
Cyprus	0.01	-SKIN	SE/T		-	n.a.
Czech Republic	0.1		HB		0.4	-ceiling
Denmark	1 0.01 (T)	-calcium arsenate -other inorg. As compounds	SE/T		-	n.a.
Estonia	0.03		SE/T		-	n.a.
Finland**	0.01 (I)	$^+$	SE/T		-	n.a.
France§§	0.2	-$As_2O_3^+$	SE/T		-	n.a.
Germany^2	8.3 µg/m^3 (I) 0.83 µg/m^3 (I)	-“tolerable risk”* -“acceptable risk” (2011)	HB	Lubin et al. (2008) Endpoint: carcinogenicity respiratory cancer Species: human data, cohort study	-	n.a.
Greece	0.1		SE/T	Not known or not reported	-	n.a.
Hungary	0.03 0.1 0.01	-As_2O_5, SKIN -As_2O_3, SKIN -other inorg. As compounds, SKIN	HB		-	n.a.
Ireland	0.01 (T)		HB		-	n.a.
Italy	-		SE/T		-	n.a.
Latvia	0.01	$^+$	SE/T		0.04	-15 min
Lithuania	0.03		SE/T		-	n.a.
Luxembourg	-		n.a.		-	n.a.
Malta	-		n.a.		-	n.a.
Netherlands^3	0.0028 [Excess cancer risk: 4 x 10^{-4} - 0.0028 mg/m^3]	(2012)	SE/T	Lubin et al. (2000) Endpoint: carcinogenicity respiratory cancer Species: human data, cohort study	-	n.a.
Poland	0.01 (I)		HB		-	n.a.

Portugal**	0.01		HB	Not known or not reported	-	n.a.
Romania	0.01		Not known		0.1	
Slovakia	0.1 (I)		SE/T		-	n.a.
Slovenia	0.1 (I)	-H_3AsO_4 plus salts	SE/T		0.4 (I)	-H_3AsO_4 plus salts
Spain	0.01 (T)		SE/T		-	n.a.
Sweden	0.01 (T)		SE/T		-	n.a.
United Kingdom	0.1 (T)	-SKIN	SE/T		-	n.a.
SCOEL**	-		n.a.		-	n.a.
ECHA[4]	Excess cancer risk: e.g.: 1.4 x 10^{-3} - (0.01 mg/m^3)	(2017)	HB	based on risk assessment by HCN (2012) Lubin et al. (2000) Endpoint: carcinogenicity respiratory cancer Species: human data, cohort study	-	n.a.
Selected non-EU countries						
Australia	0.05 (T)		Not known	Not known or not reported	-	n.a.
Brazil	-		n.a.		-	n.a.
Canada, Ontario	0.01 (T)		Not known		0.05	
Canada, Québec	0.1 (T)		Not known		-	n.a.
China	0.01 (T)		SE/T		0.02	-15 min
India	0.2	-soluble compounds	Not known		-	n.a.
Japan, JSOH**	0.003 [Excess cancer risk: 1 x 10^{-3} - (0.003 mg/m^3); 1 x10^{-4} (0.0003 mg/m^3)]		HB		-	n.a.
South Korea[1]	0.01 (T)		SE/T		-	n.a.
USA; ACGIH[5],**	0.01 (T)		HB	(Enterline, et al., 1987), Endpoint: carcinogenicity respiratory cancer Species: human data, cohort study	-	n.a.
USA, OSHA[6]	0.01 (T)		SE/T	Not known or not reported	-	n.a.
USA, NIOSH**	#		SE/T		0.002	-ceiling, 15 min

‡ inorganic arsenic compounds including arsenic acid and its salts, arsine exempted, for all occupations, as As, 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 are recognised values – not according to decree modified on 30 June 2004 – thus not legally binding.
** In Germany, this concentration is not regarded as a fixed OEL (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, i.e. "tolerable risk level": usually 4:1000 excess risk. However, exposures below the "tolerable risk level" but above the "acceptable risk level" need to be minimised in order to avoid cancer risk.*
 # No value 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 (https://www.cdc.gov/niosh/npg/nengapdxa.html).

References:
Questionnaire information (this project) or GESTIS (IFA, 2017), or recent country specific lists of OEL from web-search, if not stated otherwise (references 2-6, below).

1: IFA (2017) Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung. GESTIS - Internationale Grenzwerte für chemische Substanzen.
2: AGS (2011) Ausschuss für Gefahrstoffe. Positionspapier des AK Metalle im UAIII: ERB-Begründung zu anorganischen Arsen-verbindungen.
3: HCN (2012) Health Council of the Netherlands. Health-Based Calculated Occupational Cancer Risk Values. Arsenic and inorganic arsenic compounds.
4: ECHA (2017) Committee for Risk Assessment RAC. Opinion on Arsenic acid and its inorganic salts.
5: ACGIH (2001; 2016) American Conference of Governmental Industrial Hygienists. Arsenic and its inorganic compounds.
6: OSHA Online: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10024 (accessed: 10 November, 2017).

3.3 Relevant sectors, uses, and operations

3.3.1 Overview

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 the exposures please refer to Section 2.

3.3.2 Glass sector

Production of glass is together with the electrowinning of zinc the major application of arsenic compounds. Two arsenic compounds are used in significant quantities: **arsenic acid** and **diarsenic trioxide**. Both substances are used as fining agents in the production of glass. The substances can, according to Glass Alliance Europe, be used interchangeably in the glass sector (GAE, 2012).

Based on consultation with the umbrella association Glass Alliance Europe and the sub-sector organisations EDG/ICF (European Domestic Glass Committee; International Crystal Federation) and ECGA (European Special Glass Association), the arsenic compounds are mainly used in the production of special glass and domestic glass. The arsenic compounds are not used in the two major glass sub-sectors: container glass and flat glass (for windows).

It has not been possible to obtain information from manufacturers of the arsenic compounds on the distribution of the consumption between the two sectors or to obtain information on the number and size of companies using the substances (considered confidential information).

Arsenic acid. The total registered tonnage of arsenic acid is 100-1000 t/year. According to the draft background document for arsenic acid, about 97% of the total tonnage of arsenic acid is used as fining agent in the manufacture of speciality glass for removing bubbles from the glass melt (ECHA, 2012b). The addition of arsenic acid releases oxygen late in the fining process which makes the bubbles more easily absorbed by the melt.

The application is further described by Glass Alliance Europe (2012) as follows:

> "*Arsenic acid is a raw material used to produce different kinds of glass, mainly domestic glass and special glass (e.g. pharmaceutical glasses, optical glasses, display glass, glass-ceramics,…). It participates in the chemical reactions to create the glass network and is completely consumed in the new substance glass (N.B.: the arsenic does not evaporate, and stays in the substance glass) and therefore contributes to the functional structure of the new substance. During the chemical reaction it contributes to the generation the oxygen bonds between the elements. In addition, by a redox reaction, it thereby also releases gaseous oxygen that helps to remove bubbles in the glass.*"

Diarsenic trioxide. Diarsenic trioxide is used in the manufacture of lead crystal and special glass as well as the decolourisation of glass (DHI/RPA, 2010; ECHA, 2016). According to DHI/RPA (2010), overall, the estimate for EU usage of diarsenic trioxide in glass processing has been taken as 1,000 t/year, most of which is used for the production of special glass. Contrary to this, ECHA (2010) estimates that 100-150 t/year of diarsenic trioxide was used for glass on the basis of comments to the draft document. The differences may reflect an actual decline in the use of the substance for glass production and that the documents extrapolate from data from different years.

Typically, about 0.3 wt% arsenic oxides are added to the batch, although for some glass types up to 1.5 wt% arsenic trioxide may be used (IARC, 2009).

Special glass

According to information from industry, arsenic compounds are in particular used for the manufacture of optical glasses, glass-ceramics (e.g. for glass ceramic hobs), pharmaceutical glasses, and display glass. The use is by the industry considered as use as intermediate and the application is not subject to authorisation (Glass Alliance Europe, 2012).

According to the BAT (Best Available Techniques) document for the glass sector[17], certain glass compositions may involve the use of specialised refining agents such as oxides of arsenic and antimony; and some optical glasses can contain up to 35% fluoride and 10% diarsenic trioxide (JRC, 2013).

No data are available on the number of special glass producers using arsenic compounds. The E-PRTR database includes 21 companies in the sector "Manufacture of glass, including glass fibre" with reported arsenic emission above the threshold, but a number of these are manufacturers of glass fibre insulation or container glass. The source of arsenic may be the fuel if coal is used, but according to the BAT document for the glass sector it is uncommon to use coal as fuel (JRC, 2013).

ECGA (European Special Glass Association) has for this study informed that its members use arsenic in the production, but the companies have not been in a position to provide data to the study. The use of arsenic compounds has been confirmed for at least four major producers of special glass.

The processes described that may lead to exposure to inorganic arsenic compounds are according to feedback from the stakeholder consultation:

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[17] Throughout this report references are made to the Best Available Techniques (BAT) Reference Document for the various sectors prepared by the Joint Research Centre (JRC) in the context of the Industrial Emissions Directive 2010/75/EU.

- Raw material delivery and storage;
- Preparation and mixing;
- Furnace operation;
- Maintenance, cleaning and waste management.

Domestic glass

Arsenic has been used for centuries to endow artistic glass with a particularly fine clarity and as a refining and decolouring agent (Trouth, 2014).

According to the BAT document for the glass industry (JRC, 2013), the domestic glass sector used different types of refining agents and oxidising agents: nitrates, sulphates, and in some specific cases arsenic and antimony compounds (typically As: 0.1 – 1% and Sb: 0.1 – 0.4% of the batch) and cerium compounds (0.2 – 0.5% of the batch). Selenium was also used as a decolourising agent and is typically <0.005% of the batch composition (JRC, 2013).

According to the European association for the domestic glass subsector, EDG/ICF, none of its 14 members use arsenic compounds today. Furthermore national associations in Germany, France, and Czech Republic and a regional association in Italy (Veneto region) have been contacted, but the associations were not aware of any use of arsenic for domestic glass. A representative of an Italian association from the Veneto Region informed that it could not be excluded that arsenic was still used to some extent in the region around Napoli. Furthermore, the national Italian association of glass manufacturers, Assovetro has been contacted in order to clarify if diarsenic trioxide is still used in the Italian glass sector, but no answers has been obtained.

Actual use of arsenic compounds in this sub-sector has only been confirmed for domestic glass production in Northern Italy (Veneto region) where it has been widespread, but is no long used.

Apostoli et al. (1998) described six glass factories in Northern Italy producing art glass in the late 1990's. Of the six companies, three used diarsenic trioxide as a fining agent, whereas the other three used antimony compounds for the same purpose. The consumption of the latter three factories is reported as follows:

- Art painted glass: 280 t glass per month; 7.0 t diarsenic trioxide;
- Partially automated: 120 t glass per month; 8.8 t diarsenic trioxide;
- Partially automated painted; 90 t glass per month; 3.5 t diarsenic trioxide.

In total these three plants used 231 t diarsenic trioxide per year. It is reported by an ECHA Newsletter (Trouth, 2017) that in 2014, 18 companies were using arsenic trioxide for production of art glass in the Murano district (in Veneto Region). Trouth (2017) does not report on the size of the companies and consequently the consumption data for the three companies reported by Apostoli et al. (1998) cannot be extrapolated to a total for the sector in Northern Italy, but the data could indicate that the total consumption of diarsenic trioxide in the factories in the late 1990's would be well above the 231 tonnes reported for the three companies.

Montagnini et al. (2006) reported that in 2006, arsenic trioxide was still used in handmade glass production in Murano, but many industries had reduced its use, but in some specific lines of production there was still a considerable use.

According to Trouth (2017), the Italian Ministry of Health and ECHA concluded that using arsenic trioxide as a refining agent could not be considered as an intermediate use and an authorisation would be required. No application for authorisation was submitted, and Italian enforcement inspector warned the glassmakers not to use the substance after the sunset date of 21 May 2015.

Information was gathered on 300 companies producing glass in Venice. Of these, 104 companies were producing artistic glass and 18 of these (17.3%) were using arsenic trioxide in 2014 (Trouth, 2017). According to the Newsletter, 8 tonnes of diarsenic trioxide was used at that time.

An inspection campaign in 2015 and 2016 found two glass producers still using arsenic trioxide to produce their glass products. The programme of inspections will continue during 2017.

Manufacture of glass insulation materials

Among the main emitters of arsenic within this sector as reported to the E-PRTR are manufacturers of glass fibre insulation materials produced from recycled glass. Recycled glass may contain special glass and domestic glass with a content of arsenic. However, the emitted arsenic may to some extent also originate from the used fuels.

The European Insulation Manufacturers Association, EURIMA has been approached specifically and requested to distribute the questionnaire to its members, but no answers have been obtained. As the arsenic compounds, contrary to the use in special and domestic glass production, are not handled in the process, but the arsenic is present in very low concentration in the glass, it is assumed that the exposure levels will be low in comparison to the exposure levels reported from the glass production with intentional use of arsenic, and the activities has not been further assessed.

Recycling of glass

Recycled glass is to some extent used to produce other types of glass such as container glass which is reflected in emission of arsenic to the atmosphere reported to the E-PRTR from companies not intentionally using arsenic for production of glass. Two Portuguese glass manufacturers contacted as part of the stakeholder consultation confirmed that arsenic compounds was not used even though significant emission of arsenic was reported to the E-PRTR from the companies. The companies did not hold any data on arsenic content of recycled glass used or arsenic in the workplace. It is assumed that the exposure levels will be low as compared with the exposure levels reported from the glass production with intentional use of arsenic, and the activities has not been further assessed.

Use in enamels

According to ECHA (2016) diarsenic trioxide is used in small quantities in enamels. The information originates from DHI/RPA (2009) which however notes that no reliable data on the usage of diarsenic trioxide in verifiable enamels have been located. No other information on the use of arsenic compounds in enamel is available; during the stakeholder consultation it has not been possible to obtain any information on the use of arsenic compounds in enamel. It has not been possible to verify the use from the Arsenic Consortium or Arsenic Acid Consortium. Furthermore, it has not been possible to identify any literature addressing exposure to arsenic in the manufacture of enamels. If the substances are used for this application today, the application is assumed to be small as compared to the use in the manufacture of glass, and the application has not been further assessed. Data from the German

MEGA database (further described in section 3.3.12) does not demonstrate any significant exposure level in the ceramics industry.

3.3.3 Electronics sector

Arsenic compounds are used for various applications in the manufacture of electronic components and printed circuit boards. Exposure by inhalation may take place by the use of the substances for the manufacture of the components, whereas the exposure by the later use of the components and printed circuit boards for production of electronics is considered insignificant.

Manufacture of copper foils

Authorisation has been granted for use of arsenic acid in the treatment of copper foil for the manufacture of printed circuit boards by one company. According to the dossier, the company use no more than 3.2 t/year (Circuit Foil, 2015).

As described by RAC (2017a), the application for authorisation relates to the production of a wide range of different electro-deposited copper foils used in the manufacturing of printed circuit boards. The copper foils undergo a sequence of chemical and electrochemical processing steps to gain special surface qualities.

Arsenic acid and other additives are used to control the electrolytic treatment in the manufacturing process of the copper foils. This treatment is applied to increase the adhesion of the copper foil (by roughening the surface) to the glass fibre. The final product, the copper foils, does not contain arsenic acid. Any arsenic acid is removed from finished articles by rinsing.

Gold plating of circuit boards

Authorisations has been granted to the use of diarsenic trioxide (in a mixture) in a semi-closed process for the electrolytic pure soft gold plating of flexible etched circuitry. The substance is used as grain refiner for gold plating to ensure uniform and homogenous gold thickness on the etched circuits and good plating quality with high current density conditions.

Manufacture of semiconductors

According to stakeholder input from the European Semiconductor Industry Association (ESIA) the European Semiconductor Manufacturing Industry uses some inorganic arsenic compounds in gaseous form and in small amounts in the semiconductor manufacturing process. Arsenic has been used as a dopant in the silicon based semiconductor industry for decades now. According to ESIA, there is no potential exposure to the worker during normal and routine semiconductor manufacturing as the trace amounts of arsenic compounds are within a closed system manufacturing equipment tool (allowing complete reaction of the arsenic compounds), itself within a clean room environment. Some exposure at low levels may take place by cleaning and by preventive maintenance. The number of workers involved in these maintenance procedures has not been reported.

Another application within the electronics industry is the production of gallium arsenide wafers and its down-stream uses. Semi-insulation gallium arsenide wafers are produced by reacting gallium and ultrapure metallic arsenic as the main components. The wafers are supplied to other facilities where they undergo a deposition of a crystalline overlayer on a crystalline substrate process to form layer stacks (Al/Ga/In/As/P/N) compounds. These compounds are further used by device manufacturers to produce opto-electronics, LED, solar cells and a number of other electronic components. The components are subsequently used by original equipment manufacturers to produce mobile phones, WIFI, radar, solar cells, etc. ECHA (2010) indicates that 30-40 t/year disarsenic trioxide in 2010 was used for manufacture of ultrapure arsenic metal for the manufacture of gallium arsenide wafers and other components for the opto-electronics industry.

The main occupational exposure to inorganic arsenic compounds including arsenic acid and its salts (other than the gallium arsenide) is expected to be at the stage of manufacture of the gallium arsenide from ultrapure arsenic metal. Some exposure may, by the downstream uses, take place by specific maintenance procedures.

The supply chain for the gallium arsenide wafers is as follows:

1) Manufacture of disarsenic trioxide (nonferrous base metal industry, Section 3.3.7);
2) Manufacture of ultrapure arsenic (manufacturer of ultrapure metals, Section 3.3.7);
3) Manufacture of gallium arsenide wafers (electronics industry);
4) Manufacture of layer stacks (Al/Ga/In/As/P/N) compounds (electronics industry);
5) Manufacture of electronic devices (electronics industry);
6) Manufacture of electronic equipment (electronics industry).

Potential occupational exposure to arsenic substances within the scope of this study would mainly be within the first four stages of the supply chain.

3.3.4 Chemicals sector

Diarsenic trioxide and arsenic acid is manufactured as a by-product by two EU companies by recovery from waste products from the production of non-ferrous metals; this manufacture is included in Section 3.3.7 on other non-ferrous metals.

About 60 tonnes was used in the chemicals sector for production of other arsenic chemicals and the ultra-pure arsenic metal (ECHA, 2016). The available information indicates that the majority is used for the manufacture of ultra-pure arsenic metal. As this application is a use as intermediate, it is not subject to authorisation.

No detailed information on exposure to arsenic from the production of other arsenic compounds is available. Some production of arsenic compounds in volumes below the 1 t/year probably takes place by some manufacturers of laboratory standards and specialty chemicals. These compounds are used as analytic standards and possibly some small special applications of arsenic compounds other than those registered.

Export notification under the PIC Regulation for 2017 includes the following arsenic compounds or mixtures: various pesticides for ants (with sodium dimethyl arsenate), diarsenic trioxide (partly as analytical standards), sodium meta-arsenite (analytical standard), "Tellurkonzentrat ex Harris" (?), Osmose K-33 (60%) (wood preservative), CCA C60 wood preservative (with diarsenic pentaoxide). Apart from sodium meta-arsenite analytical standard, all exported arsenic substances within the scope of this study are included in Table 2-4. The export notifications are from Belgium, France, Germany, Spain and the UK. Laboratory standards and specialty chemicals produced in volumes of less than one tonne per year are expected to be produced under strictly controlled conditions and the possible exposure to inorganic arsenic compounds of a very limited number of workers has not been assessed further.

Two of the salts, **calcium arsenate** and **trilead diarsenate** are used as intermediates in the "manufacture of basic metals, including alloys" according to their REACH registrations. The same substances may be present in flue gas treatment residues from pig-iron production or non-ferrous metal production (see description below) - the majority of these residues seem to be disposed of to landfill, but a part is used as intermediate in the production of arsenic compounds or arsenic metal in the non-ferrous industry. The possible exposure by use of the substances as intermediates is covered by "other non-ferrous metals".

Industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide

This use was granted authorisation and approved by RAC in 2015 for a period of 22 months. Within this period, the use of diarsenic trioxide for this particular process should have been phased out and replaced by an alternative (vanadium pentaoxide). According to the applicant, the alternative could be implemented as of 31/3/2017. The application is not further described.

Sulphuric acid production

Sulfuric acid is made by conversion of SO_2 into sulphuric acid. The SO_2 comes from elemental sulphur, non-ferrous smelter gas and other sources. As part of the stakeholder consultation, the European Sulphuric Acid Association has been contacted and has forwarded the request for information to member companies. So far, no specific information has been obtained.

According to the BAT Reference Document for the Manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers in the EU-25, sulphuric acid was produced in 95 plants in 2004 JRC (2007). According to the BAT document for the nonferrous metal sector, all the primary copper smelters and a number of the primary zinc smelters have sulphuric acid plants; in total 19 plants in the EU (JVC, 2017). The distribution in 2003 according to the BAT document for large volume inorganic chemicals is shown in the table below. The BAT document does not include information on arsenic in the feedstocks and the possible fate of the arsenic. Occupational exposure to the arsenic is reported for the manufacture of sulphuric acid in the copper sector and for manufacture of sulphuric acid from pyrite (section 3.4.4). The arsenic content of the main feedstock, sulphur, used for the acid production is in a BAT document from the European Sulphuric Acid Association (ESA) and European Fertilizer Manufacturers' Association (EFMA) indicated at maximum 1 mg/kg (ESA, 2000). The same document indicates the arsenic content of pyrite may be up to 10%, whereas arsenic content of sulphuric acid spent catalysts is at a maximum of 0.1%.

The available information indicates that occupational exposure to arsenic would potentially take place when sulphuric acid is produced in the non-ferrous metal sector, and in particular in the copper sector, and when it is produced from pyrite.

Table 3-2: Distribution of the sulphuric acid production in 2005 according to the SO_2 source in EU25, Norway and Switzerland

SO_2 source	% distribution
Sulphur	43.7
Non-ferrous metals	39.0
H_2SO_4 regeneration	7.5
Pyrite	4.2
Recovery and others	5.6

Source: JRC, 2007.

3.3.5 Copper sector

The copper sector has been identified by the stakeholder consultation as a sector where exposure to arsenic is of major concern and a sector that could be impacted by establishing an OELV.

Information has been obtained via the European Non-Ferrous Metal Association (Eurometaux), and the sector association the European Copper Institute (ECI) and the European Foundry Associations. All primary copper smelters and some secondary have answered the questionnaire which has been circulated by ECI to its member companies. Furthermore, contact with industry has been established via the German WirtschaftsVereinigung Metalle (WVM). Furthermore, site visits at three sites has been performed.

Exposure to arsenic in the copper sector could essentially take place by three activities, which will be described separately:

- Primary copper production;
- Secondary copper production where arsenic may originate from recycled copper-arsenic alloys or arsenic impurities in the recycled materials;

  Production and casting of copper-arsenic alloys.

As metallic arsenic is not within the scope of the assessed OEL, exposure to dust of pure metallic arsenic or arsenic in alloys would not lead to exposure within the scope, and the assessment focuses on processes where inorganic arsenic compounds are formed which could lead to exposure.

Many of the processes described below for the primary copper sector where exposure could take place would be quite the same for other non-ferrous metals, but the exposure levels would in general be lower as the arsenic content of such ores and concentrates is generally lower.

Primary copper production

The main sector affected by arsenic in raw materials is the primary copper sector, where arsenic in the ores is a major issue both with regard to occupational exposure and environmental releases.

Arsenic in mined copper concentrates is increasing, which is a major concern for the copper sector. According to Rohner et al. (2017) from 2000 to 2017 the average arsenic content in world copper concentrates increased from 0.13 to 0.22%.

Based on information obtained from the stakeholder consultation it is estimated that the total content of arsenic in concentrates used in primary copper production in the EU is likely in the range of 3,000-6,000 t/year. The turnover of arsenic in copper production is thus several times the total intentional consumption of arsenic compounds for all applications in the EU. The range indicated would correspond to an average content of the concentrate of 0.05 to 0.10% if it is assumed that the copper content of the concentrates is 30% (typical content).

The schematic overview of primary copper smelter operation is shown in Figure 3-1 based on the Voluntary Risk Assessment for copper prepared by the European Copper Institute (ECI, 2007) but extended with information obtained by site visit. As described in the Risk Assessment, in primary smelting, the feed material is copper concentrate derived from ore. The steps in the manufacture of primary copper are briefly described below with indication of the options for occupational exposure.

Raw material reception, storage, blending and drying - After the reception of the concentrates, the concentrate from different sources is typically mixed in order to obtain the right content of iron and sulphur and loaded automatically via a conveyer into a dryer. In this process recycled arsenic containing residues from the smelter may also be mixed with the concentrates. Exposure to arsenic at this step would be due to arsenic containing dust from the concentrate. As the concentrate is moist prior to the drying process, the dust level by the mixing and the exposure is relatively low. The process is fully automated and exposure may typically take place during some maintenance operations.

Flash smelting and tapping - The dried concentrate is loaded by a conveyer belt into the flash smelting furnace. The furnace configuration may differ between companies.

The release of molten matte (composed primarily of copper and various sulphides) or slag from furnaces may be automated using tipping furnaces. Alternatively, the transfer is carried out manually, a process known as “tapping”. Using a long pole, a worker breaches the sand or ceramic material holding the molten metal, which then flows out through a permanent channel. Vigorous agitation of the stream may be necessary to maintain flow. Transfer of matte or slag between furnaces is performed using large tubs transported by an overhead crane. Solidified slag arising from various stages of the process, such as solidified residue emptied from the tubs, is regularly collected by a tipper truck and loaded into large skips. The skip loads are then recycled into a furnace or converter by the crane driver. The tapping step is typically the step with highest risk of exposure to high arsenic concentrations.

Conversion, anode furnace and anode casting - The final stage of purification is the oxidation of the remaining sulphur in the converter by blasting the molten metal with air. The 99% copper matte from the converter is then removed to the anode furnace and cast into anodes on a casting wheel. Some exposure may take place at this stage but at a lower level than in the tapping step.

Electrolysis in tankhouse - The anodes are then further purified electrolytically in the refinery to produce pure copper cathodes. The anodes contain some arsenic which by the electrolysis is released to the electrolyte. The exposure concentration at this stage is relatively low.

Recovery of electrolyte and sludge from electrolysis - In order to recover the electrolyte, arsenic and other impurities are removed from the electrolyte. Different processes may be applied. Exposure may take place when the arsenic-containing waste materials, which may contain high concentrations of arsenic, are removed from the process. In some smelters, historically diarsenic trioxide was produced in this step.

The sludge/slime from the electrolysis contains arsenic, selenium and various precious metals which may be further processed in order to produce commercial metal products. In this process, exposure to arsenic may mainly take place when the arsenic containing residue is removed from the sludge.

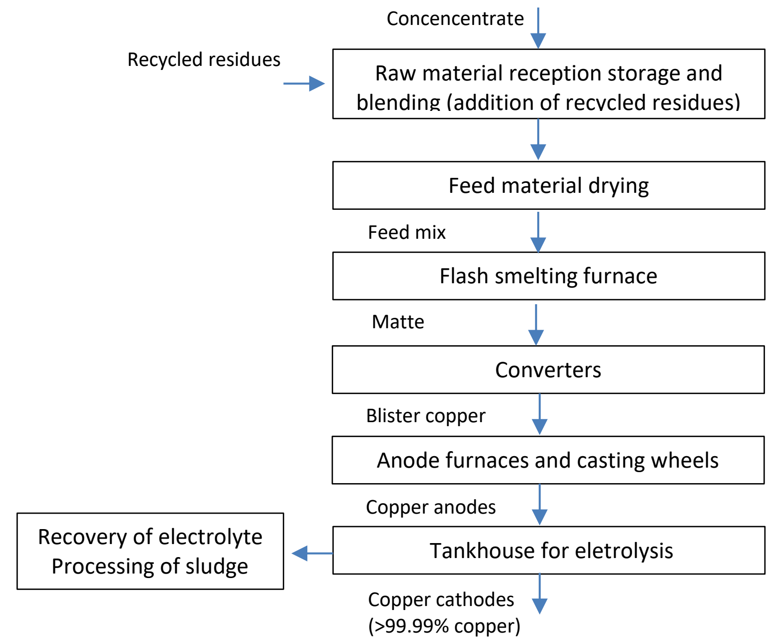

Figure 3-1: Primary copper smelter process (extended from ECI, 2007)

As described in the BAT document for the non-ferrous industry (JRC, 2017), at large smelters, primary and secondary smelting may be combined within the same building with separate and/or combined smelting furnaces feeding into a common converter and anode furnace system.

Exposure to arsenic may take place at all stages in the process but at different exposure levels. The feed material drying, flash smelter furnace, converters, anode furnaces and casting wheels would typically be situated in the same large open building and arsenic compounds released from some processes may lead to contamination in other places, even if all major release sources are equipped with local ventilation systems. The risk assessment concludes that process observation indicates that task specific exposures in smelting likely to produce the highest acute exposures are the mechanical handling of solid slag/waste for disposal or recycling within the smelting operation and manual furnace tapping.

The risk assessment for copper distinguishes between different operations where workers can be exposed in primary smelters: raw material handling, smelting furnaces, converter, anode furnace, and other. As will be described in Section 3.4.5, a slightly different grouping will be applied in this study, specifically including the maintenance workers and the recovery processes.

Primary nickel production - Primary nickel production from concentrates takes place in one facility in the EU. Compared to copper concentrates, the nickel concentrates contain less arsenic and arsenic is less of an issue in the production of nickel. In the facility, the nickel smelting takes place in the same building as the copper smelting and workers involved in the process may also be exposed to arsenic released from the copper smelting process. The workers involved in nickel smelting are consequently included in the exposed workforce for primary copper smelting.

Secondary copper production

In secondary smelting, the feed material is scrap either loaded into a smelting furnace, for example loaded through a vertical shaft into a blast furnace below, or, if sufficiently pure, loaded directly into a converter or anode furnace.

The sources of arsenic from the secondary copper production would be different from the sources in primary copper production. The sources of arsenic in secondary production is mainly arsenic present as alloying element in some copper alloys and arsenic in some residues from other industrial processes. A detailed description of the sources has not been obtained.

The overall process is shown in the diagram below.

The total arsenic flow through the secondary smelters are not reported, but as mentioned below an estimated quantity of 300 t/year of metallic arsenic are used in copper alloys and these would end up in the secondary smelters; possibly together with other arsenic containing waste materials.

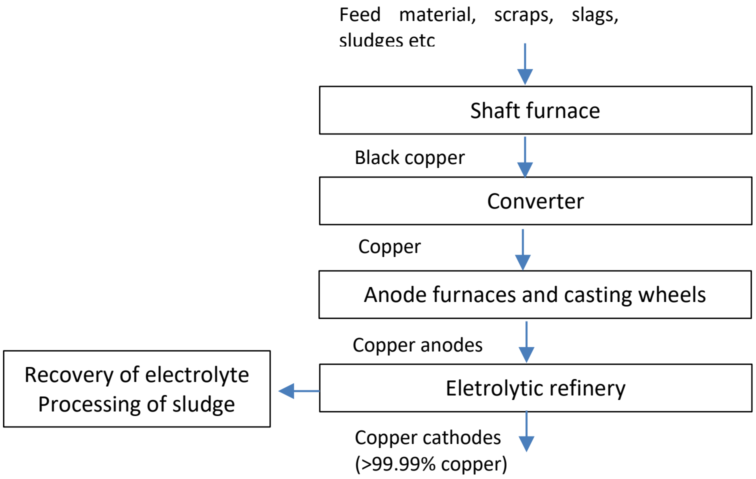

Figure 3-2: Secondary copper smelter process (extended from ECI, 2007)

Copper alloys

As described above it is estimated that about 300 t/year of metallic arsenic is used for production of copper alloys. Arsenic metal is not within the scope of the assessed OELV, but arsenic oxides may be formed by the melting of the alloys. In the process, the arsenics can be released e.g. in fumes, dusts and skimmings (GMBI, 2017).

Data have been obtained through initial requests to the Eurometaux, European Copper Institute (ECI) and European Foundry Association (EAF).

According to the obtained information copper-arsenic alloys are used for:

- Improving mechanical properties of low alloyed copper alloys;
- Dezincification inhibitor in brass;

- Improving corrosion resistance of CuAl alloys.

The first step in the manufacture of the alloys is the manufacture of copper-based master alloys. The master alloys are produced by a limited number of companies specialised in the manufacture of such alloys. A copper-arsenic master alloy typically contain 30% arsenic and 70% copper (CuAs30).

The master alloys are used by a large number of manufacturers of copper alloys where the master alloy is melted with the other alloying components. As an example, a brass alloy suited for the use in drinking water applications could typically contain 63% copper, 0.2% lead, 0.1% arsenic and the remaining part zinc.

These alloys are subsequently used to produce final articles e.g. drinking water fixtures, condenser tubes, heat exchanger, distillation tubes, etc. The brass alloys would typically be formed for the final application without melting the alloys.

The supply chain is as follows:

1) Import of arsenic metal;

2) Manufacture of CuAs master alloys;

3) Manufacture copper alloys with low arsenic content formed as bars, wire, sections and tubes;

4) Manufacture of final articles of copper alloys.

Potential occupational exposure is expected mainly to take place by the manufacture of the master alloys and the alloys. Highest exposure concentrations could be expected by the manufacture of the master alloys because of the 100 times higher concentrations of arsenic in the melt.

The voluntary risk assessment for copper notes that acute exposures to copper for melting and casting are considered to arise mainly from periodic furnace cleaning and from manual deslagging operations.

A large number of workers may be exposed to low levels of arsenic by the further machining of the alloys, but as this exposure would be to metallic arsenic, it is not considered to be within the scope of this assessment.

3.3.6 Zinc production using diarsenic trioxide

Exposure to inorganic arsenic compounds in the zinc industry can either be due to the intentional use of arsenic compounds in the electrowinning process or due to low levels of arsenic in the raw materials for the production. The exposure from the intentional use of arsenic compounds taking place in two facilities is described in this section whilst the exposure to arsenic in the ores, potentially taking place in more facilities, is described together with exposure to arsenic in ores used in the manufacture of other nonferrous metals.

The production of zinc is together with the manufacture of glass the major application area for arsenic compounds. The application is subject to authorisation, and detailed information is available from applications for authorisation from two companies: Boliden Kokkola Oy (Finland) and Nordenhamer Zinkhütte GmbH (Germany). The following is, if nothing else is mentioned, an extract from the application documents and RAC decisions (RAC 2014 a,b).

In total, the two companies use 835 tonnes diarsenic trioxide per year (Boliden 2014, Nordenhamer, 2014) in the production of 455,000 t/year of zinc. This represents ~22% of total zinc production in the EU.

The substance is used in the roast-leach-electrowinning (RLE) hydrometallurgical process of zinc production for the removal of several impurities of the zinc concentrate, including but not limited to copper (Cu), cobalt (Co), nickel (Ni) and/or cadmium (Cd) from the leaching solution before the electrowinning step, where zinc is separated from solution by electrolysis. These metals may either contaminate the resulting zinc metal or act as harmful elements in the process decreasing current (energy) efficiency of the electrowinning process.

The diarsenic trioxide powder is dissolved to form the arsenous acid solution, which acts as an essential reactant to selectively precipitate Co and Ni out of the process solutions and to concentrate them completely in the copper concentrate. The arsenous acid is completely consumed by the chemical reactions. The majority of arsenic constituents from the process are in the end bound to inorganic waste material as ferric arsenate. Ferric arsenate is precipitated simultaneously with jarosite, and filtered, washed and landfilled on a dumping area approved for hazardous waste. Technical function: Diarsenic trioxide is used to eliminate impurities such as copper, cobalt and nickel from the zinc electrowinning solution, without the co-precipitation of cadmium.

The plant's main products are pure zinc and its alloys. The main raw material is zinc sulfide concentrate. The production lines of the two plants are slightly different. For one of the plants, the production line consists of 5 departments in separate buildings as follows:

- The **roaster department** consists of the zinc smelter unit, mercury removing unit, water purification unit and units for manufacturing lead-anodes and mercury, as well as raw material storage area for zinc ore concentrate.
- The **leaching department** consists of zinc concentrate (pasute) dissolving unit, direct leaching unit, a flotation unit for sulphur, and filtering and handling unit for sulphur concentrate and jarosite.
- The **purification department** is the part of process where zinc sulphate solution is purified with the aid of diarsenic trioxide, and disturbing metal impurities (e.g. Cu, Co, Cd etc.) are removed to generate a pure electrolysis solution.
- The **electrolysis department** generates pure zinc on aluminium cathodes.
- The **foundry department** casts the ingots of pure Zn and Zn alloys.

As indicated, the diarsenic trioxide is used in the purification department. Some exposure to arsenic in the roaster department may take place, but this is further described in the section on "Other non-ferrous metal production".

Occupational exposure to diarsenic trioxide may take place by the following Worker Contribution Scenarios (conditions of exposure further described in Section 3.4.6):

- Unloading and dissolving diarsenic trioxide
- Leaching process and selective precipitation
- Quality control, sampling and analysis
- Maintenance work
- Cleaning of site and handling of waste

3.3.7 Other non-ferrous metals

Occupational exposure to arsenic may take place by a number of processes in the non-ferrous sector.

Data have been obtained through initial specific requests to Eurometaux, the International Lead Association (ILA), the International Zinc Association (IZA), the International Cadmium Association (ICdA), European Precious Metals Federation (EPMF), Association of European Automotive and Industrial Battery Manufacturers (EUROBAT), Association of European Manufacturers of Sporting Ammunition (AFEMS), European Cable and Wire Association (Europacable), and European Foundry Association (EAF). Furthermore, contact to industry has been established via the German WirtschaftsVereinigung Metalle (WVM).

Manufacture of ultrapure arsenic metal

Arsenic metal is not registered, and consequently no detailed information from registrations has been available. Arsenic is included in the substances managed by the Arsenic Consortium, and the arsenic metal is planned to be registered before the 1-100 tonne deadline of 31 May 2018. Metallic arsenic is beyond the scope of the assessed OEL, but inorganic arsenic compounds may be released from the manufacture and processing of alloys with arsenic.

Arsenic metal is used in ultrapure grade to produce gallium arsenide wafers described in Section 3.3.3. The raw materials for the manufacture of ultrapure arsenic metal originate from the EU.

Other applications of arsenic metal are mainly in various alloys. The arsenic used in the manufacture of alloys is mainly imported from countries outside the EU.

Lead alloys with arsenic

In a response to the stakeholder consultation ILA indicates that all smelters in the sector:

"could potentially face the issue of being affected by an OELV. In the case of secondary lead producers, for example, scrap almost always contains (even a small amount) of As and/or As compounds, but the chemical identity is not necessarily known since it is (presumably) not relevant for the recovery operation when recycling the metals.

In the case of companies producing alloys, which are often formulated to contain arsenic, although those companies would use metallic As (which would not be in scope of the OEL), compounds such may be produced during the production, but they might not necessarily know the speciation. In reactions such as oxidation, even on the surface of a metal (the patina), As compounds might be produced and could thus be released, which I presume would be in scope of the OEL."

Lead alloys with small concentrations of arsenic is produced by the main producers of lead in the EU.

According to the obtained information, lead alloys and copper alloys account for the major part of the use of metallic arsenic. Based on information from industry approximately 100 t/year arsenic metal is used for lead alloys.

The alloys are sold as ingots and further cast into the final articles by the manufacturers of final articles such as batteries, ammunition and cables.

According to DHI/RPA (2009), the main use of lead-arsenic alloys are:

- Battery grids: trace quantities of arsenic are added to lead/antimony grid alloys used in lead-acid batteries using liquid electrolyte.

- Ammunition: the addition of arsenic (0.5–2%) improves the sphericity of lead shot

- Cable sheathing: lead with arsenic is according to the literature also used for cable sheathing, but current application has not been confirmed.

More recently, Lovreglio et al. (2017) studied exposed workers at a birdshot factory in Italy. The factory produces lead birdshot with a lead alloy with 2% antimony and 0.2% arsenic.

The supply chain is as follows:

1) Import of arsenic metal
2) Manufacture of lead alloys with arsenic
3) Manufacture of batteries, ammunition and cable sheathing
4) Recycling of batteries and other lead products.

The higher exposure to arsenic compounds within the scope of this assessment is expected by the manufacture of the lead alloys and by the recycling of batteries etc. From one major recycling company for lead batteries it is reported that the arsenic content of the recycled lead is below 0.01% indicating that the use in batteries today is low. The company further informs that exposure to arsenic by the recycling is not an issue; it is exposure to lead (more than 1,000 times higher concentrations in the alloy) which is of concern. EU usage of lead metal in 2015 was in the region of 1,520,000 tonnes; approximately 84% of this was used for lead-based batteries (ILA, 2017). If the lead contained 0.01% arsenic it would correspond to 130 t/year arsenic.

Primary lead, zinc and cadmium production

As mentioned, arsenic is naturally present as impurity in ores, fossil fuels, soil, plant material, etc. and may be released to the air by thermal processing/combustion of these materials. Furthermore, arsenic compounds would be present in dust formed by the processes.

Compared to primary copper production, arsenic is less an issue in primary lead and zinc production because the arsenic content of the concentrates is lower. No actual data have been obtained from the relevant industry associations. According to the Technical Rules for Hazardous Substances in Germany, the key component in primary zinc production is cadmium and not arsenic (GMBl, 2017).

Precious metals and other non-ferrous metals

Precious metals (gold, silver and platinum group metals) and other metals such as selenium, cobalt, and germanium are produced either from ore concentrates, from waste products from other non-ferrous metal production or from scrap e.g. from electronic products. Arsenic may be present in all the raw materials e.g. in the form of nickel arsenide, but in particular large quantities are processed with waste products from other non-ferrous metal production. Some of these activities are undertaken at sites manufacturing primary copper and are in these instances included in the description for this sector. A detailed description is restricted by the fact that many of the activities are undertaken by one or two companies only, and details cannot be revealed for reasons of confidentiality.

The processes differ between the companies, but the following worker exposure scenarios have been indicated in responses to the stakeholder consultation:

- Transportation and unloading of raw materials
- Sampling of raw materials
- Sampling as part of process control
- Smelting of raw materials
- Refining of final products
- Packaging final products (if the end products include arsenic compounds)
- Maintenance operations

According to the Technical Rules for Hazardous Substances in Germany, an exposure to arsenic compounds cannot be excluded in the area of aluminium gravity die casting (GMBI, 2017). No data on this application have been obtained from relevant industry associations.

Secondary zinc production

Arsenic is not used as alloying element in zinc and not present in significant concentrations in scrap zinc. One major recycling company has indicated that arsenic is not an issue in the production of secondary zinc from scrap.

3.3.8 Welding, plasma cutting and similar processes

Exposure to arsenic by welding are often mentioned in general introductions to exposure to hazardous substances in welding. Very limited data, however, has been identified describing the sources of arsenic in the welding processes and the differences in exposure levels between different processes. Data from the German MEGA database presented in section 3.4.11 demonstrates exposure to arsenic in different welding and thermal cutting processes. Exposure to arsenic has not been addressed specifically by welding organisations contacted as part of the assessment of introduction of an OELV for chromium (VI). The pages on welding fumes on the website of the UK Health as Safety Executive (HSE, 2017) mentions exposure to chromium, nickel, vanadium, manganese, iron, cadmium and beryllium but not to arsenic. Welding is neither mentioned as a source of occupational exposure to arsenic in a leaflet on the issue from the same agency (HSA, 2013). A guide from an American insurance group on welding fume hazard indicates that the source of arsenic in welding is copper alloys (GAIG, 2017). Some brass alloys used for many applications contain 0.1% arsenic.

3.3.9 Ferrous basic metal production

The Carex Canada (2017) estimates that <5% of the workers in the "Iron and steel mills and ferroalloy manufacturing" are potentially exposed to arsenic. Likewise, the European Carex database (form 1997) estimates that some 7,000 workers may be exposed in the iron and steel basic industries. None of the databases include actual data on exposure levels.

As shown above, 15 facilities in the sector report a total emission of arsenic to the air of 1.4 t/year. The origin of the arsenic may partly be arsenic in iron ore, partly arsenic in the used fuels.

No data on occupational exposure in the EU to arsenic in pig-iron production (sinter plants, pelletisation plants and blast furnaces) or other non-ferrous metal production have been identified so far.

As part of the stakeholder consultation EUROFER, the European Steel Association, has been requested information and the organisation has forwarded the request to member companies and associations. No feedback to the stakeholder consultation has been obtained.

The BAT document for iron and steel production (JRC, 2013b) describes that bleed water from scrubbers from pelletisation plants (first step in the pig iron production in some plants; in others the first step is sinter plants) in some cases is treated in an "arsenic removal plant". The waste water from the water treatment plant contains dissolved arsenate (As^{5+}) and arsenite (As^{3+}). In the arsenic removal plant, an arsenic containing filter cake is formed which can be recycled or disposed of (JRC, 2013b). The BAT document does not include other information indicating high arsenic concentrations in the processes.

Likely, some exposure could take place by maintenance of the arsenic removal plant and by handling the filter cake. Furthermore, maintenance and cleaning works on electrostatic precipitators and bag filters on sinter plants, pelletisation plants and blast furnaces may likely lead to some exposure to arsenic as has been demonstrated by maintenance of similar filters in some coal power plants. The total number of sinter plants in EU-27 in 2008 is reported at 34 in 14 MS, and the total number of pelletisation plants were 6 in two MS (JRC, 2013b).

3.3.10 Power sector

Workers in coal and oil-shale powered power plants may be exposed to arsenic in fly ash during cleaning. Fly ash contains arsenic and a number of other heavy metals which the workers are exposed to e.g. by cleaning and maintenance.

During coal combustion, arsenic readily oxidizes to form arsenic oxide vapour which combines with calcium oxide and condenses on the surface of fly ash (RAC, 2017). Solid by-products of the combustion process, including fly ash and bottom ash, are major sinks for arsenic. Workers in power plants may first of all be exposed to arsenic found in the fly ash during cleaning of fabric filters and boilers.

As part of the stakeholder consultation, the Union of the Electricity Industry - EURELECTRIC has been contacted for collection on information on potential exposure to arsenic within the sector. The organisation has answered that it has no information on exposure to arsenic in the sector.

As part of the stakeholder consultation information has been obtained from Danish utility companies with coal power plants. Arsenic in coals are analysed periodically together with other element and the arsenic content varies considerably. Occupational exposure to arsenic has not been measured and is not considered to be of specific concern. Workers involved in cleaning and maintenance in any case wear full-face respirators.

Information on exposure to arsenic by maintenance of fabric filters and boilers are very limited. Two studies from Slovakia in the same power plant (Yager et al. 1997; Buchancova et al., 1998) report on significant exposure of boiler cleaners, boiler makers and technicians during boiler maintenance work. The plants used mainly local low-grade brown lignite coal containing a mean concentration of approximately 800 ppm arsenic (maximum 1.350 ppm). Buchancova et al. (1998) furthermore report that the occupational exposure was historic, as workers at the time of publication of the results had started to wear respirators.

It is further discussed in section 3.4.10 to what extent these results may be representative for thermal power stations in the EU.

3.3.11 Other sectors

Mining sector

Some exposure to arsenic from metal ore mining is reported in the Carex database (see section 3.5) and some exposure from mining activities has been reported in the literature. No specific data on exposure to arsenic compounds by the manufacture of concentrates in mining sites in the EU have been reported by the stakeholder consultation nor identified in the literature

The main activity where exposure to arsenic may take place is expected to be mining of copper because copper concentrates compared to other concentrates contain relatively high concentrations of arsenic. By handling of copper concentrates in the primary copper smelters, significant workplace concentrations, e.g. by sampling of raw materials and by maintenance procedures, are reported and workers would typically use RPE (respiratory protective equipment) for these processes. Similar work processes may be expected to take place by the manufacture of arsenic-containing concentrates in mining sites.

Other processes in the metal industry

Data from the German MEGA database indicates that exposure to arsenic may take place by various processes in the metal industry such as soldering, casting/melting and similar process, dry sanding, and various machining processes. As details are not provided it is not clear if the exposure is due to intentional use of arsenic in e.g. copper alloys or due to low levels of arsenic as unintentional trace element in e.g. sandblasting and abrasive materials.

Wood preservatives and preserved wood

Historically, **diarsenic pentaoxide** was used in chromated copper arsenate (CCA) wood preservatives (DHI/RPA; 2009). The substance is subject to authorisation, but no companies have applied for authorisation.

The use of **chromated copper arsenate (CCA)** solutions in the preservation of timber and import of CCA treated timber is regulated by the Biocidal Product Regulation and is no longer permitted. The use of CCA and CCA-treated timber is further restricted under Annex XVII to the REACH Regulation (552/2009). In practice the Regulation applies to reclaimed timber and included some derogations for wood treated with CCA solution placed on the market for professional and industrial use, provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely. In recent years, one export notification per year of the Osmose K-33 from the UK was notified under the PIC Regulation indicating the export is from stockpiles. RAC (2017) notes that the use of CCA to preserve wood has effectively ceased in the EU, as has the import of CCA treated timber. However this leaves a considerable legacy of treated timber still in use with implications for occupational exposure in relation to waste treatment and recycling for the future (RAC, 2017). Workers may be exposed to arsenic by recycling of wood for exempted purposes. As the exposure may take place on an irregular basis and in artisanal settings it has not been possible to obtain specific information on the exposures to arsenic in wood but some data for woodworking and building sector from the MEGA database may represent this exposure source (see section 3.4.11). Potentially, a large number of workers may occasionally be exposed to low levels of arsenic in dust from the wood.

Taxidermists and preservators

Traditionally diarsenic trioxide has been used by taxidermists for the preservation of animals. According to Lassen et al. (1999) there were about 15 establishments doing fulltime preservation and about 50 taxidermists in Denmark in 1999. Diarsenic trioxide was the most used biocidal product for 'dry' preservation. Diarsenic trioxide was mixed with soap flakes, calcium hydroxide, camphor and water. This paste was painted with a brush to the inside of the skin. Diarsenic trioxide is not approved for the use as biocide today, but workers e.g. in natural history museums may be exposed to arsenic from preserved animals. The exposure concentrations today are considered low and are not further assessed.

Dismantling and recycling of waste of electrical and electronic equipment

Arsenic is intentionally used in some electronic components and some exposure to arsenic by dismantling and recycling of electronics may take place. According to the Technical Rules for Hazardous Substances in Germany, an exposure to cadmium and arsenic compounds is to be expected, in particular with recycling of photovoltaic modules which are not silicon-based (GMBl, 2017).

Laboratory use

Various arsenic compounds are applied for **laboratory use**. Besides the use of the compounds as analytical standards, apparently mainly organic arsenic compounds have specific applications as reagent in chromatography, separations, and environmental chemistry, materials science in polymers, proton-exchange membranes, and optical materials. When used as analytical standards typically much lower quantities are used as compared to uses as reagent. The exposure in laboratories by use of inorganic arsenic compounds as analytical standards, where the substances are used in quantities of a few gram or less under strictly controlled conditions, is considered insignificant.

3.3.12 Summary

The information on uses are summarised in the following table.

Table 3-3: Inorganic arsenic compounds – sectors and uses

Sector	Use or activity	Intentional use of substances
1: Glass sector	Production of special glass	Arsenic acid, diarsenic trioxide
	Production of domestic glass	Diarsenic trioxide
	Recycling of glass	Unintentional, from former use in glass
2: Electronics sector	Manufacture of copper foil for printed circuit boards	Arsenic acid
	Gold plating of circuit boards	Diarsenic trioxide
	Manufacture and use of gallium arsenide wafers and semiconductors	Diarsenic trioxide, arsenic metal
3: Chemicals sector	Manufacture of arsenic compounds	Diarsenic trioxide, various compounds
	Production of sulphuric acid from pyrites and residues from non-ferrous production	Unintentional
4: Copper sector	Primary copper smelters	Unintentional
	Secondary copper smelters, recycling of copper alloys	Unintentional (dross, slags, etc.); arsenic metal in alloys

Table 3-3: Inorganic arsenic compounds – sectors and uses		
Sector	**Use or activity**	**Intentional use of substances**
	Production of copper-arsenic alloys, production of articles of brass and other alloys	Arsenic metal in alloys
5: Zinc production using diarsenic trioxide	Use in the electrowinning process	Diarsenic trioxide
6: Other non-ferrous metals	Nickel, zinc, lead, precious metal smelters	Unintentional
	Production of alloys of lead and tin with arsenic Use of lead-arsenic alloys to produce batteries, ammunition, etc.	Arsenic metal in alloys
	Manufacture of ultrapure arsenic metal	Diarsenic trioxide
7: Cross-sector	Various welding processes. Plasma cutting and other thermal cutting processes.	Arsenic metal in alloys; unintentional
8: Ferrous metals	Pig iron production (sinter plants and pelletization plants)	Unintentional
9: Power sector	Maintenance of boilers and equipment for flue gas treatment	Unintentional
10: Other	Mining operations and production of concentrates	Unintentional
	Other metalworking processes	Arsenic metal in alloys; unintentional
	Shredding and dismantling of WEEE	Gallium arsenide, various As compounds in semiconductors
	Maintenance and recycling of wood treated with arsenic compounds	Various arsenic compounds use in CCA treated wood
	Various uses as analytical standards in laboratories	Various compounds
	Reclamation of CCA wood	Former use of arsenic compounds

Source: RPA/COWI

3.4 Exposure concentrations

3.4.1 Overview

The following section includes information on exposure concentrations for inorganic arsenic compounds including arsenic acid and its salts in the workplace. The data is obtained from registrations, applications for authorisation, stakeholder consultation as part of this study or from the published literature.

No broad datasets for measured concentrations in the workplace across different sectors have been identified from other sources such as US OSHA, literature reviews, industry associations, or national surveys. Some data across sectors have at a late stage of the stakeholder consultation been provided by Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) extracted from the German MEGA Database (IFA, 2017b). The data in the database are gathered within the framework of the measurement system for exposure assessment of the German Social Accident Insurance Institutions.[18]

A challenge in the data collection has been to obtain data on low exposure concentrations as these are generally not reported. For the intentional uses of the arsenic compounds within the scope, data on exposure concentrations and exposed workforce are for most applications available.

For other applications where the arsenic compounds are present as unintentional impurities or are generated from uses of metallic arsenic (not in scope), exposure data are in general only available for those where significant exposure to the arsenic compounds occur and where exposure to arsenic is of concern. As arsenic is present at low levels in most raw materials and fuels, the potential number of exposed workers is quite high as e.g. reported in the Carex database for the EU and Canada, but no data are available for the majority of the workers exposed at low levels.

For this reason, this section describes the available data on exposure concentrations, and the estimates on number of exposed workforce in the next chapter will be linked to the description of exposure levels, i.e. the number of significantly exposed workers will be those represented by the available datasets for exposure concentrations.

Possible bias in obtained data - The obtained data have some bias, as in general, mainly companies that have been complying with low OELs have available data, because they have to a larger extent been forced to monitor exposure concentration. This is taken into account when estimating exposure concentration distributions. The companies answering are not considered to have any incentives for indicating too low concentrations nor to demonstrate that they are well performing. The data are consequently not considered to be biased against well performing companies.

3.4.2 Glass sector

For glass production it is relevant to distinguish between exposure by manufacturing of special glass in large industrial facilities and manufacturing of domestic glass in medium-sized companies and small artisanal workshops.

Special glass

Data from one company, who has responded in the stakeholder consultation and from two registrations of the arsenic compounds used for manufacture of glass are summarised in the table below. The data are reported as mean values of 8-h TWA. One other major producer of special glass has for the stakeholder consultation indicated that the concentrations reported in the REACH registration Chemical Safety Reports (CSRs) are well in accordance with the current concentrations. The workers have been grouped into four groups. The original data include for some of the companies more groups, but have been allocated to these four groups in order not to disclose confidential information.

The number of exposed workforce within the four processes is for one larger company reported to be about 80. The majority are involved in waste management and maintenance processes. The measured and calculated concentrations reported as geometric means range from about 1 to 4 µg/m^3, with no major difference between the three datasets. Original data allowing an estimation of a mean value for the entire dataset and a standard deviation are not available. It is not reported in the CSRs whether the measured and estimated concentrations take PPE into account but it is expected that the figures are without RPE.

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[18] http://www.dguv.de/ifa/gestis/expositionsdatenbank-mega/index-2.jsp

Based on the data, the AM (arithmetic mean) will be estimated at 2.5 µg/m³ and in the absence of 90th and 95th percentiles, the Standard Deviation (SD) of the log-normal distribution will be based on distributions of concentrations in the other sectors. As RPE is used in all high exposure workplace (loading of arsenic compounds, cleaning and maintenance work in dusty areas such as conveyer belt enclosures, and by waste management) the actual mean concentrations is estimated to be at least a factor of 2 lower than the non-adjusted mean.

Data are not available for estimating the total number of workers exposed in the special glass sector, but based on the available information it is estimated to be within the range of 300 - 600. Besides that, a larger number of workers may potentially be indirectly exposed at very low concentrations.

Companies answering the questionnaire have indicated that compliance with an OEL of 10 µg/m³ could be achieved without implementation of further RMMs. The fact that most companies using the arsenic substances have not answered the questionnaire might indicate that establishing an OELV for inorganic arsenic compound are unlikely to require implementation of any significant additional RMMs.

According to the Technical Rules for Hazardous Substances in Germany (GMBl, 2017), most exposure concentrations of arsenic compounds in special glass production are below the acceptable concentration (0.83 µg/m³) and in some cases between the acceptable and tolerable concentration (tolerable: 8.3 µg/m³). This is quite well in accordance with the data indicated in the table below.

Table 3-4: Exposure to arsenic in industrial use of diarsenic trioxide in the production of special glasses

Process	Worker contribution scenario	Duration (min)	Containment	Respiratory protection	Exposure concentration 8-h TWA (µg/m³), arithmetic mean (AM) *		
					Site 1	Site 2	Site 3
Raw material delivery and storage	Delivery, storage and internal transport	30-60	Sealed containers (storage is segregated)	No	0 (estimated)	0 (estimated)	0 (estimated)
Preparation and mixing	Opening of drums and dosing (manual or automatic)	60-240	Partially enclosed to closed system	Yes (P3 mask)	1.2 (measured)	0.03 (estimated)	3.1 (estimated)
Furnace operation	Control walks, manual re-feeding, supervision	5-30	Partially enclosed to closed system	Yes (full face)	2.5 (measured)	2.5 (measured)	1-4 (means for various processes, measured)
Maintenance, cleaning and waste management	Cleaning, emptying of dust collector	< 60	Closed system except for changing dust collectors	Yes (full face)	2.8 (estimated)	2.5 (estimated)	4 (measured)

Answers to Duration, Containment and Respiratory protection are derived from the CRSs and only valid for two of the companies.
* Median and percentiles not available for the data sets.
Sources: CSRs and questionnaire responses.

Data from the German MEGA database are shown in the table below. The data represent the period 2000-2017. It is not indicated whether the data represent special glass or domestic glass, but only use of diarsenic trioxide in special glass production in Germany has been identified. It is not indicated to what extent RPE is used in the processes. The exact processes undertaken are not indicated.

The process "shaping and surface treatment" is expected to represent the use of diarsenic triselenide, which according to the registration dossier is used for "Add thin film into coating and assemble into a lens assembly; Glass shaping: grinding, polishing, moulding and DTP". Diarsenic triselenide is beyond the scope of this assessment and not further assessed.

The applications indicated as "batch production " and "Other work processes" are expected to represent the same work processes as described above, where the major exposure may take place by preparation and mixing the arsenic compounds into the glass raw materials, furnace operation and maintenance and cleaning e.g. of conveyer belts loading the glass raw materials into the furnace. Thus it is expected that typically RPE would be used for the processes. The <2h measurements represent peak exposures e.g. when loading the substance into a contained. The ≥ 2h personal samples for the batch process and the other work areas are quite well in accordance with the data provided in the table above, and will be used for the estimates of the potential exposure.

Notably the dataset represents at least 19 companies (stationary sampling in batch processes), but it is not indicated to what extent the companies use the arsenic compounds intentionally or arsenic is present in recycled glass.

For the calculations, it is assumed that RPE is used for high exposure concentrations in accordance with the information reported for the stakeholder consultation.

Table 3-5: Data from the German MEGA database 2000-2017, glass industry

Process step	Sampling duration	Number of samples	Number of enterprises	Max LOD µg/m³ *	<LOD *	Exposure concentrations, arsenic compounds, µg/m³ **		
						50th	90th	95th
Personal samples (without adjustment for RPE)								
Shaping and surface treatment	≥ 2h	13	5	0.92	10	<LOD	0.5	8.1
Batch production	≥ 2h	32	16	4	7	1.5	6.2	9.3
	< 2h	22	11	3.4	4	6.7	24.6	33.2
Other work areas	≥ 2h	12	5	4.8	10	<LOD	2.1	5.8
Stationary samples								
Shaping and surface treatment	≥ 2h	53	15	0.8	18	0.3	6.1	8.0
Batch production	≥ 2h	53	19	3.8	20	0.6	4.3	19.2
	< 2h	38	11	4.0	6	2.5	33.6	45.0
Other work areas	≥ 2h	18	17	0.6	26	<LOD	0.8	3.1
	< 2h	13	6	1.2	7	<LOD	11.2	15.1

* The LOD differs among the analysis, the max LOD indicates the maximum LOD in any analysis in the dataset whereas the <LOD indicates the numbers below the actual LOD of the individual analyses.

** It is noted that results collected for ≥ 2h can be considered as representative for the entire shift (i.e. 8-h TWA) whereas results for < 2h only represent the sampling time.

Source: IFA, 2017

Domestic glass sector

As described in section 3.3.1, no actual use of diarsenic trioxide for domestic glass production has been identified but it cannot be excluded that the substance is still used to some extent. Furthermore, no data on the current exposure to arsenic compounds in domestic glass sector have been obtained from the stakeholder consultation for this study.

From the widespread former use of diarsenic trioxide in Northern Italy, some data on exposure concentrations are available.

Apostoli et al. (1999) examined 51 male workers employed in art glass manufacture in Italy with different degrees of exposure to dust containing diarsenic trioxide. The study included six glass companies of which three companies used diarsenic trioxide as fining agent. The three companies had a glass production from 90 to 280 t/months. The number of workers in the companies is not indicated. Glass workers exposed to arsenic trioxide were monitored by measuring dust in the breathing zone, with personal air samplers. The workers studied were 28 oven chargers, 10 batch mixers, and 13 moulders or finishers. Environmental monitoring was conducted by collecting the airborne particulate matter in the breathing zone, on cellulose ester membranes (0.8 µm porosity, 20 mm diameter), by personal samplers (at a constant flow of 2.5 L/min) worn at the end of the collar, for a period of 6 hours on a normal working day. During environmental monitoring the workers did not regularly use respiratory masks. The best correlations between As in air and its urinary species were found for total inorganic arsenic (iAs), As^{3+} and As^{+5}.

The concentrations measured in the workplace air were much higher than reported from the industrial production of special glass above and besides, the workers did typically not wear RPE.

Table 3-6: Concentration of arsenic in air (µg/m^3), 6-h TWA *

	n	AM	SD	Median	Range
Batch mixers	10	59.0	56.4	26	10–154
Oven chargers	28	127.0	89.4	123	10–312
Moulders, finishers	13	4.1	3.7	39	1.5–15
Total	51	82.9	87.4	42	1.5–312

* Please note that the concentrations are reported as 6-h TWA and not 8-h TWA.
Source: Apostoli et al., 1999

Another quite similar dataset from the same study, is presented in Apostoli et al. (1998).

Chrostek et al. (1980) investigated 35 crystal glassworkers working in the mix and melt area and batch house in a glass factory in the USA who were exposed to various compounds, including diarsenic trioxide. Personal air monitoring of eight workers revealed arsenic concentrations of 2-11 µg/m^3 i.e. more in the same range as reported from special glass production in industrial facilities above.

Ide & Bullough (1988 as cited by IARC) undertook personal and background sampling of arsenic in air of decorative glassworks in the UK. Measured 8-h TWA for mixers in the two companies were 380 and 110 µg/m^3, respectively, whereas chargers in one of the companies were exposed to 5 to 20 µg/m^3.

Andersson et al. (1990) measured arsenic and other heavy metals in three Swedish glassworks, one producing heavy crystal glass and two producing semi-crystal glass. In all samples the concentration of arsenic in the workplace air was < 6 µg/m^3. It is not reported whether the glassworks used arsenic compounds in the production.

Biological monitoring of workers in glass manufactories in the Murano district of Venice, carried out by Montagnani et al. (2006, as cited by RAC, 2017) through urinary arsenic measurement, revealed that workers employed in the mixture preparation and in the furnace work were significantly exposed to arsenic, despite the technical preventive measures adopted (mean concentrations of different arsenic species in the urine samples of workers were 2-3 times higher than the upper limit of reference for the non-exposed population).

As indicated elsewhere, the use of arsenic in the glass production in the Veneto region of Italy, from where data are available in the literature, has stopped. Before it stopped the working conditions in the Veneto region was different from the conditions in the late 1990's when the measurements were done by Apostoli et al. (1999). According to information obtained from SSV - Stazione Sperimentale del Vetro in Murano, the companies today have to carry out a chemical risk assessment and define the best operational conditions (OC) and the best RMMs to reduce as much as possible the risk for worker and to be in compliance with the National and European legislations. Based on the available information all the glassmakers have their "batch house" (small room dedicated to mix the different raw materials" equipped with local ventilation system. Moreover, the furnace is under a small vacuum (exhausts fumes suction) to avoid workhouse contamination and the workhouse has big open windows in the roof to guaranty natural ventilation. The workers are normally using PPE when needed.

However, it is assumed that some uses of the substance could still continue in MS or regions where it is not considered that authorisations would be required. In the absence of newer data, the reported data from Italy will be used as the best data representing any remaining use of diarsenic trioxide in small-scale production of domestic art glass in the EU. Apostoli et al. (1999) reported that typically RPE was not used. The data are nearly 20 years old and it is for the calculation assumed that today at least a simple mask with an efficiency of 60% will be used.

Summary

Special glass sector - Based on the available data, assuming that RPE is used in high-exposure areas, the AM (arithmetic mean) will be estimated at 2.5 µg/m^3 and the log-normal distribution will be based on distributions of concentrations in the other sectors. Data are not available for estimating the total number of workers exposed in the special glass sector, but based on the available information it is estimated to be within the range of 300 - 600.

Domestic glass sector - Current use has not been confirmed, however is assumed that some uses of the substance could still continue in MS or regions where it is not considered that authorisations would be required. The exposure levels are assumed to similar to those reported in the literature from Northern Italy, however it is assumed that today at least a simple mask with an efficiency of 60% will be applied.

3.4.3 Electronics sector

Available information on exposure to inorganic arsenic compounds by production of electronic components in the EU is described below.

Manufacture of copper foils

Data on exposure concentrations by manufacture of copper foils are summarised in the table below based on data from the RAC opinion to the application for authorisation (RAC, 2017), which include more exposure data than provided in the application itself. The assessment for inhalation exposure provided by the applicant was based on a qualitative assessment (WCS1), on modelling, and on results of air monitoring campaigns.

According to RAC (2017)

"The air measurements were undertaken with static (one measurement for WCS2) and personal sampling (one measurement for WCS3), each for about 8 hours. For WCS 2 the static monitoring was performed near the dilution zone. As this task usually lasts less than 15 minutes, the applicant states that the measurement represents a worst case. The result of the personal air monitoring (WCS3) was 0.12 µg/m^3."

The exposure assessment for WCS 4 and 5 was done by modelling, using ART, version 1.5.

Compared to many other processes addressed in this study, the concentration of arsenic compounds in the workplace air is relatively low.

Table 3-7: Exposure concentrations by manufacture of copper foils

WCS	Process description	Method of assessment	Worst case exposure concentration, µg/m^3		Total number of exposed workers
			8h TWA	Corrected for frequency and duration of exposure	
WCS 1	Delivery and storage	Qualitative assessment	0	0	5
WCS 2	Dilution of the substance into a large container	Measured data (Static measurement)	0.24	3.75 x 10^{-4}	4
		Modelled data	5.1**		
WCS 3	Electro-chemical surface treatment	Measured data (Personal sampling)	0.12	0.12	30
		Modelled data	0.50		
WCS 4	Maintenance of equipment	Modelled data	0.05	1.56 x 10^{-3}	7
WCS 5	Sampling for laboratory analysis and control	Modelled data	0.17	2.66 x 10^{-3}	2

Modelled data using ART 1.5
** Note by RAC: The difference between the modelled data and the measured data seems to be important. However, according to the applicant, the model considers that arsenic acid is directly put into the tank, falling from a wide aperture. The applicant claims that they could not take into account, in the modelling, that arsenic acid is poured through a small aperture that limits the exposure to drops.
Source: RAC, 2017a

Gold plating of circuit boards

Data on exposure concentrations by gold plating of circuit boards are summarised in the two tables below, based on data from the applications for authorisation. The RAC opinion does not include exposure data, but states that all inhalation exposures were below 0.3 µg/m^3 for all uses and scenarios. Dermal exposures were estimated at 14 µg/kg bw/day (which RAC consider a significant overestimation).

The assessment for inhalation exposure provided by the applicant was based on measurements at the site combined with modelling (TRA worker v3).

RAC (2014c) states that:

"According to the information provided by the applicant in response to a request for additional information, none of the tasks presented in Use 1 takes longer than 5 minutes. The formulation process is carried out twice a week, which leads to about 100 formulations per year using 0.5 kg of diarsenic trioxide each time. The maximum amount of diarsenic trioxide used is 50 kg per annum."

RAC (2014d) likewise states for Use 2 that:

"According to the information provided by the applicant in response to a request for additional information, WCS 2, 4 and 5 do not take longer than 5 minutes each. The duration of WCS 3 is described as "a few minutes" and it is stated that there is no opportunity for exposure in WCS 1 because the actual mixing of the stock solution is fully automated and enclosed."

Table 3-8: Exposure concentrations by formulation of diarsenic trioxide into a mixture (use 1)

WCS	Process description	Method of assessment	Inhalation systemic and local, µg/m³		Dermal systemic *		Total number of exposed workers **
			Long-term ***	Short term***	Long-term mg/kg bw/day	Acute mg/cm²	
WCS 1	Use in batch processes	Measured	<0.2	<0.2	-	-	100
		TRA Worker v3	0.6	12	0.014	0.002	
WCS 2	Mixing of the substance in batch processes for formulation of preparations	Measured	<0.2	<0.2	-	-	100
		TRA Worker v3	0.6	12	0.027	0.004	
WCS 3	Transfer of the substances from containers at dedicated facilities	Measured	<0.2	<0.2	-	-	100
		TRA Worker v3	0.06	1	0.027	0.002	
WCS 4	Transfer of the substances into small containers (including weighting)	Measured	<0.2	<0.2	-	-	100
		TRA Worker v3	0.6	12	0.069	0.01	

* Due to the small quantity of diarsenic trioxide used, none of the existing modelling tools is fully reliable to estimate dermal exposure. Therefore the given values are considered to represent an overestimation of actual exposures. ** SEA (afa_diarsenic_trioxide-00011-02-sea_en) states that there are 100 workers in the facility in France, but no data are given on how many of these workers are actually exposed to the substance. ***It is not indicated if measure data are 8-h TWA. Short term is usually 15 min.

Source: Linxens (2014).

Table 3-9: Exposure concentrations by industrial use of diarsenic trioxide as processing aid in gold electroplating (use 2)

WCS	Process description	Method of assessment	Inhalation systemic and local, µg/m^3		Dermal systemic *		Total number of exposed workers **
			Long-term ***	Short term ***	Long-term mg/kg bw/day	Acute mg/cm^2	
WCS 1	Mixing of the formulation containing the substance into a large container	Measured	<0.2	<0.2	-	-	100
		TRA Worker v3	0.3	6	0.014	0.002	
WCS 2	Calendering operations	Measured TRA Worker v3	<0.2 0.6	<0.2 12	- 0.027	- 0.002	100
WCS 3	Transfer of the substances from containers at dedicated facilities	Measured TRA Worker v3	<0.2 0.06	<0.2 12	- 0.014	- 9.997E-4	100
WCS 4	Transfer of the substances (in preparation) into small containers for analytical verification of the concentration	Measured TRA Worker v3	<0.2 3	<0.2 12	- 0.034	- 0.005	100
WCS 5	Potentially closed processing operations with minerals/metals at elevated temperature	Measured TRA Worker v3	<0.2 3	<0.2 12	- 0.014	- 5.003E-4	100

* Due to the small quantity of diarsenic trioxide used, none of the existing modelling tools is fully reliable to estimate dermal exposure. Therefore the given values are considered to represent an overestimation of actual exposures. ** SEA (afa_diarsenic_trioxide-00011-02-sea_en) states that there are 100 workers in the facility in France, but no data are given on how many of these workers are exposed for the substance. ***It is not indicated if measure data are 8-h TWA. Short term is usually 15 min.
Source: Linxens (2014).

Manufacture and use of gallium-arsenic wafers and other semiconductors

According to a response from the European Semiconductor Industry Association (ESIA) to the stakeholder consultation, the industry uses some inorganic arsenic compounds in gaseous form and in small amounts in the semiconductor manufacturing process. According to ESIA

"*Arsenic use is strictly controlled and monitored to prevent human exposure. This is accomplished through application of a combination of technologies and risk management control measures, including sealed tools, negative air pressure, constant monitoring, control equipment, automatic shutdown* *capability and containment. Arsenic has been used as a dopant in the silicon based semiconductor industry for decades now, and it is a well characterized material and the safety issues of handling this material as well as the environmental impact of this material in manufacturing have been addressed to the satisfaction of regulatory agencies. Stringent risk management measures are implemented in the manufacturing factories. There is no release to the work place environment during production due to the use of closed systems, thus preventing worker exposure. Automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment*."

According to the note, some exposure may take place by maintenance work and the note distinguishes between two types of maintenance: cleaning and preventive maintenance.

Cleaning maintenance - "*During the cleaning maintenance phase of the equipment tool, the tool is briefly opened. In considering the potential risk and exposure in this maintenance scenario, it is important to note the following; the duration and frequency of such cleaning maintenance for semiconductor equipment tools is not very high. Typically the duration of cleaning takes from around 30 minutes up to 1 hour. Typically the cleaning frequency per equipment tool is around once every 2 weeks per technician. Typically technicians are rotated in cleaning maintenance activity. Based on personal air sampling (in the breathing zone) on arsenic during various maintenance scenarios, results taken from some European semiconductor factories sampling concluded that most measurements taken, were below the detection limit of 0.0010 mg/m^3 (as a total sum of arsenic in terms of airborne contaminant) and all were significantly below the relevant applicable occupational exposure limit value for arsenic in those respective European countries. To note those results do not take into account personal protective equipment - typically in cleaning maintenance activity scenario, fresh air helmets (SATA type) are worn."*

Preventive maintenance - "*Based on personal air sampling (in the breathing zone) on arsenic during various maintenance scenarios, results taken from some European semiconductor factories sampling concluded that most measurements taken were below the detection limit of 0.0010 mg/m^3 (as a total sum of arsenic in terms of airborne contaminant). Some measurements conducted during the preventive maintenance were less than 25% of the local applicable arsenic 8hr TLV. To note those results do not take into account personal protective equipment - typically in preventative maintenance activity scenario, fresh air helmets (SATA type) are worn. Scenario 2: 'Preventive Maintenance' in addition semiconductor manufacturing companies implement another tier of maintenance for equipment tools called 'preventive maintenance'. These are conducted with a frequency of once or twice a year typically per equipment tool and they typically last several hours. All equipment are fluxed before opening and local ventilation is available during the whole preventative maintenance operation. Based on personal air sampling (in the breathing zone) on arsenic during various maintenance scenarios, results taken from some European semiconductor factories sampling concluded that most measurements taken were below the detection limit of 0,0010 mg/m^3 (as a total sum of arsenic in terms of airborne contaminant). Some measurements conducted during the preventive maintenance were less than 25% of the local applicable arsenic 8hr TLV. To note those results do not take into account personal protective equipment - typically in preventative maintenance activity scenario, fresh air helmets (SATA type) are worn*".

According to this information, the concentration by maintenance operations will be below 1 µg/m^3 (not taking into account PPE).

According to information provided as part of the stakeholder consultation by a company involved in the production of gallium arsenide wafers, measurements of inhalable dust in the air at workplace by personnel sampler fixed at the coat revealed 8-h TWA concentrations by monitoring at machines at

4.3 µg/m^3 and by cleaning of machines at 37 µg/m^3 i.e. significantly higher than the concentrations reported from the semiconductor industry above. As the duration of cleaning operations was maximum 2 h/day and operators have to wear respiratory masks, the actual exposure concentrations would be, according to the company, well below 10 µg/m^3, and the company assess that no further measures would be needed to meet an OELV of 10 µg/m^3.

Park et al. (2010) reviewed arsenic level statistics from air and wipe samples taken from studies conducted in the semiconductor industry in the USA, Taiwan, and the UK. A total of 40 statistical summaries from seven articles were identified that represented a total of 423 airborne arsenic measurements. Arsenic exposure levels taken during normal operating activities in implantation operations (weighted arithmetic mean: 1.6 µg/m^3; 77 samples) were found to be lower than exposure levels of engineers who were involved in maintenance works (7.7 µg/m^3; 181 samples), while the highest level (218.6 µg/m^3; 76 samples) was associated with various maintenance works performed inside an ion implantation chamber. The measured concentrations did not take PPE into account.

According to Sheehy and Jones (1993), NIOSH conducted a study of arsenic exposures and control systems for gallium arsenide operations at three microelectronics facilities in the USA during 1986 – 1987. Results at the plants showed noticeable varying concentrations. In one plant with the highest concentration in all processes evaluated but one, the average arsenic exposures were equal to or above 5 µg/m^3, with a maximum exposure of 8.2 µg/m^3 while cleaning the liquid encapsulated Czohralski pullers. It is indicated that no ventilation was in place. Area arsenic samples collected at the plant in break-rooms and offices, 6 – 20 meters from the process rooms, had average arsenic concentrations of 1.4 µg/m^3.

Workers involved in the production of CdTe-based photovoltaic modules may be routinely or accidentally exposed to As- or Cd-containing inorganic compounds. Spinazzè et al. (2015) investigated exposure to As and Cd by environmental monitoring following a worst-case approach, and biological monitoring from the preparation of the working facility to its decommissioning. The highest mean airborne concentrations were found during maintenance activities with arsenic concentrations of 0.0068 µg/m^3 and by laboratory simulations with arsenic concentrations of 0.0075 µg/m^3 (lower than the reported LOQ). These types of operations were conducted for a limited time during a typical work shift and only in specifically suited containment areas. The paper does not specify how arsenic is used in the process, but the semiconductor material gallium arsenide (GaAs) is also used for single-crystalline thin film solar cells and would likely be the source.

Summary

The available data support the view of the ESIA that in general the exposure levels by use of arsenic-containing semiconductors in the electronics industry is low, but higher exposure concentrations occur by some maintenance procedures, where the use of PPE is required in order to be in compliance with existing OELs in the MS. According to the available information, PPE is today used by these operations.

None of the companies indicated that compliance with an OELV of 10 µg/m^3 would require any additional RMMs.

An average figure of 1 µg/m^3 will for the assessment be used as AM for all exposed workers in the sector, and the distribution of concentrations will be based on distributions from other sectors. By this approach the few workers exposed at higher concentrations (but with the use of RPE) will be taken into account.

3.4.4 Chemicals sector

Production of the substances with major uses, diarsenic trioxide and arsenic acid, takes place in the metallurgical sector and the exposure concentrations in the workplace is included in "secondary copper production".

The only granted authorisation for the sector, "Industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide by potassium carbonate" has, according to the available information, ceased as the arsenic compounds have been substituted.

No data on exposure concentration by manufacture or use of other inorganic arsenic compounds in the chemicals sector have been obtained from the stakeholder consultation. CEFIC has been contacted as part of the stakeholder consultation but no specific data on inorganic arsenic compounds have been obtained.

Former major uses of inorganic arsenic compounds in the chemicals sector was in the production of biocides and pesticides but as the use of arsenic compounds as biocides and pesticides is no more permitted, this use has ceased.

The MEGA database contain a dataset with 10 samples in 6 companies indicated as "Chemicals and polymer industry". The 95th percentile of the data is 0.5 µg/m^3 but the highest detection level is 0.9 µg/m^3 (IFA, 2017).

No data on exposure to arsenic in the chemicals sector have been identified in the literature.

Arsenic compounds within the scope may be produced in quantities below 1 t/year, e.g. for use as analytical standard, but no specific data on such production have been obtained. The export notifications reported for the PIC Regulation are from Belgium, France, Germany, Spain and the UK; all Member States with traditions of manufacture of fine chemicals. As indicated before, the compounds are expected to be produced under strictly controlled conditions and the possible exposure to inorganic arsenic compounds of a very limited number of workers has therefore not been assessed further.

Sulphuric acid production

As indicated in Section 3.3.4, occupational exposure to arsenic in the manufacture of sulphuric acid is expected mainly to take place in facilities where the source of sulphur dioxide is gas from non-ferrous smelters and pyrite.

One of the companies in the copper sector reported during the stakeholder consultation that some 60 workers may be exposed in a sulphuric acid plant manufacturing sulphuric acid from gas from the primary smelter. The geometric mean of personal samples was 0.6 µg/m^3 (other parameters not reported). Two companies have mentioned that the workplace concentrations in the sulphuric acid plant at the site was low and not of concern, and did not provide any specific exposure data. According to the BAT document for the nonferrous metal sector, all the primary copper smelters and a number of the primary zinc smelters have sulphuric acid plants; in total 19 plants in the EU.

Offergelt et al. (1992) studied the relation between exposure to diarsenic trioxide fumes and dust, and the urinary excretion of in-organic arsenic metabolites in 18 workers from a sulphuric acid producing plant (country not indicated). The concentration of arsenic in the breathing zone of each worker was measured during five consecutive days and urine samples were obtained after one shift and before the next. The study was conducted in a chemical factory producing sulphuric acid by a process involving the roasting of pyrite containing 0.45% of arsenic; diarsenic trioxide dust and fumes were released mainly during the early steps of the production process. Twenty-two male workers participated in the study; four of them (controls) were occupied in a section of the plant with no occupational exposure to arsenic. None of the workers used a respiratory protective device.

The time weighted average exposure (TWA) concentrations of diarsenic trioxide ranged from 6 to 502 µg/m^3 diarsenic trioxide and were log normally distributed. The average of personal samples for 15-18 workers in the five executive days showed daily averages (GM of the 15-18 samples each days) ranging from 37.3 µg/m^3 (6.5-159) to 52.2 µg/m^3 (6.2-502). The GM for all days was about 45 µg/m^3 diarsenic trioxide corresponding to an arsenic concentration of 34 µg/m^3. For the four control workers, the breathing zone air concentration of arsenic ranged from 0.1 to 0.3 µg/m^3. Statistically significant correlations (log scales) were found between airborne TWA of diarsenic trioxide and the inorganic arsenic metabolites in urine collected immediately after the shift, or just before the next shift. For a TWA of 50 µg µg/m^3, the GM concentration of the sum of the three inorganic arsenic metabolites in a post shift urine sample amounted to about 55 µg arsenic/g creatinine (95% confidence interval : 47-62).

No new data on exposure to arsenic by production of sulphuric acid from pyrite have been obtained. Sulphuric acid from pyrite is today produced in Finland (OEL of 10 µg/m^3) and Germany (OEL of 8.3 µg/m^3 "tolerable risk") and it is most unlikely that the processes are undertaken without the use of an RPE with an efficiency of at least 95%. As the companies would not be impacted by establishing an OELV of 10 µg/m^3, these activities are not further assessed.

Summary

Based on the available data, the major potential source of exposure to inorganic arsenic substances in the chemical sector is the production of sulphuric acid from pyrite where arsenic is present as impurity in the raw materials.

3.4.5 Copper sector

Primary copper and nickel production

Data on exposure levels have been received from all 7 primary copper smelters in the EU as part of the stakeholder consultation. The data also represent primary nickel production taking place in the same facilities.

The questionnaire results are shown in Table 3-10 as reported by the companies. The measurements are personal samples and not adjusted for the use of PPE. All companies report that respiratory protection equipment is used in all areas with high exposure. The driver for the use of RPE is typically the content of sulphuric dioxide and arsenic in the workplace air. In order to be in compliance with the existing national OELs, workers in many parts of the production need to wear PPE, ranging from simple half-piece masks with filters to powered air purifying respirators with a hood face-piece. It seems to be common that RPE is not used all the time in the electrolytic plant where exposure levels are relatively high.

In order to not disclose information that can be related to one company, the total for groups of processes is provided, but the underlying data are used for calculations. The grouping into processes is not the same for all sites as some companies report aggregated data for all processes. For most sites exposure concentrations in the tankhouse is not reported because the exposure level is in general low and for the same reason only one company report on the exposure level by production of sulphuric acid.

For most of the sites, the data show higher concentrations in the flash furnace area (arithmetic means of 11 - 36 µg/m^3) and lower concentration in the electrolysis tankhouses (arithmetic means of 0.8 - 3 µg/m^3 and not reported from several of the companies.)

One site differed significantly from the others with 90th percentiles of 730, 150 and 61 µg/m^3. The 90th for one of the processes was thus 10-20 times higher than seen for the high exposed workforce in other sites. However the number of workers is low indicating that the site only report for the workplaces with the highest exposure levels.

From one site, the measurements represent an average for a working day with rotation i.e. the workers are only in high exposure areas for a part of the day. The same would be true for other companies, but in other companies measurements in high exposure in order areas are typically calculated as 8-h TWA for the area concerned.

All companies are large enterprises with more than 250 employees.

The total number of exposed workers indicated in the questionnaires is approximately 3,200.

In order to better understand how the numbers of exposed were determined, more detailed data were obtained from one site as part of a site visit. Of the total number of employees at the site, it was estimated by those responsible for the monitoring programme at the site that 75-85% of the staff may potentially be exposed directly or indirectly. The biomonitoring programme included ~ 65% of the total staff. Of the biomonitored employees, about 50% had levels not significantly different from the non-exposed population in the area. It means that ~31% of the total staff was occupationally exposed at measurable level above the background level in the area. The percentage exposed may be relatively high in a process where arsenic is present as an impurity and dust with arsenic may be spread to a large area of the facilities.

According to the European Copper Institute (ECI, 2017) about 10,000 people are employed across 13 copper refineries in the EU, of these a part in secondary smelters. As the measured concentrations concern the 3,200 most exposed workers, this number will be used for the further estimates. However as mentioned above, up to 85% of the total workforce in the sector may potentially be exposed at low levels (below those reported by the companies).

The primary smelters are located in Finland (OEL of 10 µg/m^3), Germany (8.3 µg/m^3 "tolerable risk"), Spain (10 µg/m^3), Sweden (10 µg/m^3), Poland (10 µg/m^3) and Bulgaria (50 µg/m^3). If an OELV of 10 µg/m^3 or above is established, only the company in Bulgaria would need to comply with a lover level than the national level today.

Some companies have pointed to the situation that the company cannot comply with the national OEL or "tolerable risk" level without the use of RPE. A group of workers which potentially may be exposed to high levels of arsenic (and was so in the past), are crane drivers; however the cranes are today typically closed and equipped with filters so the workplace concentration within the crane is low.

Table 3-10: Data reported by primary copper smelters for the stakeholder consultation

Process	Process step (as reported)	Total number of workers exposed	Number of samples, n	Exposure concentrations, µg/m³, Personal samples, 8h-TWA (without adjustment for RPE)					Use of RPE
				AM	GM	90th	95th	Max	
Raw materials handling, incl. sampling and control	Raw materials handling, incl. sampling and control	391	11	3	-	3	8	11	Most of the working processes
	Raw materials handling, incl. sampling and control		3		1 *				RPE used in high exposure areas
	Raw material handling incl. sampling		-	4	Median: 1	-	-	23	RPE used
	Raw material handling incl. sampling		304	1.7		3	7		RPE type depends on exposure level
Smelting processes	All smelting processes - incl. cleaning and maintenance in smelting area	1618	70	12	-	33	45	79	RPE used
	Flash furnace area furnaces, tapping		3		3 *				In high exposure areas
	Converting and fire refining		3		2 *				In high exposure areas
	Operation in flash furnace area		-		-	61 15 min:18**			RPE used
	Smelter area works, lifting works		-		-	150 15 min:160			RPE used outside crane cabins
	Maintenance work in smelter		-		-	730 15 min: 980			RPE used
	Furnace area (flash furnace, converter and anode furnace)		-	19	Median: 13	-	--	98	RPE used
	Anode casting		-	2	Median: 1	-	-	6	RPE used
	Manufacturing and processing of minerals and/or metals at substantially elevated temperature		-	36	-	-		-	RPE used
	Open processing and transfer operations at substantially elevated temperature		-	22	-	-		-	RPE used

Table 3-10: Data reported by primary copper smelters for the stakeholder consultation

Process	Process step (as reported)	Total number of workers exposed	Number of samples, n	Exposure concentrations, µg/m^3, Personal samples, 8h-TWA (without adjustment for RPE)					Use of RPE
				AM	GM	90th	95th	Max	
	Smelting furnaces, tapping	429	634	11		18	28		RPE type depends on exposure level
	Converter, anode furnace, anode casting		287	6.9		17	26		RPE type depends on exposure level
	Primary copper smelting - all processes		115		Median:4	19		212	ABEK P3 filter masks
Tank house - electrolysis plant	Electrolytic refining/Tank house		-	3	Median: 2	-	-	9	RPE used
	Tankhouse – electrolysis plant		136	0.8		2.0	3.5		RPE type depends on exposure level
	Electrolysis		66		Median: 2	5		12	ABEK P3 filter masks
Processing of spent electrolyte and other waste handling	Recovery of electrolyte and processing of sludge	200	31	0.8		2.5	2.7		RPE type depends on exposure level
	Electrolysis plant, slime recovery		3		2 *				RPE used
	Waste handling		11	6	-	11	17	25	Most of the working processes
	Processing of electrolytes		9	1	-	9	10	10	PPE used during tapping
	Processing of spent electrolyte		-	12	Median: 3	-	-	49	RPE (respirator)
Sulphuric acid production	Acid production	60	3		0.6 *				
Maintenance work, general	Maintenance operations	534	612	4.8		9	15		RPE type depends on exposure level
	Maintenance works		-			63			RPE used
Total number of workers (rounded)		3,200							

* The measurements represent an average for a working day with rotation i.e. the workers are only in high exposure areas for a part of the day

**As reported but seems incorrect

Sources: Stakeholder responses

Sińczuk-Walczak et al. (2010) studied 21 workers in a copper smelter in Poland. Occupational exposure of workers was assessed by determining As concentration in urine and workplace air. Workplace concentration was measured by individual air sampling in the worker's breathing zone. The concentration in the workplace air measured using individual dosimetry ranged from 4 to 30 µg/m^3 (8h TWA) which is well in accordance with the data reported in the table above. Use of PPE was not reported.

Similar results have been obtained in a further study on the same company by Sińczuk-Walczak et al. (2014), where symptoms of neuropathy (fatigue and pain of the extremities, paraesthesia of lower extremities) were increased in the exposed workers. The workplace concentration ranged from 0.7-92.3 µg/m^3 (mean 25.2 µg/m^3), exceeding the Polish OEL of 10 µg/m^3 in 12 of the 21 examined workers. Use of PPE was not reported.

Newer data has been obtained from both the Polish primary copper smelters and included in the table above.

Secondary copper production

Secondary copper production takes place at 8 sites in the EU. At some sites, both primary and secondary production takes place; the secondary production, (or processes shared between the processes), has not been reported separately and is included in the data and the estimates of exposed workforce under primary smelters.

In many of the companies lead and other metals are produced as by-products.

The sources of arsenic in secondary production are mainly arsenic in some residues from other industrial processes and arsenic present as alloying element in some recycled copper alloys.

A detailed description of the sources has not been obtained. Likely the total arsenic in the raw materials may vary between the smelters depending on the composition of the waste materials.

In general the companies report that RPE is used. The RPE is e.g. indicated as "RPE (FFFP3)"[19] or "specific RPE used" or it is indicated that RPE is used by cleaning work and in areas with high exposure concentrations.

Questionnaire responses for four sites with a total of 1,325 exposed workers are shown in Table 3-11 below. The concentrations have not been adjusted for the use of RPE. It is reported by all companies that respiratory protection equipment is used by exposed workers. One of the companies provided the data with a correction factor of 40 for RPE (FFP3 masks), which has been recalculated in the table into figures without RPE. Furthermore one company has reported that a few samples were taken, all below 10 µg/m^3. As the exact values are not reported they are not included in the table.

The overall pattern is that the mean concentrations is lower in the secondary smelters than in the primary smelters, but one of the companies still reported an AM of 10 µg/m^3 for workers involved in smelting of raw materials - all processes.

The numbers below represent four of the major sites, and it is estimated that the total number of exposed workers at all 8 EU sites will be in the range of 2,000-3,000 with 2,500 as the best estimate. The total for primary and secondary smelters is estimated at 5,700. If the total is 10,000 employees in the sector, the percentage of the workforce exposed to arsenic compounds will be approximately 57%.

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[19] FFFP3 filters are comparable to RPE designated "simple filter" in the RMM section.

However, the data may also indicate that the total employed in the sector may be higher than the reported 10,000.

Table 3-11: Data reported by secondary copper smelters for the stakeholder consultation

Site	Process step (as reported)	Total number of workers exposed	Number of samples, n	Exposure concentrations, µg/m³, Personal samples, 8h-TWA (without adjustment for RPE)					Use of RPE
				AM	GM	90th	95th	Max	
Sampling and transport	Sampling of raw materials	271	67	12					Yes
	Transportation of materials [a]		54	0.4					Yes
	Quality and Sampling dept.		10	0.1		0.3		0.9	Yes
Smelting processes	Smelting of raw materials (all processes)	730	>50	3.2		10			RPE in high exposure situations
	Operating furnaces /metallurgical process		72	1.0		2.1		9	RPE (FP3)
	Smelting of raw materials (all processes		150	11		24		141	RPE by cleaning work by high concentrations
	Smelting in blast furnace		103	9.2					Yes
	Smelting the raw materials		79	1.6					Yes
Refining and distillation	Refining of metals	265	205	1.2; 2.2 (2 processes)					Yes
	Operate distillation		27	1.0		2		9	Yes
	Operating the chemical department in the tankhouse / dust fumes		19	7.5		20		49	Yes
	Electrowinning		20	1.4					Yes
Maintenance	Maintenance dept.	59	8	0.5				1.5	Yes
	Total workforce	1,325							

* Data were reported with correction factor of 50 for PPE (FFP3 masks) and have here been recalculated without PPE

Sources: Stakeholder responses

The secondary smelters are located in Belgium (OEL of 10 µg/m^3), Sweden (10 µg/m^3), Germany (8.3 µg/m^3 "tolerable risk"), Spain (10 µg/m^3), Slovakia (100 µg/m^3), and Austria (100 µg/m^3). If an OELV of 10 µg/m^3 is established, the companies in Austria and Slovakia would need to comply with a lover level than the national level today.

No data on occupational exposure to arsenic in secondary copper smelters have been identified in the literature.

Copper-arsenic alloys

No specific data regarding exposure concentrations by manufacture and use of copper alloys have been obtained by the stakeholder consultation and or have identified in the literature.

A manufacturer of copper, tin and lead master alloys with arsenic, report that these alloys are produced in fully contained and ventilated rooms, by personnel that wears full protection equipment: a full face mask and a disposable overall that is disposed of directly after use. With the use of these protective measures contact to arsenic is avoided as much as possible. Regular measurements take place, that show that exposure levels to arsenic remain below 10 µg/m^3 (actual data not further reported).

It should be noted that arsenic in the final alloys are present as metallic arsenic and exposure to the metallic arsenic e.g. by machining of the alloys, would not be within the scope.

Sulphuric acid

One of the primary copper smelters reported for the stakeholder consultation that some 60 workers may be exposed in a sulphuric acid plant manufacturing sulphuric acid from gas from the primary smelter. The geometric mean of personal samples was 0.6 µg/m^3 (other parameters not reported). Two companies have mentioned that the workplace concentrations in the sulphuric acid plant at the site was low and not of concern, and did not provide any specific exposure data. According to the BAT document for the nonferrous metal sector, all the primary copper smelters have sulphuric acid plants. The arsenic typically ends up in a sludge in the primary step of the flue gas cleaning before the sulphuric acid production, and exposure may e.g. take place by maintenance and cleaning operations. These operations may likely be included under cleaning and maintenance operations and not specifically reported for the production of sulphuric acid. Consequently, it is expected to be included in the estimations for the primary copper smelters.

3.4.6 Zinc production using diarsenic trioxide

The opinions of the RAC to the two applications for authorisation discuss the exposure concentrations in the different processes. The applications include both actual measured exposure concentrations and modelled concentration.

Personal and stationary air measurements, modelling of exposure, and biomonitoring data were used by the applicants to assess worker exposure and reported in the non-confidential parts of the CSRs. In addition, some information has been submitted by the applicants for the stakeholder consultation.

Personal sampling data are shown in the table below.

Static sampling data (n=51) close to As_2O_3 feeding area was available: mean: 4 µg/m^3, median: 2 µg/m^3, 90th percentile: 8.2 µg/m^3, max: 27 µg/m^3.

Table 3-12: Data reported by companies using diarsenic trioxide for electrowinning

Site	Process step (as reported)	n, exposed	n, samples	Exposure concentrations, µg/m³, Personal samples, 8h-TWA (without adjustment for RPE)					Use of RPE
				AM	GM	90th	95th	Max	
Site 1	Unloading/mixing work (WCS 1)*		51	8.7		23		46	RPE 90% efficiency
	Handling/mixing, service of the process equipment, cleaning **	15				23			Full-face respirator mask
Site 2 ***	Solution purification department, control of process *		5	0.15		0.22		0.25	
	PROC code : 3	25	8	3.2				6.6	RPE gem. ABE1, P3 Eff. 95% efficiency
	PROC code : 1/2/3	16	8	3.2				6.6	Not indicated
	PROC code : 1/2/3/9/26	16		<LOD					Not indicated
Sources: * Authorisations application, ** Apparently same data reported for stakeholder consultation PROC: Process category *** Stakeholder consultation.									

In the other company, the most recent **personal sampler data** (n=5) in workplace air of the solution purification department showed concentrations of 0.06 – 0.25 µg/m^3 (mean: 0.15 µg/m^3, 90th percentile: 0.22 µg/m^3; personal samplers, full 8 hr shift). Tasks of the operators' process were the control of process, sampling, cobalt- and cadmium-analysis, supervision of the emptying of filter presses, routine cleaning works. For workplace air in a distance of 2-3 m to the packing station, the most recent stationary air quality measurements (year 2013) was 0.3 µg/m^3 As. The use of personal protective equipment (PPE) (including respiration protective equipment (RPE)) was assumed by the applicant to reduce the exposure by at least 90%.

The exposure concentrations used by RAC for risk estimates are summarised in the table below. RAC noted that RPE (respiratory mask) was used for WCS 1 "Preparation of arsenous acid solution (PROC 3)", whereas for all other WCS, RPE was normally not needed but was still available if necessary if dust is generated. According to this estimate, in total 90 workers were exposed. The total for the questionnaire response as shown above was 40 exposed workers. However, the 90 would be used for the further assessment.

The weighted average modelled data with RPE will be used as best estimate for the AM and the distribution will be estimated from experience from other sectors.

Table 3-13: Exposure concentrations by zinc production using diarsenic trioxide used for risk estimate					
WCS	**Process description**	**PPE**	**Method of assessment**	**Worst case exposure concentration µg/m^3** **Company 1; Company 2**	**Total number of exposed workers**
WCS 1, 3, 5 (high exposure)	Unloading and dissolving As2O3, Quality control, manual sampling and analysis, Cleaning of site and handling of waste	With RPE	Modelled	1.85 ; 0.12	20
		Without RPE	Modelled	18.5 ; 1.2	
WW 2, 4 (Low exposure)	Leaching process and selective precipitation, Maintenance work	With RPE	Modelled	0.25 ; 0.02	70
		Without RPE	Modelled	2.5 ; 0.22	
Sources: RAC, 2014 a,b					

Summary

Diarsenic trioxide is used by two companies in the sector. Exposure data are available as measured and modelled data. The weighted average modelled data with RPE (20 workers exposed at 1.9 µg/m^3 and 70 workers at 0.25 µg/m^3) will be used as best estimate for the AM and the distribution will be estimated from experience from other sectors.

3.4.7 Other non-ferrous metals

Limited data have been available regarding exposure to inorganic arsenic compounds by the manufacture and processing of other non-ferrous metals.

The dataset from the German MEGA database contain some measurements from a process indicated as metal production, but it is not indicated whether the data represent copper production and the data are not used here to represent other non-ferrous production.

Production of precious and rare metals - A number of responses to the stakeholder consultation have been obtained from companies undertaking various processes which involve processing and handling of rare metals including arsenic and arsenic compounds. In order not to disclose company-specific information, the various processes reported are described collectively in the table below. Some precious and other rare metals are produced as by-product in both primary and secondary copper smelters and these activities are included under the copper sector (several of the copper smelters are members of the European Precious Metals Federation).

It is not possible to assess to what extent the stakeholder responses are representative for the sector. The companies undertake unique processes and likely these companies handle larger amounts of arsenic containing raw materials than the average.

Table 3-14: Data reported for production of rare metals

Process step (as reported)		Number exposed	Number of samples	Exposure concentrations, µg/m^3, Personal samples, 8h-TWA (without adjustment for RPE)					Use of RPE
				AM	GM	90th	95th	Max	
Pre-treatment	Transfer	9		0.4[b]					No
	Unloading containers	9	4	5.4				9.2	Dust mask (P3)
	Loading and unloading activated carbon[a]	9	1	1.9					No
Process	Crushing	3	n.i.	0.6					No
	Handling of arsenic trioxide	9	n.i.	150					Full RPE
	Sampling and packaging[a]	11	n.i.	2					No
	Sampling before reduction and drying[a]		n.i.	2.2					No
	Sampling during concentration process[a]	15	3	0.8				1.0	No
	Taking samples and maintenance[a]	6	1	7.9					RPE
	Production of metal	9	n.i.	14					Full PPE
Post treatment	Filling containers[a]	2	n.i.	22.8					Dust mask (P3)
	Packing	2	n.i.	2.9					No
	Waste water treatment plant	1	n.i.	5					No
Total number of workers		85							

[a] also include cleaning and maintenance

[b] no distinction between personal and static measures given

Sources: Stakeholder consultation

Primary zinc and cadmium - The International Cadmium Association (ICdA) has been requested information on exposure concentrations for inorganic arsenic compounds from the production of zinc and cadmium, but no data has been obtained.

The international Zinc Association (IZA) has to the stakeholder consultation answered that most, if not all, the zinc smelters have some arsenic as impurity in their concentrate and so in their process, but in very low concentrations (<0.5%). The organisation estimates that if As exposure take place, it must be at very low levels.

The two zinc plants using diarsenic trioxide (previous section) for the stakeholder consultation report on exposure from the use of the arsenic substance but do not mention other sources of exposure.

For one of the zinc plants using diarsenic trioxide for electrowinning it is reported that the annual use of diarsenic trioxide is 700 t/year maximum corresponding to 530 t/year As. The overall amount of As in the zinc plant process is reported at 900-1,300 t/year, which means that 470 - 870 t/year is arsenic present in the zinc ore (Boliden, 2014). If the raw materials used in other zinc plants in the EU correspond to this, to total content of arsenic could be in the range of 2,000 - 4,000 t/year or of same size as the total in copper ore. This would suggest some potential exposure to arsenic compounds by the primary production of zinc.

Gaweda (2005, as cited by RAC, 2017) measured cadmium, nickel and arsenic concentrations in the workplace air at a Polish zinc smelter. Personal air samples (15 minutes, sampled once or twice and extrapolated to full shift) were taken at "several dozen" workstations, each with 2-6 workers involved in copper, zinc, cadmium, lead, silver refining, sulphate of Ni(I), and selenium production. In the zinc smelter the amounts of arsenic determined in the air were all below 3.3 µg/m^3 for production of raw zinc.

Bochman et al. (2002) reported on the trend in concentration of cadmium, lead and arsenic in a cadmium smelter in Sachsen in Germany. During the period from 1970 to 1990 the average concentration in measured workplace air decreased from 57 to 10 µg/m^3. The further conditions regarding the measurements and the trend since 1990 are not reported.

Lead alloys - The International Lead Association (ILA) and the trade associations for batteries (EUROBAT) and sporting ammunition (AFEMS) have been contacted. As mentioned in section 3.3.7, according to ILA all smelters in the sector could potentially face the issue of being affected by an OELV, but very limited specific exposure data have been obtained from the stakeholder consultation.

Several stakeholders have mentioned that lead is the metal of concern in the lead foundries and determining for the RMMs implemented and for this reason arsenic, present in much lower concentrations, is not monitored. This is also indicated in the German technical rules for hazardous substances 561 which for lead production states: "*The protective measures which are required due to the lead concentration cover the additional hazards caused by the carcinogenic metals*" (GMBI (2017)

The website of the European Association of Manufacturers of Sporting Ammunition lists two manufacturers of lead shot in the EU: one in Italy and one in Greece. Both produced lead shot from lead recovered from waste batteries. Lovreglio et al. (2017) studied 18 exposed workers at a birdshot factory in Italy and 18 control workers by the determination of both airborne lead and airborne arsenic. The factory produces lead birdshot with a lead alloy with 2% antimony and 0.2% arsenic. The factory recovers the lead from waste lead batteries and adds the arsenic metal as alloying element. The measured data of personal samples are shown in the table below. Concentrations of airborne lead (12–42 µg/m^3) were strongly correlated with airborne arsenic (1–4 µg/m^3) with the concentrations of arsenic at approximately 1/10 of the lead concentration. Use of RPE is not reported. It is also reported that urinary arsenic of occupationally exposed workers was significantly above the level in non-exposed controls.

Table 3-15: Concentration of airborne arsenic in lead shot factory in Italy, personal sampling, 8-h TWA *

	n	Measured concentration, µg/m³
Recycling waste batteries plant	2	2; 2
Foundry/rotary furnace	2	2; 3
Birdshot production plant	1	4
Lead wire production plant	1	1
Buckshot moulding plant	2	1; 1
Warehouse	1	1

The LOD in terms of µg/m³ is not reported
*The sampling lasted about 6 hours but the concentrations are indicated as TLV-TWA ACGIH and assumed to be 8-h TWA.
Source: Lovreglio et al. (2017)

From one major recycling company for lead batteries it is reported that the arsenic content of the recycled lead is below 0.01% indicating that the use in batteries today is low. The company further informs that exposure to arsenic by the recycling is not an issue. One smaller recycler of lead informs that arsenic in workplace air is not measured and not considered an issue. A former director of a lead foundry informs that arsenic in workplace air was not measured.

Two recycling companies for batteries report arsenic emission to the E-PRTR. The reported emission in 2015 was 163 and 52 kg/y, respectively.

According to a stakeholder response from AVNeG, the branch association of Dutch metal casting companies, arsenic is sometimes measured in foundry dust. The metals are part of the castings alloys in low concentrations. The exposure is reported to be below the present OEL in the Netherlands (2.8 µg/m³) and it is reported that exposure to these substances through foundry activities is no source of concern to the companies.

According to a stakeholder consultation response from the Central Institute for Labour Protection, National Research Institute in Poland, some studies conducted by the institute found arsenic and its compounds at workplaces of foundry moulders (type not specified) at the level of 0.4 - 3 µg/m³.

Summary

The reported data from the stakeholder consultation represent in total 85 workers from rare metal production with a weighted AM at 20 µg/m³. With the reported use of RPE for the processes with high exposure concentrations, the AM is reduced to around 3 µg/m³. Data from a birdshot factory indicates exposure levels in the range of 1–4 µg/m³. The AM of 3 µg/m³ will be used as a best estimate for assumed 300 - 1000 workers (650 best estimate) exposure at similar levels as reported. The distribution of exposure levels will be derived from other exposure sources.

3.4.8 Welding, plasma cutting and similar processes

Data from the German MEGA database for welding, plasma cutting and similar processes are shown in Table 3-16. The data represent the period 2000-2017. It is in general not reported where in the sectors samples are taken and the possible sources of arsenic is not reported.

The dataset on welding, plasma cutting and similar thermal processes represent 432 personal samples and demonstrates that some exposure to arsenic is widespread in the sector with 90th percentiles in the range of 1.4 to 4.0 µg/m³. Some stationary samples for cutting processes from three companies demonstrate very high short-term levels (< 2 h) with a 90th percentile at 66 µg/m^3. It is not reported if analysis of arsenic has been undertaken in process where the risk of exposure to arsenic is particularly high. Even if the number of companies is high (89 for one of the processes), the data may not be considered random samples and representative for the entire sector. In comparison to this dataset, the dataset for chromium (VI) in welding, plasma cutting, etc. of stainless steel contain 3,695 samples (Pesch et al., 2015). Some of the processes may also take place in buildings with a general high level of arsenic in workplace air e.g. in copper smelters. Even if the data may not be representative for all welding, plasma cutting and similar thermal processes; they demonstrate that a high number of workers may be exposed to arsenic from these processes.

Table 3-16: Data from the German MEGA database 2000-2017, welding plasma cutting and similar processed

Process step	Sampling duration	Number of samples	Number of enterprises	Max LOD µg/m^3 *	<LOD *	Exposure concentrations, arsenic compounds, µg/m^3 **		
						50th	90th	95th
Personal samples (without adjustment for RPE)								
Laser, plasma and oxy-fuel cutting	≥ 2h	21	14	0.84	8	0.4	2.0	2.1
MAG (Metal Active Gas) welding	≥ 2h	215	89	7.2	108	<LOD	1.5	2
	≥ 2h	32	20	1.5	4	0.8	2.8	3.5
TIG (Tungsten Inert Gas) welding	≥ 2h	78	18	10	76	<LOD	<LOD	<LOD
Welding, other processes	≥ 2h	75	31	10	51	<LOD	1.4	2.2
	≥ 2h	11	7	1.3	5	0.7	4.0	4.6
Stationary samples								
Laser, plasma and oxy-fuel cutting	≥ 2h	20	3	5.9	4	66	340	370
MAG (Metal Active Gas) welding	≥ 2h	34	18	2	21	<LOD	0.5	0.7
Welding, other processes	≥ 2h	25	11	1.5	16	<LOD	0.7	0.8

* The LOD differs among the analysis, the max LOD indicates the maximum LOD in any analysis whereas the <LOD indicates the numbers below the actual LOD of the individual analyses.

** It is noted that results collected for ≥ 2h can be considered as representative for the entire shift whereas results for < 2h only represent the sampling time. i.e. the ≥ 2h can be considered 8-h TWA.

Source: IFA, 2017

Summary

The MEGA dataset on welding, plasma cutting and similar thermal processes represent 432 personal samples and demonstrates that some exposure to arsenic is widespread in the sector with 90th percentiles in the range of 1.4 to 4.0 µg/m^3. The levels are in general below the levels of the reference OELVs assessed in this report, and it is assessed that these processes would not be impacted by the assessed OELVs.

3.4.9 Ferrous basic metal production

No data on exposure levels has been obtained from the ferrous basic metal industry or identified in the literature. The German MEGA database does not include data that can be allocated to the ferrous basic metal production.

As mentioned, most likely exposure to higher concentrations could take place by maintenance of the arsenic removal plant and by handling the filter cake. Furthermore, maintenance and cleaning works on electrostatic precipitators and bag filters on sinter plants, pelletisation plants and blast furnaces may likely lead to some exposure to arsenic as has been demonstrated by maintenance of similar filters in some coal power plants.

The number of sinter plants and pelletisation plants is 40 of these 15 in MS with no OEL or an OEL above 10 µg/m^3. (JRC, 2013b)

Emission from pig iron and steel plants to the E-PRTR is on the same magnitude as emission from power plants with a maximum of 418 kg from one plant indicating significant levels of arsenic in fly ash or other pollution control residues. The levels are lower than the power plants with highest emission and likely the arsenic content in dust varies considerably due to variation in arsenic content of ores and coal. In the absence of actual measurements, the exposure concentrations by maintenance operations are expected to lower than coal power plants using high arsenic coals and that simple RPE with an efficiency of 50% is used.

3.4.10 Power sector

During combustion of coal and oil-shale, arsenic readily oxidizes to form arsenic oxide vapour, which combines with calcium oxide and condenses on the surface of fly ash (RAC, 2017). Solid by-products of the combustion process, including fly ash and bottom ash, are major sinks for arsenic. Workers in coal-fired power plants may first of all be exposed to arsenic found in the fly ash during cleaning.

Data from consultation - No specific data have been obtained from consultation with the European association for the power sector Eurelectric. It has as part of the stakeholder consultation been attempted to obtain information from power plants in the Czech Republic and Slovakia, but no specific information has been obtained. According to information from Danish utility companies with coal power plants, exposure to arsenic by maintenance and cleaning operations has not been considered of specific concern and no measurements are available. In any case, full mask respirators are used for the operations. It should be noted that no emissions of arsenic to the air is reported for the E-PRTR database from Danish coal power plants indicating that coal with relative low concentration of arsenic is used.

Data from the literature - Yager et al. (1997) reported arsenic concentrations (8-h TWA) between 0.17 and 375.2 µg/m^3 in the breathing zone of maintenance workers during a routine maintenance outage in a coal-fired power plant in Slovakia. During the initial stages of a maintenance outage, work activities are routinely directed towards removal of accumulated fly ash and clinker from inside the boiler structure as well as the electrostatic precipitators (ESPs).

Arsenic was measured in the breathing zone of workers during 5 consecutive workdays, and urine samples were obtained for analysis of arsenic metabolites. Results from a small number of cascade impactor air samples indicated that approximately 90% of total particle mass and arsenic was present in particle size fractions >/= 3.5 µm. The 8-hr TWA GM arsenic air concentration was reported at 48.3 µg/m^3 (range 0.17-375.2) and the mean sum of urinary arsenic (SigmaAs) metabolites was 16.9 µg

As/g creatinine (range 2.6-50.8). The concentration varied between three groups of workers (GM and geometric standard deviation):

- Boiler cleaners (n= 9): 59.5 ± 1.3 µg/m^3;
- Boiler makers repairing the boilers (n= 13): 17.2 ± 1.3 µg/m^3;
- Technicians (n=18): 2.1 ± 1.2 µg/m^3.

Note: n = the number of workers in the category.

According to the authors, standard respirators at this plant consisted of washable fabric dust masks held in place by tie strings. Analyses were run with and without inclusion of per-cent daily time recorded wearing a cloth dust mask respirator; no discernible effect on regression of inclusion of the variable for respirator usage was noted; therefore, final analyses excluded this variable. The plant used mainly local low-grade brown lignite coal containing a mean concentration of approximately 800 ppm arsenic (maximum 1.350 ppm). In a follow up study Yager el al. (1999) investigated the connection between the respiratory tract deposition and urinary excretion of arsenic. In the study the mean respirator fit factor for the applied masks were measured at about 2 and it is noted that the masks could have reduced the personal exposures by 30 to 50% only.

In another study, 70 power plant employees in the same Slovakian plant, (especially stokers, maintenance workers, boiler cleaners), were exposed to averaged arsenic concentrations of 4.6-142.7 µg/m^3 for an average of 22 years. According to the authors, after 1989, the intoxications with As did not occur any more due to technical measures and health protection of the workers (Buchancova et al., 1998). As the OEL in Slovakia is 100 µg/m^3 it may just indicate that the exposure concentrations are below this level for all workers.

Data from the German MEGA database for "energy production" is shown in the table below. The data represent the period 2000-2017. It is not reported where in the sector samples are taken, but it is likely that they represent some maintenance operations in places with potential exposure to arsenic. The personal samples are significantly higher than the stationary samples which could indicate that the processes are maintenance processes where dust is mobilised by the process.

Table 3-17: Data from the German MEGA database 2000-2017, energy production

Process step	Sampling duration**	Number of samples	Number of enterprises	Max LOD*	<LOD *	Exposure concentrations, arsenic compounds, µg/m^3		
						50th	90th	95th
Personal samples, 8h-TWA (without adjustment for RPE)								
Not specified	≥ 2h	13	6	4.4	9	<LOD	3.0	9.6
Stationary samples								
Not specified	≥ 2h	14	5	12	14	<LOD	<LOD	<LOD

* The LOD differs among the analysis, the max LOD indicates the maximum LOD in any analysis in the dataset whereas the <LOD indicates the numbers below the actual LOD of the individual analyses.
** It is noted that results collected for ≥ 2h can be considered as representative for the entire shift.
Source: IFA, 2017b

Arsenic in coal - No data on exposure to arsenic by maintenance works in power plants have been identified from other MS. The distribution of coals with high arsenic content may be, however, used as an indicator of the exposure levels across the EU. According to Yudovich and Ketris in a review of arsenic content in coal (2005), the World average As content in coals for the bituminous coals and lignites are 9.0 ± 0.8 ppm and 7.4 ± 1.4 ppm, respectively i.e. 100 times lower than the coal used in the power plant studied by Yager et al. (1997). According to the authors, bituminous coals in Eastern Germany, Czech Republic and SE China are enriched in arsenic. However examples are provided of some type of coals used in other MS with the maximum levels in the range of 1,200 - 3,300 ppm in the UK, Poland, Czech Republic, Germany and Bulgaria. Arsenic enrichment is commonly related to sulphide mineralization. According to Murcot (2012), arsenic enriched coal is found in five basins in the Czech Republic. The Chep sedimentary basin has arsenic concentrations up to 3,245 ppm, while de Ostrava and Karvina deposits are reported to have 165 and 110 ppm, respectively.

Data from E-PRTR - According to the E-PRTR, 93 power plants report on emission to the air of arsenic in quantities of more than 20 kg (total emission of 16.4 t/year in 2015). The total number of coal power plants in the EU in 2014 is reported to be around 280 (CAN Europe, 2017) i.e. the emission from 187 plants is below the reporting limit. As the total emission to the air will depend on the size of the plant and the efficiency of the flue gas controls, the data cannot directly be used to indicate the potential of occupational exposure. However, typically about 99% of the arsenic will be 97-99% of the arsenic will be retained in fly ash and bottom ash (i.e. total content in the coal used in the EU is about 820 tonnes). The data does not indicate a clear trend in higher emission from some countries than from other. The two highest emissions are from separate oil-shale power plants in Estonia with 1.3 and 5.8 t/year, respectively. An indication of arsenic enrichment can be obtained by normalising the emission of arsenic to the reported emission of NOx (can only be used as a rough estimation). The power plant in Slovakia studied by Yager et al. (1997) has a relatively low NOx:As ratio of 5.9 (total As emission of 646 kg/year) which is shared with a number of plants in Czech Republic. Two major power stations in Greece also show relatively low ratios of 8.7 and 16.5. For power plants in most MS the ratios are markedly higher and up to 183 for a station in the UK. The studied power plant in Slovakia is the only Slovakian plant reporting on As emission to the E-PRTR, but many of the Slovakian coal power plants are relatively small and may for this reason be below the reporting limit. Four power plants in Estonia stands out (two of them mentioned above) with NOx:As ratios around 1 indicating that the used oil-shales are highly enriched with arsenic (or NOx removal very efficient). Much literature is available on the Slovakian power plant (incl. environmental levels), which could indicate it is outstanding, but none of the reviewed papers indicates that it should be so.

Summary

The exposure concentrations found by maintenance work in a power plant in Slovakia seems to be relatively high compared to the EU average, but is not outstanding and similar levels may be expected in coal power plants in at least the Czech Republic and Greece, whereas even higher concentrations may be found in oil-shale power plants in Estonia. Yager et al. report that the applied PPE reduce the exposure concentrations by only 30-50%. In Denmark, Powered Air Purifying Respirator (>95% protection) is used for similar maintenance operations, but data are not available on the RPE used in other countries. For the estimations it will be assumed that various masks are used for protection with an average protection of 90% (factor 10). The GM (without RPE) is set at the 48 µg/m^3. The 90th percentile is not reported but the range is reported at 0.17 to 375.2 µg/m^3. The AM and 90th percentile is, based on experience from other dataset of the relation between AM, GM and 90th percentile, set at 87.2 µg/m^3 and 183.2 µg/m^3 without RPE and 10 times less assuming an RPE with an efficiency of 90%.

3.4.11 Other sectors

Mining sector

No data on exposure to arsenic compounds by the manufacture of concentrates in mining sites or by other mining activities in the EU have been reported by the stakeholder consultation nor identified in the literature. The dataset from the German MEGA database do not include data for mining.

Manufacture of copper concentrates - By handling of copper concentrates in the primary copper smelters, significant workplace concentrations, e.g. by sampling of raw materials and by maintenance procedures, are reported and workers would typically use RPE for these processes. Similar work processes may be expected to take place by the manufacture of arsenic-containing copper concentrates in mining sites. At expectedly lover levels, exposure would also take place by other mining activities.

Some copper concentrates from mining in the EU may contain significantly higher arsenic concentrations than the 0.1-0.2% typically used by primary copper smelters in the EU. Copper concentrate from the Chelopech mine in Bulgaria is reported to contain 6% arsenic (International Mining, 2016). The high arsenic concentrates are not used for copper smelting in Bulgaria but exported. Potential exposure from the production of the concentrate must be expected to be significant. With a mine production of copper at 108,000 t/year in 2015, Bulgaria is the second largest copper mining MS after Poland.

According to British Geological Survey (2017) in 2015 the copper mine production in the EU was as follows: Bulgaria: 111,746 tonnes, Cyprus: 2,121 tonnes, Finland; 41,085 tonnes, Poland: 426,196 tonnes, Romania: 4,400 tonnes, Slovakia: 58 tonnes, Spain: 111,700 tonnes and Sweden: 75,125 tonnes. Of these, Bulgaria and Slovakia have an OEL above the lowest of the assessed OELs.

In the absence of actual data from the mining sector in Bulgaria data for raw materials handling in primary copper smelter without any adjustment for the use of RPE will be used as starting point. The highest reported AM from one smelter is 4 µg/m^3 with a max value of 23 which will be applied. According to USGS (2015), Bulgaria has 5 companies producing copper concentrate and the available data indicated that the concentrations of the concentrates is well above the average in the EU. As a worst-case assumption, an AM from of 4 µg/m^3 will be applied.

Table 3-18 shows a difference in urinary concentration of arsenic in workers from five different groups in copper production. Employees working in the smelting of copper (and electrolytic procession) were found to have a much higher concentration of inorganic As than employees working in administration (background level), whereas workers involved in copper ore mining and grinding had only slightly higher level, indicating that the exposures by the specific mining activity was lower than in the smelter.

Table 3-19: Distribution of the different urinary species of arsenic workers in copper mining and processing plant in China (AM + SD)

	Group 1 (administration)	Group 2 (copper ore mining)	Group 3 (copper ore grinding)	Group 4 (electrolytic procession)	Group 5 (copper smelting)
Number	19	83	26	27	15
Inorganic As (µg/g creatinine)	4.69 ± 1.85	4.82 ± 3.53	4.89 ± 3.05	8.16 ± 3.07	8.97 ± 3.81
Total As (µg/g creatinine)	52.55 ± 19.62	57.32 ± 45.85	64.49 ± 39.20	81.60 ± 36.92	103.22 ± 39.86

Source: Sun et al, 2015

Mining of zinc, lead and precious metals - The EU zinc mine output is essentially accounted for by Ireland, Sweden and Poland and was 818 000 tonnes of zinc concentrates in 2007 (JRC, 2017). As the mining takes place in MS with an existing OEL of 10 µg/m^3, and the arsenic content of concentrates in general is lower than for copper concentrates, the possible exposure by the mining activities are not further assessed. The main producers of lead concentrates from mining are Ireland, Sweden and Poland; all with an OEL of 10 µg/m^3. The only significant mining of precious metal takes place in Sweden, Finland and Poland; all with an OEL of 10 µg/m^3.

Other processes in the metal industry

For other processes in the metal industry such as soldering, casting/melting and similar process, dry sanding, and various machining processes (incl. blasting) 90th percentiles are reported in the MEGA Database at 0.6 to 1.3 µg/m^3. For sanding, the data represent 25 companies and with a 90th percentile of 1.3 it demonstrates a widespread exposure by such processes. It is not reported if the sanding is of articles of arsenic containing alloys (such as some brass alloys) or the arsenic is present as impurity in the abrasive materials.

The process indicated as "Further machining processes (incl. blasting and CNC machines)" may include sandblasting with materials with a content of arsenic. The 90th percentile of 23 samples is indicated at 2.2 µg/m^3. High exposure levels have been demonstrated by use of copper slags for sand blasting. Stephenson et al. (2002) measured by personal samples levels of arsenic in workplace air from indoor use of two types of copper slag. The measured concentrations in the breathing zone was 140 and 270 µg/m^3 respectively (geometric mean) and even higher concentration when the blasting media are used together. The authors calculate that the OSHA PEL-TWA of 10 µg/m^3 will be reached after 15 minutes.

For other processes not defined, the 90th percentile of 12 samples is reported at 38 µg/m^3. As the processes are not described in detail, it is not possible to determine to which extent the data represent processes e.g. in the copper or other non-ferrous subsectors addressed above. It should be noted that none of the processes in the MEGA dataset is specifically indicated to take place in the non-ferrous sector, which make it likely that several of the listed processes in fact take place in this sector.

A few papers report on occupational exposure to arsenic in workers in steel industry.

Gigante et al. (2006) examined 195 workers at a steel foundry in Italy, exposed to very low concentrations of inorganic arsenic and two control groups consisting of 105 subjects resident near the factory, and 144 subjects resident approximately 20 km away. The environmental concentration of arsenic for the foundry workers was in all samples lower than 0.1 µg/m^3.

The highest exposure levels by primary iron production are expected to be in sinter plants and pelletisation plants. No data for these processes have been obtained from the stakeholder consultation, literature or the MEGA database.

Dismantling and recycling of electronic waste

The personal samples form recycling of waste electrical and electronic equipment (WEEE) in the MEGA database are reported to be below the detection limit which is up to 0.6 µg/m^3 whereas a single of the 15 stationary samples were above the detection limit.

Julander at al. (2014) studied occupational exposure of 55 workers to a range of toxic metals by recycling of WEEEE in recycling companies in Sweden. The workplace exposure concentration for inhalable fraction of arsenic for the recycling workers was 0.042 µg/m^3 (0.001-0.73, n=77), while exposure concentrations for office workers in the plants was measured at 0.002 µg/m^3 (0.001 - 0.003, n=3). The processes included dismantling of the equipment, but not any thermal recovery processes. The available data thus do not indicate significant exposure by the dismantling.

The recovery of metals from WEEE takes typically place in secondary copper smelters and the arsenic present in the electronics is one of the sources of arsenic in the workplace air in these smelters (see section 3.4.5).

Laboratory use

Various arsenic compounds are applied for laboratory use. Besides the use of the compounds as analytical standards, apparently mainly organic arsenic compounds have specific applications in chromatography, separations, and environmental chemistry, materials science in polymers, proton-exchange membranes, and optical materials. The exposure in laboratories by use of inorganic arsenic compounds as analytical standards is considered insignificant

Woodworking - recycling of CCA wood

MEGA Data for woodworking, building industry and construction miscellaneous, may represent some recycling of arsenic containing wood (Table 3-20). The 95th percentile for woodworking is 3.2 µg/m^3 based on 13 stationary samples from 7 companies. For construction, miscellaneous of 14 personal samples the 90th percentiles was 1.9 µg/m^3 while the 95th percentile was represented by one outlier at 18 µg/m^3. It is not reported if the activity involves the handling of CCA wood. No actual data on exposure by working with recycled CCA wood have been reported for the stakeholder consultation nor identified in the literature, but some experience from the past is reported in the literature.

Nygren et al. (1992) found the mean airborne concentration of arsenic around various types of joinery machines working with CCA wood was in the range from 0.54 to 3.1 µg/m^3.

Jensen and Olsen (1995) found median exposures of workers working indoors producing garden fences and weekend cottages at 3.7 and 0.9 µg/m^3, respectively. For wood processing outdoors levels below 2.8 µg/m^3 were found. The study concluded that only for the application of the CCA preservatives (now prohibited) the Danish OEL of 10 µg/m^3 was exceed. The available data indicates that exposure levels from the reclamation of CCA wood would be below the lowest of the assessed OELVs of 10 µg/m^3.

Other branches

Ceramics and bricks - Data for ceramics and brick products do not indicate that arsenic compounds are used for ceramics, which is in accordance with the expectation that arsenic compounds are not used for ceramics.

The data for "metal production" with a 90th percentile of 6.0 µg/m^3 would likely represent the non-ferrous metal industry, but as details are not provided, the data are not allocated to a specific process.

Several of the processes are so general that it is difficult to allocate them to a sector. As an example. "Wholesale and retail trade, warehousing, transport" could be any process where arsenic substances or arsenic containing raw materials or waste is handled.

Summary

Of other sectors, processes with potential of high exposure to inorganic arsenic compounds are expected to be within the mining sector, and within this sector manufacture of copper concentrates. No actual exposure data are available, but exposure concentrations are estimated on the basis of measured concentrations by handling of concentrates in primary copper smelters.

Table 3-20: Data from the German MEGA database 2000-2017 (IFA, 2017b), data not addressed elsewhere

Sector	Process	Personal (P) / stationary samples (S) ***	Sampling duration	Number of samples	Number of enterprises	Max LOD, µg/m^3 *	<LOD *	Exposure concentrations, arsenic compounds, µg/m^3 **		
								50th	90th	95th
Metalworking incl. mechanical engineering, electrical engineering, precision mechanics	Soldering, casting/melting and similar process	P	≥ 2 h	16	12	0.6	8	0.2	0.6	2.4
	Dry sanding	P	≥ 2 h	39	25	2.4	18	0.5	1.3	1.7
	Further machining processes (incl. blasting and CNC machines)	P	≥ 2 h	23	18	4.8	12	<LOD	0.9	2.2
		S	≥ 2 h	19	12	2.4	10	<LOD	1.6	2.2
	Other work areas	P	≥ 2 h	12	11	0.55	4	0.6	38.0	59.2
		S	≥ 2 h	27	17	2.4	23	<LOD	1.2	1.2
Other branches	Construction, miscellaneous	P	≥ 2 h	14	9	9	4.2	<LOD	1.9	18.0
		S	≥ 2 h	15	9	14	4.2	<LOD	<LOD	1.4
	Educational institutions, services	S	≥ 2 h	29	13	29	5.8	<LOD	<LOD	<LOD
	Electronic waste recycling	P	≥ 2 h	14	2	14	0.66	<LOD	<LOD	<LOD
		S	≥ 2 h	24	6	21	0.43	<LOD	0.2	0.2
	Railroad track construction, track bed cleaning	P	≥ 2 h	24	10	21	1.6	<LOD	0.7	0.8
		S	≥ 2 h	41	16	36	3.1	<LOD	1.2	1.4
		S	< 2 h	12	5	7	5.3	<LOD	8.3	11.0
	Wholesale and retail trade, warehousing, transport	P	≥ 2 h	16	7	1.8	9	<LOD	0.7	1.1
		S	≥ 2 h	11	9	2.4	7	<LOD	1.7	9.5
	Woodworking	S	≥ 2 h	13	7	2.5	11	<LOD	1.1	3.2
	Ceramic industry, brick products	P	≥ 2 h	19	5	1.4	18	<LOD	<LOD	0.7
		S	≥ 2 h	32	9	0.2	32	<LOD	<LOD	<LOD
		S	< 2 h	11	2	0.4	11	<LOD	<LOD	<LOD
	Metal production	P	≥ 2 h	23	14	4.8	10	0.6	6.0	12.0
		S	≥ 2 h	36	18	4.8	24	<LOD	1.1	1.4
	Further waste disposal and recycling	P	≥ 2 h	11	8	1.1	9	<LOD	2.5	3.2
		S	≥ 2 h	23	9	1	21	<LOD	<LOD	0.5

Table 3-20: Data from the German MEGA database 2000-2017 (IFA, 2017b), data not addressed elsewhere

Sector	Process	Personal (P) / stationary samples (S) ***	Sampling duration	Number of samples	Number of enterprises	Max LOD, µg/m^3 *	<LOD *	Exposure concentrations, arsenic compounds, µg/m^3 **		
								50th	90th	95th

* The LOD differs among the analysis, the max LOD indicates the maximum LOD in any analysis whereas the <LOD indicates the numbers below the actual LOD of the individual analyses.

** It is noted that results collected for ≥ 2h can be considered as representative for the entire shift.

***Personal samples**,** 8h-TWA (without adjustment for RPE)

Source: IFA, 2017b

3.4.12 Summary

The data on reported exposure levels for different processes and sectors are summarised in Table 3-21. The ranges indicate ranges of reported concentrations from different companies for the parameter concerned.

The data are reported without any adjustment for the use of RPE but the table indicate to what extent RPE is used. For the estimations of current burden of disease and the possible impact of establishing an OELV, the data are adjusted in order to account for the use of RPE.

The table indicates the number of workers covered by the reported concentrations i.e. in general the data are not extrapolated to the entire sector. The extrapolation is done in section 3.5 on exposed workforce.

The table shows the parameters reported. The methodology used to calculate concentration probability distributions on the basis of the various parameters is described in section 3.13.1.

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, $\mu g/m^3$, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
1. Glass sector	**Special glass sector:** *-Raw material delivery and storage*	300 - 600 (estimated, 80 represented by date from stakeholder consultations; for data from CSRs numbers of workers not reported)	0						No	CSRs and stakeholder consultation
	- Preparation and mixing		Range: 0.03-3.1						Yes	
	- Furnace operation		Range: 1- 4						Yes	
	- Maintenance, cleaning and waste management		Range: 2.5-4						Yes	
	Domestic glass sector: **-** *Batch mixers*	10	59		26			154	No	Apostoli et al., 1999
	- Oven chargers	28	127		123			312		
	- Moulders, finishers	13	4.1		**			15		
	Subsector not reported: (DE) *Shaping and surface treatment (likely exposure to substance out of scope)*	n.i.			<LOD	0.5	8.1		n.i.	MEGA database 2000-2017
	Batch production,	n.i.			1.5	6.2	9.3			
	Other work areas	n.i.			<LOD	2.1	5.8			
2. Electronics sector	Manufacture of copper foils	48	Range: 0 -5.1 "worst case" modelled data; <0.12 with adjustment for duration and frequency; personal samples: 0.12						n.i.	RAC, 2017a
	Gold plating of circuit boards	25	Personal samples: < 0.2; modelled: 0.06-0.6							Linxens (2014)

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, µg/m^3, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
	Manufacture of semiconductors	n.i.	Most samples: < 0.1; some maintenance work: "*below the relevant applicable occupational exposure limit value for arsenic in those respective European countries".*						Yes, by higher exposure levels	Stakeholder consultation, ESIA
	Manufacture of semiconductors: *Normal operating activities in implantation operations*	n.i. (data generated across a number of studies)	1.6						n.i.	Park et al. (2010) [USA, Taiwan, UK]
	Semiconductor industry: Maintenance work		7.7					218.6	yes	
	Manufacture of CdTe-based photovoltaic modules	n.i.	<0.0068							Spinazzè et al. (2015)
3: Chemicals sector	Sulphuric acid production from pyrite	15-18		Range: 37.3-52.2						Offergelt et al. (1992)
4: Copper sector	**Primary copper:** *Raw materials handling, incl. sampling and control*	391	Range: 1.7-4	1		3	Range: 7-8	23	Used in most of the working processes incl. areas of high exposure. Type depends on exposure level.	Stakeholder consultation
	Smelting processes, various processes in furnace areas	1618	Range: 2-36			Range: 17-730	Range: 26-45 (not reported in all datasets)	212		
	Tank house - electrolysis plant: electrolytic refining, tankhouse – electrolysis plant	429	Range: 0.8-3		2	Range: 2-5	3.5	12		

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, µg/m^3, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
	Processing of spent electrolyte and other waste handling	200	Range: 0.8-12	2 (one company only)		Range: 2.5-11	2.7-17	49 (one company only)		
	Sulphuric acid production: Acid production	60		0.6					No	
	Maintenance work, general: maintenance operations, works	534	4.8 (not reported in all datasets)			Range: 9-63	15		Used, type depends on exposure level	
	Secondary copper: *Sampling and transport*	271	Range: 0.1 -12						Used in most working processes	Stakeholder consultation
	Smelting processes, various processes in furnace areas	730	Range: 1.0-9.2			Range: 2-24 (not reported in all datasets)		Range: 9-141 (not reported in all datasets		
	Refining and distillation	265	Range: 1.0-7.5			Range: 2-10 (not reported in all datasets)		Range: 9-49 (not reported in all datasets)		
	Maintenance	59	0.5					1.5	Yes	
	Copper-arsenic alloys	One manufacturer reports that concentrations are below 10 µg/m^3								Stakeholder consultation

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, µg/m^3, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
5: Zinc using diarsenic trioxide	Zinc production using diarsenic trioxide	72	Range: 0.15-8.7			Range: 0.22-23		46		Stakeholder consultation
6: Other non-ferrous metals	**Production of rare metals (incl. handling of arsenic compounds):** *Pre-treatment, loading, unloading*	27	Range: 0.4-5.4					9.2	RPE use depends on the process and exposure levels	Stakeholder consultation
	Various processes	38	Range: 0.8-150							
	Post treatment, packing, etc.	5	Range: 5-22.8							
	Lead battery recycling and lead shot production	18	1.8		2			4.0	n.i.	Lovreglio et al. (2017)
	Primary zinc smelter	n.i.						3.3		Gaweda (2005, as cited by RAC, 2017)
7: Cross sector, welding	Laser, plasma and oxy-fuel cutting, MAG (Metal Active Gas) welding, TIG (Tungsten Inert Gas) welding, other processes (DE)	n.i.				Range: 1.4-4	Range: 2.2-4.6		Not indicated	MEGA database 2000-2017
9: Power sector	Power plant (SK) Boiler cleaners	9		59.5				375.2	Simple masks	Yager et al. (1997)

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, µg/m^3, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
	Boiler makers repairing the boilers	13		17.2						
	Technicians	18		2.1						
	Energy production (no further details)	n.i			<LOD	3.0	9.6		Not indicated	MEGA database 2000-2017
10: Other	Metalworking: Soldering, casting/melting and similar processes, dry sanding, further machining processes (incl. blasting and CNC machines) and other work areas (DE)	n.i				Range: 0.6-38.0	Range: 1.7-59.2		Not indicated	MEGA database 2000-2017
	Construction, miscellaneous (not further specified)	n.i			<LOD	1.9	18.0		n.i	
	Railroad track construction, track bed cleaning	n.i			<LOD	0.7	0.8		n.i	
	Wholesale and retail trade, warehousing, transport	n.i			<LOD	0.7	1.1		n.i	
	Ceramic industry, brick products	n.i			<LOD	<LOD	0.7		n.i	
	Metal production (not further specified)	n.i			0.6	6.0	12.0		n.i	
	Further waste disposal and recycling	n.i			<LOD	2.5	3.2		n.i	

Table 3-21: Inorganic arsenic compounds – exposure concentrations, all values respirable concentration without adjustment for the use of RPE

Sector	Activities	Total number of workers exposed represented by reported concentrations	Exposure concentrations, µg/m^3, personal samples, 8h-TWA						Use of RPE	Source
			AM	GM	50th median	90th	95th	Max		
	Electronic waste recycling	n.i			<LOD	<LOD	<LOD		n.i	
	Electronic waste recycling	55	0.042							Julander at al. (2014)
	Joinery machines working with CCA wood	n.i						3.1	n.i	Nygren et al. (1992)
	CCA wood processing indoors	n.i			0.9-3.7				n.i	Jensen and Olsen (1995)
	CCA wood processing outdoors							2.8	n.i	

n.i.: No information

Italics indicate the processes is a sub-process of the sector indicated above

* Concentrations are reported as 6-h TWA and not 8-h TWA

** reported as 39, but the maximum is 15 so the data is excluded

3.4.13 Trends in exposure concentrations

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.

Copper sector

The exposure levels in the copper sector were significantly higher in the past, as documented in several studies.

Hakkala and Pyy (1995) measured airborne arsenic concentrations by stationary sampling and occupational exposure to arsenic in 24 copper smelter and arsenic trioxide refinery workers in Finland. The concentrations varied between 1 and 670 µg/m^3 (mean 57.8 µg/m^3, n = 52) in the arsenic trioxide refinery, and 1 and 150 µg/m^3 (mean 24.7 µg/m^3, n = 77) in the copper smelter. These values for the smelter are significantly higher than the current values as reported by the company for the stakeholder consultation (the arsenic trioxide refinery is closed).

Workers in the arsenic refinery used, when in the process areas, a half face-piece respirator equipped with a combined dust and vapour cartridge. Hence the samples for exposure concentrations were collected through a tube inserted into the face-piece (not a common methodology for measurements reported elsewhere in the present report). The 8-h TWA concentrations of arsenic in the workers' breathing zone are presented in the table below. According to the authors, the mean arsenic concentrations in the air of the plant, measured by stationary sampling, indicated higher values than the TWA exposure of workers. A natural explanation is that during a shift, workers also stayed in the areas of low air-borne arsenic concentration, such as control cabins and lunch room, and that in the arsenic refinery personal respiratory protection was used in the production areas. The correlations between the TWA concentrations of arsenic in air and the concentrations of arsenic species in urine 0, 0-8, 8-16 and 16-20 h after the exposure were calculated. The best correlation (r = 0.78, P = 0.0001) was found for the sum of As (III) and As (V) concentration in urine collected between 0 and 8 h after the exposure.

Table 3-22: Airborne arsenic exposure, share of As^{5+} in air and concentrations of arsenic species in urine after the exposure. Note that TWA is measured inside the RPE and thus take into account the efficiency of the RPE

	Arsenic in air		Arsenic species in urine (µg As/L)					
	TWA (µg/m^3)	$As^{5+\,a}$ (%)	As^{3+}	AS^{5+}	MMA	DMA	Asitm	Astot
Arsenic trioxide refinery:								
Ore pre-handling	9.5	18	4.3	1.8	3.7	18.8	29	148
Chemical department.	4.3	34	5.4	2.3	6.0	28.8	42	189
Copper smelter:								
Ore drying	6.6	67	3.4	<1.0	3.4	20.2	27	54
Copper flame furn.	10.1	36	4.4	2.0	3.5	18.3	28	50
Copper conv.	8.1	1	4.2	1.1	1.9	18.7	26	36
Anode ovens	19.4	82	7.6	3.7	3.4	32.8	48	108
Anode casting	16.4	76	3.7	3.5	3.8	15.8	27	40

Values are AM. LOD: 1.0 µg As/L. As^{3+}, AS^{5+} :trivalent and hexavalent arsenic. Asitm: Sum of inorganic arsenic metabolites in urine; Astot: Total concentration of arsenic.
[a]Analysed from stationary samples (n=2-5).
Source: Hakkala and Pyy (1995).

Total concentration of arsenic in the breathing zone was measured by personal air samplers in two departments of a smelter producing copper, arsenic and other metals in Northern Sweden (Vahter et al., 1986). The arsenic concentration (8-h TWA) varied between 1 and 194 µg/m^3, and urinary arsenic between 16 and 328 µg As/g creatinine. Lagerquist and Zetterlund (1994) reports from the same facility that the concentration of inorganic arsenic in work-room air at the smelter was reported to have been about the same level as the Swedish occupational standard:

- 500 µg/m^3 from the 1950s to 1975
- 50 µg/m^3 from 1975 to 1987
- Since 1987 until 1994, it was about 30 µg As/m^3.
- The air levels, however, are reported to have been much higher, especially during the 1940s and 1950s.

Grimsrud et al. (2005) present data on the historic trend in arsenic exposure in a nickel smelter in Norway. The data are shown in order to illustrate the overall trend in the industry. The trend was partly due to changes in the raw materials and partly in changes in hygienic measures. Around 1930, the proportion of arsenic in the matte increased 10-fold because of importation of matte from Canada (from 0.02% to 0.2% by weight). Changes in the electrolyte purification system led to recycling and a build-up of arsenic, causing concern as to industrial hygiene and production efficiency until the mid-

1950s. Data on arsenic in the process were summarized in 1995 by a retired chief chemist from the company. A time- and department-specific exposure matrix was constructed from these data and from the nickel exposure matrix, under the presumption that the proportion of arsenic to total nickel in aerosols was equal to the ratio in the intermediates. High levels were estimated for 22 departments and 6 periods between 1930 and 1955, with a maximum air concentration in the roasting department of about 400 µg/m^3 during the 1940s and early 1950s. Selected results are shown in the figure below. Further details on the application of RMMs are not reported.

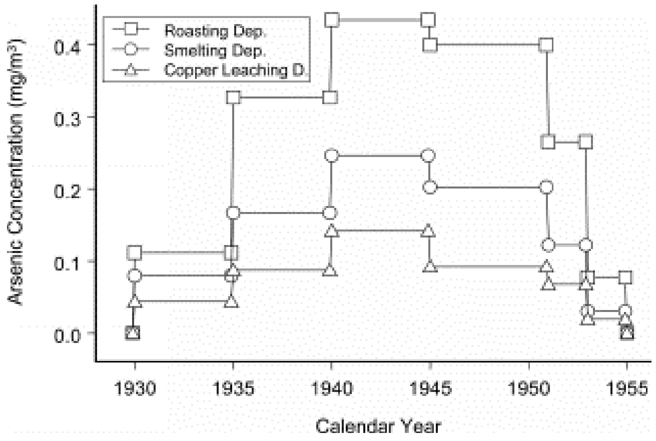

Figure 3-3: Time trends for the concentration in air of arsenic in the roasting, smelting, and copper leaching departments at a nickel refinery in Norway
Source: Grimsrud et al., 2005

The higher exposure levels in the past are also illustrated by the study of 1,800 men from the Anaconda smelter in the USA (Welch et al., 1982). Average arsenic concentrations were estimated for each smelter department based on industrial hygiene measurements made from 1943 to 1965. Departments with similar concentrations were combined into four categories of exposure: 1) low (less than 100 µg/m^3), 2) medium (100-499 µg/m^3), 3) high (500-1499 µg/m^3) and 4) very high (greater than or equal to 5,000 µg/m^3). The very high values as compared with today's levels in most facilities illustrates the effects of the RMMs established during the last fifty years.

Data from stakeholder consultation - Time trends in urinary inorganic arsenic concentration (line) and in percentage of exposed workforce exposed above the national biomonitoring action limit (bars) from a primary copper smelter are shown in Figure 3-4. The data are original data from stakeholder consultation. According to the company, the overall trend with decreasing urinary levels is mainly obtained by use of better RPE and implementation of better hygiene. As shown, keeping the level below the national biomonitoring action limit is still a challenge for the company. Trend data on workplace concentrations are not available. Due to a lower number of measurements of workplace concentrations and the fact that measurements from different years do not represent the same workplaces, any trends during the period are not significant.

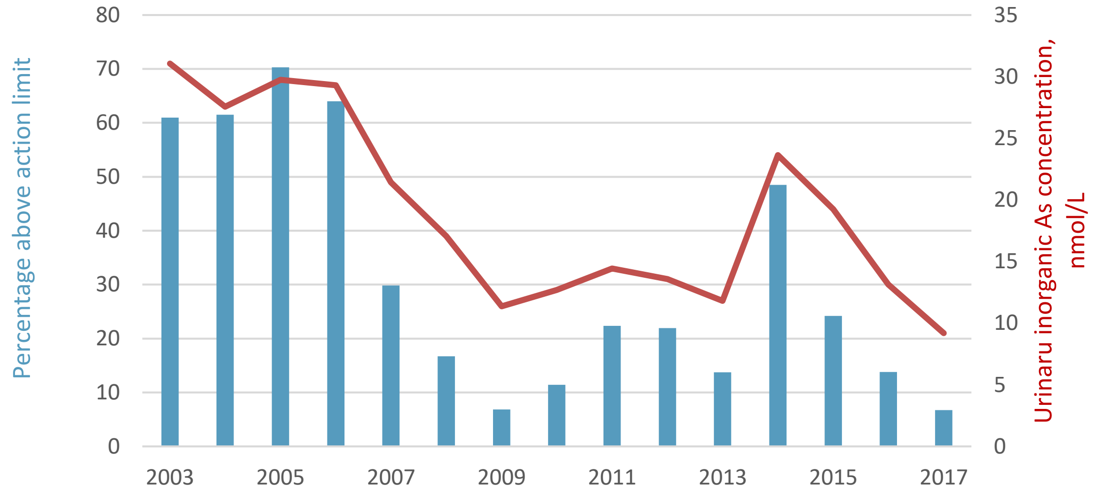

Figure 3-4: Time trends in urinary inorganic arsenic concentration (line) and in percentage of exposed workforce exposed above the national biomonitoring action limit (bars). Number of samples range from 60 to 166 per year.
Source: Original data from primary copper smelter provided by stakeholder consultation

A similar, but more pronounced trend is seen in the average urinary concentrations of workers in another primary smelter (Figure 3-5). The decrease is attributed to implementation of better LEV, better RPE and better hygiene.

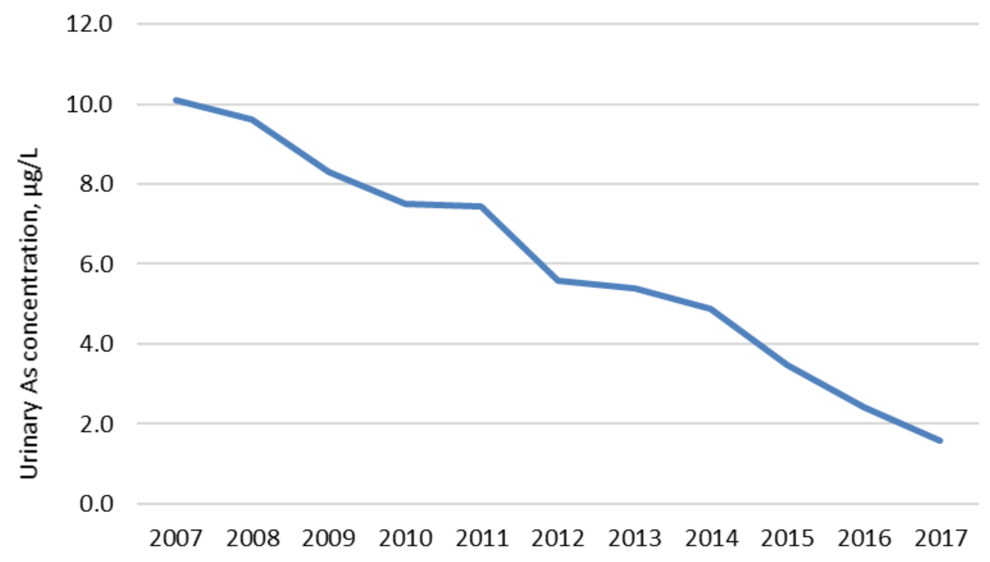

Figure 3-5: Time trends in average urinary total As concentration. Total dataset consist of 1570 samples.
Source: Original data from primary copper smelter provided by stakeholder consultation

Other sectors - High levels of exposure has been reported for domestic glass making in the past as discussed in section 3.4.2. As no present use of arsenic compounds has been identified and no recent exposure concentrations has been reported it is not possible to assess to what extent the exposure concentrations in any remaining use would be lower.

3.5 Exposed workforce

3.5.1 Available overall estimates of number of potentially exposed workers

According to IARC (2012a):

"*Historically, the greatest occupational exposure to arsenic occurred in the smelting of non-ferrous metal, in which arseniferous ores are commonly used. Other industries or industrial activities where workers are or were exposed to arsenic include: coal-fired power plants, battery assembly, preparation of or work with pressure-treated wood, glass-manufacturing, and the electronics industry".*

According to the UK Health and Safety Executive, the following industrial sources may lead to exposure to arsenic and arsenic compound:

- **Chemical industry**: In the chemical industry, e.g. in the manufacture of pesticides and fireworks;
- **Non-ferrous metal industry:** In dust and fumes arising from the refining and smelting of metals and ores such as copper, lead and tin;
- **Alloys with arsenic:** In the production and use of alloys, e.g. some lead, copper and bronze alloys;
- **Electronic industry**: In the manufacture of coatings for photocopier drums; and in the microelectronics industry, often as a waste residue, and in the production of gallium arsenide. (HSE, 2013)

OSHA (2008) indicates that arsenic may be found in contaminated workplace air resulting from smelting operations, in recycling facilities that deal with various nonferrous metal alloys, or with electronic semiconductors.

European CAREX data

Data from the CAREX (CARcinogen EXposure) database is shown in Table 3-23. The table shows the number of workers exposed to arsenic or arsenic compounds in 1991-1993 (EU15), supplemented with data from 1997 for four additional MS (Estonia, Czech Republic, Latvia and Lithuania).

In total it is estimated that 166,000 workers were potentially exposed to arsenic and arsenic compounds in the European Union (15 MS) in 1990-1993, with over 50% of workers employed in the non-ferrous base metal industries (n = 45,250), manufacture of wood and wood and cork products except furniture (n = 41,193), and construction (n = 14,740) as the main sectors. Since the use of arsenic in wood preservatives is now prohibited, the number of workers exposed to arsenic in manufacture of wood products and construction is expected to be very low and includes some recycling of CCA-preserved timber only. No data on actual exposure levels are available from the database. The data are to a large extent derived from the reported data from the Finish ASA database and extrapolated to the EU by assuming similar sector-specific exposures.

It should be noted, that the survey also include exposure to arsenic metal (e.g. processing of copper alloys) and organic arsenic compounds (the main use of arsenic chemicals in laboratories) which are out of scope of the current study.

If applications phased out or beyond the scope, are excluded from the total it is approximately 86,000 workers in EU15+4.

The database includes exposure by all exposure routes, whereas the summaries for the most exposed workforce presented later in the section concern exposure via workplace air.

Table 3-23: Numbers of workers in different industries in 15 + 4 MS exposed to arsenic and arsenic compounds in 1993/1997 (for countries where data from 1993 were unavailable data from 1997 was used instead).		
Industry	**Number of workers**	**Likely linked to be phased out use in CCA-treated wood, pesticides and biocides, or to organic As compounds**
Agriculture and hunting	4,600	Pesticides, biocides, CCA-treated wood
Construction	16,271	CCA-treated wood (but may also be welding activities within the scope)
Electricity, gas and steam	2,387	
Financing, insurance, real estate and business services	200	
Iron and steel basic industries	7,050	
Manufacture of electrical machinery, apparatus, appliances	11,428	
Manufacture of furniture and fixtures	11,658	CCA-treated wood
Manufacture of glass and glass products	9,649	
Manufacture of industrial chemicals	5,965	Partly CCA-treated wood
Manufacture of other chemical products	265	
Manufacture of other non-metallic mineral products	2,475	
Manufacture of transport equipment	121	
Manufacture of wood and wood and cork products	41,193	CCA-treated wood
Medical, dental, other health and veterinary services	1,400	Biocides, organic As compounds
Metal ore mining	600	
Non-ferrous metal basic industries	45,250	
Other manufacturing industries	327	
Petroleum refineries	279	
Printing, publishing and allied industries	300	
Recreational and cultural services	148	
Sanitary and similar services	3,305	Biocides
Wholesale and retail trade and restaurants and hotels	1,400	CCA-treated wood
Total	166,271	79,827
Source: CAREX Database (1993/97)		

Finish ASA register

The original CAREX data was to a large extent based on data from the Finnish ASA register. During its existence between 1979 and 2014, 127,500 workers from 8,300 work departments were recorded in the Finnish register of workers exposed to carcinogenic substances and processes (ASA register). According to the latest report from 2014, the total number of workers exposed to arsenic and its inorganic compounds in Finland was 2,472 (ASA, 2104) (see Table 3-24). The register is based on information from employers who annually reports to the Finnish Institute of Occupational Health to be registered in the national ASA register. The employer must keep a list of the agents and products containing carcinogenic agents at the workplace and of those workers who are exposed to carcinogens at work significantly above the general population. Exposure concentrations are not reported. The distribution to some extent reflects the extensive mining and non-ferrous metal industry in Finland. It should be noted that the survey also include exposure to arsenic metal, organic arsenic and arsenic compounds which are out of scope of the current study.

Table 3-24: Numbers of workers in different industries exposed to arsenic and arsenic compounds in Finland in 2014

Industry	Men	Women	Total
Agricultural and industrial machinery installers and repairers	315	3	318
Metalworking process workers	262	7	269
Office and institutional cleaners, etc.	206	29	235
Metal processing processors	169	11	180
Laboratories, etc.	51	100	151
Process controllers of waste incineration and water treatment plants	101	6	107
Mining and quarry workers	102	2	104
Line installers and repairers	77	1	78
Enrichment workers	66	2	68
Mining, metallurgy, etc.	50	13	63
Other professions	811	88	899
Total	2,210	262	2,472
Source: ASA, 2014			

Finnish biological monitoring programme

Kiilunen (2012) reports on the results of the biological monitoring programme in Finland (the most recent statistics). The non-exposed reference line for urine inorganic arsenic (U-As-i) is 30 µmol/L, while the biological action limit (BAL) is set at 70 µmol/L. About 1,600 people were occupationally exposed to arsenic in Finland whereas the number of indirectly exposed people is bigger. The total number of biological samples in 2012 was 612 representing 55 different workplaces. The BAL was exceeded in 27 samples from the following workplaces: in installation, maintenance, masonry and process work; cleaning and reparation work in the production of the metals (Cu, Ni) and research related work (Kiilunen, 2012). The number of workers exceeding the BAL for each workplace is not reported. It is noted that exposure to arsenic has been stable in recent years. Most of the BAL exceedances were observed in people who worked in different tasks in the refining of metals: cleaning and casting. The latter is in accordance with the results of the current survey estimating that the main exposure is in the copper and other non-ferrous industry.

French surveys

A French survey from 2003 of occupational exposure to chemicals in France indicates exposure to arsenic compounds as "*not significant*" (SUMER, 2003).

A survey from 2005 indicates, besides the use of diarsenic trioxide and diarsenic pentaoxide for wood preservatives, that 0.03 t/year of arsenic acid and its salts was used for manufacture of pigments and that <100 persons were occupationally exposed in France in manufacture of pigments (Inrs, 2005).

Romanian survey

A Romanian survey of occupational exposure to carcinogens reached a number of 411 workers exposed to arsenic and its compounds in Romania in 2002 (Inspecţia Muncii, year not indicated). The further distribution between occupations is not shown, but it is indicated that exposure to arsenic may take place in ceramics industry, mineral fibre industry, glass industry, and by extraction of metals (lead, iron, copper, zinc).

CAREX Canada

According to CAREX Canada, 12,500 Canadians are currently exposed to arsenic at work, due to the use of arsenic in CCA wood preservatives and additional 12,500 Canadians are currently exposed at work to arsenic in industries other than wood preservation. The largest industrial group is non-ferrous metal production and processing, followed by iron and steel mills, where arsenic is produced as a by-product of the processing of other metals. When exposure is examined by occupation, the largest groups of workers exposed to arsenic are machinists and machining tool workers (2,600 exposed), industrial mechanics (1,000 exposed), glaziers (800 exposed), and welders (500 exposed). Other important occupational groups include sandblasters, boilermakers, and auto-body workers.

No data on actual exposure levels are available from the database. The year of reference is not indicated.

Table 3-25: Numbers of workers exposed to arsenic in the five largest exposure groups in Canada (except exposure to arsenic due to work with CCA wood)

Industry	Number of workers	Proportion of industry exposed
Total number of exposed workers (excl. CCA wood)	12,500	
- Non-ferrous metal production & processing	*1,000*	*8%*
- Iron & steel mills and ferroalloy manufacturing	*900*	*<5%*
- Oil and gas extraction	*800*	*<5%*
- Metal and ore mining	*800*	*<5%*
- Water, sewage and other systems	*600*	*<5%*

Source: CAREX Canada at: www.carexcanada.ca/en/arsenic/occupational_estimate/

NIOSH - Based on the National Occupation Exposure Survey conducted during 1981–83, NIOSH estimated that 70,000 workers, including approximately 16,000 female workers, were potentially exposed to arsenic and arsenic compounds in the workplace in the USA (NIOSH, 1990 as cited by IARC, 2009). Given that the data are more than 25 years old, they have not been considered for the estimate of the current potential exposed workforce.

The use of arsenic compounds for preservation of wood is now prohibited and some of the exposure sources mentioned above may be historic.

For the assessment provided in this report priority has been given to the exposed workforce where actual exposure to arsenic has been demonstrated and where occupational exposures may result in exposure to arsenic above the level of the population in the same area not exposed to arsenic.

As discussed in Section 3.3.5 on the copper sector, the total number of employees in copper smelters in the EU (primary and secondary) is about 10,000. Of these, some estimated 75-85% may be directly or indirectly exposed to arsenic, but more than half of these at levels where the exposure is not significantly above the level in the population not occupationally exposed. The percentage of the employees exposed at significant levels is considered to be approximately 25-30%. The exposure concentrations reported would typically concern this groups of workers, whereas exposure concentrations are generally not available for workers exposed at lower concentrations. In zinc production intentionally using diarsenic trioxide the companies estimate that about 9% of the workers are exposed to arsenic from the use of diarsenic trioxide in the process. Other workers may also be exposed at very low levels to arsenic from the zinc concentrate, but exposure concentrations have not been reported because the concentrations are low. Likewise, a large number of workers potentially will be exposed in the production of other non-ferrous metals, and the manufacture, use and recycling of arsenic alloys. In total, the number of potentially exposed workers in the non-ferrous industry could likely be 40,000 as estimated in the CAREX database, but the number of workers exposed to levels which may be relevant in the current impact assessment is considerably lower. This will be further discussed for each sector below.

3.5.2 Glass sector

Special glass: The number of exposed workforce is for one larger company (>250 employees) reported to be about 80 (which are represented by the dataset on exposure concentrations). The measured and calculated concentrations reported as geometric means from three companies (two from the CSR not reporting on number of exposed workforce) range from about 1 to 4 µg/m^3 with no major difference between the three datasets.

Data are not available for estimating the total number of workers exposed in the special glass sector, but based on the available information it is estimated to be within the range of 300 - 600 with 450 as the best estimate. The number of workers in the special glass sector is not reported. The special glass sector represents approximately 3% of total EU glass production in tonnage (GlassAlliance, 2017). The total number employed in the glass sector in 2016 was 185,666. Assuming 3% were employed in the production of special glass, this would correspond to 5,600. The percentage of the workforce in the sector exposed would consequently be 5-11%. Besides the 300 - 600 exposed at significant level, a larger portion of the workers may potentially be exposed at low levels.

Domestic glass: The number of workers exposed to arsenic in artisanal and small scale production of artistic and other domestic glass has probably in the past been several thousands, but the use of arsenic has now ceased in the Veneto region in Northern Italy, where diarsenic trioxide has been used for centuries.

Domestic glass is according to the website of GlasAlliance Europe manufactured by more than 300 facilities, mainly SMEs, which are spread throughout Europe.[20] The sector association European Domestic Glass (EGD) indicates the number of European manufacturers of domestic glassware to be below 50 (EGD, 2017) and the total number of employees at 35,000. As mentioned elsewhere none of the members of the EGD use diarsenic trioxide today.

No current use has been confirmed. The fact that the use in the special glass sector is considered an intermediate use, the same interpretation may be taken by authorities in other EU MS for use in the domestic glass sector.

In the absence of a confirmation of actual uses of diarsenic trioxide within the sector, but assuming that some small companies may still use it, the total number of exposed workers is estimated at 0-200 with 100 as the best estimate used for estimation. The distribution between counties is roughly done on the basis of general information on production of high-end artistic glass.

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[20] http://www.glassallianceeurope.eu/en/main-glass-sectors

3.5.3 Electronics sector

The number of exposed workers in the electronics sector is summarised in the Table 3-26. In total, the number of exposed workers, at a significant level above the unexposed population, in the electronics sector is estimated at approximately 225 - 375 with 300 as the best estimate.

The estimate for manufacture of gallium arsenide wafers and semiconductors is based on information on the actual exposed workforce in companies producing gallium arsenide wafers and an estimate of the workforce involved in cleaning and maintenance operations in approximately 20 companies using small amounts of arsenic in the manufacture of semiconductors.

In addition to these, a large number of workers may be exposed at low levels by downstream uses of gallium arsenide wafers and other semiconductor uses. The number is not reported but could be several thousands.

Table 3-26: Number of exposed workers in the electronics sector

Process	Number of exposed workers	Total number of workers in the facilities **	Percentage of workforce
Manufacture of copper foils	48	250	19%
Gold plating of circuit boards	27**	100	not reported
Manufacture of gallium arsenide wafers and semiconductors	150 - 300	no data	not reported
Total (rounded)	220 - 380		

**Estimated on the basis of total number of workers in the company

Sources: Applications for authorisation; RPA/COWI estimates

3.5.4 Chemicals sector

Production of the substances with major uses, diarsenic trioxide and arsenic acid, takes place in the metallurgical sector and the workforce exposed is included in "other non-ferrous metals".

Former major uses of inorganic arsenic compounds in the chemicals sector included the production of biocides and pesticides, but as the use of arsenic compounds as biocides and pesticide is no longer permitted this use has ceased.

The only granted authorisation for the sector, "Industrial use of diarsenic trioxide as a processing aid to activate the absorption and desorption of carbon dioxide...", has ceased according to the available information.

No specific information on the remaining exposed workforce in the manufacture of fine chemicals with other inorganic arsenic compounds has been obtained. The available exposure levels are according to the available data from the MEGA database low.

The number of companies involved in the manufacture of other arsenic chemicals is roughly estimated at 2-10 companies and the exposed workforce (e.g. by cleaning and maintenance operations) is roughly estimated to be in the range of 10-100.

Production of sulphuric acid (excl. by-product by copper production)

All primary copper smelters have sulphuric acid plants and the possible exposure from these is included under the copper sector.

According to the BAT document for the nonferrous metal sector, all the primary copper smelters and a number of the primary zinc smelters have sulphuric acid plants; in total 19 plants in the EU (of these 7 in the copper sector). As the content of arsenic in the concentrate for copper production in general is higher than the concentrate for zinc and lead it is estimated that exposure at the levels reported would mainly take place in sulphuric acid plants in connection with copper production. Based on the information that 60 workers were exposed at relatively low levels in one of the sulphuric acid plants connected to the smelters, it is roughly estimated that 200-600 workers may potentially be exposed at low levels in the 12 plants not in the copper sector.

No data has so far been available on the number of workers potentially exposed in the production of sulphuric acid from pyrite. In 2005, manufacture from pyrite accounted for 4.2% of the total production of sulphuric acid. Only three plants were indicated to use pyrite: one in Finland and two in Germany. The total exposed workforce is roughly estimated at 30-170 workers with 100 as the best estimate.

3.5.5 Copper sector

Primary copper production

Based on data provided for the stakeholder consultation from all 7 sites, the number of exposed workers is estimated at 1,500 (1,400 - 1,600) which has been covered by monitoring of arsenic in the workplace air. This corresponds to about 25% of the approximately 6,000 people employed in primary smelters. In addition, some 1000- 2000 workers may potentially be exposed at very low level (below monitored level)

The number of workers is distributed by production volume between the MS with primary copper production in 2015 (Table 3-48). The number has been indicated in questionnaire responses but the different companies seem to have reported differently with regard to the percentage of the workforce considered to be exposed at significant level.

Secondary copper production

The number of workers in secondary copper smelters is estimated at 1,300 (1,000 - 1,600). If 4,000 of the 10,000 employees in the sector work in the secondary smelters, the percentage of the workforce exposed to arsenic compounds will be approximately 33%.

In addition, some 1,000-2,000 workers may potentially be exposed at very low level (below monitored levels).

The number of workers is distributed on the basis of the amount of copper produced by secondary production calculated from the difference between reported refinery production and primary production. For a few of the companies some correction has been done because the smelter and refinery are not located in the same country.

Copper-arsenic alloys

No data has been provided on the number of exposed workers by the production of copper-arsenic master alloys.

Summary

The exposed workforce in copper smelters is estimated at 2,400 - 3,200. Besides this a significant part (in total 75-85% of workforce) of the 10,000 employed in the sector may be exposed indirectly or directly to lower levels of arsenic. Table 3-27 provides a summary of exposed workers in the copper sector.

Table 3-27: Number of exposed workers in the copper sector

Process	Number of exposed workers *	Total number of workers in the facilities **	Percentage of workforce exposed at significant level
Primary copper smelters	1,500 (1,400 - 1,600)	~ 6000 **	~ 25%
Secondary copper smelters	1,300 (1,000 - 1,600)	~ 4000 **	~ 33%
Copper-arsenic alloys	10-30	50-200 (masters alloys)	no data
Total			

* This concerns the total reported by the companies, besides this a number of workers may potentially be exposed at low levels in the companies.
** The total for primary and secondary copper smelters is reported at 10,000 employees, here roughly distributed between the two types. In reality some companies combine secondary and primary production. The distribution between the two types is done because the available data indicated different exposure concentrations for the two types
Sources: RPA/COWI estimates

3.5.6 Zinc production using diarsenic trioxide

According to the RAC opinions (RAC, 2014 a,b) for the two applications for authorisation for the use of diarsenic trioxide in zinc production, the total number of workers exposed to arsenic trioxide is 90 as described in Table 3-28. The information on exposure levels is further discussed in Section 3.4.6.

Table 3-28: Number of exposed workers in zinc production using diarsenic trioxide

Exposure level	Workers scenarios	Exposure levels µg/m³ *	Number of exposed workers	Total number of workers in the facilities **	Percentage of workforce
Highest exposure levels	WCS 1, 3 and 5	<18.5	20		
Lowest exposure levels	WCS 2 and 4	<1	70		
Total			90	888	~ 9%

* The highest realistic worst case scenario assessed by RAC for one of the companies
** Number of workers in the facilities, not the department where exposure takes place
Sources: Boliden 2014; Norderhamer,2014; RAC 2014 a,b

3.5.7 Other non-ferrous metals

The reported data from the stakeholder consultation represent in total 85 workers involved in the production of precious and other trace metals. Few exposure data has been obtained from the stakeholder consultation, but relatively high levels of exposure to arsenic has been reported in the literature for other processes. In the absence of more specific data it is roughly estimated that some 300-1000 workers (650 best estimate) may be exposed at a similar levels as reported for the stakeholder consultation. In addition to this a significant number may be exposed at lower levels due to intentional use in lead alloys and the presence of arsenic in raw materials.

According to the industry association Eurometaux, the total number of workers directly employed in the non-ferrous sector is 500,000. According to an assessment by the International Cadmium Association (ICdA), for the stakeholder consultation (for the cadmium assessment), 1,350 workers were exposed to cadmium at significant level in zinc smelters and cadmium refiners, where arsenic will likely also be present in the workplace due to its presence in raw materials (adjusted to 850 for the assessment). The total number of employees in the primary lead production, secondary lead production and lead battery production around 2005 is reported at approximately 14,000 in the voluntary risk assessment for lead (VRAR, 2008). Of these a significant part may be exposed at low levels. The International Zinc Associations (IZA) has answered for the stakeholder consultation that the exposure levels are low. The 11 zinc smelters in Europe employ, according to the association, some 3,000-5,000 people.

According to the CAREX data, in the mid 1990's about 45,250 workers was exposed in the non-ferrous metal basic industries. If 10,000 were in the copper sector, still some 35,000 were in other subsectors. On this basis it is roughly estimated that some 5,000- 20,000 workers may be exposed at lower levels than those reported for the stakeholder consultation.

3.5.8 Welding, plasma cutting and similar processes

At EU level, about one million workers are involved in welding and thermal cutting (see background in assessment report for Cr(VI) in welding and other thermal processes). If the data from the German MEGA database is considered representative for the various welding processes, a significant part of the one million workers would be exposed to levels in the range of 1 to 4 µg/m^3 (90th percentiles). Such high numbers are not supported by other surveys and more likely the MEGA data are representative for welding and thermal cutting processes where some exposure to arsenic could be expected. This could be welding of alloys with intentional content of arsenic or welding in workplaces with high arsenic content in the air due to other sources (e.g. in copper smelters and then included in section 3.5.5). The CAREX database does not include a specific category for these processes but they may be included in "construction" or "manufacture of electrical machinery, apparatus, appliances" with a total of about 30,000 workers. The Finnish ASA data does not include a specific category for welders, but the Canadian Carex database estimate the number of exposed welders in Canada at 500. Based on the available data it is roughly estimated that some 1,000-4,000 workers (2,500 used as best estimate) may be exposed to arsenic at those levels reported in the MEGA database (i.e. about half of these would be exposed at levels below the detection limit).

3.5.9 Ferrous basic metal production

The Carex Canada (2017) estimates that <5% of the workers in the "Iron and steel mills and ferroalloy manufacturing" are potentially exposed to arsenic (corresponding to 1000 in Canada). Likewise, the European Carex database estimates that in the mid-1990's some 7,000 workers may be exposed in the iron and steel basic industries. None of the databases include actual data on exposure levels or details on where in the industry exposure takes place. Arsenic is not used as alloying element in steel. The exposure at higher concentrations most likely take place by maintenance operations in sinter plants and pelletisation plants. The total number of sinter plants in EU-27 in 2008 is reported at 34 in 14 MS, and the total number of pelletisation plants were 6 in two MS (JRC, 2013b). If 25 workers in each plant is involved in maintenance work with potential exposure to arsenic the total is 1,000. On the current basis it is estimated that the total number of workers exposed at a higher level (above detection limit) could be 500-1,500 while 600-6,000 could potentially be exposed, but at relatively low levels.

3.5.10 Power sector

In a studied Slovakian plant, 70 power plant employees were exposed to arsenic by various processes. In total 93 power plants report to the E-PRTR on emission to the air of arsenic in quantities of more than 20 kg. Furthermore, some smaller power plants may have emission below the threshold. If all has 70 workers potentially exposed to arsenic, the total would be approximately 6,500. The CAREX database estimates the total number of exposed workers in mid-1990's in the sector "Electricity, gas and steam" at 2,387. The Canadian CAREX database does not specifically report on exposure in power plants but coal only account for a small part of the power production in Canada.

The available data from the E-PRTR indicates that high-arsenic coals or oil shale are used by a least 5-10 power plants and on this basis it is roughly estimated that some 50-500 workers may be exposed at levels comparable to the levels reported from Slovakia (but with use of RPE) while another 500-2,500 may be exposed at lower levels.

3.5.11 Other sectors

Mining sector

No specific data on exposed workforce in the mining sector have been obtained. The CAREX data estimate the number at 600, while the Finnish ASA database report on 104 mining and quarry workers exposed to arsenic in Finland.

High exposure levels would mainly be expected in the production of copper concentrates. As described in section 3.4.11 copper concentrates is produced in approximately 10 mines, of these 5 in Bulgaria. The number of exposed workers is not reported. The number of workers involved in various sampling and maintenance works with high exposure in copper mines is in the absence of actual data set at 200-600 (20-60 per site). By production of concentrate of other metals the exposure levels are estimated to be significantly lower.

Some mining of zinc, lead, and precious metal may also result in lower levels of exposure. The mining of these metals virtually all taken place in MS with an OEL of 10 $\mu g/m^3$ and would not be affected by establishing an OELV at this level.

Other processes in the metal industry

According to the MEGA database workers involved in various specific processes in the metal industry may be exposed at levels from 0.8 to 38 $\mu g/m^3$ (90th percentiles). As for the welding discussed above, due to limited description it is difficult to assess to what extent the data are biased toward processes with expected high exposure to arsenic. The processes include soldering, casting/melting, dry sanding, blasting, and other processes. The data are included in a category for metalworking and would not include sandblasting in construction. The processes may take place in the non-ferrous sectors and be included elsewhere. According to the CAREX database 11,428 exposed workers were involved in "Manufacture of electrical machinery, apparatus, appliances" but the exposure sources in this category was also electronic components. The Finnish AFA register lists 269 workers in the category "Metal processing processors" while the Canadian CAREX estimates 2,600 exposed "Machinists and machining tool workers" and 1,000 exposed "industrial mechanics", but these categories may include workers in the non-ferrous sector addressed elsewhere. In the absence of specific data it is roughly estimated that 500-5,000 workers may be exposed to arsenic at those levels reported in the MEGA database in other sectors than those addressed elsewhere.

Wood preservatives and preserved wood

As the use of arsenic containing wood preservatives (CCA) in CCA-treated wood has ceased, the data from the CAREX databases are not applicable for estimating the number of exposed workers. Furthermore, the use of reclaimed CCA-treated wood is restricted to some specific applications in construction. It is assumed that workers would only occasionally use this reclaimed wood. In the absence of actual data it is roughly estimated the some 200-2,000 workers may be involved in some activities of use of reclaimed CCA-wood. By normal disposal operations, dermal exposure to the arsenic in the wood may take place, whereas the exposure to dust from the wood is considered small as compared to actual processing of the wood.

Dismantling and recycling of waste of electrical and electronic equipment

The available data indicates that the exposure to arsenic by dismantling of WEEE is low and generally below the detection limit of the applied analytical methods. Based on consultation response and WEEE statistics the total workers in WEEE recycling which may potentially be exposed to low levels of arsenic is estimated at 2,000[21] (range: 1,000-3,000). Note that the thermal recycling of the electronic, equipment where the arsenic is released, is included in secondary copper production.

Laboratory use

Arsenic compounds within the scope of this assessment are only used as analytical standards and the exposure by laboratory use is considered insignificant.

3.5.12 Summary with sectoral brake-down

Numbers of occupationally exposed workers extrapolated from the literature and from stakeholder consultations are shown below.

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

Table 3-29: Occupationally exposed population in the EU28 as extrapolated from published data and stakeholder consultation (inorganic arsenic compounds including arsenic acid and its salts)

Source estimate	EU28 extrapolation
A: CAREX EU14+5 mid-1990s	EU15+4: 166,000 (total) EU15+4: 86,000 (applications/substances within the scope of this study) EU28 extrapolated: 99,000 (applications/substances within the scope of this study) * [22]
B: ASA 2014 exposed workers in Finland	Finland: 2,472 EU28 : 230,000 ** (incl. applications/substances beyond the scope of this study)
C: Rumanian survey 2002	Romania: 411 EU28 : 10,711 ** (incl. applications/substances beyond the scope of this study)
Number of workers directly covered by stakeholder responses with exposure concentrations and data from application from applications authorisation	4,899 (actual data reported, without extrapolation, for extrapolation see next table)

* Extrapolated from EU15+4 to EU28 based on population data at: https://en.wikipedia.org/wiki/Statistics_relating_to_enlargement_of_the_European_Union

** Note that these extrapolations are made solely on the basis of the population and not as the CAREX extrapolated based on workers in the different sectors in the MS and the EU, respectively. Finland has relatively many workers in the mining and non-ferrous sector.

As mentioned in section 3.5.1, a challenge has been to fill in the gap between the large number reported in CAREX and national surveys and the number of workers covered by the available exposure concentrations.

The estimated number of workers exposed to inorganic arsenic compounds including arsenic acid and its salts by sector is summarised in Table 3-30. The table distinguish between two groups.

- Workers exposed at higher levels as demonstrated by measurements, modelling or from comparison to similar processes, with reference to the exposure concentrations reported in section 3.3.12. Midpoint in the range will be used for modelling purposes.
- Other workers which may potentially be occupationally exposed. The latter group either works in sectors and with processes where arsenic may be present in raw materials at relatively low levels, or they work in high-exposure sectors (as the copper sector), but are not routinely working with the high-exposure processes covered by the monitoring of workplace concentrations.

The total for the two groups is 25,900 – 117,300 (average 71,600) which is quite well in accordance with the total of 99,000 estimated for the mid 1990's in the CAREX database as extrapolated to EU28 (when applications phased out or otherwise beyond the scope of the current study are subtracted the total in the CAREX database).

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[22] Extrapolated from EU15+4 to EU28 based on population data at: https://en.wikipedia.org/wiki/Statistics_relating_to_enlargement_of_the_European_Union

Table 3-30: Inorganic arsenic compounds – exposed workforce

Sector	Use/operation	At exposure level as demonstrated by measurements or modelling		No of workers potentially exposed at relatively low levels **
		Sites	Exposed workers *	
1: Glass sector	Fining agent in special glass	10-20	300-500	1,000-3,500
	Fining agent in domestic glass	0-20	0-200 no use confirmed	
	Recycling of glass	30-50	-	1,000-3,000
2: Electronics sector	Manufacture of copper foils	1	48	-
	Gold plating of circuit boards	1	25	-
	Manufacture and use of gallium arsenide wafers and semiconductors	18-25	150-300	1,000-5,000
3: Chemicals sector	Manufacture of arsenic compounds, not included elsewhere	2-10	-	20-200
	Production of sulphuric acid (from pyrite and by-product from other than copper production)	15	30-170	200-600
4: Copper sector	Primary copper smelters (incl. prod of sulphuric acid)	7	3,200	2,000-4,000
	Secondary copper smelters	8	2,000-3,000	
	Production and use of copper-arsenic alloys	10-30	50-200 (masters alloy)	
5: Zinc production using di-arsenic trioxide	Purification in zinc electrowinning	2	90	-
6: Other non-ferrous metals	Primary production of lead, zinc, precious metals, ultrapure arsenic	50-200	300-1,000	5,000-20,000
	Production of alloys of lead and tin with arsenic	-	-	
	Use of lead-arsenic alloys to produce batteries, ammunition, etc.			
7: Cross-sector	Various welding processes. Plasma cutting and other thermal cutting processes.	>500	1,000-4,000	-
8: Ferrous base metals production	Pig iron production (sinter plants and pelletisation plants)	40	500-1,500	600-6,000
9: Power sector	Maintenance operations in coal and oil-shale power plants	93	50-500	500-2,500
10: Other	Mining operations and production of concentrates	10-30	200-600 (copper)	500-2,000
	Other metalworking processes	>500	-	5,000-50,000
	Shredding and dismantling of WEEE	20	-	1,000-3,000
	Reclamation of CCA wood	-	-	20-2,000
	Laboratory use	-	-	Insignificant
TOTAL (round)			7,900-15,300	18,000-102,000

Table 3-30: Inorganic arsenic compounds – exposed workforce

Sector	Use/operation	At exposure level as demonstrated by measurements or modelling		No of workers potentially exposed at relatively low levels **
		Sites	Exposed workers *	

Source: RPA/COWI on basis of above section

3.5.13 Trend in exposed workforce

For the major sectors, no significant trends in exposed workforce are observed, but exposure concentrations have been decreasing i.e. the number of workers exposed at high levels has decreased.

3.6 Current Risk Management Measures (RMMs)

The objective of this section is to describe the risk management measures (RMM) currently in place to comply with the obligations of the CMD to minimise exposure to carcinogenic/mutagenic chemical agents, and to determine what RMMs are currently used to achieve different exposure concentrations.

Information on currently RMMs in the various processes has mainly been collected form the following sources:

- Authorisation dossiers for applications subject to authorisations, and RAC opinions
- Confidential CSRs of registrations dossiers (very limited information; as most registered applications are subject to authorisation and more detailed information is collected from authorisations dossiers)
- Questionnaire responses
- Interviews with specific companies and site visits (key data source)
- Relevant data from Annex XV dossiers, RAC/SEAC opinions and other publications issued under REACH
- For processes where data are not available from the sources listed above, exposure data may be taken from reports on national monitoring programmes (Clerc et al., 2015; Cocker et al., 2009; Keen et al., 2010; Pesch et al., 2015; Steinhausen et al., 2011; Vincent et al., 2015)[23] and additional information from other sources (as fully discussed in OSHA-EU (2014)[24]).

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[23] Separate evaluations of the German MEGA database (not published in the peer-reviewed literature) are e.g. available for beryllium and 4,4'-methylenedianiline; see http://www.dguv.de/ifa/GESTIS/Expositionsdaten-bank-MEGA/Expositionsdaten-aus-MEGA-in-Publikationen/Publikationen-nach-Stoffen/index.jsp, accessed: March 2017

[24] EU-OSHA, European Agency for Safety and Health at Work, 2014, "Exposure to Carcinogens and Work-related Cancer: A Review of Assessment Methods", *European Risk Observatory Report*. Available at: https://osha.europa.eu/en/tools-and-publications/publications/reports/report-soar-work-related-cancer

A wide range of RMMs have been considered, reflecting the hierarchy of RMMs in the CMD, see below. Data have been collected both through literature review and consultation.

Table 3-21: Hierarchy of measures to be applied by the employers, as listed in the CMD and as found in companies using inorganic arsenic compounds including arsenic acid and its salts

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

Source: CMD

In the sections below detailed examples of RMMs applied are presented while section 3.6.6 provides a summary across all sectors.

3.6.1 Glass sector

An example of current RMMs in the special glass sector, as reported for the questionnaire, is shown in Table 3-31 overleaf. No data has been reported for domestic glass as no actual uses in the domestic glass sector has been reported.

Table 3-31: RMM in glass production example of questionnaire response

RMM	Transfer from container to weighing, mixing reactor and tunnel compo in closed system	Raw material loading	Transfers in tunnel compo and from tunnel compo to bunker and oven	Waste management – transfer and drum loading	General maintenance and cleaning	Tunnel compo cleaning
Substitute/reduce quantities chemical agent	Substitution successfully performed for more than 90% of the Glass production (the remaining production only concerns light glass for which there is an ongoing R&D process)					
Reduce the number of workers exposed (fewer, rotate, etc.)	Polyvalent operator with reduction of individual exposure					
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Access forbidden except for maintenance activities	Medium containment level during loading (contact between cane and drum).	Medium level of containment. Complete segregation with ventilation and filtration of recirculated air.	Yes (no specification)	Preventive maintenance for reducing maintenance operation (scheduled and unscheduled)	Limitation of cleaning operations
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	Supervision in place to check that the RMMs in place are being used correctly and OCs followed.	Yes (no specification)	-	High level of containment during waste transfer; medium level of containment during waste drum loading.	Dispose of empty containers and wastes safely	Yes (no specification)
Reduce the concentration at the workplace: Detect unusual exposures	-	-	-	-	-	-

Table 3-31: RMM in glass production example of questionnaire response

RMM	Transfer from container to weighing, mixing reactor and tunnel compo in closed system	Raw material loading	Transfers in tunnel compo and from tunnel compo to bunker and oven	Waste management – transfer and drum loading	General maintenance and cleaning	Tunnel compo cleaning
Reduce worker exposure: Collective protection measures to reduce exposure to workers	No exhaust ventilation system in place	-	-	-	Local exhaust ventilation for maintenance (scheduled and un scheduled)	Local exhaust ventilation
Reduce worker exposure: Individual protection measures to reduce exposure to workers	Yes (no specifications)	Power assisted filtering devices incorporating TM3 full face mask gas Wear chemically resistant gloves (tested to EN374) and eye protection in combination with specific activity training	-	-	Power assisted filtering devices incorporating TM3 full face mask gas - especially in case cleaning before intervention is not sufficient/efficient Wear chemically resistant gloves (tested to EN374) and eye protection in combination with specific activity training.	Power assisted filtering devices incorporating TM3 full face mask gas Wear chemically resistant gloves (tested to EN374) and eye protection in combination with specific activity training

Table 3-31: RMM in glass production example of questionnaire response						
RMM	Transfer from container to weighing, mixing reactor and tunnel compo in closed system	Raw material loading	Transfers in tunnel compo and from tunnel compo to bunker and oven	Waste management – transfer and drum loading	General maintenance and cleaning	Tunnel compo cleaning
Other measures, please specify	Avoiding frequent and direct contact with the substance. Minimisation of manual phases. Regular cleaning of equipment and work area.	Avoiding frequent and direct contact with substance. Minimisation of manual phases. Regular cleaning of equipment and work area. Supervision in place to check that the RMMs in place are being used correctly and OCs followed. Avoid splashing .	Avoiding frequent and direct contact with the substance. Minimisation of manual phases. Regular cleaning of equipment and work area. Supervision in place to check that the RMMs in place are being used correctly and OCs followed	Avoiding frequent and direct contact with the substance. Minimisation of manual phases. Regular cleaning of equipment and work area. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.	Avoiding frequent and direct contact with substance. Minimisation of manual phases. Regular cleaning of equipment and work area. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.	Dispose of empty containers and wastes safely. Avoiding frequent and direct contact with substance. Minimisation of manual phases. Regular cleaning of equipment and work area. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.

Source: Stakeholder consultation

3.6.2 Electronics sector

An example of questionnaire response of RMMs used in the electronics sector is shown below.

Table 3-32: RMM in different process, manufacture of electronic components and boards, example of questionnaire response

RMM	Preparation of synthesis crucibles Operating synthesis recipients (load and unload of crucibles) Cleaning of recipients
Substitute/reduce quantities chemical agent	Raw material cannot be reduced or substituted
Reduce the number of workers exposed (fewer, rotate, etc.)	Job rotation system, total number of exposed workers is constant
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Closed system, wet cleaning of equipment
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	General ventilation of working rooms, central vacuum cleaning system
Reduce worker exposure: Collective protection measures to reduce exposure to workers	Organisational measures: operator training with instruction to maintain distance during machine cleaning
Reduce worker exposure: Individual protection measures to reduce exposure to workers	Special work clothing, PPE (gloves, goggles, respirator mask P3)

Source: Stakeholder consultation

RMMs in the production of copper foil for circuit boards is shown below.

Table 3-33: RMM production of copper foil for circuit boards

ECS/WCS	Task	Technical RMM	Organisational RMM	PPE
ECS1	ERC 6b – Surface Treatment			
WCS1	PROC 1 – Use in closed process, no likelihood of exposure	Closed system 5-10 air changes/hr	Duration < 1 hour BS-OHSAS 18001 Safety training	Gloves Safety goggles Protective suit
WCS2	PROC 5 - Dilution of the substance into a large container	Preparation site only 5-10 air changes/hr Other employees circulation forbidden	Duration < 15 min Frequency : 1 x / wk BS-OHSAS 18001 4 persons only Specific safety training	Nitrile Gloves Safety Respirator Disposable all-in-one suit
WCS3	PROC 13 - Electrochemical surface treatment	LEV by lip extraction Specialised room ventilation with more than 10 air changes/hr	Duration < 1 hr Frequency : 1 x / d BS-OHSAS 18001 Safety training	Nitrile Gloves Safety goggles Protective suit
WCS4	PROC 8b - Maintenance	Specialised room ventilation with more	Duration < 15 min / d / y	Nitrile Gloves Safety Respirator

Table 3-33: RMM production of copper foil for circuit boards

ECS/WCS	Task	Technical RMM	Organisational RMM	PPE
	of equipment	than 10 air changes/hr	Frequency : 2 x / y BS-OHSAS 18001 Safety training	Disposable all-in-one suit

Source: Circuit Foil,2015

3.6.3 Copper sector

An overall description of RMMs applied in the copper sector is given below. More details on specific RMMs considered best practice is described in section 3.8.1.

Primary and secondary copper production

Two examples of questionnaire responses for primary and secondary copper production are shown in Table 3-34 and Table 3-35, respectively. The answers demonstrate that a combination of different RMMs are used for all processes, but are at a general level where it would be difficult to assess the efficiency of different measures.

***Reducing the quantities of the chemical agents used* -** In the primary copper production the total amount of arsenic entering the process depends on the arsenic content of the concentrates. As described elsewhere the arsenic content of concentrates on the world market is increasing and there is a competition for concentrates with low content of arsenic. Around 30% of world copper concentrates output contains more than 0.1% arsenic.

Reducing the number of workers exposed - As indicated in Table 3-34 rotation is used in many processes in order to reduce the exposure levels of the workers, but this measure may increase the number of workers exposed at lower levels. The number of workers exposed has first of all been reduced by increased automation. It is the impression from contact with industry that the automation is today at a level, where reduction in number of workers exposed in recent years has been limited.

Reduce the concentration at the workplace - The concentration in the workplace is generally reduced by use of general ventilation in all processes combined with LEV in specific places where fumes and dust are generated e.g. above the furnaces or dusty processes.

A characteristic of the processes is that many of the processes take place in very large facilities with a small number of workers actually present in the rooms where the processes takes place. Furthermore, the places with high exposure levels are not necessarily the places where fumes and dust are generated. As indicated in the questionnaire answer in Table 3-34 slightly different method are used in different processes. It is the impression from site visits that reduction of concentrations in many workplaces require major changes in the entire process setup and it is often difficult to reduce the workplace concentrations in place with high exposure levels by means of LEV.

For dusty processes, the removal of dust and changes in the processes in order to reduce the dust levels have over the years reduced the general level of dust in the air.

For control rooms and cranes, exposure has been reduced by clean air supply or use of filters, and dust is prevented by hygienic measures.

Reduce worker exposure - For most of the worker exposure scenarios, exposure is currently reduced by use of PPE. For processes such as sampling and raw material control, maintenance and cleaning, handling or arsenic-containing waste etc. the use of RPE and rotation is the only way to keep the exposure at an acceptable level. The tendency is toward increased use of full-mask powered filtering devices which provide a better protection than filtering half mask and apparently are more convenient to use than half mask filters because it is easier to breathe. Of the processes listed in the tables, work in the electrolytic cell room would often be undertaken without RPE, whereas all processes with high exposure levels would require use of RPE when the specific process is undertaken. The exposure levels shown in section 3.4.5 are levels in the breathing zone without adjustment for use of PPE. The PPE use would typically reduce the exposure level by a factor of >20.

Monitoring workers revealed that using the same PPE may have quite different arsenic levels in the urine which point at the need for a good hygiene to prevent cross contamination and oral exposure to arsenic containing dust. Biological monitoring of arsenic in urine (in particular As $^{5+}$ and As $^{3+}$) is a tool to identify work processes with high exposure but also individual hygienic practices that may lead to high exposure of the individual worker (e.g. non-proper use of the PPE).

Consequently proper use of the PPE requires training in use and maintenance of the equipment and training in good hygiene in order to prevent exposure by other routes than inhalation.

For work process with high exposure (to arsenic but also to sulphur dioxide) it is common to only work partially in areas with high exposure. As an example from one site, the workers working in the tapping area of the flash furnace was working for 20 minutes in the tapping area followed by 40 minutes in a control room.

Table 3-34: RMM in different process, primary copper production, example of questionnaire response

RMM	Refining furnace, casting mill	Flash furnace, electrical furnace	Sulphuric acid production/acid plant	Electrolytic cell, anodic slime recovery	Raw material storage/silo
Reduce the number of workers exposed (fewer, rotate, etc.)	Rotation, Biological Monitoring, Clean Cloth Service	Rotation, Biological Monitoring, Clean Cloth Service	Rotation, Biological Monitoring, Clean Cloth Service	Rotation, Biological Monitoring, Clean Cloth Service	Rotation, Biological Monitoring, Clean Cloth Service
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Specific Standard Operating Procedures (SOP)	Specific SOP	Specific SOP	Specific SOP	Specific SOP
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	Secondary hoods	Extraction hoods	Closed process, occasional exposure during sampling /maintenance	Local extraction, forced ventilation	Closed silo
Reduce worker exposure: Collective protection measures to reduce exposure to workers	Secondary hoods, specific SOP	Secondary hoods, specific SOP	Specific SOP	Local extraction, forced ventilation, specific SOP	Closed silo, specific SOP
Reduce worker exposure: Individual protection measures to reduce exposure to workers	Personal protective equipment	Personal protective equipment	Personal protective equipment	Personal protective equipment	Personal protective equipment

Source: Stakeholder consultation

Table 3-35: RMM in secondary copper production example of questionnaire response			
RMM	**Operating furnaces/ metallurgical processes / dust, fumes**	**Operating tankhouse (chemical department) / dust, fumes**	**Operate (vacuum)distillation / dust, fumes**
Substitute/reduce quantities chemical agent	Entrance control with penalties	Entrance control with penalties	Entrance control with penalties
Reduce the number of workers exposed (fewer, rotate, etc.)	Restricted areas	Restricted areas	Restricted areas
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Design metallurgical processes, cleaning routines	Design metallurgical processes, cleaning routines	Design metallurgical processes, cleaning routines, closed process
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	Exhaust-ventilation, filter-installation, encapsulation	Exhaust-ventilation, filter-installation, encapsulation, enclosures	Exhaust-ventilation, filter-installation
Reduce the concentration at the workplace: Detect unusual exposures	Workplace air monitoring (stationary and personal), continuous biomonitoring, follow-up of relevant process parameters	Workplace air monitoring (stationary and personal), continuous biomonitoring, follow-up of relevant process parameters	Workplace air monitoring (stationary and personal), continuous biomonitoring, follow-up of relevant process parameters
Reduce worker exposure: Collective protection measures to reduce exposure to workers	LEV, water spray/mist	LEV, concentration measurements chemical baths	LEV, water spray/mist
Reduce worker exposure: Individual protection measures to reduce exposure to workers	PPE (FFFP3, versaflo), hygiene routines	PPE (FFFP3), hygiene routines	PPE (FFFP3, versaflo), hygiene routines
Other measures, please specify	Procedures to reduce/limit dust formation	Procedures to reduce/limit dust formation	Procedures to reduce/limit dust formation
Source: Stakeholder consultation			

3.6.4 Zinc production using diarsenic trioxide

Technical and organisational conditions and measures in the use of diarsenic trioxide for the production electrowinning of zinc of relevance for occupational exposure are described by one of the applicants as follows:

- *"Arsenic trioxide drums are stored in a locked cage in a chemical storehouse. Handling of solid As takes place in a pressurised room equipped with exhaust pipes and scrubbers. The As solution tank and all the equipment are isolated with a separate sewer system.*

- *Processing stage: Closed system, automatically operated continuous leaching process (80 °C). The reactors are equipped with an exhaust system and scrubbers. General ventilation rate of the refinery department hall is 33,500 m3/h. Local Exhaust Ventilations (LEVs) are installed in all significant As emission points of the refinery department. Dust filters are installed in the ventilation exhausts. Continuous automated on line detectors for arsine gas are installed in the process hall."*

The current risk management measures used are further summarise the application for authorisation and summarised as follows:

Table 3-36: RMM in zinc production using diarsenic trioxide - site 1

ECS/WCS	Task	Technical RMM	Organisational RMM	PPE
ECS1	Industrial use of diarsenic trioxide to produce copper concentrate (ERC 6a)	-Containment -Closed automated process	-Regular training -ISO 9001 and 14001 certification -Well-educated staff	See WCS 1-5
WCS1	Preparation of arsenious acid solution (PROC 3)	- Pressurised dissolving station - Containment	- Regular training - ISO 9001 and 14001 certification - Authorised, skilled and instructed staff - 2 persons per shift involved (job rotation) - Online monitoring via PLS Written procedures - Supervision	- General working clothes - Respiratory mask - Protective rubber gloves - Robber boots Disposable all-in-one suit
WCS2	Use in purification process (PROC 1 PROC 2 PROC 3)	- Continuous closed process - General ventilation - Under pressure equipment	- Regular training - ISO 9001 and 14001 certification - Well-educated staff - Online monitoring via PLS -Written procedures - Supervision - Job rotation - Duration and frequency of involvement reduces to a minimum - Housekeeping	- General working clothes - Gloves - Safety glasses

Table 3-36: RMM in zinc production using diarsenic trioxide - site 1				
ECS/WCS	**Task**	**Technical RMM**	**Organisational RMM**	**PPE**
WCS3	Packing, transport and storage of copper concentrate (PROC 1 PROC 2 PROC 3 PROC 9 PROC 26)	- Containment - General ventilation	- Regular training - ISO 9001 and 14001 certification - Well-educated staff -Written procedures - Supervision - Duration and frequency of involvement reduces to a minimum - Job rotation - Housekeeping	- General working clothes - Gloves - Safety glasses - Protective overalls
WCS4	Cleaning work and handling of waste (PROC 8b PROC 9 PROC 26)	- Wet suppression - Dust abatement systems - Closed sewage system - Water collection facilities	- Regular training - ISO 9001 and 14001 certification - Well-educated staff - Written procedures - Supervision - Duration and frequency of involvement reduced to a minimum - Job rotation	- General working clothes - Gloves - Safety glasses
WCS5	Maintenance work (PROC 8b)	- Pressure measuring devices	- Regular training - ISO 9001 and 14001 certification - Well-educated staff - Written procedures - Permit system - Supervision - Duration and frequency of involvement reduced to a minimum - Job rotation	- General working clothes - Gloves - Safety glasses - Full face mask (P3), chemical protective gloves (ADF 20) and safety shoes for high risk task
Source: Applications for authorisation				

According to RAC (2014, b), the occupational RMMs described in the application seem appropriate/adequate to protect the workers (closed systems where possible, general and local exhaust ventilation, job rotation, training, PPE).

In addition to training, job rotation, general ventilation and local exhaust ventilation the use of personal protective equipment (PPE) reduces the risk to the individual worker. For all WCS protective clothing including gloves are used. For WCS1 respiration protective equipment (RPE) is always used. For all other WCS RPE is not normally needed but still available if necessary if dust is generated. Effectiveness of both RPE and gloves was assumed by the applicant to be minimum 90% in the CSR (RAC, 2014b).

For both companies RAC agrees that the operational conditions and risk management measures in place are appropriate in reducing the exposures and the risk.

Table 3-37: RMM in different process, zinc production, example of questionnaire response

RMM	PROC code: 3	PROC code: 1/2/3	PROC code: 1/2/3/9/26
Substitute/reduce quantities chemical agent	-	-	-
Reduce the number of workers exposed (fewer, rotate, etc.)	Job-Rotation	Job-Rotation	Job-Rotation
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Defined work processes	Defined process flows	Defined process flows
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	Indoor, Systems under low pressure, closed system, integrated ventilation system	Containment, General ventilation	Containment, General ventilation
Reduce the concentration at the workplace: Detect unusual exposures	Housekeeping	Housekeeping	Housekeeping
Reduce worker exposure: Collective protection measures to reduce exposure to workers	General hygiene measures; general PSA incl. regular change of the PSA, training of the employees	Regular training; ISO 9001 and 14001 certification; authorised, skilled and instructed staff; 2 persons per shift involved; Online-Monitoring via PLS; written procedures; supervision	regular training; ISO 9001 and 14001 certification; well-educated staff; written procedures; supervision; duration and frequency of involvement reduced to a minimum
Reduce worker exposure: Individual protection measures to reduce exposure to workers	RPE; Biomonitoring	General working clothes; gloves; safety glasses; Biomonitoring	General working clothes; gloves; safety glasses; protective overalls; Biomonitoring

Source: Stakeholder consultation

3.6.5 Other non-ferrous metals

An example of RMMs applied in different processes in a company involved in the production of precious and other rare metals is shown below.

Table 3-38: RMM in different process, production of other metals, example of questionnaire response

RMM	Production of metal	Crushing of metal, pre-packing	Packaging of metal	Waste water treatment plant
Reduce the number of workers exposed (fewer, rotate, etc.)	Only few workers are doing this work	Only few workers are doing this work	Only few workers are doing this work	Only few workers are doing this work
Reduce the concentration at the workplace: Process related measures - design of work processes, etc.	Ventilation	Ventilation	Ventilation	Ventilation
Reduce the concentration at the workplace: Control equipment to enclose, extract, or ventilate, etc.	The production unit is nearly closed	The work is done in glove boxes	The substance is already packed in closed bottles	Closed containers
Reduce worker exposure: Individual protection measures to reduce exposure to workers	Worker is wearing full PPE during work. After work with PPE there is a time for showering / recreation.	When substances are put in or out the glove boxes or for cleaning activities the workers are wearing suitable masks	Workers are wearing protective clothes, shoes	In case of expected exposure e.g. emptying containers worker is wearing a suitable mask
Other measures, please specify	Biomonitoring: As in urine at least 10 times a year	Biomonitoring: As in urine at least 10 times a year	Biomonitoring: As in urine at least 10 times a year	Biomonitoring: As in urine at least 10 times a year

Source: Stakeholder consultation

3.6.6 Costs and efficiency of RMMs

Costs of various RMMs used as background for the costs assessment are shown in Table 3-34. The table has been derived from experience across sectors and the figures may need adjustment for specific measures.

The background for the figures is further discussed in the general methodology report under this contract. The OPEX consists mainly of maintenance costs. The LEVs in general consists of an enclosure and piping, possibly a heat exchanger, a ventilator and various filters (or other emission control devices) to prevent that contaminants in the air are released to the surroundings. The filters have to be maintained regularly and the waste has to be disposed of and this account for a significant part of the OPEX. Furthermore, ventilators and other parts of the LEV may need to be replaced within the lifetime of the LEV.

For the copper smelters which typically have between 300 - 2,000 exposed employees, the column for "large enterprises" should at the least be multiplied with a factor of 3-5. In the section on best practice examples of costs of various measures are provided for the copper sector in section 3.8.1. As an example, about €10 million was invested for an existing system to capture and treat fugitive gas in a primary copper smelter - including a bag filter, piping, hoods, fans, and process control. In another example EUR 7 million for measures to capture diffuse emissions from the anode furnace and casting wheel (see section 3.8.1). This is quite well in accordance with a multiplication by factors of 3-5 of the estimates for a full enclosure indicated in Table 3-34.

The costs of maintenance of PPE in order to reduce indirect exposure (e.g. wash every day as is practiced in some companies) may quite well be higher than the OPEX indicated in the table, but these costs are not considered to be allocated to the compliance with the OELV.

For LEVs, a significant OPEX is due to the energy losses by the use of the LEV which may be particular high in colder climate. The energy loss has not been taken into account.

Table 3-39: Cost of various RMMs in €

Size of company	Small 2 workers exposed Exposed workers on 1 machine			Medium 27 workers exposed 14 machines			Large 75 workers exposed 40 machines		
Type of RMM	CAPEX 2017	Life-span years	OPEX (% of CAPEX)	CAPEX 2017	Life-span years	OPEX (% of CAPEX)	CAPEX 2017	Life-span years	OPEX (% of CAPEX)
RWK: Rework	25,000			350,000			1,000,000		
LEV 3: Full enclosure	45,000	20	10%	440,000	20	10%	1,700,000	20	10%
LEV 2: Partial enclosure	30,000	20	10%	240,000	20	10%	650,000	20	10%
LEV 1: Open hood	7,000	20	10%	90,000	20	10%	260,000	20	10%
WE 2: Pressurised or sealed	30,000	20	10%	240,000	20	10%	650,000	20	10%
WE 1: Simple enclosed cab	7,000	20	10%	90,000	20	10%	260,000	20	10%
RPE 3: Breathing apparatus	2,540	2	1000%	8,890	2	1000%	38,100	2	1000%
RPE 2a: Powered helmets or full face mask	2,000	3	30%	27,000	3	30%	75,000	3	30%
RPE 2: HEPA filter - unpowered	300	Mask: 1 month, Filter: 1 month	50%	4,000	Mask: 1 month, Filter: 1 month	50%	11,000	Mask: 1 month, Filter: 1 month	50%
RPE 1: Simple mask	500	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year	7,000	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year	20,000	Not relevant, 1 per day	Not relevant but CAPEX 2017 incurred every year
OH 1: Organisational measures	2,000		50%	27,000		50%	75,000		50%
GDV 1: General dilution ventilation	6,000	20	30%	40,000	20	30%	100,000	20	30%

Source: RPA/COWI

Table 3-40: Percentage reduction in exposure achieved with RMM	
Type of RMM	**% reduction in exposure**
Discontinuation	100%
Substitution	100%
Rework	50%
Full enclosure	99.5%
Partial enclosure	90%
Open hood	80%
No LEV	0%
Pressurised or sealed	99.5%
Simple enclosed cab	80%
No enclosure	0%
Breathing apparatus	99.5%
Powered helmets or full face mask	97.5%
HEPA filter	95%
Simple mask	60%
No mask	0%
Organisational measures	30%
No organisational measures	0%
General dilution ventilation	30%
No general ventilation	0%
Source: RPA/COWI and manufacturers of RMMs	

3.7 Voluntary industry initiatives

No voluntary initiatives specifically addressing occupational exposure to arsenic have been identified.

Some voluntary initiatives, however, may have had an influence on lowering the occupational exposure to arsenic.

The following initiatives have been identified:

- The **EUROBAT Blood Lead Mitigation Programme**[25]. EUROBAT adopted this mitigation programme in 2000 and revised it in 2013 with the aim of lowering the occupational exposure to lead in the manufacturing and recycling of lead-based batteries in Europe. As arsenic may be present in the lead alloys, the initiatives would also result in lowering the exposure to arsenic. The basic levels of the Blood Lead Reduction Guidelines are a list of control measures that combine activities in the following areas:

- Technical controls

- Personal & general hygiene rules & practices

- Personal protective equipment

- Training and Counselling

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[25] https://eurobat.org/occupational-health-safety

- The **voluntary risk assessment report**[26] completed by the European Copper Institute in 2008. Among others the report forms the basis of a risk reduction plan in a few, specific local exposure situations where risk management actions may be required. The preparation of the risk assessment report has put a common focus in the industry for reducing human and environmental exposure to copper, which may also have an impact on exposure to other hazardous substances in the sector.

3.8 Best practice

This section provides examples of best practice RMMs.

The aim is for the output of this section to be a catalogue of examples organised by:

- Applications, 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.

- Technology types, 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 will be very application specific).

3.8.1 Copper sector

No best practice documents with regard to workplace exposure in the copper sector have been identified. In the following, the BAT reference document for the non-ferrous industry, which describes best available techniques for reducing the environmental releases is used for those parts of the workplace exposure where the reduction of environmental releases is linked to reducing the workplace concentrations.

Reducing the quantities of the chemical agents used - In the primary copper production the total amount of arsenic entering the process depends on the arsenic content of the concentrates. As mentioned previously the arsenic content of concentrates on the world market is increasing and there is a competition for concentrates with low content of arsenic. Around 30% of world copper concentrates output contains more than 0.1% arsenic. According to an article in International Mining (2016) complex copper concentrates have an As content greater than 0.2% (2,000 ppm) with no upper limit, although China imposes a limit of 0.5% As (5,000 ppm) on imported base metal concentrates. Many copper smelters able to process complex concentrates with high arsenic content prior to the 1990s, have either stopped this practice or closed for environmental reasons. Currently only a few copper smelters in the world can process complex concentrates.

During the last years many attempts has been done to reduce arsenic content in concentrates with very high content in response to the increasing trend in the arsenic content of concentrates.

An example is the Outotec® Copper Arsenic Partial Roasting (Outotec, 2017) which can reduce arsenic concentrations in concentrate from 12% to < 0.3% i.e. to a higher arsenic concentration, than the concentration in the concentrate typically used today. For copper concentrates, partial roasting is used as a pre-treatment step prior to the flash smelting process. The BAT reference document for the non-ferrous metal industries (JRC, 2017) describes this roasting technique. A fluidised bed roaster furnace was installed at the in a primary smelter in 1980 for the roasting of copper concentrates containing high grades of arsenic. Investment estimates provided by Outotec for the BAT document say the

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[26] See http://copperalliance.eu/industry/voluntary-initiatives/voluntary-risk-assessment

cost is EUR 200 million in an existing plant with infrastructure. The cost estimation includes the furnace, cooling towers, cyclones and filters. The technique has not been applied to remove arsenic from concentrates with an arsenic content of 0.1-0.2 which is commonly used today in European smelters, but the above cost estimate may indicate the costs if exposure concentrations should be reduced by reducing the arsenic content of raw materials.

A new process for removing arsenic from the concentrates is the Toowong process developed by Core Resources (2017) in Australia. According to the company, the hydrometallurgical process achieves over 90% arsenic and antimony removal from many copper, lead and nickel concentrates. The patented Alkaline Leaching (AL) process selectively leaches arsenic and antimony. Copper, lead and nickel are not solubilised (dissolved) in the process and the final product from the process is a cleaned saleable copper, lead or nickel concentrate (Core Resources, 2017). By use of the technology, according to the company, the process chemically separates arsenic at the mine site, captures arsenic in an environmentally stable form, and returns arsenic to its original native location. According to Rohner et al. (2017), the process has been tested on concentrate from three global resources: Bulgaria, Philippines and Chile in a $4.5 million 34 day pilot plant operation. The method was successfully reducing the arsenic content from 1.1% to 0.1%. The economics of the process is described by Rohner et al. (2017). The CAPEX for a ferric arsenate option is estimated at USD 37 million for a plant capacity of 40,000 t/year of concentrate with an arsenic content of 2.5% and USD 147 million for a capacity of 400,000 t/year. The 400,000 t/year would roughly correspond to the amount of concentrate used by one of the primary copper smelters in the EU. The OPEX of treating concentrates with 2% As are indicated at USD 5.49 and USD 4.48/lb. As removed for the 40,000 t/year and the 400,000 t/year capacity, respectively. The OPEX is divided with 68% for consumables, 21% labour costs, 7% plant equipment costs and 4% power. Including capital amortisation, OPEX is in the range of: USD 5.30/lb As removed for the 400,000 t/year plant and USD 7.80 /lb As removed for the 40,000 t/year plant (Rohner et al., 2017). With an USD/EUR rate of 0.85 (Dec 2017), the OPEX capital amortisation can be estimated at EUR 9.9/kg As and EUR 14.6/ kg As. With an As content of concentrates used in the EU of 2,000-5,000 t/year the annual costs of reducing the As by a factor 3 would be in the range of EUR 13-33 million assuming the use of plants of a capacity of 400,000 t/year. The estimate is just illustrative of the range of likely minimum costs, as no data are available on the costs of bringing the concentrations well below 0.1%, which would be necessary to obtain this reduction.

Another technology is the CESL Cu-As technology developed by the Canadian company Teck and Aurubis in Germany. The CESL Process uses existing technologies such as pressure oxidation, solvent extraction and electrowinning but combines them in a novel way (CESL, 2017). The final product is copper cathodes and the arsenic is precipitated as stable basic ferric arsenate and scorodite. The method is not applied within the EU and is still in the pilot testing stage. The method is not a pre-treatment process but rather an alternative to current smelter technology. The processed concentrates ranged from 1.4 – 10.0% arsenic (CESL, 2017) and the applicability of the process to remove arsenic from ores with lower content has not been tested.

Reduce the concentration at the workplace - The concentration in the workplace is generally reduced by use of general ventilation in all processes combined with LEV in specific places where fumes and dust are generated e.g. above the furnaces or dusty processes.

In large installations such as copper smelters reducing the workplace exposure is closely linked to reducing the diffuse emission from the installations. Diffuse emissionsare released through openings below the roofs, windows and gable openings, etc. Major sources of diffuse emission are the secondary emissions which are emissions escaping from the furnace lining or during operations such as charging or tapping and which may be captured with a hood or enclosure.

According to the BAT reference document, in order to reduce secondary emissions to air from furnaces and auxiliary devices in primary copper production and to optimise the performance of the abatement system, BAT is to collect, mix and treat secondary emissions in a centralised off-gas cleaning system.

Table 3-41 summarise the BAT conclusions for the copper sector for processes where the techniques may contribute to reducing the workplace concentration and to reducing the potential exposure to dust in the workplace. The table does not include the BAT from various specific converter processes described in the BAT reference document, but these measures typically also include the use some of the same measures as indicated for other processes in the table below.

For some of the measures, the measures may contribute to reducing the overall risk of exposure or workers, but for some groups of workers, especially workers involved in maintenance operations, the measures may have limited effect. As an example, use of enclosed conveyers or pneumatic transfer systems for dusty materials may reduce overall exposure, but for maintenance workers involved in maintenance of enclosed conveyers may still lead to high exposures and the need for proper PPE.

Reduce worker exposure - For most of the worker exposure scenarios, exposure is currently reduced by use of RPE. For processes such as sampling and raw material control, maintenance and cleaning, handling or arsenic-containing waste etc. the use of RPE is the only way to keep the exposure at an acceptable level. The tendency is toward increased use of full-mask powered filtering devices which provide a better protection than filtering half mask and apparently are more convenient to use than half mask filters because it is easier to breathe.

Monitoring of workers reveal those workers using the same RPE may have quite different arsenic levels in the urine which point at the need for a good hygiene to prevent cross contamination and oral exposure to arsenic containing dust.

Best practice with regard to keeping the RPE clean and functioning is to wash the masks and check the filters every day. In an example from one smelter, three full time employees were responsible for cleaning and maintaining the RPE and other PPE, and the workers picked up cleaned equipment every day.

Furthermore the use requires training in the proper use and maintenance of the equipment and training in good hygiene in order to prevent exposure by other routes than inhalation.

For work process with high exposure (to arsenic but also to sulphur dioxide) the best practice is to only work partially in areas with high exposure. As an example from one site, the workers in the tapping area of the flash furnace were working for 20 minutes in the tapping area followed by 40 minutes in a rest room.

For some of the main measures, further information including example of costs of the measures is included below the table

Table 3-41: BAT for reducing diffuse emission from primary and secondary copper smelter is to use combinations of below techniques, selected processes

Technique	Applicability
Pre-treatment (such as blending, drying, mixing, homogenisation, screening and pelletisation)	
Use enclosed conveyers or pneumatic transfer systems for dusty materials	Generally applicable
Carry out activities with dusty materials such as mixing in an enclosed building	For existing plants, application may be difficult due to the space requirements

Table 3-41: BAT for reducing diffuse emission from primary and secondary copper smelter is to use combinations of below techniques, selected processes	
Technique	**Applicability**
Pre-treatment (such as blending, drying, mixing, homogenisation, screening and pelletisation)	
Use dust suppression systems such as water cannons or water sprinklers	Not applicable for mixing operations carried out indoors. Not applicable for processes that require dry materials. The application is also limited in regions with water shortages or with very low temperatures
Use enclosed equipment for operations with dusty material (such as drying, mixing, milling, air separation and pelletisation) with an air extraction system connected to an abatement system	Generally applicable
Use an extraction system for dusty and gaseous emissions, such as a hood in combination with a dust and gas abatement system	Generally applicable
Charging, smelting and tapping operations in primary and secondary copper smelters and from holding and melting furnaces	
Briquetting and pelletisation of raw materials	Applicable only when the process and the furnace can use pelletised raw materials
Enclosed charging system such as single jet burner, door sealing, closed conveyers or feeders equipped with an air extraction system in combination with a dust and gas abatement system	The jet burner is applicable only for flash furnaces
Operate the furnace and gas route under negative pressure and at a sufficient gas extraction rate to prevent pressurisation	Generally applicable
Capture hood/enclosures at charging and tapping points in combination with an off-gas abatement system (e.g. housing/tunnel for ladle operation during tapping, and which is closed with a movable door/barrier equipped with a ventilation and abatement system)	Generally applicable
Encapsulate the furnace in vented housing	Generally applicable
Maintain furnace sealing	Generally applicable
Hold the temperature in the furnace at the lowest required level	Generally applicable
Boosted suction systems	Generally applicable
Enclosed building in combination with other techniques to collect the diffuse emissions	Generally applicable
Double bell charging system for shaft/blast furnaces	Generally applicable
Select and feed the raw materials according to the type of furnace and abatement techniques used	Generally applicable
Use of lids on throats of rotary anode furnace	Generally applicable
Anode casting in primary and secondary copper smelters	
Use an enclosed tundish (where molten copper flows from holding furnace to the casting wheel)	-
Use a closed intermediate ladle	-
Use a hood, equipped with an extraction system, over the casting ladle and over the casting wheel	-
Source: JRC, 2017	

According to the BAT reference document for the non-ferrous metal industries, the primary smelters usually contain dust very well and are effectively sealed to minimise diffuse emissions; concentrate burners or lances are used and are therefore easier to seal. Good maintenance of the furnaces and ducts is practised to minimise diffuse emissions, and the collected gases are treated in dust removal systems prior to the sulphur recovery processes. Secondary smelters are more prone to diffuse emissions during charging and tapping cycles. These furnaces have large charging doors and the warping and missealing of these doors is a significant factor. In secondary bath smelters, the burden is charged via an enclosed charging system, and diffuse emissions occur at the taphole and runners and are captured by hoods and routed to the gas-cleaning system. The gases that are collected are usually cooled and dust is removed from gas streams by electrostatic precipitators or fabric filters.

Table 3-42 provides examples of BAT for the reduction of diffuse emissions and examples of costs of the system in European smelters as reported in the BAT reference document.

The techniques concern reducing dust from handling of raw materials and waste materials and releases from hot processes. Within the smelter house releases may in particular take place from the smelting furnace, converter furnace, anode furnace and casting wheel and the transfer of the molten products or intermediates from one operation to another. Overall the techniques are the installation of primary and secondary hut systems. The systems basically consist of the huts, fans, piping and system for cleaning the off-gas. The prevailing temperatures of the various metal, slag or matte fractions are above the volatilisation points of arsenic and its oxides, so that the latter accumulate in the furnace off-gas that is channelled and treated by the flue-gas treatment system.

As far as possible, diffuse emissions should be captured at the source via secondary hoods and the extracted off-gas routed to the gas-cleaning system. Moreover, dust emissions are generated during the handling and pre-treatment of the secondary raw materials (e.g. size reduction, shredding, pelletising). The emissions at secondary copper smelters can be dominated by diffuse dust emissions which account for approximately 70% of total emissions.

One of the new technologies applied is the house-in-house concept (tertiary fume collection). The concept can be applied to existing installations if the space inside the building allows. The units (holding furnace, converters and casting facilities) installed inside closed production buildings are not only provided with capture hoods, but are additionally accommodated in a largely sealed enclosure which is vented to a filter system. Capital expenditure for the 'house-in-house' system was reported as up to EUR 6 million.

Table 3-42: Examples of BAT for reducing diffuse emission from copper smelter which may also reduce workplace exposures

Emission source	Techniques	Economics - examples of investments
Emission from reception, storage and handling of primary and secondary materials	Includes use of enclosed conveyor belts for material transportation; use of closed buildings for storage and handling of raw materials; collecting dust in cranes; bag filters in ventilation systems; and keeping material moist.	Investments for installation of storage and blending buildings are for four smelter reported to be in the range of EUR 6.5 - 10 million Data on enclosing conveyers and establishing not provided

Table 3-42: Examples of BAT for reducing diffuse emission from copper smelter which may also reduce workplace exposures

Emission source	Techniques	Economics - examples of investments
Transfer of dusty material, pre-treatment	An enclosed building, enclosed conveyor; pneumatic transfer system and extraction system connected to the filtration equipment (e.g. bag filters) are applied for dust-forming material	EUR 0.67 million for a bag filter with an afterburner in the chimney for waste gases from the dryer EUR 7.5 million for the construction of a covered storage area with an integrated crushing, screening and conveying facility connected to a bag filter. EUR 7.5 million for the construction of a covered storage hall for dust-forming input materials including special ground construction with liquid-tight concrete, and an application of water spray nozzles and tyre washing for departing trucks.
Emission from smelting furnaces in primary copper production	Includes, sealed/encapsulated furnaces, oxygen enrichment, and operation under negative pressure.; Housing, enclosures, covered launders and capture hoods with an efficient extraction and boosted suction system; treatment of off gas.	About EUR 10 million for an existing system to capture and treat fugitive gas in a primary copper smelter - includes a bag filter, piping, hoods, fans, and process control. About EUR 1.7 million for improving the collection of fugitive emissions in a primary smelter. This included improvements to the hoods at the flash furnace area, closing the ladle tunnels with metal barriers during tapping, and the installation of a three-stage converter secondary hoods system.
Emission from charging of furnace	Includes briquetting and pelletisation of raw material (primarily done to meet the furnace requirements, but is also effective for the reduction of diffuse emissions); enclosed conveyers with ventilation; sealed charging system; encapsulated lift charging system, charging of furnaces/converters under reduced pressure; housing of the furnace; and enclosures and hoods with efficient fume extraction and subsequent off-gas cleaning.	No data provided

Table 3-42: Examples of BAT for reducing diffuse emission from copper smelter which may also reduce workplace exposures		
Emission source	**Techniques**	**Economics - examples of investments**
Emission from smelting furnaces in primary copper production	Includes sealed/encapsulated furnaces; oxygen enrichment, and operation under negative pressure; Housing, enclosures, covered launders and capture hoods with an efficient extraction and boosted suction system; gas treatment with bag filter, wet or semidry scrubber.	About EUR 10 million for an existing system to capture and treat fugitive gas in a primary smelter. Includes a bag filter, piping, hoods, fans, and process control. Included in investment of EUR 1.7 million mentioned below
Emission from converter furnaces in primary copper production	Includes capture hoods and the addition of materials (scrap and flux) through the hood for PS converters; use of closed lids for Hoboken converters (one of the two converter types); boosted suction systems to ensure fume collection and efficient extraction; treatment of off-gases in electrostatic precipitators (ESP) or bag filters.	About EUR 1.7 million for installation in a primary smelter of a three-stage converter secondary hoods system, improvement of the hoods at the flash furnace area, and closing of the ladle tunnels with metal barriers during tapping. EUR 16 million for the replacement of all primary converter hoods and scrap loaders and installation of secondary hoods and a secondary gas treatment system. EUR 6 million for an existing system to improve the capture and treatment of diffuse gas from converters in a primary copper smelter. Includes a bag filter, piping, ventilation, lime injection system, fans, and process control).
Emission from melting and fire refining (anode furnace) and anode casting in primary and secondary copper production	Include throats of rotary anode furnaces are equipped with lids to reduce the diffuse emissions during the operation; hoods and ventilation systems are applied to capture fumes at anode furnace charging and tapping sections; ventilation gases at anode furnace charging and slagging sections may be used as air for combustion in a burner at the anode furnace.	Approximately EUR 7 million for measures to capture diffuse emissions from the anode furnace and casting wheel in primary smelter. Approximately EUR 3.4 million for reducing emissions, including a wet ESP installation. Approximately EUR 2 million for a new bag filter including four filter lines, a ventilator, chimney, building and pipework.

Table 3-42: Examples of BAT for reducing diffuse emission from copper smelter which may also reduce workplace exposures

Emission source	Techniques	Economics - examples of investments
Centralised collection and abatement of secondary emissions from furnaces and auxiliary devices in primary copper production	Secondary gases from various points of the primary copper smelter, converter secondary hoods, ventilation hoods at the flash smelting furnace and at the electric slag furnace, the taphole and launder ventilation at smelting furnaces and at refining furnaces, and the ventilation hoods of anode furnaces and the casting wheel are collected in a common system.	EUR 10 million plus approximately EUR 7 million for measures to capture diffuse emissions from the anode furnace and casting wheel (the latter indicated above). A secondary gas-cleaning system involved a capital expenditure of more than EUR 12.5 million.
Smelting furnaces in secondary copper production	Includes use of feed materials according to the furnace and the abatement system installed; operation under negative pressure, encapsulated furnaces/charging systems, appropriate housing, enclosures, use of covered launders, secondary hoods with efficient extraction (and subsequent dedusting and gas-cleaning systems); use of a boosted suction system; treatment of off-gas. The use of an Ausmelt/ISASMELT furnace or KRS can prevent emissions from the transfer of materials from one furnace to another, as these furnaces can apply an intermittent two-stage smelting and converting process in the same installation.	EUR 6 million for a 'house-in-house' system. About EUR 17.5 million were reported for environmental protection measures including crane-integrated hood, gas collection system, NaOH scrubber, and new bag filter. The capital cost of the KRS installation was EUR 40 million, using the existing filter units and stack
Converter furnaces in secondary copper production	Includes encapsulated furnaces; operation under negative pressure and boosted suction system; housing and enclosures; primary and secondary hoods and the addition of scraps/fluxes through the hood; crane-integrated hood for charging and tapping; tertiary fume collection, such as 'house-in-house', with an efficient extraction system; treatment of off-gas. The house-in-house concept is an elaborate technology. The units (holding furnace, converters and casting facilities) installed inside closed production buildings are additionally accommodated in a largely sealed enclosure which is vented to a filter system.	Capital expenditure for the 'house-in-house' system (tertiary fume collection) was reported as up to EUR 6 million.

Source: JRC, 2017

3.8.2 Other sectors

Example of best practice in other sectors are shown in the table below.

Table 3-43: examples of best practice for other sectors

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
Source: Stakeholder consultation	

3.9 Standard monitoring methods/tools

Procedures for monitoring of contaminants in the workplace are typically established by national guidelines prepared by the National working environment authorities. These guidelines would typically make reference to European standards to be used for the monitoring.

As an example, in Denmark the Danish Working Environment Authority specifies requirements to occupational hygiene measurements in the guideline: At-Vejledning D-7.2-2 "Arbejdshygiejniske dokumentationsmålinger" [Occupational hygiene documentation][27]. The guidelines define the documentation that concerns:

- The workplace air content of gases, vapours, dust and other particulate pollutants from substances and materials.
- The concentration of harmful substances or their metabolites in biological fluids.
- The extent of biochemical changes in biological fluids.

Monitoring of substances in workplace air

As concerns the monitoring of substances in the workplace, guidelines make reference to two European standards:

- EN 482:2012+A1:2015 : Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents.
- EN 689:1995: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy.

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[27] https://arbejdstilsynet.dk/da/regler/at-vejledninger/a/d-7-2-arbejdshygiejniske-dokumentationsmaalinger

The latter is under revision and available as a draft: DSF/prEN 689: Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values.

EN 482:2012+A1:2015 specifies general requirements for the performance of procedures for the determination of the concentration of chemical agents in the workplace atmospheres as required by the Chemical Agents Directive 98/24/EC. The requirements given apply to all measuring procedures, irrespective of the physical form of the chemical agent (gas, vapour, airborne particles), the sampling method and the analytical method used and are applicable to all measuring procedures with separate sampling and analysis steps, and - direct-reading devices.

EN 689:1995 provides guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy. The standard refers to the latest update of EN 482 as concerning the General requirements for the performance of procedures for the measurement of chemical agents. The standard describes the monitoring strategy consisting of two phases:

- An occupational exposure assessment where the exposer is compared with the OEL
- Periodic measurements to regularly check if exposure conditions have changes

The manual outlines no formal procedure for deciding whether exposures are below the limit values within an occupational exposure assessment.

Analytical methods for inorganic arsenic compounds including arsenic acid and its salts in workplace air

Description of analytical methods is based on the Gestis database[28] hosted and maintained by the Institute for Occupational Safety and Health of the German Social Accident Insurance. This database was originally developed within the European project ‘Analytical methods for chemical agents’ and initially compiled analytical methods for 123 chemical agents. The database was then extended with the support of the European Commission and EFTA. The database was further enhanced (now including analytical methods for 229 chemical agents) by the input of experts from several European institutions. 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 analytical methods have been indicatively rated considering the requirements of European standards.

Fourteen standards are listed for analysis of arsenic and arsenic compounds. Only the four with the Category A rating "the methods meet all or most of the requirements of the EN 482 (1999)” are shown in Table 3-44 overleaf.

ISO 11041 with a limit of quantification of 0.05 µg/m^3 has the lowest LOQ of all 14 listed methods and is well below the lowest OELs in MS of 2.8 µg/m^3 in the Netherlands.

As part of the stakeholder consultation it has been considered how it is possible to exclude particulate metallic arsenic from the analysis. All four listed methods would include metallic arsenic and organic arsenic compounds together with the inorganic arsenic compounds. They would in settings where exposure to organic arsenic compounds and metallic arsenic compounds may take place (typically from the intentional use of organic arsenic compounds or arsenic metal) overestimate the exposure to arsenic compounds within the scope of the OELV. Arsenic compounds formed from unintentional

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[28] See http://www.dguv.de/ifa/gestis/gestis-analysenverfahren-fuer-chemische-stoffe/index-2.jsp

arsenic in raw materials would nearly 100% be inorganic compounds and the methods are not considered to significantly overestimate the concentration of inorganic arsenic compounds.

ISO 11041 and MDHS 41/2 are both applicable for monitoring the OELs considered in this study as the limit of quantification is less than 1/10 of the lowest of the assesses OELVs.

ISO 15202 is reported in the Gestis database with a LOQ of 3.2 µg/m^3 with a sampled volume of 480 L. Based on information on LOQ from an international laboratory, the LOQ was within this study estimated at 0.9 µg/m^3 with a sampled volume of 300 L, which make the analysis applicable for monitoring of all assessed OELVs.

Table 3-44: Substance: Arsenic and compounds, except arsine (as As); CAS-No.: 7440-38-2; EINECS-No.: 231-148-6

No	Source and method name	Language	Year of publication	Principle of the method	Flow rate/Recommended air volume	LOQ/ Validated working range	Indicative rating *	Remarks
1	ISO 11041 Workplace air - Determination of particulate arsenic and arsenic compounds and arsenic trioxide vapour	English	1996	Particulates trapped on an MCE filter in an inhalable sampler and As2O3 vapour on a Na2CO3 impregnated back-up paper pad. Dissolution with HNO3, H2SO4 and H2O2. Analysis by HGAAS.	Flow rate: Sampler–dependent Recommended sampling time: 15 min–8 h	LOQ: 0.05 $\mu g/m^3$ 960 l	A	
2	ISO 15202 Workplace air — Determination of metals and metalloids in airborne particulate matter by Inductively Coupled Plasma Atomic Emission Spectrometry Part 1: Sampling Part 2: Sample preparation Part 3: Analysis	English French	Part 1: 2012 Part 2: 2012 Part 3: 2004	Particulates trapped on a suitable filter in an inhalable sampler. Hotplate dissolution with 1+1 HNO3 and HCl; or 1+1 H2SO4, H2O2 and HCl; or HNO3, HClO4 and, if silicates are present, HF. Ultrasonic dissolution with HF and HNO3. Microwave dissolution with HNO3 and HF; or HNO3, HClO4 and HF; or HNO3 and HClO4. Analysis by ICP-AES.	Flow rate: Sampler–dependent Recommended sampling time: 15 min–8 h	LOQ: 3.2 $\mu g/m^3$ 480 l	A	Sampling procedure not suitable for As_2O_3
3	MDHS 41/2 Arsenic and inorganic compounds of arsenic (except arsine) in air	English	1995	Particulates are trapped on an MCE filter in an inhalable sampler and As2O3 vapour on a Na2CO3 impregnated back-up paper pad. Dissolution with HNO3, H2SO4 and H2O2. Analysis by HGAAS.	2 l/min 30–960 l	LOQ: 0.05 $\mu g/m^3$ 960 l	A	Similar method described in ISO 11041
4	MDHS 91 Metals and metalloids in workplace air by X-ray fluorescence spectrometry	English	1998	Particulates are trapped on an MCE or other suitable filter mounted in an inhalable sampler. Analysis by XRF.	2 l/min 240–960 l	LOQ: 4.2 $\mu g/m^3$ 240 l	A	Filter only analysis Sampling procedure not suitable for As2O3

* Category A rating "the methods meets all or most of the requirements of the EN 482 (1999)"

Source: Gestis database at http://amcaw.ifa.dguv.de/WForm09.aspx. - updated in this study to newest versions of standards

3.10 Relevance of REACH Restrictions or Authorisation

Inorganic arsenic compounds within the scope on Candidate List of substances of very high concern for Authorisation and on the authorisation list (Annex XIV to REACH) are summarised in the table below.

Table 3-45: Inorganic arsenic compounds within the scope on Candidate List of substances of very high concern for authorisation and on the authorisation list in Annex XIV [1]

Name	EC Number	CAS Number(s)	Registration tonnage band (t/year)	Date of entry to ECHA Candidate List	Latest application date for authorisation	No. of reported exposed workers
Arsenic acid	7778-39-4	231-901-9	100-1,000	19/12/2011	22/02/2016	48
Diarsenic trioxide	1327-53-3	215-481-4	100-1,000	28/10/2008	21/11/2013	117*
Diarsenic pentaoxide	1303-28-2	215-116-9	-	28/10/2008	21/11/2013	No application for authorisation
Calcium arsenate	7778-44-1	231-904-5	Intermediate use only	19/12/2011	Not included in Annex XIV	-
Trilead diarsenate	3687-31-8	222-979-5	Intermediate use only	19/12/2011	Not included in Annex XIV	-
Lead hydrogen arsenate	7784-40-9	232-064-2	Not registered	28/10/2008	Not included in Annex XIV	-

* An application for use of diarsenic trioxide for use as a processing aid to activate the absorption and desorption of carbon dioxide was granted but the use of the substances for this application has ceased.
Source: ECHA website at https://echa.europa.eu

The REACH status of worker exposure by sector is summarised in the Table 3-46. Regarding the number of workers the status can be summarised as follows:

- The total number of exposed workers in applications subject to authorisation is reported to be 165 representing approximately 1% of the exposed workforce included in this assessment.

- Other intentional applications of substances on the candidate list is the intermediate use in the glass sector with an estimated 300-700 workers representing approximately 4% of workforce included in this assessment.

- Intermediate use of calcium arsenate and trilead diarsenate take place in the non-ferrous sector in companies included in the present study (the substances originates from unintentional presence of arsenic in ores and are present in waste products which are further processed). The number of workers specifically exposed to the two compounds in the processes is not reported.

- The remaining 95% of the 7,900-15,300 assessed workers are exposed to arsenic unintentionally present in raw materials and not covered by REACH.

As indicated in Table 3-46, the following worker exposures are not covered by REACH:

- Exposure to arsenic from copper and other non-ferrous base metals ores by smelting of the ores;
- Exposure to arsenic in iron ore by sintering or smelting of the ore in pig iron production;
- Exposure to arsenic in coal by maintenance operations in coal and oil shale fired power plants; and
- Exposure to arsenic in pyrite by manufacture of sulphuric acid from pyrite.

For the following processes limited detailed exposure data are available from registrations under REACH as the application is considered use as intermediate:

- Use of arsenic acid and diarsenic trioxide in the manufacture of special glass. Glass is considered a substance under REACH but most special glass types are not registered. The CSRs include some information on this use.
- Use of diarsenic trioxide in the manufacture of metallic arsenic. Metallic arsenic is still not registered but will be registered before the deadline of 31 May 2018.

Table 3-46: REACH status of sources of worker exposure

Sector	Application	Substance involved / origin of arsenic	REACH status
Glass sector (incl. recycling of glass)	Fining agent in special glass	Arsenic acid, diarsenic trioxide	Application generally considered use as intermediate and no applications for authorisation have been submitted Glass is considered a substance under REACH but exempted from registrations
	Fining agent in special glass	Diarsenic trioxide	For former major use in Italy, national authorities consider the substance is used as auxiliary agent and subject to authorisation. As no applications have been submitted the use has been restricted for the last two years Unclear if the substance is still used in some MS which have other interpretations with regard to the use
Electronics sector	Manufacture of copper foils	Arsenic acid	Registered, subject to authorisation
	Gold plating of circuit boards	Diarsenic trioxide,	Registered, subject to authorisation
	Manufacture of gallium arsenide wafers	Gallium arsenide	Registered, not subject to authorisation. Inorganic arsenic compounds may unintentionally be formed by various processes
	Doping of semiconductors	No data - in gaseous form	Small quantities. Not covered by any of the registered substances

Table 3-46: REACH status of sources of worker exposure

Sector	Application	Substance involved / origin of arsenic	REACH status
Chemicals sector	Absorption and desorption of carbon dioxide in production of ammonia	Diarsenic trioxide	Registered, subject to authorisation - application has ceased
	Manufacture of arsenic chemicals	Diarsenic trioxide	For substances manufactured in quantities >1 tonne, registration dossiers address production of the substance Substances manufactured in quantities <1 tonne are no covered by the information requirements under REACH
Production and Use of alloys with arsenic	Production and use of alloys with arsenic (excl. recycling)	Diarsenic trioxide, calcium arsenate, trilead diarsenate, metallic arsenic	Diarsenic trioxide, calcium arsenate and trilead diarsenate may be used as intermediates in the manufacture of arsenic which is further used to produce lead and copper alloys with arsenic Arsenic metal is still not registered indicating on import/production of <100 t per company and no information on exposure to the arsenic compounds are availed from REACH dossiers
	Recycling of alloys with arsenic (batteries, etc.)	Metallic arsenic	The recycling activities are covered with regard to the produced substances which have to be registered. In recycled materials arsenic will be present as impurity in recycled lead and copper and only be included in the registrations as impurities
Zinc production using diarsenic trioxide	Purification in zinc electrowinning	Diarsenic trioxide,	Registered, subject to authorisation
Production of basic non-ferrous metal	Production of copper	Ore	Not covered by REACH
	Production of other non-ferrous base metals	Ore	Not covered by REACH
Other	Pig iron production	Ore	Not covered by REACH
	Maintenance operations in coal and oil shale fired power plants	Coal, oil shale	Not covered by REACH
	Manufacture of sulphuric acid from pyrite	Pyrite	Not covered by REACH

Source: RPA/COWI

3.10.1 Restriction

Under REACH Annex XVII (entry 19), there is a general restriction on arsenic compounds for the following applications:

1. Intended for use to prevent the fouling by micro-organisms, plants or animals of:
    - the hulls of boats,
    - cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,
    - any totally or partly submerged appliances or equipment.
2. Treatment of industrial waters, irrespective of their use.
3. Preservation of wood. Furthermore, wood so treated shall not be placed on the market (with some derogations).

As discussed in section 2.3, the use of chromated copper arsenate (CCA) solutions in the preservation of timber and import of CCA treated timber is regulated by the Biocidal Products Regulation and is no longer permitted. In practice the restricted under Annex XVII applies to reclaimed timber and included some derogations for wood treated with CCA solution placed on the market for professional and industrial use, provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely.

3.11 Market analysis

The objective of this section is to provide market data for the sectors/uses identified as relevant above.

3.11.1 Number of companies by sector

The number of companies and names of known companies in each segment and their Member State are summarised below. For some of the groups reference is made to the E-PRTR (air emission of arsenic) but company names are not listed as it is not known which of the companies may have higher exposure concentrations.

Table 3-47: Inorganic arsenic compounds – number of companies

Sector	Uses and/or activities	No of companies/sites	Known sites (excl. confidential information)
1: Glass sector	Production of domestic glass	0-10	No use confirmed
	Production of special glass	10 - 20	Confidential
	Recycling of glass, incl. production of glass insulation materials	30-50	E-PRTR lists 21 companies with emissions of arsenic from the glass sector
2: Electronics sector	Manufacture of copper foils	1	Circuit Foil - LU
	Gold plating of circuit boards	1	Linxens France SA - FR

Table 3-47: Inorganic arsenic compounds – number of companies			
Sector	**Uses and/or activities**	**No of companies/sites**	**Known sites (excl. confidential information)**
	Manufacture and use of gallium arsenide wafers and semiconductors	18 - 25	Prod of gallium arsenide: CMK, SK Freiberger Compound Materials, DE Prod of semiconductors: no data
3: Chemicals sector	Manufacture of arsenic compounds, not included elsewhere	2-10	No data
	Production of sulphuric acid (from pyrite and by-product)	22	From byproducts: Same companies as indicated for primary copper smelters and other nonferrous smelters From pyrite: Tronox - DE Sachtleben Chemie GmbH- DE Kemira GrowHow - FI
4: Copper sector	Primary copper smelters	7	Atlantic Copper - ES New Boliden Harjavalta/Pori - Fi New Boliden Rönnskär- SE Aurubis Hamburg - DE Aurubis Pirdop - Bu KGHM Głogów - PO KGHM Legnica - PO
	Secondary copper smelters	8	Aurubis Hamburg - DE Aurubis Lünen - DE Aurubis Olen - BE Metallo Belgium - BE Metallo Spain - ES Montanwerke Brixlegg - AU Krompachy - SK Umicore Hoboken - BE
	Production and use of copper-arsenic alloys	10-30	Master alloys: Affilips NV - BE A.M.P.E.R.E. Alloys - FR
5: Zinc production using diarsenic trioxide	Purification in zinc electrowinning	2	New Boliden - Kokkola - FI Nordenhamer Zinkhütte - DE
6: Other non-ferrous metals	Extraction and refining of Cd and Zn	Zinc and cadmium Companies: 7 Sites: Zn refining: 10-11 Cd refining: 5 of the 11 Zn refiners	Zinc and cadmium New Boliden - Kokkola FI Nyrstar - Auby FR Nyrstar - Balen BE Nyrstar - Overpelt BE Xstrata - San Juan - SP Portovesme - IT Nyrstar - Büdel - NL Xstrata - Nordenham - DE KCM - Plovdiv - BU HCM - Miasteczko Slaskie - PL

Table 3-47: Inorganic arsenic compounds – number of companies			
Sector	**Uses and/or activities**	**No of companies/sites**	**Known sites (excl. confidential information)**
	Production of precious and other rare metals		Copper smelters listed elsewhere Umicore Olen - DE PPM metals - DE Heraeus - DE
	Primary and secondary lead smelters, battery and ammunition production	Lead (JRC, 2017): 3 primary lead smelters (apart from lead production as part of other non-ferrous production) 30 secondary lead smelters incl. battery recyclers 15-25 lead battery producers 2-5 ammunition producers	KCM AD - BU Recyclex - DE, FR, BE Hals Metal - DK APSM - FR BMG Metall und Recycling GmbH: DE Campine Recycling - BE Exide Technologies -PT, ES ECOBAT Technologies - DE, UK, FR, AU, NL,IT Kovohutě Příbram nástupnická - CZ Moll GmbH - DE Locatelli s.r.l. - IT Metplast - GR
7 Cross sector - welding		estimated >500	no data
8: Ferrous metals	Pig iron production (sinter plants and pelletization plants)	40	See BAT reference document (JRC,)
9: Coal Power sector	Maintenance operations	78 (listed in E-PRTR)	78 power plants with reported atmospheric emission of arsenic are listed in E-PRTR
10: Other	Mining, production of copper concentrate	Copper mines: 10-20	Mines in Bulgaria (USGS, 2014): Assarel-Medet JSC - BU Ellatzite-Med AD - BU Chelopech Mining EAD - BU Bradtze - BU Burgaskii Mines Ltd - BU
	WEEE (shredding of electronic waste)	Companies: 20 (consultation response for Cd study under this contract extrapolated over EU28 on the basis of WEEE collection data)	
Sources: Various sources summarised by RPA/COWI			

3.11.2 Copper sector

According to the BAT document for the nonferrous metal sector, European copper smelting and refining activity has been able to grow primarily by securing raw materials on the international market and by making use of 'domestic mining' (JRC, 2017). The 'domestic mining' consists of copper scrap and residues generated by consumers and processors, as well as by building demolition and end-of-life waste (e.g. vehicles and electric and electronic waste).

The structure of the European copper smelting and refining industry is as follows (updated from JRC, 2017):

- Atlantic Copper S.A. in Huelva, Spain;
- New Boliden AB with sites in Harjavalta and Pori, Finland and Rönnskär, Sweden;
- Aurubis AG with sites in Hamburg and Lünen, Germany; Pirdop, Bulgaria and Olen, Belgium;
- KGHM Polska Miedź S.A. with sites in Głogów (1 and 2) and Legnica, Poland;
- Metallo in Beerse, Belgium with its daughter company Metallo Spain;
- Montanwerke Brixlegg (owned by Swiss Group UMCOR AG), Austria with its sister company Kovohuty, Slovakia;
- Umicore S.A. in Hoboken, Belgium.

"*Some of these are clear primary smelters (Atlantic Copper, KGHM Głogów, Aurubis Pirdop and New Boliden Harjavalta) which use copper concentrates as their primary feedstock. Others are clear secondary smelters (Metallo-Chimique, Montanwerke Brixlegg, and Aurubis Lünen), where the main feedstocks are scrap from the downstream value chain plus recycled products at the end of their life. Some have the flexibility to process both primary and secondary feedstocks, like Boliden Rönnskär, KGHM Legnica and Aurubis AG Hamburg*." (JRC, 2017).

Overall, secondary raw materials account for the production of about 40% of EU copper, but in some cases, such as brass rods, the product is made entirely from recycled copper and brass, with only a small input of primary zinc.

The primary smelter production by MS, the 8 "competitor countries" assessed in this study and world other Top-3 counties as shown in Table 3-49. The total EU production of primary copper increased slightly during the period of 2011 to 2015.

Table 3-48: Primary smelter production of copper 2011-2015 (tonnes)

Country	2011	2012	2013	2014	2015	Percentage of world production (2015)
Bulgaria	283,800	269,100	294,000	305,000	301,600	1.9
Finland	124,360	129,256	135,840	146,542	141,474	0.9
Germany	335,000	352,400	289,900	349,700	338,300	2.1
Poland	481,875	466,715	458,789	503,111	514,774	3.2
Spain	260,730	270,200	212,000	285,400	286,300	1.8
Sweden	161,500	151,100	140,400	150,000	150,000	0.9
EU total	1,647,265	1,638,771	1,530,929	1,739,753	1,732,448	10.9
8 competitor countries						
Australia	442,190	422,398	445,520	468,468	432,843	2.7
Brazil	223,500	170,400	202,800	213,085	157,800	1.0
Canada	304,724	287,051	254,509	288,699	281,416	1.8
China	3,036,700	3,601,400	4,228,919	5,167,900	5,500,000	34.6

Table 3-48: Primary smelter production of copper 2011-2015 (tonnes)

Country	2011	2012	2013	2014	2015	Percentage of world production (2015)
India	671,200	695,400	617,000	766,000	792,600	5.0
Japan	1,173,275	1,274,690	1,261,348	1,323,500	1,243,813	7.8
Korea (rep of)	449,200	477,300	478,800	500,000	511,200	3.2
USA	538,400	485,300	516,500	522,000	527,000	3.3
World top 3, other						
Chile	1,522,300	1,342,400	1,358,300	1,356,200	1,496,200	9.4
Russia	652,200	646,000	650,000	664,000	661,000	4.2
Zambia (a)	520,000	519,200	520,300	525,800	648,800	4.1
World Total	13,100,000	13,300,000	13,900,000	15,300,000	15,900,000	100

(a): including leach cathodes

Source: World Mineral Production 2011-2015; British Geological Survey 2017.

The production of refined copper by MS is shown in the table below. The difference between the quantity of refined copper and primary smelter production indicates largely the size of the secondary production. For Austria, some of the refined copper production actually is recycled in a secondary copper smelter in Slovakia but refined in Austria. This is taken into account by the distribution of the secondary copper production between MS.

Table 3-49: Production of refined copper in 2015 (tonnes)

Country	2015	Percentage of world production (2015)
Austria	102,900	0.4
Belgium	378,600	1.7
Bulgaria	230,000	1.0
Cyprus	2,121	0.01
Finland	141,474	0.6
Germany	678,100	3.0
Italy	7,300	0.03
Poland	574,310	2.5
Spain	419,900	1.8
Sweden	206,059	0.9
EU total	2,740,764	12.0
World total	22,900,000	100

Source: World Mineral Production 2011-2015; British Geological Survey 2017.

Copper mining production in the EU was 847,000 tonnes copper in 2014 corresponding to 4.6% of the total world production copper mine production (ECI, 2017). The EU raw materials supply sources for copper was 847,000 tonnes from EU mining (20%), 1,094,000 tonnes in imported ore or concentrate (25%), 1,875,000 tonnes in EU scrap (43%) and 503,000 tonnes in net import of copper metal (12%).

According to ECI (2017) "*With copper prices being global, and discovered on a transparent basis through global commodity exchanges, such as the London Metal Exchange, the competitiveness of individual EU producers is directly related to their cost base. Higher energy prices, environmental* *abatement and social costs have made it increasingly difficult for EU producers to compete, on the global market, for the primary and secondary (scrap) raw materials they need. While this is partly due to copper mining countries integrating downstream into their own smelting and refining facilities, the main cause is the strong demand from producers in Asia, many of whom receive state support, or operate under a less strict regulatory umbrella."*

Boulamanti and Moya (2016) reach another conclusion in an analysis of production costs of the copper and zinc sector in the EU and other countries (Chile, Peru, Zambia, China, Russia, Kazakhstan, Norway and Namibia). Taking into consideration the complex structure of the industry, costs are broken down to three components: (1) Energy, (2) Labour and other costs (salaries, consumables and other on-site costs) and (3) Credits the authors conclude that the EU industry does not have the highest production costs. On the contrary, especially in the case of copper refineries and zinc, it has lower production costs than most of the countries included in the study.

In a study of the competitiveness of the EU Non-ferrous Metals Industries, Ecorys et al. (2011) notes that while China may be among the biggest producers of non-ferrous metals, it also uses most of its own production and net exports of China in the three major nonferrous metal (NFM) sub-sectors aluminium, copper and zinc, were in fact negative in 2009. According to the study "*Trade patterns thus seem to suggest the NFM sector still has a strong international competitive position, although it has weakened for primary activities, in particular, where the EU has substantial trade deficits, while in secondary production emerging economies such as China are catching up. ".* The study further concludes that the impact of the high cost EU environment on the NFM industry is exacerbated by an uneven global playing field and distorted markets. "*This is the case in a number of areas relevant for the EU NFM, including notably: (1) the unilateral introduction of very strict environmental and energy policies (including ETS); and (2) third country (State interventionist) industrial and trade policies to support NFM industries through e.g. export restrictive measures (raw materials), direct and indirect subsidies, dual pricing of energy, import measures, etc. The latter can be observed especially in countries such as China, Russia, India, and the Gulf States. ".* Industry data shows that the number of NFM operators in the EU has decreased since the early seventies. Further relocation of the NFM industry's primary production segments would lead to job losses and a decrease in R&D (Ecorys et al., 2011). The study does not include an assessment of costs of occupational health measures in the industry.

3.11.3 Zinc production using diarsenic trioxide

The two companies using diarsenic trioxide in the production of zinc produces in total 455,000 t/year of zinc. The total EU zinc primary production in 2015 was approximately 2,080,000 as shown in . Consequently, the production using diarsenic trioxide accounted for approximately 22% of the total primary production.

According to the BAT document for the nonferrous metal industry (JRC, 2017), primary zinc is essentially produced by roast-leach-electrowinning (RLE) processes and by the Imperial Smelting Furnace (ISF) distillation process. The two sites using arsenic acid in the RLE process are located in Finland and Germany, while other ten sites using the RLE process without arsenic are located in Belgium, Bulgaria, France, Germany, Italy, The Netherlands, Poland and Spain. The ISF process is used by two sites in Poland and Romania.

In addition to the primary zinc production, zinc is recycled from end-of-life products such as sheets, brass and die-casting parts which are re-melted and reused. It is also recycled from the re-melting of scrap steel in electric arc furnaces where the zinc is fumed and captured with the flue-dust and recovered in specialised facilities. The total recycling of zinc in 2007 was 285,000 tonnes (JRC, 2017).

Table 3-50: Production of slab zinc 2011-2015 (tonnes)						
Country	2011	2012	2013	2014	2015	Percentage of world production (2015)
Belgium (a)	282,000	250,000	252,000	262,000	260,000	1.9
Bulgaria	88,400	73,100	69,600	74,200	75,500	0.5
Finland	307,352	314,742	311,686	302,024	305,717	2.2
France	164,000	161,000	152,000	171,000	169,000	1.2
Germany	170,000	169,000	162,000	168,000	169,000	1.2
Italy	110,200	97,200	111,000	138,100	139,200	1.0
Netherlands	261,000	257,000	275,000	290,000	291,000	2.1
Poland	144,100	138,300	146,300	154,000	161,000	1.2
Spain	490,000	486,000	484,000	501,000	509,300	3.7
EU Total	2,017,052	1,946,342	1,963,586	2,060,324	2,079,717	15
8 competitor countries						
Australia	507,316	498,259	498,291	481,573	489,030	3.5
Brazil	284,770	245,526	245,417	246,120	231,000	1.7
Canada	662,151	648,619	651,638	649,217	683,118	4.9
China	5,212,200	4,881,200	5,279,600	5,806,970	6,155,000	44.3
India	783,647	704,228	767,994	732,792	758,944	5.5
Japan	544,674	571,312	587,291	583,021	566,619	4.1
Korea (rep of)	828,735	881,100	886,000	901,000	940,195	6.8
USA	247,600	261,400	233,200	180,000	172,300	1.2
Top 3, others						
Mexico	322,116	323,569	322,781	320,923	326,642	2.3
Peru	313,714	319,280	346,400	336,500	335,422	2.4
Russia	249,000	250,000	216,000	223,000	216,000	1.6
World Total	13,100,000	12,600,000	13,000,000	13,500,000	13,900,000	

(a): Years ended 31 March following that stated.
Source: World Mineral Production 2011-2015; British Geological Survey 2017.

According to the application for authorisation, the zinc producers mainly compete on production efficiency and operating costs. Similarly to the EU zinc industry in general, the highly efficient process using arsenic trioxide is according to the application for authorisation the companies' main competitive advantage. Zinc is a commodity product without much differentiation and it will therefore not be possible to pass on additional costs to downstream users. Further one of the applications states:

"*The dynamics of the zinc industry have changed substantially over the last decade. European zinc producers' share of the global market has been significantly reduced due to strong progress in Asian countries and a reduced level of investments in Europe. In 2000 the EU's total production was 2.4 million tonnes, in 2007 it was 2 million tonnes and in 2009 it dropped to 1.7 million tonnes. In 2009, the EU imported 1.24 million tonnes of zinc and had a net import of 320,000 tonnes. This made it the world's third-largest net importer of zinc. The European zinc production industry is facing fierce competition from low-cost countries, such as China and India*."

For the general discussion of the international competition situation for the non-ferrous metal industry see the section on copper.

3.12 Alternatives

This section on alternatives focuses on the intentional use of the inorganic arsenic compounds including arsenic acid and its salts within the scope of this assessment. In some sectors, such as in metals fabrication and recycling, mining, and post-consumer recycling, substitution is not possible since As is present in the source material (post-industrial or post-consumer waste or ore).

3.12.1 Glass sector

The background document for diarsenic trioxide (ECHA, 2010) lists a number of alternatives to diarsenic trioxide. Names and classification is listed in the table below. The diantimony trioxide is classified as Carc. 2 which makes it a less attractive alternative, whereas cerium oxide and selenium can are not considered CMR substances. Note that the sodium and potassium nitrates are used in combination with the diantimony trioxide.

Table 3-51: Alternatives to inorganic arsenic compounds including arsenic acid and its salts in glass

Application	Substance name	CAS No	Classification	Comment on application
Fining agents	Sodium sulphate	7757-82-6	No harmonised. Self-classification joint entry: Not classified	Used in lead crystal
	Diantimony trioxide	1309-64-4	Harmonised: Carc. 2	Used in lead crystal
	Sodium nitrate *	7631-99-4	No harmonised. Self-classification joint entry: Eye Irrit. 2	Used with diantimony trioxides used in special glasses
	Potassium nitrate *	7440-09-7, 7757-79-1	No harmonised. Self-classification joint entry: Not classified	
	Cerium oxide	11129-18-3	No harmonised. Self-classification joint entry: Not classified	
Decolourising agents	Diantimony trioxide	1309-64-4	Harmonised: Carc. 2	Decolourising agent for glass and an opacifier in ceramics and enamels
	Selenium	7782-49-2	Harmonised: Acute Tox. 3 (toxic if swallowed or inhaled) STOT RE 2 (may cause damage to organs) Aquatic Chronic 4	Particularly in lead crystal
	Cerium oxide	11129-18-3	No harmonised. Self-classification joint entry: Not classified	In special glass and as an opacifier in enamels/ceramics

* Indicated as sodium/potassium nitrates; here exemplified with two examples. Used together with diantimony trioxide

Source (except classification): ECHA 2010; Classification: C&L inventory at https://echa.europa.eu/information-on-chemicals/cl-inventory-database

Domestic glass

For use in the manufacture of domestic glass in Northern Italy, diarsenic dioxide has been replaced by alternatives. The substitution process has been described by Trouth (2017). According to the description, diarsenic trioxide in the manufacture of domestic art glass in Norther Italy has during the last ten years been phased out:

"*Two substitutes had previously been proposed: cerium oxide and ground granulated blast furnace slag (GGBS). However, they were seen to be too expensive and not always meeting the production requirements. "While the use of alternative substances reduces the occupational health risks and improves the environment, the glass does not have the same fine clarity that is formed when using arsenic trioxide," Mr Cipolla says*".

Furthermore, it is reported that:

"*Other alternative substitutes include a mix of antimony trioxides and nitrate or carbonates of alkaline metals. As has been their tradition, the glassmakers' recipes remain confidential. Some companies are using the alternative chemicals, others have found a way to adjust their process so they do not need to use arsenic trioxide – the quality of the glass is a bit different, but considered acceptable. Others have stopped producing the type of glass for which arsenic trioxide was used.*" (Trouth, 2017)

No classification is available for the ground granulated blast furnace slag. The main components of blast furnace slag are CaO (30-50%), SiO_2 (28-38%), Al_2O_3 (8-24%), and MgO (1-18%) (Source: Wikipedia).

Special glass

The background document refers to an input made by CPIV (now Glass Alliance Europe), highlighting the following applications in speciality glass that show technical difficulties in replacing arsenic compounds (ECHA, 2010):

- Pharmaceutical packaging glass which would require further investigation into the suitability of any alternative materials.
- Although some glass-ceramic hobs (cooker tops) are now arsenic-free, producing clear glass hobs remains a difficult challenge.
- Some optical filter glass relies on the intrinsic properties (i.e. optical wavelengths) of arsenic for which there are no alternatives.
- Use of alkali-free glass in opto-electronic applications.

According to a position paper of the European Glass Industries on the Proposed inclusion of arsenic acid on Annex XIV GlassAlliance Europe (GAE, 2012) states that alternatives cannot be used for special applications where a very high glass quality is required. In the opinion of the European glass industries, it is also not advisable to replace a substance that possesses all required properties for a certain product, by another substance that is potentially harmful, but degrading the glass quality level.

One company in the special glass sector answers for the stakeholder consultation that substitution successfully has been done for more than 90% of the company's glass production; for the remaining production an ongoing R&D process is in progress.

Many producers of special glass indicate for many glass types in the technical data sheets that the glass is free of arsenic, but do not indicate that the entire range of special glass is arsenic free. The fact that it is indicated that the glass is free of arsenic demonstrates that there is a request from customers after arsenic-free glass.

One company which has phased out arsenic for most applications indicates that the main driver has been to reduce workers' exposure and to reduce emissions to the environment and thereby the possible exposure in the neighbourhood to the plant.

3.12.2 Electronics sector

Copper foils

The application for authorisation mentions that (Circuit Foil, 2015) an acceptable alternative has been identified (name not disclosed) and tested for previous 5 years. At the time of the application, the alternative was used for approximately 30% of the production and any new copper foil would be developed without arsenic acid. It is indicated that the alternative is economically available and affordable and that the investments had already been done and the use of alternative would not increase the copper foil price. The copper foils when using the alternative had similar physical properties but the colours were different.

Gold electroplating

According to the application for authorisation, due to the proprietary nature of the Linxens process there are no drop-in alternatives to be considered (Linxens, 2014). Every alternative needs at least partial development to suit the specific needs of the applicant. All alternatives assessed by the applicant contain potassium gold cyanide with some additives.

According to the application, the total one-off cost expected in the “non-use” scenario (use of alternative) has been estimated at €3,998,969. The total ongoing increase in operative cost has been quantified at €4,360,000. According to the opinion of RAC (2014d), SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant. Furthermore,

"*SEAC considered that the applicant's assessment of (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two is based on acceptable socio-economic analysis. Therefore, SEAC does not raise any reservations that would change the validity of the applicant’s conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment.*" (RAC, 2014d).

Semiconductors

No data on alternatives to the use of arsenic in semiconductors have been identified. In a response to a proposal on restricting arsenic and arsenic compounds in consumer products in Norway, the European Semiconductor Industry Association (ESIA, 2007) stated that gallium arsenide is a fundamental semiconductor material and forms the core substrate for semiconductor technology, and that semiconductor technology devices based on GaAs circuitry are a key element of many wireless and Wi-Fi consumer electronic products. The restriction did not go into force.

3.12.3 Copper sector

The inorganic arsenic compounds within the scope of this assessment are not intentionally used in the copper sector. Intentional use of arsenic metal in copper alloys may, however, by smelting and casting lead to exposure to inorganic arsenic compounds. Arsenic metal is not classified carcinogenic and the presence of arsenic in copper alloys seems not to be of general concern. An internet search for "arsenic free" copper alloys did not reveal a market for "arsenic free" copper alloys which could substitute for the existing uses of low levels of arsenic in many copper alloys. For alloys e.g. for drinking water fixtures many "lead-free" alloys are marketed but arsenic is generally not addressed.

3.12.4 Zinc production using diarsenic trioxide

According to the applications for authorisation, it was found that diantimony trioxide (Sb_2O_3) or antimony potassium tartrate (($K_2Sb_2(C_4H_2O_6)_2$)) are used by other companies within the same industry for similar processed (Nordenhamer, 2014).

"*The antimony compound based processes can remove the metal impurities, although it will reduce the overall production efficiency. In addition, cadmium is co-precipitated with copper, cobalt and/or nickel, which hampers the further utilisation of these valuable metals. To achieve the same result as the As_2O_3 based process, a further purification step must be introduced to separate cadmium from the other metals."*

The costs of introduction of alternative was calculated by one company at €104 million over the next 20 years while the annual costs for the other company was calculated at €49 million. Further details are available in the Analysis of Alternatives reports from the application for authorisation" (Nordenhamer, 2014; Boliden, 2014).

RAC (2014a) notes regarding the alternatives:

"It is not clear to RAC if the alternatives would result in a lower risk to workers and humans exposed via the environment. There is not enough information on hazards nor on the resulting exposure should these substances be used instead of As_2O_3. However, as the applicant has presented arguments that the alternatives are not economically feasible to justify that the alternatives are not suitable, the assessment of the risk from alternatives is not assessed further by RAC." SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant (RAC 2014a).

3.12.5 Other non-ferrous metals

The arsenic compounds within the scope of this assessment are not intentionally used in other non-ferrous metal production.

Intentional use of arsenic metal in lead alloys may, however, by smelting and casting lead to exposure to arsenic compounds. Arsenic metal is not classified carcinogenic and the presence of arsenic in lead alloys seems not to be of general concern. An internet search for "arsenic free" lead alloys did not reveal a market for "arsenic free" lead alloys which could substitute for the existing uses of low levels of arsenic in many lead alloys.

3.12.6 Other sectors

The arsenic compounds within the scope of this assessment are not intentionally used in other sectors and alternatives have not been investigated.

3.13 Current and future burden of disease

3.13.1 Input data for calculation of disease burden

Distributions of workplace concentrations

For every process, the number of workers exposed to a given concentration was estimated using a lognormal distribution fitted to the reported data.

The data are not reported uniformly in the questionnaires, the MEGA database and in the literature and this restrict the use of exact data processing procedures. Consequently a log-normal distribution has been determined by a manual procedure to fit the available data. In many instances only arithmetic means (AM) or geometric means (GM) has been reported without an indication of 90th or 95th percentiles which could be used for the fitting procedure. In these instances, the percentiles have been determined on the basis of experience from datasets where more parameters have been indicated.

In order to understand the relationship between the different parameters reported by the companies, a dataset matching the parameters reported for a large dataset (based on more parameters than shown in the table above) was generated.

The reported parameters were as follows:

- AM: 12 µg/m^3
- 75th percentile: 15 µg/m^3
- 90th percentile: 33.4 µg/m^3
- 95th percentile: 44.5 µg/m^3
- Lowest value: 1 µg/m^3(detection limit)
- Highest value: 79 µg/m^3

A matching model dataset is shown below:

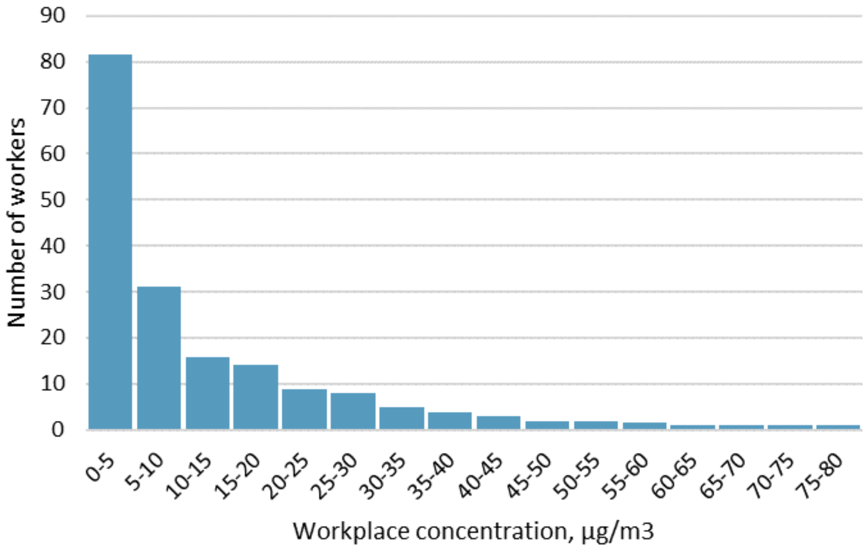

Figure 3-6: Model dataset of monitoring result matching the parameters reported from a site with 180 exposed workers in primary smelter

For this dataset the parameters would be as follows:

AM:	12.3 µg/m^3
GM:	6.9 µg/m^3
Median:	6.0 µg/m^3
75th percentile	15.0 µg/m^3
90th percentile	33.0 µg/m^3
95th percentile	44.5 µg/m^3
AM/GM	1.8 (in two real datasets obtained, the AM/GM was 1.7 and 1.8)
AM/median	2.1 (in two real datasets obtained, the AM/median was 1.6 and 1.4)
90th perc./AM	2.7 (varies from 1.0 to 3.1 in reported datasets with an average of 2.1)
95th perc./AM	6.4

The following parameters for a log normal distribution modelling the workplace concentration probability distribution were derived by manual fitting:

Mean log	1.93
SD log	1.08

The distribution is shown in Figure 3-7.

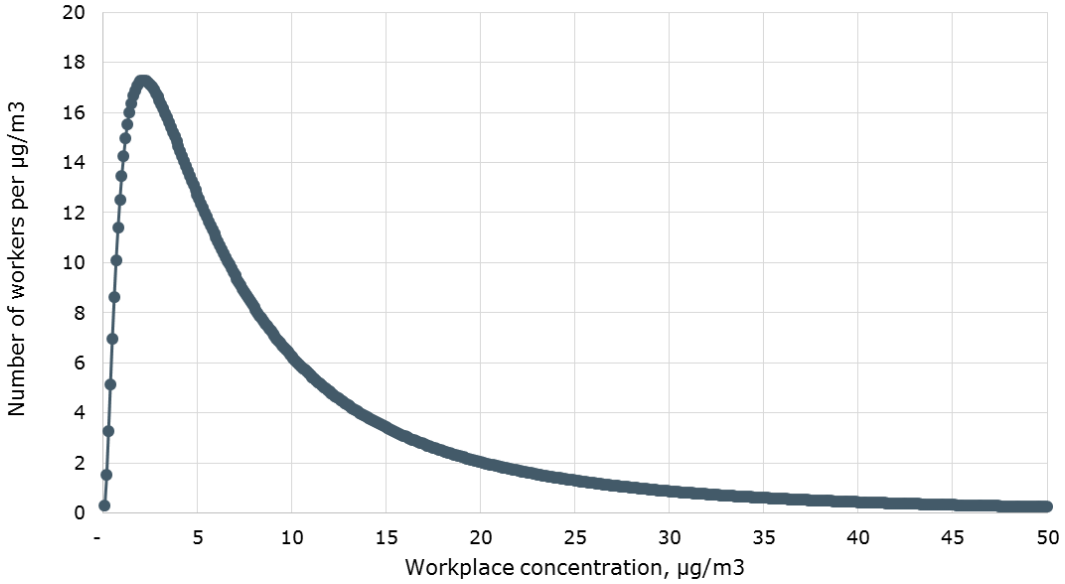

Figure 3-7: Log normal distribution fitted to model dataset

Similar distributions have been derived for each sector or subsector on the basis of the available parameters. For those data where only arithmetic mean values were available, the 90th percentile has been set at 2.1 x AM and the distribution have been fitted to the AM and 90th percentile. On the basis of the distributions, the number of workers in each of eight bands has been calculated as shown in Table 3-52.

The calculations have included nine sectors with separate exposure concentration distributions and distributions by MS. The sectors are selected on the basis of data availability and are considered to include the majority of subsectors which most likely could be affected by establishing an OELV at the levels assessed. For the primary copper sector, the calculations have been done for two subgroups with different exposure distributions, but the data are reported as aggregated figures.

All estimates have been done for both the measured concentrations in the workplace without any adjustment for the use of RPE and for adjusted data (see explanations for each sector in section 3.3.12). All companies report that RPE is used for all worker exposure scenarios with high exposure concentrations.

Group of workers ***not included in the assessment***

In addition to the workers included in the assessment it is estimated that 60,000 workers (mean of the range of 18,000-102,000) is exposed. In the absence of specific data, an average exposure concentration in 2017 of 1 µg/m^3 is assumed. For cancer without a lower limit the exposure of this large group contributes significantly to the total burden. For the neurotoxic effects with a zero effect threshold at 1 µg/m^3, the large group exposed at lower levels does not contribute to the current burden.

Distribution by Member States

For the further use of the data for the benefits and costs analysis, the data for each sector included in the analysis have been distributed by MS as shown in Table 3-54. The basis for the distributions is indicated in the notes to the table.

Trends in workforce and exposure levels

Exposure concentration trend in the past is set at -8% per year for the dataset with adjustment for the use of RPE and at -5% per year in the dataset without adjustment (because it does not reflect the use of better RPE and more common use of RPE). The decrease the last 20 seems to be less than this while the decreases before that was higher. The data from Hakkala and Pyy (1995) from Finland in the beginning of the 1990's is as an example only slightly higher than the concentrations reported today. In older publications reporting on the concentrations in the 1940's and 50's it is common with concentrations at 500 µg/m^3 and higher i.e. more than 10 times the highest concentrations found in most smelters today.

Symanski et al. (1998a,b) conducted a comprehensive evaluation of long term changes in occupational exposure among a broad cross section of industries worldwide by compiling and assessing about 700 sets of data from 119 published and several unpublished sources. Although the rates varied, most exposures declined at rates between −4% and −14% per year (the interquartile range), with a median value of −8% per year. This concerns the rates in the 1980's and 1990's but no data on general trend the last 20 years have been identified.

The future trend is set at -1 per year for the entire dataset. With expected increasing arsenic concentrations in the raw materials for the copper sector, the exposure concentrations would increase if nothing else was done, but it is expected that this increase will be counterbalanced by various measures in the companies. The future trend is significantly lower than the past trend of -8%. The most significant decreases in exposure levels took place more than 10 years ago and for the main sectors the trend in recent years has been considerably lower.

Table 3-52: Exposed workers input data for calculation of cases at baseline. Data not adjusted for use of RPE

Concentration bands (μg/m³)		Exposed workforce (number of workers)										
		1a Special glass	1b Domestic glass	2 Electronics sector	4a Primary copper *	4b Secondary copper	5 Zinc production with diarsenic trioxide	6 Other non-ferrous metals	7 Welding, thermal cutting, etc.	8: Ferrous base metals production	9 Power sector	10 Mining sector
Band 1	0-1	91	0	148	268	700	23	60	1,906	18	0	3
Band 2	1-3	197	2	145	887	849	36	197	562	154	0	52
Band 3	3-5	71	3	5	627	391	15	140	29	169	1	72
Band 4	5-10	35	11	0	656	334	11	146	3	284	5	129
Band 5	10-25	6	28	0	413	182	4	88	0	275	34	115
Band 6	25-50	0	24	0	176	36	0	16	0	78	58	24
Band 7	50-100	0	18	0	141	8	0	3	0	19	65	4
Band 8	100-1000	0	14	-	33	1	0	0	0	3	61	0
Total No.		400	100	298	3,200	2,500	90	650	2,500	1,000	225	400
Workforce trends (% p.a.)												
Workforce trend - future		0										
Workforce trend - past		- 2										
Exposure trends (% p.a.)												
Exposure level trend - future		-1										
Exposure level trend - past		- 5										

* Consists of 2 distributions which are aggregated here, but used separately for the calculations

Table 3-53: Exposed workers input data for calculation of cases at baseline. Data adjusted for use of RPE

Concentration bands (µg/m³)		Exposed workforce (number of workers)										
		1a Special glass	1b Domestic glass	2 Electronics sector	4a Primary copper *	4b Secondary copper	5 Zinc production with diarsenic trioxide	6 Other non-ferrous metals	7 Welding, thermal cutting, etc.	8: Ferrous base metals production	9 Power sector	10 Mining sector
Band 1	0-1	198	1	148	635	1,250	88	227	1,906	40	3	3
Band 2	1-3	176	7	145	1,586	862	2	285	562	296	40	52
Band 3	3-5	22	8	5	571	232	0	86	29	240	47	72
Band 4	5-10	4	18	0	308	121	0	43	3	272	72	129
Band 5	10-25	0	30	0	91	33	0	9	0	136	53	115
Band 6	25-50	0	19	0	8	3	0	0	0	15	9	24
Band 7	50-100	0	11	0	1	0	0	0	0	1	1	4
Band 8	100-1000	0	7	-	0	0	0	0	0	0	0	0
Total No.		400	100	298	3,200	2,500	90	650	2,500	1,000	225	400
Workforce trends (% p.a.)												
Workforce trend - future		0										
Workforce trend - past		- 2										
Exposure trends (% p.a.)												
Exposure level trend - future		-1										
Exposure level trend - past		- 8										

* Consists of 2 distributions which are pooled here, but used separately for the calculations

Table 3-54: Exposed workers distribution by Member States in percentage

Member state	Exposed workforce (number of workers)										
	1a Special glass	1b Domestic glass	2 Electronics sector	4a Primary copper *	4b Secondary copper	5 Zinc production with As2O3	6 Other non-ferrous metals	7 Welding, etc.	8: Ferrous base metals production	9 Power sector	10 Mining (Cu concentrate)
Austria					6%		6%	2%	7%		
Belgium	6%				43%		14%	3%	5%		
Bulgaria				17%			6%	1%			14%
Croatia								2%			
Cyprus								0.2%			
Czech Republic		30%					6%	2%	5%	8%	
Denmark								1%			
Estonia								0%		48%	
Finland				8%		64%	6%	1%	3%		5%
France	19%		18%				6%	7%	11%	1%	
Germany	48%		25%	20%	39%	36%	10%	19%	32%	4%	
Greece								2%		12%	
Hungary								2%	1%		
Ireland								1%			
Italy	3%	30%	9%				6%	17%	6%	1%	
Latvia								0%			
Lithuania								1%			
Luxembourg			16%					0.1%			
Malta								0.1%			
Netherlands			9%				6%	3%	7%		55%
Poland				30%			6%	8%	2%	9%	
Portugal								2%		1%	
Romania		10%					6%	4%	2%		1%
Slovakia		20%	12%		6%		6%	2%	4%	4%	
Slovenia								0.4%			
Spain		10%		17%			6%	8%	5%	8%	14%
Sweden				9%	6%		6%	3%			10%
United Kingdom	23%		9%				6%	8%	10%	4%	
Background for distribution:											

Table 3-54: Exposed workers distribution by Member States in percentage

Member state	Exposed workforce (number of workers)										
	1a Special glass	1b Domestic glass	2 Electronics sector	4a Primary copper *	4b Secondary copper	5 Zinc production with As2O3	6 Other non-ferrous metals	7 Welding, etc.	8: Ferrous base metals production	9 Power sector	10 Mining (Cu concentrate)
1a Special glass: Roughly distributed on the basis of information on location of special glass manufacturers obtained from the ESGA, European Special Glass Association. 1b Domestic glass: Roughly distributed between MS where remaining used is most likely. 2 Electronics sector: Partly based on stakeholder responses, partly roughly distributed between MS with major producers of electronic components 4a Primary copper: Based on production volume of primary copper in 2015 (see section 3.11.2). Companies seems to have included different shares of the workforce in stakeholder responses (i.e. some companies report a low number by high exposure concentrations indicating data 4b Secondary copper: Based on the difference between production volume of refined copper and primary copper in 2015 (see section 3.11.2). Takes into account that some secondary copper is smelted in Slovakia and refined in Austria. 5 Zinc production with diarsenic trioxide: Based on zinc production volume in 2015. (see section 3.11.2). 6 Other non-ferrous metals: Roughly distributed on the basis of knowledge on location of companies and distribution of production volume in 2015 for relevant metals. 7 Welding, thermal cutting, etc.: Based on distribution used in assessment of Cr (VI) in welding, etc., under this contract where the background is further described. 8 Ferrous base metal production: Based 9 Power sector: Distributed on the basis of reported emission to the air in countries where high arsenic in coal and oil shale is most likely 10 Mining: Based on distribution of copper mining volume in 2015 (*British Geological Survey 2017*).											

Other parameters for calculation of current, past and future burden of disease are shown in Table 3-55.

Other parameters

Other parameters for the calculations are listed in the table below.

Table 3-55: Input data for calculation of cases at baseline and reference OELs at current, future and past exposures for copper smelters

Parameter	Unit	Value
OELV		
Reference OELVs	µg/m³	10 ; 25; 50
Reference % compliance with OELV	%	100
MS OELs	µg/m³	See Table 3-1
Health endpoints		
ERR cancer risk	/µg/m³	1.4 x 10-4 per 40 years no effect threshold
DRR non-cancer risk:		
5 µg/m³		Threshold, zero effect:
50 µg/m³		10% affected fraction
[5- 300] µg/m³		**yy [fraction affected]= 0.00222x – 0.0111** per 20 years period
Time periods		
Period for baseline cases:		
Future period	a	40 ; 60
Past period	a	50

3.13.2 Current burden of disease due to past exposure

The current burden of disease due to past exposure is summarised in Table 3-56. The data are based on data adjusted for the current use of RPE. The estimated past trend of -8 p.a. takes into account the less efficient RPE or no RPE was used in the past.

The total is very sensitive to the assumptions regarding use of RPE. For domestic glass it is assumed that some use of diarsenic trioxide takes place and result in exposure levels comparable to those measured in Italy in the late 1990'ies where it was reported that the workers did typically not wear RPE. No actual use today has, however, been identified but as the application takes place in small glass huts it cannot be excluded considering that diarsenic trioxide was used until recently in glass huts in Northern Italy.

The estimates presented Table 3-56 relate to the sectors where exposure to inorganic arsenic compounds currently occurs and do not represent the total burden of past occupational exposure to inorganic arsenic compounds. The total burden from all past occupational exposure to inorganic arsenic compounds would require consideration of sectors where occupational exposure no longer takes place e.g. use in CCA wood preservatives, CCA-preserved wood (except for recycling), other biocides and pesticides which are not relevant to the problem definition for this Impact Assessment.

A recently published report for ETUI (Vencovsky et al., 2017) comes out with estimates that occupational exposure to arsenic accounts for 0.2 % of 310,000 new cases of lung cancers per year corresponding to 620 cases/year. The two estimates differ as the ETUI estimate include all exposure sources in the past, whereas the estimate of this study excludes the exposures to discontinued uses of arsenic e.g. use of CCA preservatives and other biocides and pesticides which has been major exposure sources (represent approx. 50% of the former exposed workforce but possibly a higher percentage of estimated cases). Furthermore, the current study does not include exposure to organic arsenic substances. The ETUI study uses another approach estimating the "relative risk" of the different carcinogens and attributes the total number of cancer cases to the different carcinogens. The relative risk of arsenic is based on a study by t'Mannetje et al. (2003). This approach is fundamentally different from the approach used in the current study. The current study has used the ERR established by RAC. The study uses number of workers and exposure levels estimated on the basis of available data. The estimates of cancer cases in the current study include lung cancer only, and furthermore include only the inhalation pathway, which may result in some underestimation. RAC only provided risk estimates for lung cancer in their quantitative estimates. Furthermore, it is common to associate only lung cancer to occupational exposure to arsenic (see e.g. Rushton et al., 2010).

Table 3-56: Current burden of disease due to past exposure

Endpoint	Number of cases in 2017 due to past 60 years exposure *
Lung cancer	17.2
Neurotoxic effects	905

* Current exposure concentrations used for today's exposure are adjusted for use of RPE used as background. The -8% trend on exposure concentrations take into account that less efficient RPE or no RPA was used in the past.

3.13.3 Future burden of disease

The baseline future burden of disease is shown in Table 3-57.

These estimates are based on the assumption that the number of workers exposed to inorganic arsenic compounds will remain unchanged while the associated exposure concentrations will decrease by 1% p.a.

Table 3-57: Baseline burden of disease – constant workforce

Endpoint	Number of cases over 40 years	Number of cases over 60 years	Monetary value PV 60 years (method 1)*	
			Static discount rate	Declining discount rate
Lung cancer	12	20	€16,356,000	€18,462,000
Neurotoxic effects	376	574	€23,310,000	€25,106,000
Total			€39,666,000	€43,568,000

* See section 4.2.1 for calculation method 1.

3.13.4 Summary

A summary for the burden of disease across all sectors is provided in Table 3-58.

Table 3-58: Inorganic arsenic compounds - Summary of the baseline burden of disease	
Carcinogen	***Inorganic arsenic compounds*** Diarsenic pentaoxide Diarsenic trioxide Arsenic acid, sodium salt Arsenic acid Disodium hydrogenarsenate Calcium arsenate Arsenic trichloride Potassium dihydrogenarsenate Diammonium hydrogenarsenate Sodium dioxoarsenate Iron arsenate Iron bis(arsenate) Arsenic acid, magnesium salt Arsenic acid, copper salt Arsenic acid, calcium salt Ammonium dihydrogenarsenate Trisodium arsenate Zinc arsenate Sodium metaarsenate Triammonium arsenate 3-methyl-4-(pyrrolidin-1-yl)benzenediazonium hexafluoroarsenate Arsenic acid, copper(2+) salt Vanadium(4+) diarsenate (1:1) Sodium hexafluoroarsenate(V) Calcium hydrogen arsenate Sodium arsenate dibasic heptahydrate
Classification	Carc. 1A
Key sectors used	**Intentional**: Glass sector, electronics sector, primary zinc sector **Unintentional in raw materials**: Non-ferrous metal sector, ferrous base metal sector, energy sector, chemical sector, **Unintentionally formed from arsenic metal**: Non-ferrous metal sector
Types of health effect caused	Lung cancer (main cancer type for occupational exposure) Non-cancer: peripheral neuropathy, cardiovascular effects and immunotoxicity
No. of exp. workers	7,900-15,300 (included in assessment with measured or modelled data) 18,000-102,000 (potentially exposed; at levels below the lowest OELV assessed)
Change in exposure levels	Past: -8% Future: -1%
Change number of exposed workers	Past: -2% Future: 0

Table 3-58: Inorganic arsenic compounds - Summary of the baseline burden of disease

Period for estimation	60 years (past and future)
Current disease burden (CDB) no. of cancer cases in 2017 based on previous 60 years exposure	17.2 *
Future disease burden (FDB) no. of cancer cases, over 60 years	20
Current disease burden (CDB) - no. of peripheral neuropathy cases in 2017 based on previous 60 years exposure	905 *
Future disease burden (FDB) - no. of peripheral neuropathy disease cases, over 60 years	574
Exp. no. of deaths (FDB) cancer, 60 years	16
Exp. no. of deaths (FDB) from chronic peripheral neuropathy, 60 years	None
Monetary value FDB cancer, 60 years, static discount rate**	€16,356,000
Monetary value FDB, peripheral neuropathy, 60 years, static discount rate**	€23,310,000

CDB - Current disease burden; FDB - Future Disease Burden

* Excludes burden of disease from exposure to prohibited applications; first of all the former use in CCA wood preservatives, CCA-preserved wood, other biocides and pesticides which have been major exposure sources. According to CAREX data, these applications accounted for half of the exposed workforce in 1993/97.

** Method 1 - See section 4.2.1.

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

Table 4-1: The benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[29]	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[30]: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY: Mortality	
	Approach 2 DALY: Morbidity	

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[29] 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.

[30] WTP: Willingness to pay

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

Method 1: Ctotal= Ch+Ci+Cp+Cvsl+Cvsm

Method 2: Ctotal= Ch+Ci+Cp+Cl+Cdaly

The abbreviations are explained below.

The methods are further described in the common methodology report for the studies under this contract. In short, Method 1 is based on value of cancer morbidity while Method 2 is based on value of disability adjusted life years.

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 (VSL)
	Cvsm	Value of cancer morbidity/value of statistical morbidity (VSM)
	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;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

The key scenario is modelled for the exposed workforce. This is:

- **ExW-Constant:** 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.

For the two health endpoints considered for arsenic, assuming a changing workforce would give the same results as for the constant workforce. The excess risks are assumed to be linear to the number of years exposed. It means that the estimated number of cases will be the same whether a given workforce is exposed over 40 years to two groups of workers are exposed each for 20 years.

A detailed overview of the key features of the model for the estimation of the benefits and the assumptions underpinning it are set out in the methodology report.

4.2.2 Relevant health endpoints for inorganic arsenic compounds including arsenic acid and its salts

For inorganic arsenic compounds including arsenic acid and its salts, the benefits (i.e. changes in the costs caused by ill health) have been quantified for two health endpoints:

- lung cancer; and
- peripheral neuropathy.

Peripheral neuropathy covers a range of effects including:

- Reduced nerve conduction velocity of peripheral nerves;
- Reduced tibial motor nerve and sural sensory nerve conduction velocities;
- Joint/muscle pain and numbness/paraesthesia/leg cramps.

Other relevant endpoints, which have not been quantified, include cardiovascular effects and immunotoxicity (see section 2.4). These have not been included due to limited data for deriving a DRR

4.2.3 Summary of the key assumptions for inorganic arsenic compounds including arsenic acid and its salts

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, respectively) 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 peripheral neuropathy 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
Peripheral neuropathy	0	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*

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 4-1).

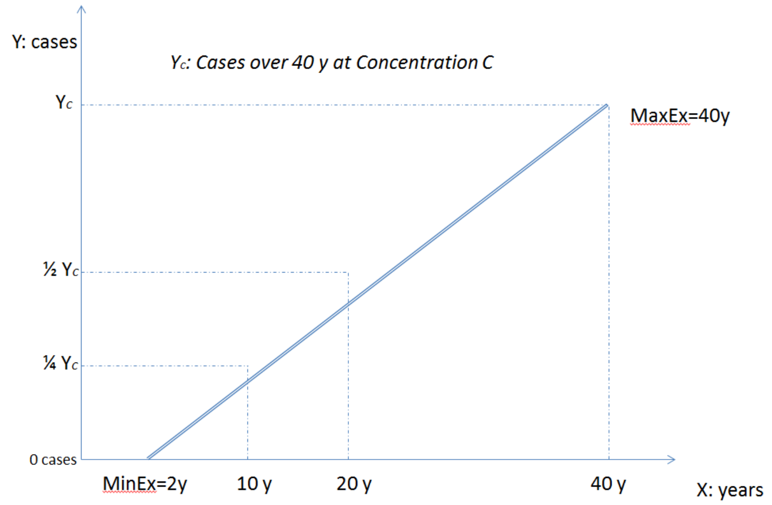

Figure 4-1: Lung cancer risk – distribution over time

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 to workers and ensure that relevant cancer cases are assessed within the 60 year assessment period for this study.

The time typically needed for neurotoxic effects is assumed to be relatively long, e.g. 20 years. The distribution is expected to be linear.

The estimated latency period for peripheral neuropathy 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 arsenic 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 Peripheral neuropathy; 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. For lung cancer the treatment period is estimated at 5 years, see the methodology report for details. For peripheral neuropathy, the evidence suggest that it is a chronic diagnosis and the treatment period is therefore assumed at 30 years.

Table 4-4: Treatment period	
Endpoint	**Treatment period (years)**
Cancer	5
Peripheral neuropathy	30
Source: RPA/COWI on the basis of above-mentioned	

Mortality rate

The mortality rates used in the model are given below.

Table 4-5: Fatality rates (MoR)	
Endpoint	**MoR (years)**
Cancer - lung	80%
Peripheral neuropathy	0%
Source: RPA/COWI	

Cost of treatment

The costs of treatment for lung cancer are the same for all the substances subject to this contract (As, Be, Cd, Cr(VI), CH_2O, and MOCA) and the approach and assumptions are described in the methodology report. For peripheral neuropathy, there are no studies that can guide the assessment of the treatment costs. It is therefore assumed that there is a cost of establishing the diagnosis. There is no data on the specific costs. It is assumed that establishing a diagnosis could costs about €1000 per case. This a one-off cost per case.

There is no specific treatment of Peripheral neuropathy, but in case of muscle pains etc. various pain relief might be used. As nominal value, it assumed that there are annual costs of €100 per case.

Willingness to Pay (WTP) values

The WTP values for a case of fatal and non-fatal cancer are €4,100,000 and €420,000; 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 peripheral neuropathy has been estimated. There is no direct assessment of this diagnoses. Consultation with medical expert suggest that it is difficult to estimate the specific effects for example in terms on the number restricted activity days. In order to illustrate the potential benefits, the following considerations and assumptions have been made. The symptoms for peripheral neuropathy cases suggest that they will affect and restrict a diagnosed worker. It is assumed that number of restricted activity days could be from 10% to 30% equivalent to 36 to 110 days. The value per restricted activity day is assumed at €50. It means an annual loss of welfare at €1800 to €5500 per year per patient. The average of €3650 is used a base estimate.

Disability weights

The disability weights used are summarised overleaf.

Table 4-6: Disability weights collated in European Burden of Disease study (2015)		
Type of cancer	**Stage of disease**	**Disability Weight**
Lung	Operable	0.265
	Inoperable	0.358
	Disseminated	0.515
Peripheral neuropathy	-	0.01 to 0.05*
Source: Haagsma et al. (2015): Assessing disability weights based on the responses of 30,660 people from four European countries. Available at: http://pophealthmetrics.biomedcentral.com/articles/10.1186/s12963-015-0042-4 * Estimated using data from above source. *Source: RPA/COWI*		

No disability weight has been identified for peripheral neuropathy. Haagsma et al. (2015) estimated disability weights for large number of health stages, including estimated disability weights for mild and moderate motor impairments. These disability weights of 0.01 to 0.05 are used to estimate the impacts of peripheral neuropathy.

Summary

The applied unit costs are summarised below for the two health end points.

Table 4-7: Unit costs			
Category	**Cost**	**Lung cancer**	**Peripheral neuropathy**
Direct	Healthcare	€7,000 /year	€100 /year €1,000 per case
	Informal care	€3,000 /year	No direct cost estimated
	Cost for employers	€12,000 /case	No direct cost estimated
Indirect	Mortality – productivity loss	€5,000 /year	No mortality
	Morbidity – lost working days	€1,000 /year	€1,000 /year
Intangible	Approach 1 WTP: Mortality	€4,100,000 /case	No mortality effect
	Approach 1 WTP: Morbidity	€420,000 /case	€3,600 /year
	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. *Source: RPA/COWI*			

4.3 Avoided cases of ill health (cancer and non-cancer)

This section includes the estimation of the avoided cases of ill health. It includes only one health endpoint – lung cancer.

It is for the estimates assumed that introducing the OELV would cut the upper parts of the concentration distributions which are above the OELV. The RMMs introduced to would however result in a general reduction in exposure concentrations for the worker groups addressed by the RMMs i.e. the entire distribution would be displaced. For the assessment, average distributions for each sector are applied i.e. the distributions represents different worker groups. In order to take into account that for some worker groups within the sector introduction of the OELV displace the entire distribution, it is for simplification estimated that all concentrations above ½ * OELV will be reduced to ½ * OELV.

The avoided cases of ill health at the reference OELV levels are summarised below.

Table 4-8: Cases of lung cancer and elevated peripheral neuropathy for each reference OELV

Reference point (inhalable fraction)	Lung cancer		Peripheral neuropathy	
	40 years	60 years	40 years	60 years
Baseline	12	20	376	574
10 µg/m^3	10	17	0	0
25 µg/m^3	11	18	69	106
50 µg/m^3	11	19	119	181
Source: RPA/COWI				

These reference points have been used to plot the number of cases as continuous functions (Figure 4-2 and Figure 4-3).

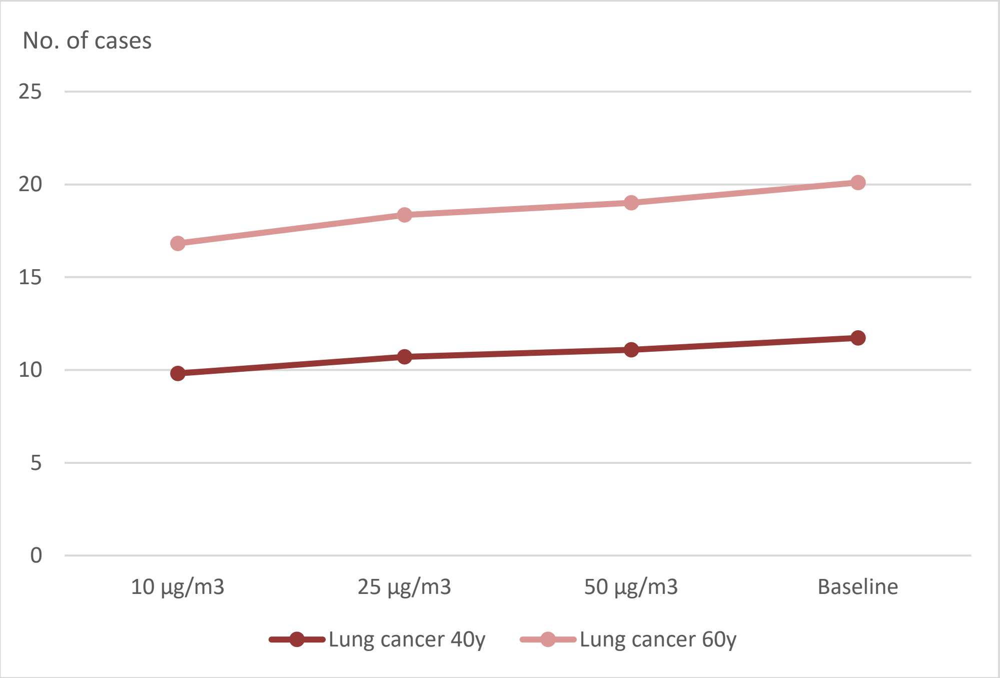

Figure 4-2: Lung cancer cases due to occupational exposure to arsenic relation to different OELV levels

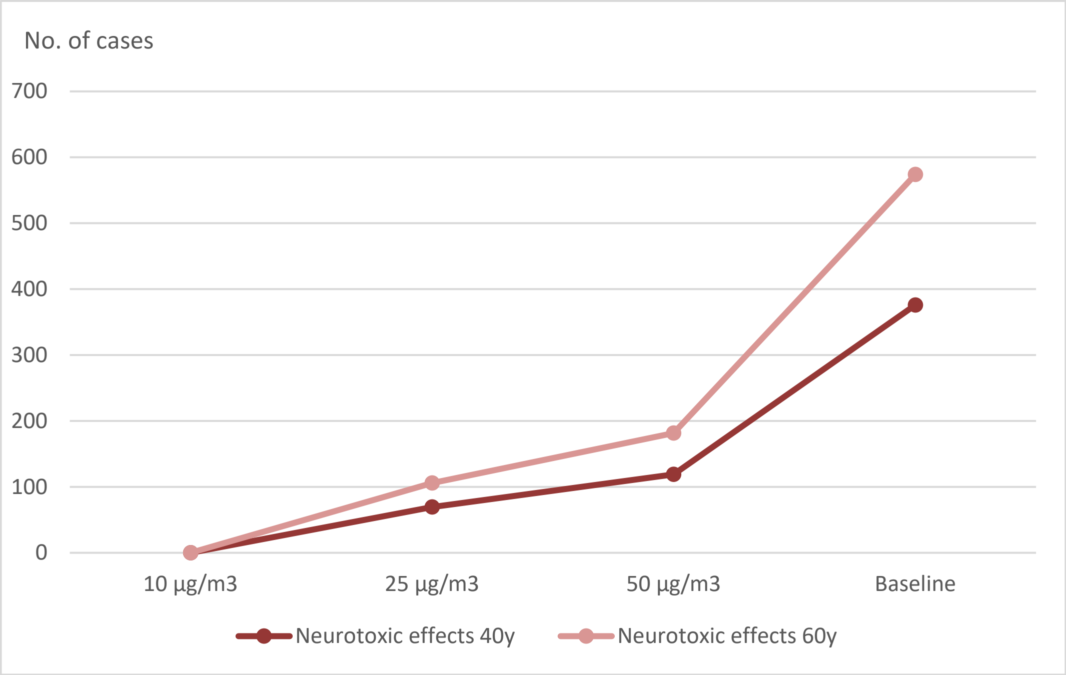

Figure 4-3: Cases of peripheral neuropathy in relation to different OELV levels

The number of DALYs are provided below. The table presents the reduction in the number of DALY lost.

Table 4-9: Reduction in the number of DALYs compared to baseline for each reference OELV

Reference point (inhalable fraction)	Lung cancer	Peripheral neuropathy	Total
	60 years	60 years	60 years
10 µg/m^3	65	516	581
25 µg/m^3	35	421	456
50 µg/m^3	22	353	375
Source: RPA/COWI			

4.4 Benefits to workers & families

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

Table 4-10: Benefits for workers and their families (avoided cost of ill health)

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

The benefits of each reference OELV are summarised below.

Method 1 relies on WTP values for mortality and morbidity.

Table 4-11: METHOD 1: benefits to WORKERS & FAMILIES (reference OELVs vs baseline)

Reference point (inhalable)	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
		Constant workforce		
Lung cancer	€2,635,000	€1,403,000	€885,000	€0
Peripheral neuropathy	€19,200,000	€15,654,000	€13,129,000	€0
Total	€21,835,000	€17,057,000	€14,013,000	€0

Source: RPA/COWI

The benefits calculated on the basis of Method 1 are depicted below.

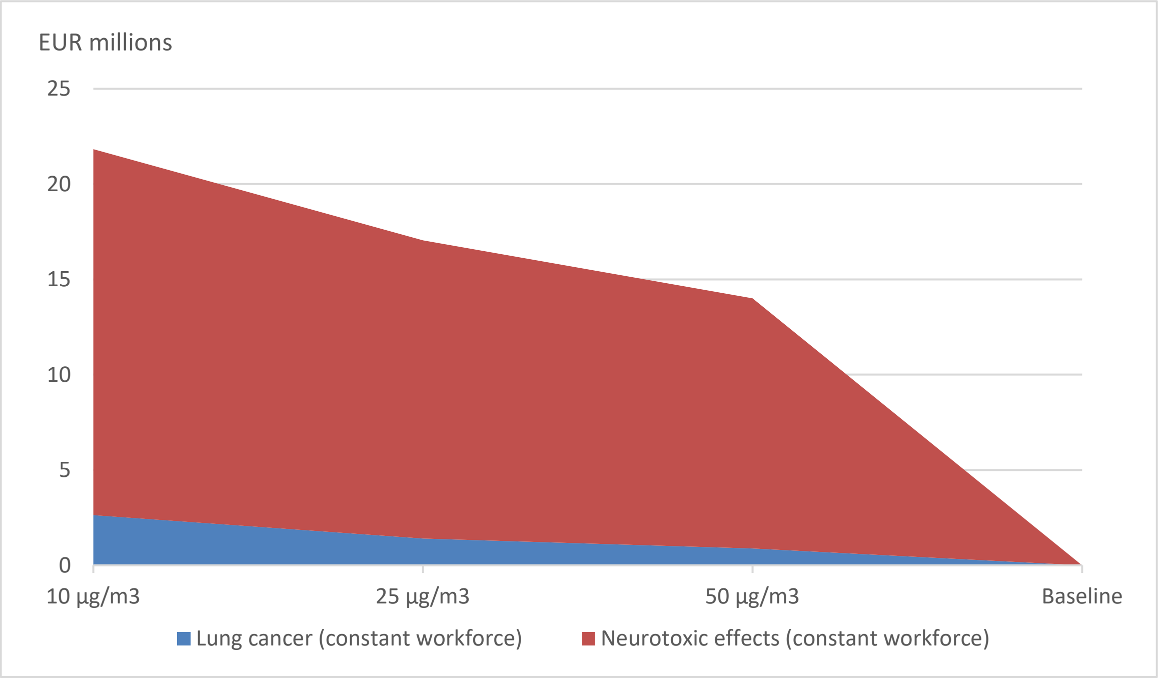

Figure 4-4: METHOD 1: benefits to WORKERS & FAMILIES (reference OELVs vs baseline), € millions

Method 2 relies on monetised DALYs.

Table 4-12: METHOD 2: benefits to WORKERS & FAMILIES (reference OELVs vs baseline)

Reference point (inhalable)	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
		Constant workforce		
Lung cancer	€1,718,000	€915,000	€577,000	€0
Peripheral neuropathy	€19,200,000	€15,654,000	€13,129,000	€0
Total	€20,918,000	€16,569,000	€13,705,000	€0

Source: RPA/COWI

The benefits calculated on the basis of Method 2 are depicted below.

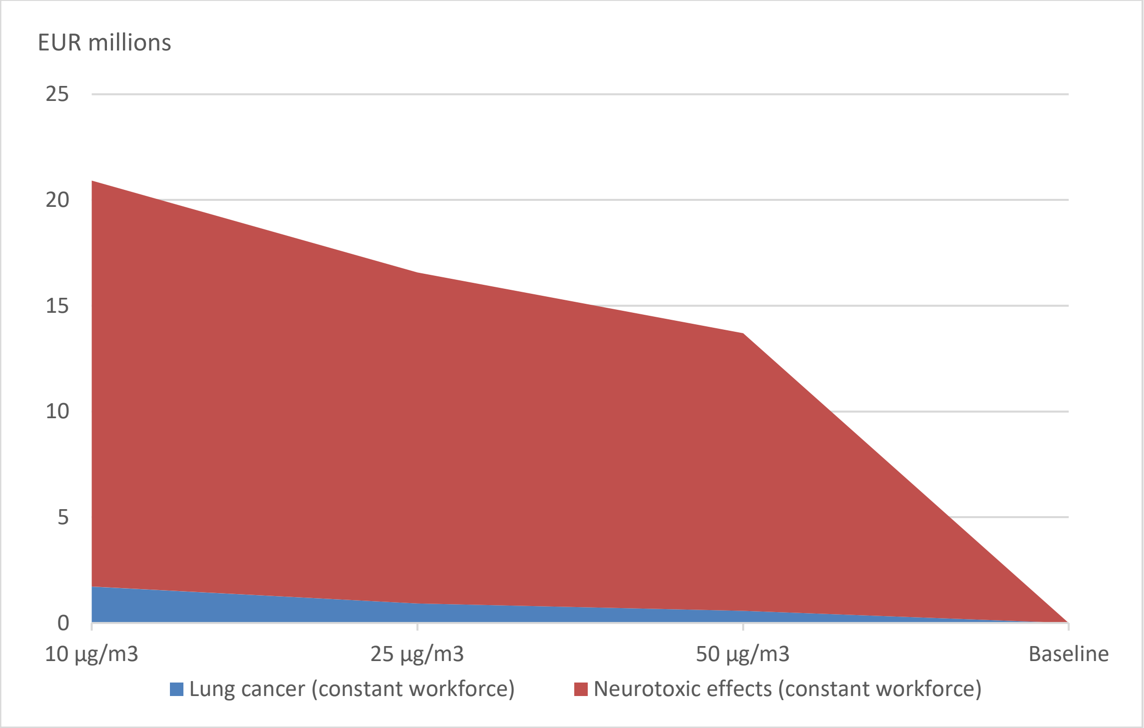

Figure 4-5: METHOD 2: benefits to WORKERS & FAMILIES (reference OELVs vs baseline), € millions

The assessment of the number of cases is uncertain. However - just as for the calculation of the benefits from avoided cancer cases - the benefit estimates for non-cancer effects include the value of knowing that the risks of symptoms are reduced and the value originating from the actual reduced number of workers with symptoms.

4.5 Benefits to the public sector

The benefits to the public sector include reducing costs in the health care sector. The magnitude of the benefit depends on the how the health care is organised in the different MS. In some MS, the health care is primarily financed through health care insurances, in other MS it is financed through general or specific taxes.

The benefits (avoided costs of ill health) for the public sector are calculated using the method summarised below.

Table 4-13: 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)*[31]

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[31] Assumes 20% tax.

The benefits of each reference OELV are summarised below.

Table 4-14: Benefits to the PUBLIC SECTOR (reference OELVs vs baseline)

Reference point (inhalable)	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
Constant workforce				
Lung cancer	31,000	16,000	10,000	€0
Peripheral neuropathy	1,276,000	1,040,000	873,000	€0
Total	1,307,000	1,057,000	883,000	€0

Source: RPA/COWI

The benefits to the public sector are also depicted below.

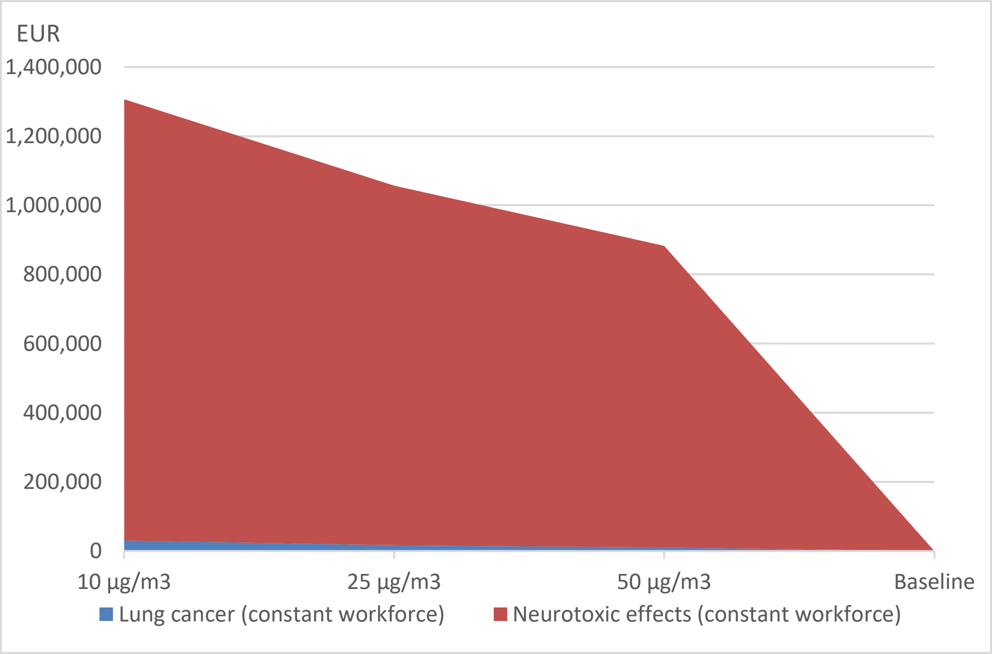

Figure 4-6: Benefits to the PUBLIC SECTOR (reference OELVs vs baseline), €

4.6 Benefits to employers

The benefits to employers include the saved costs in case of workers being absent due to ill health cases.

In addition to the direct effects of reduced absence, there is a CSR perspective of the company improving its occupational health record.

It is difficult to estimate these effects in financial terms.

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

Table 4-15: Benefits to EMPLOYERS (avoided cost of ill health)		
Stakeholder group	**Costs**	**Method of summation**
Employers	Ce, Cp	*CtotalEmployer=Ce+0.8*Cp*
Note: 0.8 corresponds to 80% mortality-caused productivity loss		

The benefits of each reference OELV are summarised below.

Table 4-16: Benefits to EMPLOYERS (reference OELVs vs baseline)				
Reference point (inhalable)	**10 µg/m³**	**25 µg/m³**	**50 µg/m³**	**Baseline**
Constant workforce				
Lung cancer	€14,000	€7,000	€5,000	€0
Peripheral neuropathy	€2,834,000	€2,311,000	€1,938,000	€0
Total	€2,848,000	€2,318,000	€1,943,000	€0
Source: RPA/COWI				

The benefits to employers are also depicted below.

Figure 4-7: Benefits to EMPLOYERS (reference OELVs vs baseline), €

4.7 Aggregated benefits & sensitivity analysis

4.7.1 Aggregated benefits

Cost of ill health

The total costs of ill health (over 60 years) are summarised below for the baseline and each of the three reference OELVs.

Method 1 relies on WTP values for mortality and morbidity. Note that for peripheral neuropathy, Method 1 has been set to give the same results as Method 2.

Table 4-17: METHOD 1: total cost over 60 years of ill health (baseline and reference OELVs)

Reference point (inhalable)	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
Constant workforce				
Lung cancer	€13,688,000	€14,935,000	€15,460,000	€16,356,000
Peripheral neuropathy	€0	€4,305,000	€7,371,000	€23,310,000
Total	€13,688,000	€19,240,000	€22,831,000	€39,666,000

Source: RPA/COWI

The total costs calculated on the basis of Method 1 are depicted below.

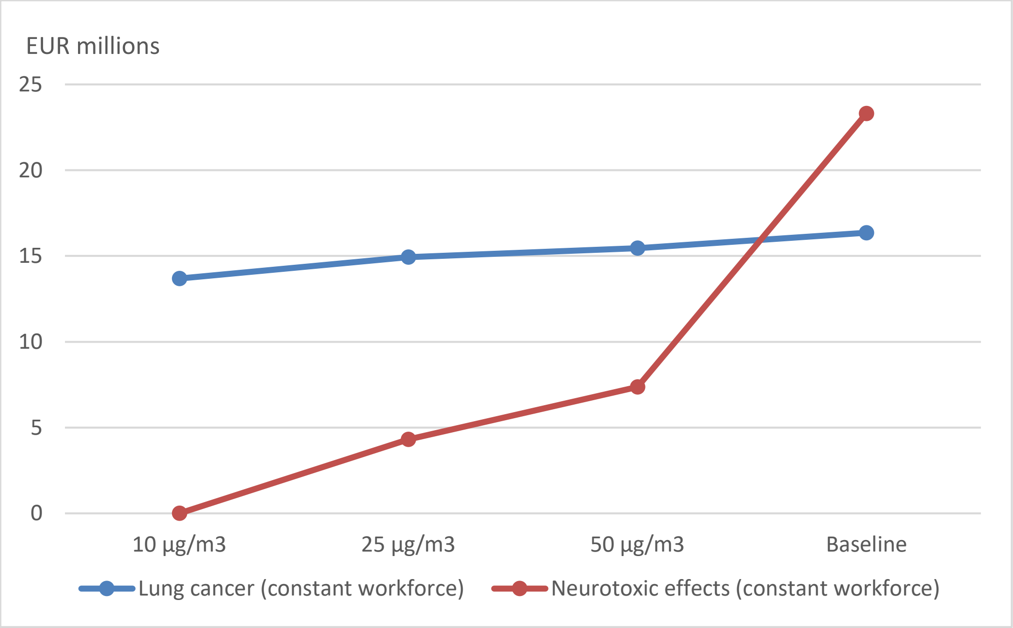

Figure 4-8: METHOD 1: total cost of ill health (baseline and reference OELVs), €

The results of the assessment of the benefits in monetary terms show that baseline costs of peripheral neuropathy are higher than for the lung cancer health endpoint. As discussed the assessment of peripheral neuropathy are uncertain in particular the monetary valuation.

The results also indicate that the proposed alternative OELVs do not lead to substantial cancer benefits. For peripheral neuropathy, there are more substantial reductions and therefore significant benefits.

Method 2 relies on monetised DALYs for mortality and morbidity.

Table 4-18: METHOD 2: total cost over 60 years of ill health (baseline and reference OELVs)

Reference point (inhalable)	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
Constant workforce				
Lung cancer	€8,983,000	€9,802,000	€10,146,000	€10,734,000
Peripheral neuropathy	€0	€4,305,000	€7,371,000	€23,310,000
Total	€8,983,000	€14,107,000	€17,517,000	€34,044,000

Source: RPA/COWI

The total costs of ill health calculated on the basis of Method 2 are depicted below.

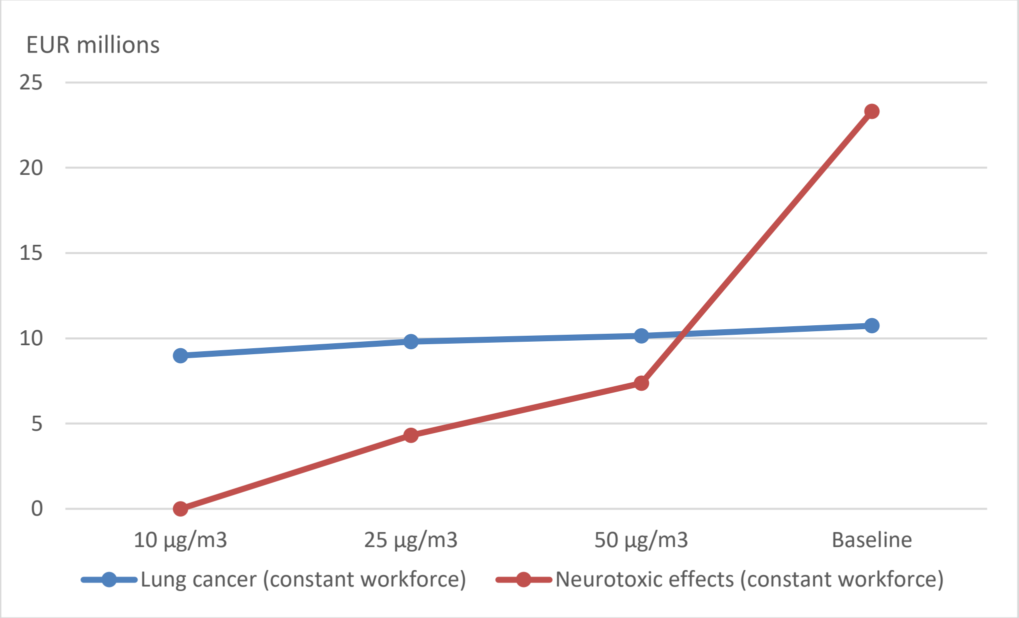

Figure 4-9: METHOD 2: total cost of ill health (baseline and reference OELVs), €

Benefits – avoided ill health vis-à-vis the baseline

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

Method 1 relies on WTP values for mortality and morbidity.

Table 4-19: METHOD 1: total cost over 60 years of ill health (baseline and reference OELVs)

Reference point (inhalable)	*10 µg/m³*	*25 µg/m³*	*50 µg/m³*	*Baseline*
Constant workforce				
Lung cancer	€2,668,000	€1,420,000	€896,000	0
Peripheral neuropathy	€23,310,000	€19,005,000	€15,939,000	0
Total	€25,978,000	€20,426,000	€16,835,000	0
Source: RPA/COWI				

The benefits calculated on the basis of Method 1 are depicted below.

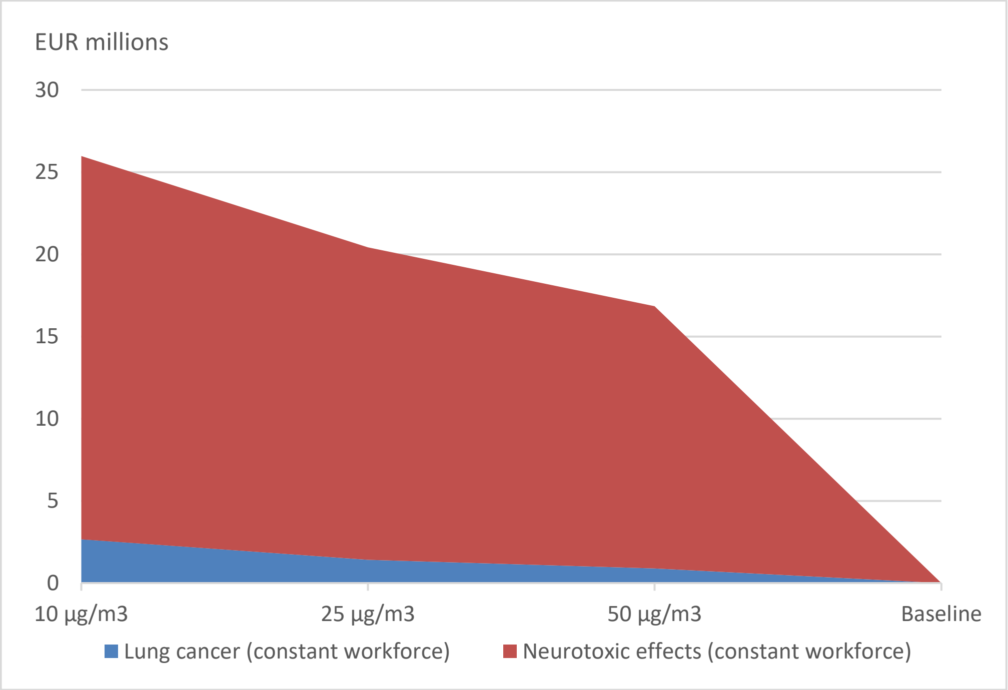

Figure 4-10: METHOD 1: benefits from avoided ill health (reference OELVs vs baseline), € millions

Method 2 relies on monetised DALYs for mortality and morbidity.

Table 4-20: METHOD 2: total cost over 60 years of ill health (baseline and reference OELVs)

Reference point (inhalable)	*10 µg/m3*	*25 µg/m3*	*50 µg/m3*	*Baseline*
Constant workforce				
Lung cancer	€1,751,000	€932,000	€588,000	0
Peripheral neuropathy	€23,310,000	€19,005,000	€15,939,000	0
Total	€25,061,000	€19,938,000	€16,527,000	0
Source: RPA/COWI				

The total benefits calculated on the basis of Method 2 are depicted below.

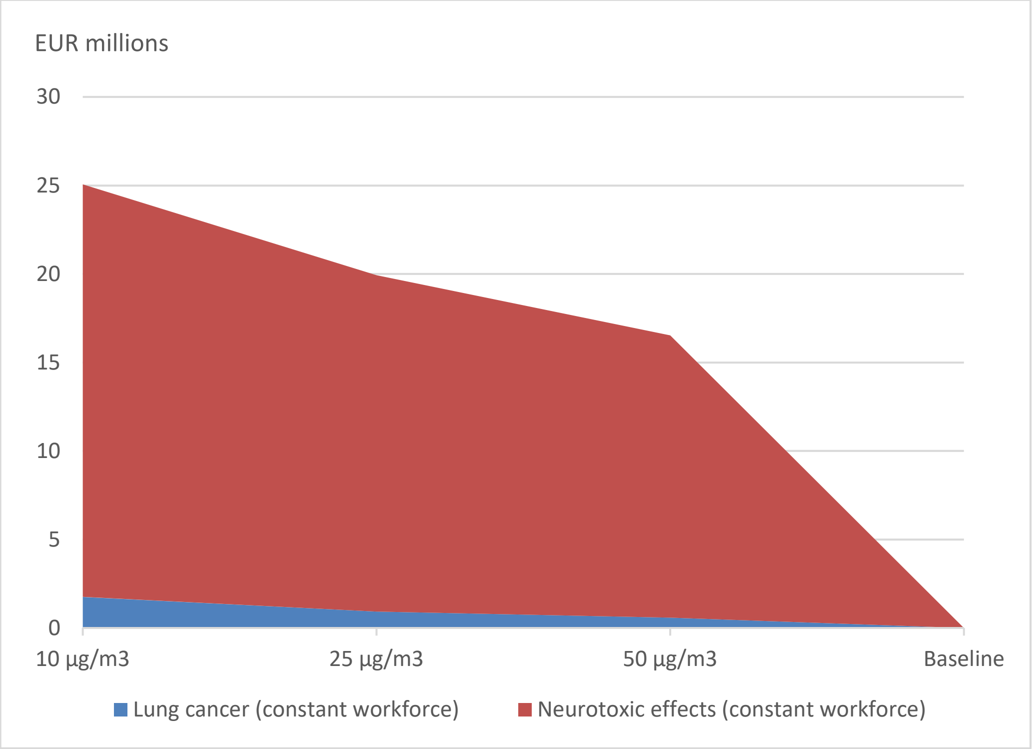

Figure 4-11: METHOD 2: Benefits from avoided ill health (reference OELVs vs baseline), € millions

4.7.2 Sensitivity analysis

The benefits estimate is sensitive to a number of uncertainties.

Toxicological parameters for cancer and non-cancer effects (ERR, DRR) and endpoints not quantified

Costs and benefits of alternative OELs for inorganic arsenic compounds including arsenic acid and its salts depend on the toxicological parameters (ERR, DRR), as derived in Section 2.5. However, those parameters include some uncertainties, because of the completeness of endpoints and because of the respective selected slope of the ERR or DRR (effects and severity in higher doses compared to lower doses).

Generally, only the most sensitive tumour site (highest associated risk at low level exposures as agreed by SCOEL) has been selected. For arsenic, lung cancer has been chosen as critical tumour site. There are some uncertainties on the ERR of lung cancer. As reported in Section 2.4.3, Lubin et al. (2008) used an exposure reduction factor of 10 in the higher exposure categories to account for the use of personal protection equipment, which was not included in Lubin et al. (2000). This increased the risk for lung cancer from 1.4×10^{-4} to 4.8×10^{-4} per µg As/m^3 of occupational lifetime exposure. HCN (2012) and ECHA (2017a) considered this an arbitrary value, not used in common practice in risk calculations. However, a range of risk estimates within a factor of about 3.5 has to be considered as good agreement of different risk estimates. A linear relationship of risk with cumulative exposure was found; however, the slope of the relationship increased with the average concentration at which exposure had taken place, that is, the effect of a particular cumulative exposure was greater if received at a faster rate (IARC, 2012).

Further cancer several sites may be relevant:

- Digestive system tumours (Sobel et al., 1988);
- Stomach cancer (Bulbulyan et al., 1996);
- Colorectal cancer cases (Enterline et al., 1995);
- Bone tumours (Enterline et al., 1995);
- Skin tumours (Qiao et al., 1997).

However, the results are regarded less reliable. Quantitative data from single studies provide a higher or lower relative risk (standard mortality ratio or odds ratio) compared to lung cancer. Therefore 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 tends to underestimate total number of cancer cases to be expected after occupational exposure to arsenic (inorganic arsenic compounds including arsenic acid and its salts).

Regarding non-cancer effects, peripheral neurotoxicity has been assessed as the most critical effect with qualified data to describe the DRR (at least in the low concentration range). Peripheral neuropathy and cardiovascular effects have been examined in the same cohort (Blom et al., 1985; Lagerkvist et al., 1986; 1988; Lagerkvist and Zetterlund, 1994). However, neurotoxic and cardiovascular effects have been examined separately. Therefore it is not described, whether the same individuals of this cohort are affected in both endpoints. i.e. it is unclear whether there is an additional or concurrent risk. A decrease of the severity of neurotoxic effects after exposure reduction indicated partial reversibility (Lagerkvist et al., 1986; 1988) and was interpreted as indication of the lower exposures in the more recent years of occupation as effect concentration (AGS, 2011). A LOAEC of 50 µg/m^3 was derived, and in absence of graded exposure data a DRR was extrapolated using standard factors. This implies relevant uncertainties about the “true” DRR. Other non-cancer endpoints have not been selected for OEL derivation by SCOEL. Furthermore, the studies often do not provide a dose response relationship validated for the occupational exposure scenario and those studies are not equally analysed for reliability. Consequently, a quantitative sensitivity analysis is not feasible, but it may be concluded that the reference to only peripheral neurotoxicity tends to underestimate total number of cases of disease to be expected after occupational exposure to inorganic arsenic compounds including arsenic acid and its salts.

RMM in place - Data obtained by the stakeholder consultation and from the literature have all been presented as measured workplace concentrations not adjusted for the use of RPE. In one instance, the data were reported from the stakeholder consultation adjusted for RPE with the conversion factor provided (a factor of 40), and the data were recalculated into workplace concentrations before aggregated with other data. For most processes, it is indicated that RPE is used or that RPE is used when the workers are in high exposure areas. In smelters, e.g., it is common that workers constantly bring RPE (but not necessarily use it) to be used in case of faults or when the workers undertake processes or are in areas of the buildings with potentially high concentrations (of arsenic and other substances). For some work processes, such as maintenance work in areas with arsenic-containing dust or when handling arsenic compounds, RPE is always used. The estimate is more sensitive to the assumption regarding the percentage of workers using RPE than to the efficiency of the RPE as most RPE used in the relevant sectors have an efficiency of 90% or better. The future burden of disease is calculated with and without adjustment for the use of RPE. The difference is more than a factor of 4. The actual uncertainty is lower, because RPE is used in all high-exposure situations according to the stakeholder consultation. The uncertainty related to the adjustment for RPE may for the entire dataset be up to a factor of 2. The data has not been adjusted for rotation, where workers are exposed to the measured concentration for less than a 8-h work day, because they are only in high-exposure settings for a limited period of time every day. This may result in an overestimation of the actual number of cases.

Non-confirmed processes and exposed workforce - Both benefits and costs estimates are sensitive to the estimate on number of exposed workforce. It has for the estimations been assumed that arsenic trioxide is still used in some small-scale production of domestic glass, which has not been confirmed. As the exposure levels are expected to be high, the total number of cases of ill health may be overestimated in case this application in fact has ceased (represents about 20% of the estimated future burden). The costs would be reduced accordingly. The number of workers exposed at levels above the assessed OELVs in the power sector and in ferrous basic metal production has not been confirmed and may result in an overestimation of both benefits and costs.

A high number of workers are exposed to inorganic arsenic compounds at relatively low levels. The actual number is very uncertain which has influence on the baseline. However, the exposure concentrations for this group are considered to be well below the lowest of the assessed OELVs and consequently the uncertainty has no influence on the estimated benefits and costs of establishing an OELV.

Determinations of exposure concentration distributions - For the main exposure groups separate exposure distributions have been established. As different parameters have been reported from stakeholder and in the literature it has for some sectors been necessary to establish the distributions form general experience from other sectors regarding e.g. the AM/90th percentile ratio. Compared to the uncertainty related to the adjustment for RPE, the uncertainty from the conversion into exposure concentrations distributions is considered to be relatively low.

Inhalable vs. respirable fraction - The ERR for cancer effects and DRR for neurotoxic effects both refer to the inhalable fraction. The commonly used standards for sampling and analysis, e.g. ISO 11041 and ISO 15202, measure the inhalable fraction and all national OELs refer to the inhalable fraction. It is thus expected that the reported concentrations represent the inhalable fraction unless specified and the estimations are not sensitive to this.

Changes in exposure concentrations - It is assumed that the exposure concentrations will decrease by a 1% (-1% increase) p.a. in the future whereas the past trend is estimated at -8%. This reflects information obtained from stakeholder consultations indicating that for some of the main sectors the focus today is much on reducing the total exposure, e.g. by better hygiene and rotation. The effectiveness of these measures is demonstrated in significant decreases in urinary arsenic levels. If the future decrease in exposure concentrations is higher than the 1% (-1% increase), the benefits as compared to the baseline may be overestimated.

Discount rate – The assessment has been done using a constant discount rate at 4% as recommended in the Better Regulation Guidance. The assessment is not very sensitive to using an alternative discount rate profile where the discount rate is reduced to 3% after 20 years. Using the declining discount rate will increase the estimated monetary value of the benefits by around 8%.

Cases after the 60-years period - Due to the applied latency time of 10 years, approximately 1/6 of the cancer cases will occur after the 60-yearsassessment period. This systematically underestimates the long-term benefits of introduction of the OELV as a significant part of the cancer cases induced by the exposure during the 60 years period does not contribute to estimated costs of cancers (in case the OELV is not introduced).

5 Costs of the measures under consideration

5.1 Introduction

This section comprises the following subsections:

- Section 5.2: The cost framework
- Section 5.3: OELVs – compliance and administrative costs for companies
- Section 5.4: OELVs – indirect costs for companies
- Section 5.5: STELs or skin notation - compliance and administrative costs for companies
- Section 5.6: STELs or skin notation - indirect costs for companies
- Section 5.7: OELVs, STELs, skin notation – costs for public authorities
- Section 5.8: Aggregated costs & sensitivity analysis

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 inorganic arsenic compounds including arsenic acid and its salts 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 involves 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?
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 connecting these estimated to estimate the costs for the intervening OELV values.

5.3 OELVs – compliance and administrative costs for companies

5.3.1 Current level of actual exposure in the companies

As demonstrated in the summary of exposed workforce in section 3.5.12, a very high number of workers are potentially exposed to arsenic in thousands of companies. Most are exposed at low levels as result of the unintentional presence in raw materials or formed from arsenic metal by thermal processes. A challenge in the data collection has been to obtain data on low exposure concentrations as these are generally not reported.

As a consequence, for the costs assessment, focus will be on the processes where workers may be exposed at levels higher than the lowest OELV assessed (10 µg/m^3). This section addresses the number of workers exposed by sectors whereas the following sections addresses the number of companies that may be affected by establishing at the three different reference levels.

The copper sector is the only sector for which information has been obtained that complying with the lowest of the assessed OELVs of 10 µg/m^3 may be a challenge. According to the ASCS (2017), after a preliminary assessment for copper smelting, it is currently not technically achievable to comply with the suggested OELV at 10 µg/m^3.

In the stakeholder consultation, organisations and companies have been asked to what extent they expect challenges in complying with the assessed OELVs. The lead sector has indicated that some companies may be affected, but no specific information has been obtained. It has been a focus area in the stakeholder consultation to ensure that in fact all sectors and subsectors with potential exposure to inorganic arsenic substances have been addressed.

Intentional uses of inorganic arsenic compounds including arsenic acid and its salts

For the intentional uses of the arsenic compounds within the scope, data on exposure concentrations and exposed workforce are available for most applications. Data for the four major sectors of intentional use of inorganic arsenic substances are shown in Table 5-1. Some intermediate use of inorganic arsenic substances are included in "other nonferrous metal" below. The distribution by concentration band is derived from fitted lognormal distributions as described in section 3.13.1. Note that the concentration bands are not of same width and the distributions consequently visually do not resemble log-normal distributions. The data are represented as the 8-h TWA from personal samples without adjustment for the use of RPE (lower figure) and as adjusted based on information on the use of RPE (upper figure). For special glass production, RPE is always used when handling the pure substances and by various maintenance and cleaning processes; this result in the differences in the 10-25 concentration bands between the two distributions. Most of the applications of inorganic arsenic compounds including arsenic acid and its salts are subject to authorisation, and the exposure is strictly controlled. The exposure to inorganic arsenic substances in the special glass sector, electronics sector and zinc production (using diarsenic trioxide) is at a level where the companies would not be affected by establishing an OELV at 10 µg/m³. These sectors are therefore not further assessed.

As described in previous chapters, the only intentional application that may be affected by establishing an OELV at the assessed levels could be the use in small-scale domestic glass production. Until recently, diarsenic trioxide has been widely used in the Veneto Region in Italy and the reported exposure levels were very high. No current use has been identified, but small-scale domestic glass production in some MS (if any) may likely not have been addressed by the stakeholder consultation. As the reported exposure concentrations are very high, even when adjusted for the use of RPE, the potential impact on this subsector is addressed in section 5.3.3.

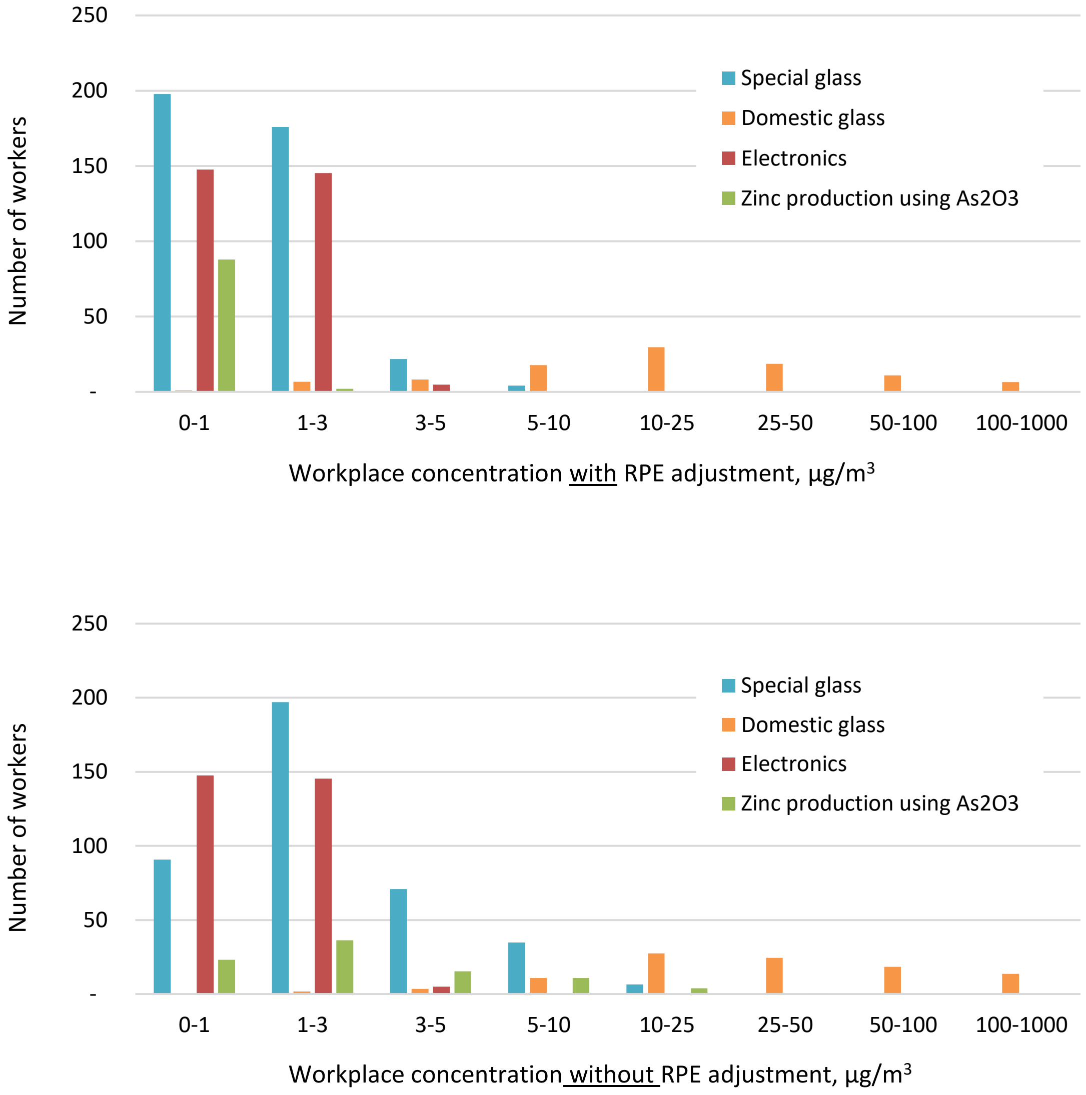

Figure 5-1: Distribution of workers in concentrations bands with (upper) and without (lover) adjustment for the use of RPE for the major intentional applications of the inorganic arsenic compounds including arsenic acid and its salts. Please note that size bands are not of same width.

Unintentional use or formation

Distributions from main sectors where exposure is due to unintentional use are shown below. Emissions of inorganic arsenic compounds including arsenic acid and its salts from welding are generally below 10 µg/m^3 and not further assessed. Current exposure in power plants has not been confirmed but expected to take place in some MS. Exposures in power plants, in the copper and other non-ferrous sectors are addressed in the following sections.

For some sectors, where it cannot be excluded that some exposure above 10 µg/m^3 may take place, no data have been obtained from neither stakeholder consultation, literature nor databases. They have not been included in the assessment and comprise the following sectors: Ferrous basic metal production, mining operations, and recycling of CCA wood. Relevant industry associations have been contacted for the two first, whereas recycling of CCA wood may take place in companies which have not been reached during the stakeholder consultation. For sulphuric acid produced from pyrite, high exposure concentrations in the past have been reported in literature but, no current data have been obtained confirming these levels. As production of sulphuric acid from pyrite only takes place in Finland and Germany, both MS with an OEL at or below 10 µg/m^3, the sector is expected not to be impacted and not further assessed. German MEGA data indicates for some processes exposure levels above 10 µg/m^3, but the specific processes are not specified and therefore assumed to represent processes within the sectors assessed.

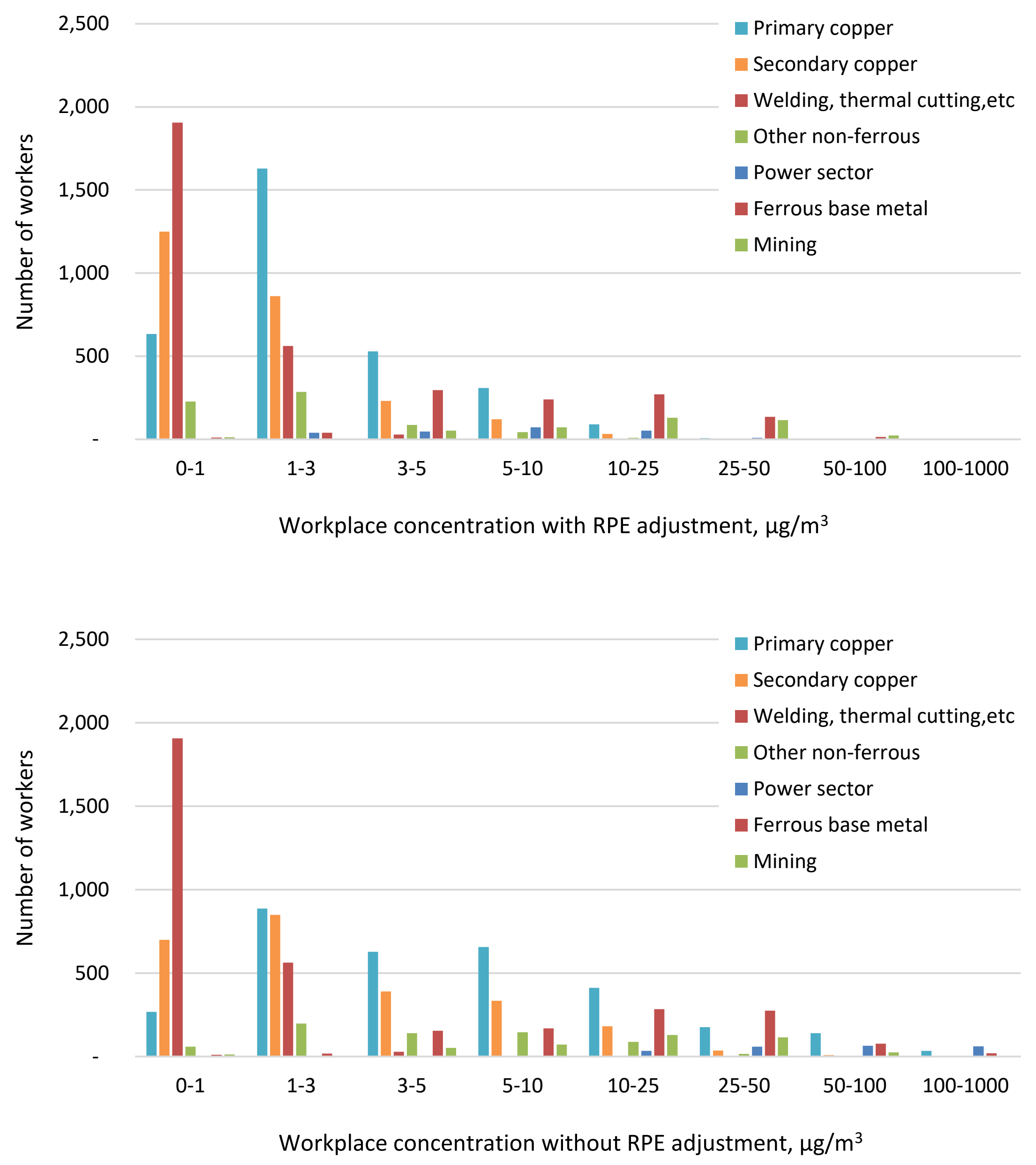

Figure 5-2: Distribution of workers in concentrations bands with (upper) and without (lover) adjustment for the use of RPE for inorganic arsenic compounds including arsenic acid and its salts. Please note that size bands are not of same width.

5.3.2 Compliance and administrative costs for the copper sector

It has been indicated by several companies that an OELV below 10 µg/m^3 would currently not be feasible. As discussed in the section 3.8.1, the sector is challenged by increasing average arsenic concentration of mined copper concentrates. According to Rohner et al. (2017), the average arsenic content in world copper concentrates increased from 0.13% in 2000 to 0.22% in 2017. This increase is expected to continue. Consequently, the workplace concentration will likewise increase unless the companies buy more expensive concentrates with lower arsenic content or take additional measures to lower the workplace concentrations. In some years' time it may be necessary to remove the arsenic from the concentrates before the smelting (which would typically be done in the mining sites where the concentrate is produced).

The distribution of companies by MS and size is shown below. All companies except two secondary smelters are large companies and often with more than 1000 employees per site. Most companies already today have to comply with an OEL at 10 µg/m^3. For many processes, the workplace concentration is, however, higher than 10 µg/m^3 and the worker's exposure has to be reduced by minimizing the time at high exposure and by use of RPE. With increasing arsenic content of raw materials, the companies would need to take additional measures in the future. For the assessment of potential impacts on companies which currently comply with the national OELs (also those > 10 µg/m^3), it must been considered that they within a few years also would need to take additional measures.

Table 5-3: Distribution of companies by Member States and size and existing national OELs

MS	Existing OEL µg/m^3	Number of sites		
		Small	Medium	Large
Austria	100	0	0	1 secondary
Belgium	10	0	0	3 secondary
Bulgaria	50	0	0	1 primary
Finland	10	0	0	1 primary (two locations)
Germany	8.3 "tolerable risk")	0	0	1 primary 2 secondary
Poland	10	0	0	2 primary
Slovakia	100	0	1 secondary	0
Spain	10	0	1 secondary	1 primary
Sweden	10	0	0	1 primary/secondary

Source: RPA/COWI; OELs derived from Table 3-1

Within the applied assessment framework only costs incurred by introducing of an OELV at levels below the national level would be allocated to the introduction of the OELV. Within this framework only additional costs for companies in Bulgaria, Austria and Slovakia will be assessed. Even though companies in some other MS may have challenges complying with the national OELs, this would not affect the cost assessment.

The distribution of workers in concentrations bands above 10 µg/m^3 with (upper figure) and without (lower figure) adjustment for the use of RPE in primary and secondary copper smelters are shown below. The estimated number of workers exposed is highly dependent on the adjustment to the use of RPE and to what extent the data available are representative for companies not providing information. The data show that 24% of the exposed workers in the primary copper smelters would be exposed at levels above 10 µg/m^3 if RPE was not used whereas the percentage for the secondary smelters is 9%.

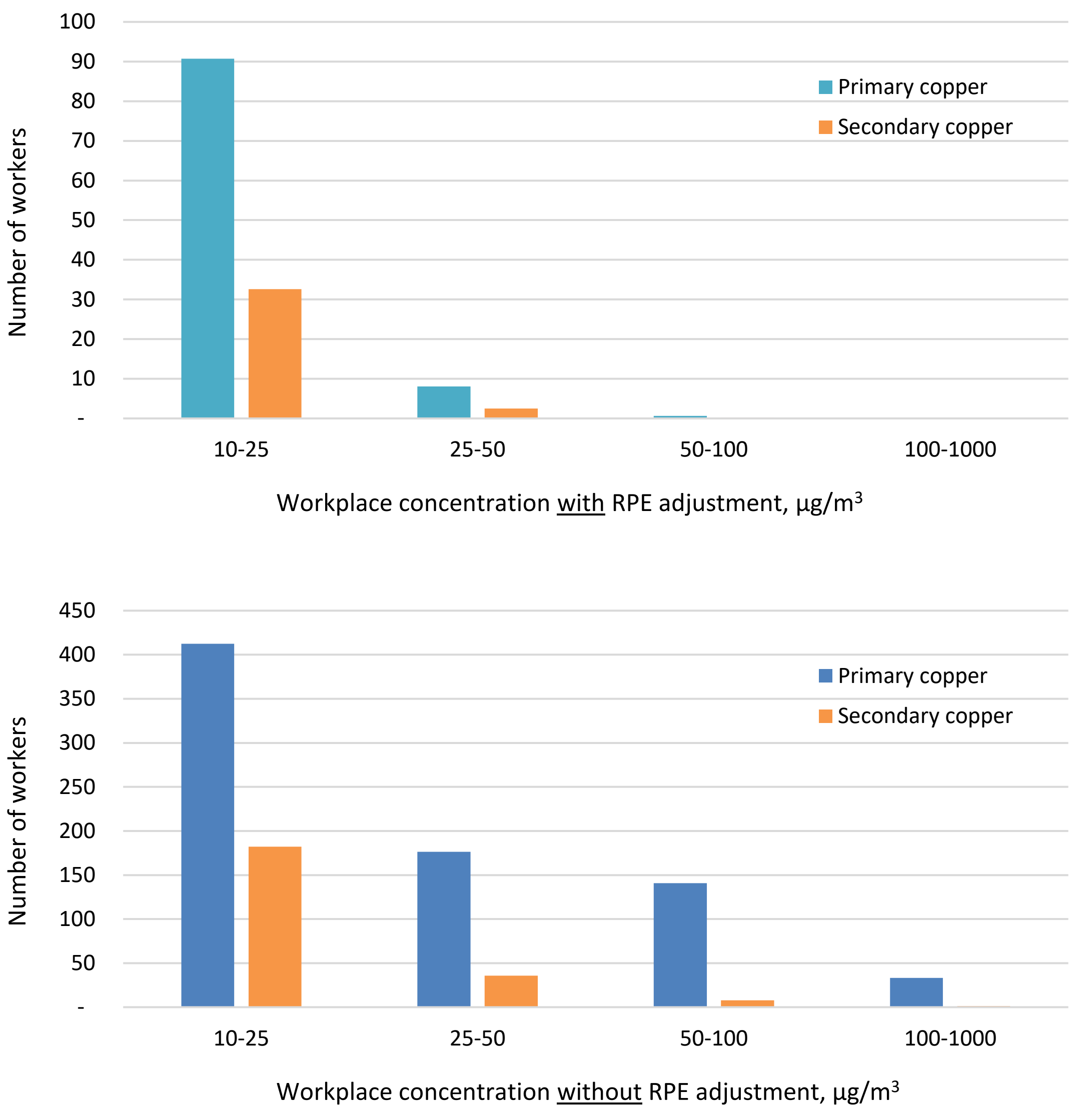

Figure 5-3: Distribution of workers in concentrations bands above 10 µg/m^3 with (upper figure) and without (lower figure) adjustment for the use of RPE. Please note that concentration bands are not of same width.

The three impacted companies have been asked about their assessment of possible costs of establishing an OELV at 10 µg/m^3. One of the sites has provided exposure data indicating very high exposures compared to other companies. The company informs that establishing tertiary hoods within the existing building would not be feasible. Most likely, compliance should be obtained by more efficient RPE. Another company replied that only few data on occupational exposure concentrations were available and that these data were analysed using a method with a LOD of 10 µg/m^3 (data not provided). The company indicates that complying with a level of 10 µg/m^3 would be challenging and could imply use of more efficient RPE, improvements of technical equipment (i.e. ventilation systems, cleaning systems) and the use of better methods for monitoring of arsenic in the workplace air. The third company has not answered.

RMMs

The exposure situation in the copper sector is overall characterised by two types of worker scenarios with high exposure levels:

- Different duties in the smelter room with high ambient arsenic levels due to releases from molten copper from flash furnaces (shaft furnaces in secondary smelters), conversion and anode furnaces and as well as from the molten copper during tapping, internal transport and anode casting. The workplace exposure levels may be reduced mainly through establishment of primary, secondary and tertiary hoods and partial enclosing of processes e.g. of the anode wheels. Worker exposure is further reduced by use of RPE and rotation.

- Different duties with exposure to arsenic containing dust from raw materials and various waste materials incl. sampling, maintenance, cleaning, transfer, etc. The worker exposure may primarily be reduced by the use of RPE, possibly in combination with various RMMs to reduce dust levels and organisational measures.

The total number of workers in the three companies is 1,250; of these 800 in a primary smelter and 300 and 150 in two secondary smelters. It is assumed that about 450 workers are exposed at the reported exposure levels. In the secondary smelters only about 10% of the exposed workers would without the use of RPE be exposed at levels above 10 µg/m^3, whereas the figure for the primary smelter would be significantly higher.

Reducing the workplace concentration by better LEV

In large installations such as copper smelters reducing the workplace exposure is closely linked to reducing the diffuse emission from the installations. The diffuse emissions are emissions released through openings below the roofs, through windows and gable openings, etc. Major sources of diffuse emission are the secondary emissions which are emissions escaping from the furnace lining or during operations such as charging or tapping. Such emissions may be captured with a hood or enclosure. Some examples of successful reduction of diffuse emissions from copper smelters are described in the BAT reference document for the non-ferrous industry (JRC, 2017).

The specific sites already have implemented various systems for reducing diffuse emissions (JRC, 2017):

At one site, the loading and tapping sections of the shaft furnace, the holding furnace, the converter and the anode furnace are equipped with ventilation systems for fume collection and centralised cleaning in a bag filter.

Another site is equipped with ventilation system in the loading and tapping section supplemented with secondary hoods with bag filter.

At the third site, the tapholes are equipped with capture hoods, launders are covered and the ladle is placed in a housing with a hood. The diffuse emissions produced during tapping are captured and treated for SO_2 and dust removal in a common secondary gas-cleaning system (wet scrubber and bag filter). Roof extraction captures residual fugitive emissions and directs them to the gas-cleaning system

At one of the sites, investment costs of about EUR 1.7 million were reported for improving the collection of fugitive emissions in the smelter. This included improvements to the hoods at the furnace area, closing the ladle tunnels with metal barriers during tapping, and the installation of a three-stage converter secondary hoods system. The capture of secondary gases during converter charging, skimming or metal pouring is ensured by a secondary hood system at each converter.

From the description, the sites seem to be equipped with systems similar to those used in many other smelters and it is estimated that additional LEV would not be required at all sites. At one site, however, very high exposure levels have been reported in the stakeholder consultation. One site has answered that tertiary fume collection would not be possible within the existing building. Another smelter replied that it cannot be excluded that additional LEV would be needed.

Improving the LEV for larger smelters implies typically investments in the €5-10 million range. One of the technologies used as a supplement to existing primary and secondary hoods is the "house-in-house" concept (tertiary fume collection). The concept can be applied to existing installations if the space inside the building allows for it. The units (holding furnace, converters and casting facilities), installed inside closed production buildings are not only provided with capture hoods, but are additionally accommodated in (sealed) enclosures which are vented to a filter system. Capital expenditure for the 'house-in-house' system was reported as up to EUR 6 million (JRC, 2107).

Whereas the installation of the fume collection systems reduces diffuse emissions of arsenic to the surroundings, it does not necessarily reduce the exposure of workers in workplaces with the highest exposures, i.e. the tapping area of flash furnaces or exposure during various maintenance work. Even smelters, which have done large investments in order to reduce diffuse emission, still report considerably high workplace concentrations in certain areas. Furthermore, some measures for reduction of diffuse emission to the environment, e.g. storage of raw materials inside a building may in fact increase the workplace concentrations.

In the absence of actual data on the need for further LEV, it is roughly estimated that one of the smelters may need to invest in better LEV (partial enclosure) in order to meet the 10 µg/m^3 level. The CAPEX (using the general costs levels for the studies under this contract) are estimated at €1.4 million (considering an average of 145 exposure workers per site). The uncertainty is very high, one the one hand it cannot be excluded that the installation of additional LEV could actually be dispensable in any of the companies, one the other hand it is also possible that significant investments would be needed in one or more of the smelters.

Monitoring programmes

Monitoring in the smelters consists of monitoring of arsenic in the workplace and biological monitoring as part of the health surveillance programmes. Health surveillance is required by the CMD independently of the OELVs. As compliance with the OELs in many workplaces cannot be obtained without the use of RPE, results of the biological monitoring is to some extent used to monitor if the RPE and other PPE provide sufficient protection and if workers use the equipment properly. If the companies are to comply with lower OELs for inorganic arsenic compounds including arsenic acid and its salts, they may likely improve the biomonitoring programmes with regard to these compounds. In one smelter it was specified that the costs of analysis of arsenic (excluding sampling, as the samples were analysed for other substances as well) in the biological samples was €20,000/year. Even the number of biological samples may increase it is expected that the costs of the health surveillance programme cannot be considered a cost of compliance with the OELV.

It is expected that all three companies would have to reduce exposures and would need to re-measure to demonstrate compliance with the new OELV. The three companies already have to comply with national OELs and take some samples, but with a significantly lower OEL the requirements for monitoring is expected to increase. Smelters that have to comply with an OEL of 10 µg/m^3 or lower experience that regular monitoring of workplace concentrations is required in combination with biomonitoring programmes. The number of required samples differs significantly; some smelters have provided results of hundreds of samples whereas others have to provide quite few. Some smelters have regular monitoring programmes whereas others only re-measure concentrations when process changes have been introduced.

For the present cost assessment it will be assumed that the companies on average take 20 samples to assess the workplace concentration (more in the larger company and less in the small). The planning and sampling is done in accordance with national guidelines making reference to the European standards EN 482:2012+A1:2015 ISO 15202. The costs are based on a salary of an EHS consultant undertaking planning and sampling and the costs of analyses of the inorganic arsenic compounds. The details of the model used under this contract are shown in the methodology report. The monitoring costs vary by the salaries in the MS The costs for 5 indicator MS are shown in Table 5-4.

The data for Denmark will be used for the company in Austria whereas the figure for Poland will be used for Slovakia and Bulgaria.

Table 5-4: Estimated cost of a monitoring campaign for inorganic arsenic compounds including arsenic acid and its salts, 20 samples

Member State	Cost per company
Denmark	€13,820
UK	€11,789
Latvia	€5,026
Poland	€5,650
Slovenia	€6,898

Source: RPA/COWI

It will be assumed that the monitoring programme has to be repeated from time to time when process changes are introduced or if the biological monitoring indicates changes in the exposure concentrations. This is calculated as an OPEX of 25% of CAPEX.

RPE

Due to the nature of the exposure sources in copper plants, RPE is required in many workplaces because the exposure concentration cannot be sufficiently reduced by other measures. Furthermore, workers move during the day from low to high exposure situations, so efficient RPE have to be available to most of the exposed workers. One site has, however, answered that three levels of RPE are used dependent on the exposure concentration. The current trend in smelters is to use powered helmets/ full face masks which are more convenient to wear than traditional filter masks as it is easier to breath. Furthermore, these masks have a higher efficiency than traditional filter masks. This equipment is used in both high and low exposure situations where RPE is required.

It varies between sites whether the powered helmets or full face mask are cleaned and maintained by the individual workers or by maintenance departments cleaning the equipment on a daily basis. It will be assumed that the affected companies would be able to comply with an OEL of 25 µg/m^3 with the use of more simple HEPA filters as the workers would not need to wear masks so often, whereas powered helmets/ full face masks would be required to reach 10 µg/m^3.

It will be assumed that powered helmets or full face mask should be available to most of the exposed workers. The price of a mask is approximately €1000 and lasts for 3 year and the OPEX is set at 30% of CAPEX. This OPEX is in accordance with data from one primary smelter, whereas the costs if the equipment is washed and controlled every day by a special department (as done in at least one smelter) would be significantly higher.

Organisational measures

Among the RMMs mentioned by companies complying with 10 µg/m^3 are a number of organisational measures (see section 3.6.3): cleaning routines, procedures to reduce/limit dust formation, entrance control and restricted areas, hygiene routines, rotation, and clean cloth service. Furthermore, training would be needed. The experience from two of the sites with demonstrated declining trend in urinary arsenic concentrations as shown in section 3.4.13, is that a combination of many measures is necessary in order to reduce exposure to arsenic to an acceptable level. The three concerned companies already have organisational measures to reduce the exposure to arsenic and other pollutants and this will be taken into account. It is be expected that additional measures have to be implemented in all three companies in order to comply with an OELV of 10 µg/m^3, and less would be necessary to comply with 25 µg/m^3.

Costs estimates

The costs of various measures used for the assessments under this contract are listed in Table 3-39.

The costs have been adjusted to an average number of exposed workers per company of 150 (except for organisational where the figure for 75 exposed workers is used to take into account that some measures are already implemented). At an OELV of 50 µg/m^3, no costs are expected as the primary smelter already has to comply with an OEL at this level, while the exposure levels in secondary smelters are estimated to be below this level.

Table 5-5: Considered RMMs for the copper sector

RMM	CAPEX	Life span year	OPEX	No of companies at		
				10 µg/m^3	25 µg/m^3	50 µg/m^3
Partial or full enclosure to capture e.g. diffuse emissions from the furnaces and casting wheel, secondary huts or house-in-house	€1,400,000	20	10%	1		
RPE 3a: Powered helmets or full face mask	€100,000	3	30% of CAPEX	3	1	
RPE 3: HEPA filter	€11,000	Mask: 1 month, Filter: 1 month	50% of CAPEX		2	
Organisational measures	€75,000	-	50% of CAPEX	3	2	
Monitoring programs (excl. biomonitoring)	€9.205	-	25% of CAPEX	3	3	

Source: RPA/COWI; CAPEX/OPEX based on general cost model

Based on these assumptions, the total costs to the copper sector is estimated at €13,250,000 as shown in the table below.

Table 5-6: Sum of compliance costs for the copper sector for the reference OELVs (PV CAPEX and OPEX over 60 years)

RMM	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
Partial or full enclosure to capture e.g. diffuse emissions from the furnaces and casting wheel, secondary huts or house-in-house	€5,625,000	0	0	0
RPE 3a: Powered helmets or full face mask	€4,563,000	€1,521,000	0	0
RPE 3: HEPA filter	0	€281,000	€140,000	0
Organisational measures	€2,872,000	€1,915,000	0	0
Monitoring programs (excl. biomonitoring)	€190,000	€190,000	0	0
Total for the copper sector	€13,250,000	€3,907,000	€140,000	

Source: RPA/COWI on basis on information provided above the table

5.3.3 Compliance and administrative costs for other sectors

In none of the other sectors, contacted stakeholders have specifically pointed at applications where compliance with the lowest of the assessed OELV levels would be a challenge.

Domestic glass production

As mentioned elsewhere, the use of arsenic in the glass production in the Veneto region of Italy, from where data are available in the literature, has stopped. However, it is assumed that some use of the substance could still continue in MS or regions where it is not considered that authorisations would be required (as it is not for special glass). Domestic glass is according to the website of GlassAlliance Europe manufactured by more than 300 facilities, mainly SMEs, which are spread throughout Europe.[32] The sector association European Domestic Glass (EGD) indicates the number of European manufacturers of domestic glassware to be below 50 (EGD, 2017) and the total number of employees at 35,000. As mentioned elsewhere none of the members of the EGD use diarsenic trioxide today.

The potential users of arsenic trioxide are expected to be small companies producing artistic glass. As indicated in section 3.4.2, in 2014 300 companies were producing glass in Murano area. Of these, 104 companies were producing artistic glass and 18 of these were using arsenic trioxide in 2014. As indicated by ECHA (2010), diarsenic trioxide was also used in other parts of Italy than the Murano area. According to the Craftworkers' Federation of the Murano area, fake "Murano" glass from China and Eastern Europe made up between 40% and 45% of total sales in 2012.[33] Other types of artistic glass are produced in other parts of the EU, but it is not known if arsenic substances are used.

It has for this assessment been assumed that 10 (0-20) small companies with a total of 100 workers could still be using the diarsenic trioxide in MS which have national OELs at a higher level than the OELVs assessed here.

The exposure levels could be reduced by implementation of better LEVs and use of RPE, but it is considered more likely that the companies would phase out the use of diarsenic trioxide. From the phase

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[32] http://www.glassallianceeurope.eu/en/main-glass-sectors

[33] https://www.theguardian.com/world/2012/jan/30/italy-murano-glassmaking-industry-imitations

out process in Italy, much experience exists on the applicability of alternatives by Italian knowledge centre. Trouth (2014, 2017) described different alternatives and experience from the phase-out process. It is mentioned that some companies are using alternative chemicals, others have found a way to adjust their process so they do not need to use arsenic trioxide – the quality of the glass is a bit different, but considered acceptable. Others have stopped producing the type of glass for which arsenic trioxide was used. The cost of alternative fining agents does not seem to be more expensive than diarsenic trioxide. No information on costs of R&D per company is available. Polci (2017) reports that the substitution was supported by a government-funded research of €264,000 euros. It is reported that a clear picture of losses to the companies is not available due to different production capacity, type of glass produced, market, etc. Increased energy consumption by use of alternatives (+20% costs to reach higher temperatures in melting raw materials) is reported together with costs of R&D for alternatives (actual costs not reported). For one glass type no alternatives were available and the production had to cease. To have an indication of to what extent the costs for the sector could contribute to total cost estimates, it is roughly assumed that the R&D costs of each of the remaining uses would be on average €100,000.

Power plants

Very high levels of exposure to inorganic arsenic substances have been reported from a power plant in Slovakia in the late 1990's by maintenance work. The power plant was using lignite with a very high arsenic content resulting in fly ash with high arsenic content. It has not been confirmed that similar high levels are reached in other power plants. The reported arsenic emission from the power plant to the air (few percent of arsenic in the coal) is still high, but not outstanding compared to several other power plants in the area and to oil-shale power plants in Estonia. Furthermore, the arsenic levels in the coal are not outstanding compared to high-arsenic coals e.g. reported from the Czech Republic and other MS. Workers involved in maintenance and cleaning work in the boilers and electrostatic precipitators would inevitably be exposed to arsenic in the dust, but the actual levels as compared with the reported levels in the literature are still uncertain.

In the absence of more information it will be assumed that better RPE would be needed in some power plants in order to comply with at least the OELV of 10 µg/m^3. The table below indicates the number of power plants in MS with no OELs or higher OELs than the OELVs assessed. It has been reported that high arsenic coals are especially used in Slovakia and Czech Republic, and E-PRTR data indicates that oil shale used in Estonia may also have relatively high arsenic content.

In order to have a first indication of possible costs, it is roughly assumed that 10 power plants using high-arsenic coals would have to measure the actual exposure levels during maintenance works if an OELV at 10 or 25 µg/m^3 is established (it is assumed that the workers in any case wear some RPE). The costs of monitoring is set at €3.100 for 10 samples using the model described for copper above and the estimate for Poland as indicator. It is in the scenario assumed that half of the plants subsequently would need to improve the RPE used to powered helmets or full face masks for an average of 10 workers (the cleaners exposed at the highest levels). The CAPEX per plant would be €10,000 and the OPEX set at 30% of OPEX. The extra costs of training are assumed to be negligible. For an OELV at 50 the number of plants is reduced to 6 (excluding the plants in Estonia).

Table 5-7: Coal and oil-shale power plants by MS

MS	OEL, µg/m³ ***	Number reporting on As in E-PRTR *	Total number of coal and oil-shale power plants**
Czech Republic	100	13	45
Estonia	30	4	4
France	200	2	4
Greece	100	4	6
Italy	-	4	12
Malta	-	1	1
Portugal	-	4	2
Slovakia	100	1	6
Total		33	80

*Source: http://prtr.ec.europa.eu/#/home

** Source: Number of coal power plants as reported by http://www.coalmap.eu

**** OELs derived from Table 3-1*

Mining

The majority of copper mining and copper concentrate production as well as virtually all zinc and lead mining activities in the EU is undertaken in MS with an OELV at 10 µg/m³. As described in section 3.4.11, copper concentrates are produced at 5 sites in Bulgaria with an OELV of 50 µg/m³, and an insignificant amount is mined in Slovakia. The arsenic content of the concentrates, at least for some of the sites in Bulgaria, is very high compared to the world average. The number of workers involved in various sampling and maintenance works with high exposure to arsenic is in the absence of actual data set at 20-60 per site; 40 will be used for the calculations. For comparison, the average number of workers exposed by raw materials handling and control in four primary copper smelters was about 95, the lowest number in one smelter was 40. In order to have a first indication of possible costs, it is roughly assumed that 5 copper concentrate producers would have to measure the actual exposure levels during maintenance works if an OELV at 10 or 25 µg/m³ is established. The costs of monitoring is set at €3.100 for 10 samples per site using the model described for copper above and the cost estimate for Poland as indicator. It is in the scenario assumed that three of the plants subsequently would need to improve RPE to powered helmets or full face masks for an average of 10 workers (the cleaners exposed at the highest levels) at the costs indicated above.

Pig-iron production

As mentioned, most likely exposure to higher concentrations could take place by maintenance of the arsenic removal plant and by handling the filter cake. Furthermore, maintenance and cleaning works on electrostatic precipitators and bag filters on sinter plants, pelletisation plants and blast furnaces may likely lead to some exposure to arsenic as has been demonstrated by maintenance of similar filters in some coal power plants.

The number of sinter plants and pelletisation plants is 40; of these 15 in MS with no OEL or an OEL above 10 µg/m³. The MS are Austria, Czech Republic, France, Slovakia and the UK. Sinter and pelletisation plants are part of integrated steelworks which are typically large enterprises.

In order to have a first indication of possible costs, it is roughly assumed that the 15 copper concentrate producers would have to measure the actual exposure levels during maintenance works if an OELV at 10 or 25 µg/m³ is established. The costs of monitoring is set at €3.100 for 10 samples using the model described for copper above and the cost estimate for Poland as indicator.

The data for Denmark will be used for the companies in Austria, France and Italy whereas the figure for Poland will be used for Slovakia and the figure for UK for the UK. The total estimated costs of monitoring will be €6,904. It is in the scenario assumed that 10 of the plants subsequently would need to improve RPE to powered helmets or full face masks for an average of 10 workers (the cleaners exposed at the highest levels) at the costs indicated above.

Table 5-8: Sinter plants and pelletisation plants

MS	OEL, µg/m^3 **	Number of sinter plants *	Number of pelletisation plants *
Austria	100	2	
Belgium	10	4	
Czech Republic	100	2	
Finland	10	1	
France	200	5	
Germany	8.3 (indicative)	8	
Hungary	10	2	
Italy	-	2	
Netherlands	2.8 (indicative)	1	1
Poland	10	2	
Slovakia	100	1	
Spain	10	1	
Sweden	10		5
United Kingdom	100	3	
Total		33	80

*Source: JRC, 2013b

***OELs derived from Table 3-1*

Other non-ferrous industry

A large number of workers are exposed to inorganic arsenic compounds in other non-ferrous metal industry, either from the unintentional presence of arsenic in raw materials or compounds formed from arsenic metal by thermal processes. Only a few companies have responded in the stakeholder consultation, and these are mainly member companies of the Arsenic Consortium and handling arsenic compounds in various ways. The companies have responded that they will not be impacted by an OELV at 10 µg/m^3. The companies are unique and no other companies in the EU are undertaking similar processes. The International Lead Association (ILA) has indicated that establishing an OELV may impact some producers and users of lead, but no specific exposure data have been obtained from companies and the available data indicate that the exposure levels are likely to be below 10 µg/m^3. Furthermore, no specific exposure data has been obtained through contact to The Association of European Automotive and Industrial Battery Manufacturers (EUROBAT) and the Association of European Manufacturers of Sporting Ammunition (AFEMS). Concerning the zinc/cadmium sector, the International Zinc Association (IZA) has responded that the exposure levels are generally low (apart from the intentional use of diarsenic trioxide) and companies would not be impacted by establishing the assessed OELVs. No data on arsenic have been obtained from the International Cadmium Association (ICdA), which have provided data for the study on cadmium under this contract. The European Precious Metals Federation (EPMF) provided reference to one company which has refused to provide information.

The lower level of arsenic in other non-ferrous production as compared to the copper sector is furthermore illustrated by the fact that the copper sector accounts for 80% of the total reported arsenic emissions to air reported to the E-PRTR from the production of non-ferrous metals.

Even data are not available, it cannot be excluded that some exposure takes place at levels above the assessed OELVs in some companies, e.g. companies involved in the production of precious or rare metals or involved in recycling of some types of lead alloys with relatively high levels of arsenic.

As the actual activities, locations and size of companies are not known, it will be roughly assumed that total compliance costs for other companies in the nonferrous sector is well below the costs for the copper sector.

5.3.4 Total compliance costs for companies

The total compliance costs are shown below as estimated above.

Table 5-9: Sum of all compliance costs (in addition to the baseline costs) for the reference OELVs (PV CAPEX and OPEX over 60 years)

Sector	5 µg/m³	25 µg/m³	50 µg/m³	Baseline
Copper sector	€13,250,000	€3,907,000	€140,000	€0
Power sector	€792,000	€792,000	€475,000	€0
Domestic glass sector	€1,000,000	€1,000,000	€0	€0
Other nonferrous	€2,411,000	€1,607,000	€482,000	€0
Mining	€472,000	€472,000	€0	€0
Pig iron	€3,252,000	€3,252,000	€487,000	€0
Total across all sectors/companies	€21,176,000	11,029,000	€1,585,000	€0

Source: RPA/COWI on the basis of above section

5.4 OELVs – indirect costs for companies

Indirect costs could include possible ripple effects through the value chain and the potential for costs to be passed on to users further down the value chain or to consumers. No significant indirect costs have been estimated. The direct compliance costs are relatively modest or even low and therefore, no supply chain impacts are expected.

5.5 OELVs – costs for public authorities

The impacts on public authorities, mainly at the national level but in some MS 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 will be a significant cost to national authorities in the MS which already have an OEL for inorganic arsenic compounds defined in accordance with the assessed OELVS.[34] MS

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

where this is not the case may incur a one-off cost for changing their legislation and a recurring cost of increased enforcement. This may concern MS which do not have an OEL for arsenic substances and MS which have an OEL for only some arsenic substances; typically diarsenic trioxide. Thus, although the specific OELV level will determine whether a MS 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 MS.

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 Cost of transposition

Should an OELV 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 MS (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 MS).

Of the 28 EU MS, research carried out for this study has confirmed that 20 MS have an OEL(s) for inorganic arsenic compounds in accordance with the scope of the assessed OELV. There is no information with regard to an OEL for inorganic arsenic substances for the following MS and this study thus assumes that they do not have an OEL for inorganic arsenic substances: Italy, Luxembourg, Malta, and Portugal. Furthermore, the following MS have an OEL for one or more arsenic compounds but not covering the full scope of the assessed OELV: Croatia, France, Slovenia, and probably Latvia (contradictive information). It is thus assumed that these eight MS would incur costs for transposing an OELV introduced under the CMD.

Specific data on the costs of transposition of EU legislation by MS and their relevant departments/ministries are not readily available. As noted in RPA (2012)[35], 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 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 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 MS 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

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[35] 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

assessment in the MS (see, for example, RPA 2015[36]), 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 5-10: Transposition costs

Member States with no OEL covering the full scope of the assessed OELV	Transposition cost per Member State	Total cost across the EU
8 Member States: Italy, Luxembourg, Malta, Portugal, Croatia, France, Slovenia, and probably Latvia	€50,000	€400,000

Source: RPA/COWI

It is assumed that for MS that already have an OEL for inorganic arsenic compounds including arsenic acid and its salts, 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 & sensitivity analysis

5.6.1 Aggregated costs

The total compliance costs (in addition to the baseline costs) are shown below.

Table 5-11: Sum of all costs (in addition to the baseline costs) for the reference OELVs (PV CAPEX and OPEX over 60 years)

Costs	10 µg/m³	25 µg/m³	50 µg/m³	Baseline
Total across all sectors /companies /stakeholders	€21,575,505	€11,428,797	€1,984,756	€0

Source: RPA/COWI

5.6.2 Sensitivity analysis

Copper sector - The assumptions regarding the need for additional LEV and the costs of this are highly uncertain. It should be noted that the need for additional LEV, if the workplace concentration in the smelter should be on a level where no RPE was needed, would be much higher. The need for additional LEV is considered as the necessary measure to reach a similar level of other smelters in the EU

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[36] 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

complying with national OELs at 10 µg/m^3 or lower. It cannot be excluded that none of the three companies would need installation of tertiary fume collection or other additional LEV and that this cost element would be 0. On the other hand, it cannot be excluded that the primary smelter would need to establish some tertiary fume collection, which based on experience from other smelters could be an investment in the magnitude of €6-10 million (which over the 60-years period could results in costs of OPEX and replacement of approximately 6 times this investment). It is reported that it would be difficult to implements such measures in existing buildings and consequently the costs could be even higher. Without specific estimates from the companies it will be difficult to provide a more certain estimate. Regarding costs of better RPE and organisational measures it is considered very likely that the costs will be at the indicated size but with an uncertainty of a factor of 2. The need for LEV for the copper smelters is considered to represent the main uncertainty for the cost estimate.

Domestic glass sector - The current use of diarsenic trioxide for the domestic glass sector has not been confirmed and the estimated costs are sensitive to this assumption. The actual costs may be 0 if the use has ceased in all MS. However, the benefits would also decrease accordingly. As specific information on current workplace concentrations and current RMMs has not been obtained, the costs are estimated with high uncertainty and are considered to represent a worst case estimate.

Other sectors - The actual exposure levels, use of RPE and the number of power companies with high arsenic levels in the other assessed known. Therefore, both the costs and the benefits estimates are highly uncertain, but linked. The costs estimate is based on the assumption that current exposure levels would be below the actual OEL levels in the MS, but that additional measures would be needed in order to comply with an OELV below the national OELs. The estimated costs for these sectors are relatively small compared to the total estimated costs, rendering the total estimated costs not very sensitive to the estimate from these sectors.

It is assumed that additional monitoring will only be required for companies with high exposure levels but it cannot be excluded that many companies with lower exposure level will be requested monitoring to demonstrate that they are actually below the OELV. This may result in higher costs than estimated in this assessment.

Discount rate – The assessment has been done using a constant discount rate at 4% as recommended in the Better Regulation Guidance. The assessment is not very sensitive to using an alternative discount rate profile where the discount rate is reduced to 3% after 20 years. Using the declining discount rate will increase the estimated compliance costs will increase by 5%.

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 of EU business
- Section 6.5: Impact on employment

6.1 Overall impact

The market effects are assessed by comparing the estimated compliance costs to industry key figures such as turnover.

There are several types of industries affected if any alternative OELV for inorganic arsenic compounds including arsenic acid and its salts are introduced. The most significantly affected industry is the copper industry. The table below lists the estimated compliance costs for the copper industry and for other the concerned sectors compared to average turnover values.

Turnover per employee has been estimated at €240,000 per year. While there will be variations across sectors and individual companies, they are not of order of magnitude and therefore, using this average provide a good indication.

The compliance costs per sector, see Table 5-9, has been divided by the number of exposed workers in the companies for which compliance costs have been estimated, see Section 5.3 for more details. This calculation overestimates the cost burden as all the companies have more workers than those exposed. Hence, company turnover is higher compared to the compliance costs than indicated in the table.

Table 6-1: Compliance costs and industry turnover for the reference OELVs (PV CAPEX and OPEX over 60 years)

	10 µg/m^3		25 µg/m^3		50 µg/m^3	
	Cost/worker	% of turnover	Cost/worker	% of turnover	Cost/worker	% of turnover
Copper sector	€29,400	0.52%	€8,700	0.15%	€300	0.01%
Power sector	€2,900	0.05%	€2,900	0.05%	€1,700	0.03%
Glass sector	€10,000	0.18%	€10,000	0.18%	-	0.00%
Other nonferrous	€12,100	0.21%	€8,000	0.14%	€2,400	0.04%
Mining	€2,400	0.04%	€2,400	0.04%	-	0.00%
Pig iron	€21,700	0.38%	€21,700	0.38%	€3,200	0.06%
All	€15,400	0.27%	€8,000	0.14%	€1,200	0.02%
Turnover/worker/year	€0.24 million					
PV turnover (60 years)	€5.6 million					

Note: Turnover per employee is an estimated figure. Source: RPA/COWI

The table illustrates the limited economic impacts of the reference OELVs. The estimated compliance costs are below 0.5% for all cases. Though even relative small compliance costs could have impacts on the operation of the affected business, the estimated costs for compliance with OELVs are very small. The most affected sector is the copper sector where compliance costs for the OELV of 10 µg/m³ could be around 0.5% of the turnover. For the other sectors the relative cost increase is less.

The highest impacts would be in first year with relative high investment costs that need to be financed. Comparing the compliance costs (first year CAPEX and OPEX) per exposed worker in the copper sector with that annual turnover leads an impact of 5% of turnover. While this could be challenging in case the affected company would have limited accessed to finance, it is still considered manageable.

In the next sections, the different types of market impacts are discussed, but they are all assessed to be low or insignificant.

6.2 Research and innovation

Research and development are key activities in developing an industry's capacity to develop new and existing products and produce these. In 2016, Eurostat reported that expenditure in the EU on R&D was approximately €300 billion in 2015, representing 2.03% of GDP.

Better Regulation Tool #21 indicates that "All compliance costs divert resources from other purposes, potentially including research and innovation."

The effect on R&D is assessed to be low. Overall, the estimated compliance costs comprise only a very limited share of industry turnover, see Table 6-1. They also comprise a small share of industry R&D expenditure. Based on data from Eurometaux, the total annual turnover per employee can be estimated at €240,000. Over a 60 year period and for the about 10,000 workers exposed, the net present value of the turnover would be €56 billion. Assuming that R&D expenditure would amount to 2% of turnover, the R&D expenditure would be about €1 billion. The total estimated compliance costs for the case of the OELV at 10 µg/m³ is 15 million in present value over 60 years. It means that the compliance costs amount to 1.5% of the R&D costs. Hence, no significant impact on the level of R&D is expected.

Also, the effect on research and innovation regarding reduced arsenic in the work environment is assessed to be limited. In most of the sectors, the current level of arsenic concentrations are below assessed OELVs. Hence, there will be a limited or no incentive to the further research for improved processes that can reduce the emissions of arsenic in the work environment.

6.3 Single market

The below discussion on the single market effects address primarily the copper sector. For the other sectors, the cost impacts are lower as illustrated in Table 6-1. For example, the power sector is not characterised by international competition and it will generally be possible for any affected coal fired power plant to pass on the cost to the electricity consumers. Again, these costs are very insignificant. For other affected sectors, the cost impact are even lower as the workers are exposed at lower concentrations, see Table 3-52. Therefore, no single market impacts are expected on any of these other sectors where inorganic arsenic compounds including arsenic acid and its salts are present in the occupational environment.

6.3.1 Competition

The impacts of introducing alternative OELVs on competition in the copper sector are estimated to be relatively modest based on the comparison of the estimated compliance costs to the turnover of the industry. As discussed above, see Section 6.1, the average turnover in the non-ferrous metal industry can be calculated as €240,000 per employee. Over the 60 year assessment period, the turnover per employee is about €5.6 million. The compliance costs over the 60 year assessment period has been estimated at €13 million. There are about 450 exposed workers in companies that need to undertake compliance measures so the cost per exposed worker amounts to about €29,000. It means that the compliance costs over the assessment period amount to 0.5% of turnover.

The below table includes a number screening questions of the competition impacts. The table illustrates the very limited impacts that the proposed OELs could have on competition.

Table 6-2: Screening of Competition Impacts

Impacts	Key questions	Yes/No
Existing firms	Additional costs?	Yes. Costs of RMMs to meet OELs (some capital, some ongoing e.g. PPE)
	Scale of costs significant?	No, overall compliance costs are very low. There could be a few companies that need to invest in the first year, but still limited impact.
	Old firms affected more than new?	Unlikely
	Location influences?	No. OELs will apply the same, irrespective of location
	Some firms will exit the market?	Unlikely Through the use of PPE all the affected plants can achieve compliance.
	Are competitors limited in growth potential?	No, assuming they can meet the OELs
	Increased collusion likely?	Unknown
New entrants	Restrict entry?	The copper smelting and processing industry is characterised by large companies and new entrants are not likely, but the level of OELs has no or limited impacts in entry decision. For coal-fired power plants, the level of OEL has no impact on new investment decisions.
Prices	Increased prices for consumers	Unlikely. Though increased production costs for copper, the industry is global so very limited impact on prices. For power plants other factors affect prices.
Non-price impacts	Product quality/variety affected?	No.
	Impact on innovation	No or very limited. Higher production costs at most affected copper production sites might lead less financial resources for innovation.
Upstream and downstream market	Will OELs affect vertically integrated companies more or less than non-integrated ones?	No.
	Will OELs encourage greater integration and market barriers?	No.
	Will OELs affect bargaining power of buyers or suppliers?	No.

Source: RPA/COWI

Overall, the copper industry is global and competition is global; see also the discussion on the markets in Section 3.11.2. The LEVs considered in this study will only affect a few production sites. It will not affect the level of competition, see also below under the "Internal market" effects.

For other sectors, impacts of the proposed OELVs have been considered for coal-fired power plants. This is only relevant in a few MS, where there could impacts due to natural occurrence of arsenic in the used coal. The power sector is generally a regulated sector, though there is a market for producers. The possible additional costs are insignificant compared to the overall production costs.

6.3.2 Consumers

As there is not going to be any impact on the level of competition, there is not going to be any follow-on effect on prices of products that include copper. For the consumers no impacts are expected. The same is the case for the power sector.

6.3.3 Internal market

Overall, introducing OELs in the CMD means that companies in all MS will face the same requirement. This will therefore make competition more even across EU MS. Given the relatively modest compliance costs that have been estimated, this effect is limited. The majority of affected companies in the copper sector operate production sites in several Member States. They will now have to relate to only one OEL and therefore, they could the same technologies and internal procedures across all their sites. It is not possible to estimate the monetary values of this benefit.

6.4 Competitiveness of EU businesses

6.4.1 Cost competitiveness

The estimated compliance costs amount to 0.5% of turnover for the copper industry and between 0.04% and 0.38% for the other industries facing compliance costs. These values are for the OELV A of 10 µg/m³. These levels of additional costs mean that the impacts on cost competitiveness is very limited.

6.4.2 Capacity to innovate

As above, there is no significant impact on the industries' ability and capacity to innovate.

6.4.3 International competitiveness

The copper industry is global. The competitiveness of the EU industry is discussed in Section 3.11.2. Different studies have pointed to opposite conclusions regarding the competitive strength of the European industry. While any increase in production costs weakens its position, the estimated compliance costs are so low that they will not have any major impact.

6.5 Employment

The level of employment in the affected industries is not estimated to change. Hence, there are no employment impacts.

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: Humans via the environment
- Section 7.5: Conclusion

7.1 PBT screening

Arsenic acid and its salts as a group (as representative for other arsenic compounds included in this report) are very toxic to environmental organisms (Classification: H400, H410). The classification of some arsenic compounds may deviate (e.g. no substance-specific classification entry at all, or heterogeneous self-classification by different notifiers in the absence of harmonised classification), but classification H400/H410 is used to assess the environmental effects of the bulk of arsenicals of concern.

The aquatic and terrestrial PNEC (Predicted no-effect concentration) of arsenic acid were derived to 1 µg/L (assessment factor 10) and 95 µg/kg soil dry weight (equilibrium partitioning method), respectively. Arsenic trioxide is less toxic, with a PNEC of 17.1 µg/L for the aquatic environment and 700 µg/kg in soils (ECHA Dissemination, 2017, as of November 2017).

Dependent on the oxygen content (oxidative or reductive medium), arsenic is present in the environment in oxidation state III or V, and redox-reactions may occur. Some arsenic compounds tend to adsorb to soil, but leaching is possible. As (III) species are more toxic and bioactive than As (V), both because of the greater chemical reactivity of As (III), and also because As (III) enters cells more easily. The critical toxic mechanism of As (III) is the binding to sulfhydryl groups of e.g. proteins, whereas As (V) affects oxidative phosphorylation by competing with phosphate groups. Environmental toxicity varies dependent on e.g. pH, organic matter content, phosphate concentration and the extent of adsorption. Arsenic may also be methylated in organisms to organoarsenicals, being less toxic than inorganic arsenic. Marine organisms accumulate arsenic after biotransformation to arsenosugars, arsenocholine or arsenobetaine, e.g. in fish and crustaceans in concentrations up to > 100 mg/kg. These organic arsenic compounds seem not to be converted to inorganic arsenic in vivo as they are eliminated unchanged from the body (IARC, 2012; WHO, 2001). Therefore, arsenic in form of arsenobetaine and arsenocholine from fish and sea food consumption is not considered to represent a significant health risk.

As arsenic is continually cycled through all environmental compartments, it is considered to be persistent (**P**). Bioaccumulation of inorganic arsenicals is not considered relevant, as the bioconcentration factors are in general below 100 (ECHA, 2017b; WHO, 2001). Therefore the arsenic compounds of concern are not regarded as bioaccumulative (**B**).

7.2 Current environmental levels in relation to hazard data

It is evident from the data summarised above that environmental concentrations are close to and partially exceed the PNECs of sensitive organisms. WHO (2001) stated that 'if levels of arsenate are high enough, only species which exhibit resistance may be present'.

7.3 Current environmental exposure – sources and impact

Remote and rural air concentrations are in a range of 0.02 to 4 ng/m^3, in urban air they range from 3 to 200 ng/m^3, and may reach and exceed 1 µg/m^3 in the vicinity of industrial sources. Concentrations in sea water are 1-2 µg/L, in rivers and lakes in general below 10 µg/L, and up to 5 mg/L near anthropogenic sources. Groundwater levels are about 1-2 µg/L, except in areas with geogenic deposits of arsenic ores, where concentrations raise up to 3 mg/L. The sediment burden ranges from 5 mg/kg up to 3000 mg/kg in contaminated areas. Background soil levels are 1-40 mg/kg, but are elevated if arsenic ores are naturally present (WHO, 2001; 2011). These values were basically confirmed by data provided in ATSDR (2016), including more recent publications.

Currently there are no EU wide thresholds for arsenic in fertilizers. In Germany, a limit concentration of 40 mg As/kg fertilizer dry weight is in place (BMJV, 2012/2017).

A possible increase of arsenic emissions due to lower occupational limit values (more effective exhaust systems) would impact mostly environmental emissions to ambient air. According to the data provided in the European Pollutant Release and Transfer Register (E-PRTR) for the EU28 states, the main source of air emissions of arsenic and compounds is from power plants (fuel combustion), amounting to about 20-25 t/year in former years; in 2015 it was 16.4 t/year for the EU28.

The predominant industrial sources are production and processing of metals as well as mineral industry with emissions into air decreasing from 22 t/year in 2007 to about 6.2 t/year in 2015. As the total release to air including all sources was 23.1 t/year in 2015, the percentage of arsenic industry amounts to about 6.2/23.1 = 27% of total air emissions in 2015.

As consequence of Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004, an European target value of 6 ng/m^3 as yearly average was implemented in 2013. Based on the background data, this is already frequently exceeded in urban air.

According to TA Luft for Germany (BMU, 2002), arsenic deposition may not exceed a deposition rate of 4 µg/(m^2*d) as yearly average. Arsenic deposition in dust was reported to be decreasing over the years, with the most recent data of 0.97 µg/(m^2*d) (geometric mean) in North Rhine-Westphalia in 2016, with 6 sites out of 126 (5%) exceeding the limit of 4 µg/(m^2*d).

Additionally, the impact of air emissions on concentrations of other environmental media is not quantifiable. Given a ratio of air/water emissions of the arsenic industry of 22.2/12.3 t/year, respectively in 2007 from the E-PRTR database, the air emissions relatively decreased to 6.2/5.5, respectively, in 2015. That means the air emissions predominated 10 years ago, and are roughly equal to the water emissions more recently. This shift indicates a decreasing contribution of air burden to surface water.

The main source of arsenic emissions into water is waste and waste water management. The percentage of the arsenic industry release of total emissions decreased from 22% in 2007 to 6% in 2015, i.e. it is negligible compared to total emissions under consideration of the fact that additional emissions due to lower OEL are mainly expected to occur into air.

Releases to soil are in general of minor concern, because they are well below 1 t/year in total since 2007.

Emissions by the arsenic industry relevantly contribute already to date to the total current emissions, and this could, in principle, be increased after the implementation of stricter OEL (assumed that all additional emissions will be released to air without any reduction measures): Assuming as a worst case doubling of current emissions, this would lead (as in 2017) to additional 6.2 t/year release into air.

Thus the percentage of arsenic industry emissions would amount to 6.2 + 6.2/23.1 + 6.2 = 42%, compared to 27% (see above). However, this calculation would be an unrealistic worst-case scenario: arsenic emissions do not originate only from workplace exhaust systems, but the majority of emission is expected from non-ferrous metal smelting processes. Therefore the additional amounts of arsenic emitted by exhaust systems of workplaces should be in fact relevantly lower.

7.4 Humans via the environment

When establishing limit values for drinking water, it has been observed that natural background in some areas already exceeds the derived target concentration. Because of this potentially relevant background exposure, drinking water guidance values have been set to higher levels. This indicates concern for “humans via the environment” with respect to arsenic compounds.

7.5 Conclusion

Considering

- the probable PT (not B) properties of arsenic,
- the environmental exposure/PNEC ratio close to or even exceeding 1,
- the moderate contribution of industrial air emissions to the total emission and
- a widespread human exposure via the environment,

the environmental impact of inorganic arsenic compounds including arsenic acid and its salts is regarded as “significant”, but not as “substantial”.

This characterisation is independent from an additional potential environmental impact from changes of the OEL. However, quantitative calculation of an environmental impact due to OEL changes is not feasible. Qualitatively, it is expected that this impact is minor and does not modify the overall assessment result for inorganic arsenic compounds including arsenic acid and its salts.

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 are summarised below for the different reference OELVs. The benefits are mainly the reduced production loss when the number of workers being absent due to the peripheral neuropathy is reduced. This effect is very uncertain as there is no information about the severity of the symptoms and possible number of workdays where the workers are sick.

Table 8-1: Comparison of the costs and benefits to EMPLOYERS (PV over 60 years, reference OELVs vs baseline)

Reference point (inhalable)	*10 µg/m3*	*25 µg/m3*	*50 µg/m3*	Baseline
Benefits – constant workforce	€2,848,000	€2,318,000	€1,943,000	€0
Costs	€21,176,000	€11,029,000	€1,585,000	€0

Source: RPA/COWI based on data presented in chapter 5

8.2 SMEs

While a few of the affected production sites/companies in the copper sector are relatively small, they are owned by larger companies and therefore they might not be formally SMEs. It means that they are likely to have access to technical expertise and financial resources that will ease the compliance with the considered OELVs. Even for SMEs, the estimated compliance costs are very low. For the majority of affected companies, the measures needed to achieve compliance are RPEs and therefore, the costs are more of less proportional to the number of workers. The most affected sector, the copper sector mainly includes larger companies, but there is at least one affected SMEs. It might be facing a relatively higher cost burden.

Overall, there is no indication of significant issues for SMEs in any of the affected sectors.

8.3 Workers

The costs and benefits for workers and their families are summarised below for the different reference OELVs. The benefits to workers and their families are the avoided cases of ill health and therefore the main benefits of the assessed OELVs for inorganic arsenic compounds. The largest share of the benefits are related to the non-cancer health endpoint of peripheral neuropathy. As discussed, the benefit section, this estimate is uncertain due to limited data on the effects of peripheral neuropathy.

Table 8-2: Comparison of the costs and benefits to WORKERS & THEIR FAMILIES (PV over 60 years, reference OELVs vs baseline)

Reference point (inhalable)	*10 µg/m3*	*25 µg/m3*	*50 µg/m3*	Baseline
Method 1 (VSL, VSM)				
M1 Benefits – constant workforce	€21,835,000	€17,057,000	€14,013,000	€0
Method 2 (Monetised DALYs)				
M2 Benefits – constant workforce	€20,918,000	€16,569,000	€13,705,000	€0
Costs				
Costs	€0	€0	€0	€0

Source: RPA/COWI based on data presented in chapter 5.

8.4 Consumers

No significant impacts on consumers have been identified.

8.5 Taxpayers/public authorities

The costs and benefits for the public sector are summarised below for the different reference OELVs.

Table 8-3: Comparison of the costs and benefits to the PUBLIC SECTOR (PV over 60 years, reference OELVs vs. baseline)

Reference point (inhalable)	*5 µg/m3*	*10 µg/m3*	*25 µg/m3*	Baseline
Benefits – constant workforce	€1,307,000	€1,057,000	€883,000	€0
Costs	€400,000	€400,000	€400,000	€0

Source: RPA/COWI based on data presented in chapter 5.

8.6 Specific Member States/regions

MS national limits

OELs already exist in many MS, but these differ from MS to MS. Table 3-1 in Section 3.2 of this report sets out the OELs in force in the MS[37] and it can be seen that a number of MS already have equivalent or lower OELs in place than those being proposed. The table below summarises the information on national OELs for inorganic arsenic compounds including arsenic acid and its salts and lists MS having a higher national OEL at each proposed OELV. The list MS would be impacted by the introduction of each specific OEL.

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

Table 8-4: MS with OELs higher than assessed OELVs

OELV µg/m³	Member States where current limits are higher or the MS does not have an OEL covering the compounds within the scope	% of MS above reference OELV or without OEL	Notes regarding national limits
10	AT, BG, HR, CZ, EE, FR, EL, HU**, IT, LT, LU, MT, PT, SK, SI, UK	57%	
25	AT, BG, HR, CZ, EE, FR, EL, HU**, IT, LT, LU, MT, PT, SK, SI, UK	57%	
50	AT, HR, CZ, FR, EL, HU**, IT, LU, MT, PT, SK, SI***, UK	46%	Hungary has separate OELs for As_2O_5 and As_2O_3 at 30 and 100 µg/m³, respectively, whereas it is 10 µg/m³ for other inorganic arsenic compounds

Notes: Denmark has for calcium arsenate an OEL at 1,000 µg/m³. As no intentional use of calcium arsenate in Denmark has been identified it is estimated that establishing an OEL at the assessed levels in Denmark would not have any impact.

Source: Based in Table 3.1

8.7 Different timeframes for costs and benefits

Typically, the benefits only occur with some time lag. However, for the peripheral neuropathy health endpoint, benefits are likely to be seen also in the short term. Overall, there is no large difference in the timeframes for costs and benefits related to the introduction of an OELV for inorganic arsenic compounds including arsenic acid and its salts. The cost-benefit assessment presented in next section takes the differences in time frames into account and presents comparable benefits and costs.

9 Conclusions

This section comprises the following subsections:

- Section 9.1: Cost-benefit assessment (CBA)
- Section 9.2: Multi-criteria analysis (MCA)

9.1 Cost-benefit assessment (CBA)

The results of the cost-benefits assessment is shown below.

The establishment of OELVs at three levels has been assessed:

- OELV A: 10 µg/m^3,
- OELV B: 25 µg/m^3, and
- OELV C: 50 µg/m^3.

9.1.1 Overview of the costs and benefits of the reference OELVs

Reference OELV A: 10 µg/m^3

The costs and benefits estimated in this report for Reference OELV A: 10 µg/m^3 are summarised in Table 9-1 and Table 9-2, respectively.

Table 9-1: Overview of the benefits (reference OELV A: 10 µg/m^3)

Description	Amount for 60 year with a static discount rate	Comments
Direct benefits		
Reduced number of cancer cases	€54,000	Benefits to workers and their families, public sector and employers
Reduced number of peripheral neuropathy cases	€568,000	
Total	€622,000	
Indirect benefits		
Reduced number of cancer cases	€3,000	Benefits to public sector and employers
Reduced number of peripheral neuropathy cases	€3,543,000	
Total	€3,546,000	
Intangible benefits*		
Reduced number of cancer cases	€2,622,000	Benefits to workers and their families
Reduced number of peripheral neuropathy cases	€19,200,000	
Total	€21,822,000	
*Intangible-WTP VSL (method 1)		

Table 9-2: Overview of the costs (Reference OELV A: 10 µg/m^3)

		Citizens/consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Direct costs	≈ €0	≈ €0	€10,978,195	€10,197,310	€400,000	≈ €0

Table 9-2: Overview of the costs (Reference OELV A: 10 μg/m^3)

		Citizens/consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Indirect costs	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0

Reference OELV B: 25 μg/m^3

The costs and benefits estimated in this report for Reference OELV B: 25 μg/m^3 are summarised in Table 9-3 and Table 9-4, respectively.

Table 9-3: Overview of the benefits (reference OELV B: 25 μg/m^3)

Description	Amount for 60 year with a static discount rate	Comments
Direct benefits		
Reduced number of cancer cases	€29,000	Benefits to workers and their families, public sector and employers
Reduced number of peripheral neuropathy cases	€463,000	
Total	€492,000	
Indirect benefits		
Reduced number of cancer cases	€2,000	Benefits to public sector and employers
Reduced number of peripheral neuropathy cases	€2,888,000	
Total	€2,890,000	
Intangible benefits*		
Reduced number of cancer cases	€1,396,000	Benefits to workers and their families
Reduced number of peripheral neuropathy cases	€15,654,000	
Total	€17,050,000	
*Intangible-WTP VSL (method 1)		

Table 9-4: Overview of the costs (Reference OELV B: 25 μg/m^3)

		Citizens/consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct costs	≈ €0	≈ €0	€6,631,000	€4,398,000	€400,000	≈ €0
	Indirect costs	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0

Reference OELV C: 50 μg/m^3

The costs and benefits estimated in this report for Reference OELV C: 50 μg/m^3 are summarised in Table 9-5 and Table 9-6, respectively.

Table 9-5: Overview of the benefits (reference OELV C: 50 μg/m^3)

Description	Amount for 60 year with a static discount rate	Comments
Direct benefits		
Reduced number of cancer cases	€18,000	Benefits to workers and their families, public sector and employers
Reduced number of peripheral neuropathy cases	€388,000	
Total	€406,000	

Table 9-5: Overview of the benefits (reference OELV C: 50 µg/m^3)

Description	Amount for 60 year with a static discount rate	Comments
Indirect benefits		
Reduced number of cancer cases	€1,000	Benefits to public sector and employers
Reduced number of peripheral neuropathy cases	€2,422,000	
Total	€2,424,000	
Intangible benefits*		
Reduced number of cancer cases	€880,000	Benefits to workers and their families
Reduced number of peripheral neuropathy cases	€13,129,000	
Total	€14,009,000	

*Intangible-WTP VSL (method 1)

Table 9-6: Overview of the costs (Reference OELV C: 50 µg/m^3)

		Citizens/consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct costs	≈ €0	≈ €0	€961,000	€624,000	€400,000	≈ €0
	Indirect costs	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0	≈ €0

9.1.2 CBA for the reference OELVs

The overall incremental costs and benefits of establishing an OELV at the three different reference levels are shown in Table 9-7 and Figure 9-1.

Table 9-7: Summary of monetised costs and benefits

Reference OELV	PV benefits over 60 years (€2017)*	PV costs over 60 years (€2017)
A: 10 µg/m^3	€25,978,000	€21,576,000
B: 25 µg/m^3	€20,426,000	€11,429,000
C: 50 µg/m^3	€16,835,000	€1,985,000
Monetised costs and benefits	Avoided lung cancer vis-à-vis the baseline Avoided peripheral neuropathy	RMMs Measurements
Significant non-monetised costs and benefits	Simplification of rules for companies operating in several Member States Avoided cardiovascular effects and immunotoxicity	None

*Intangible-WTP VSL (method 1)

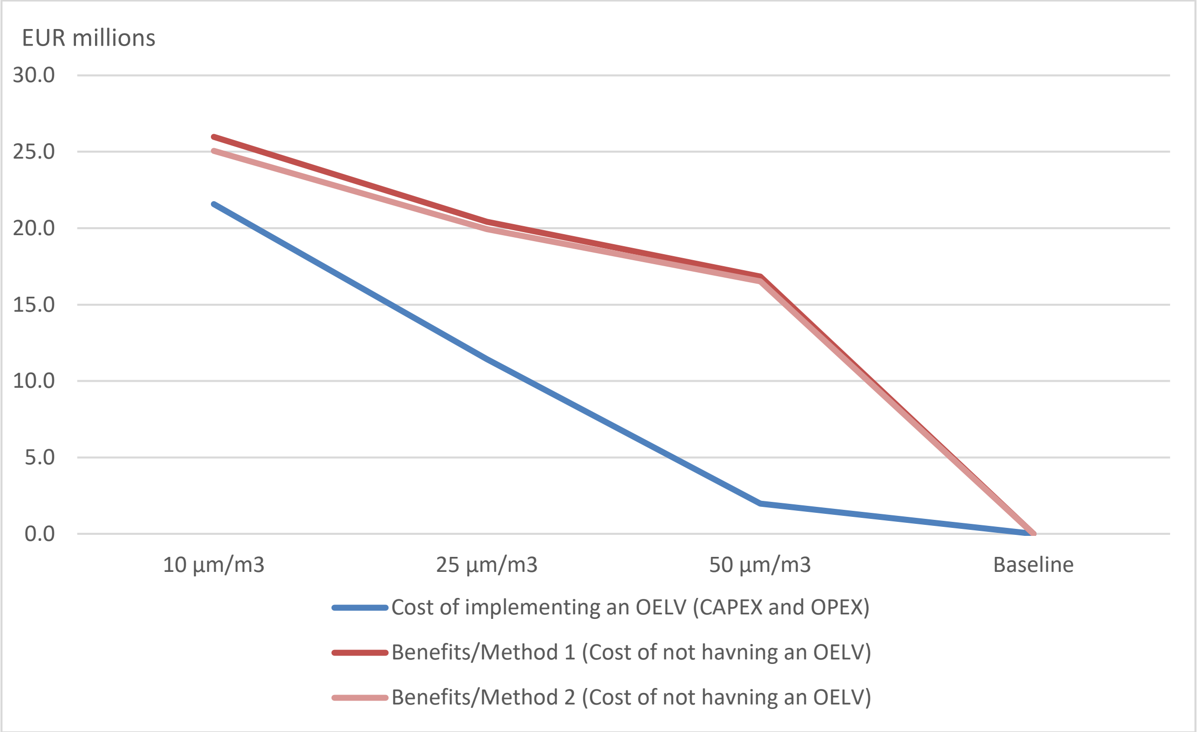

Figure 9-1: Costs/benefits of establishing an OELV for inorganic arsenic compounds including arsenic acid and its salts for all sectors in the EU. Estimated costs (CAPEX AND OPEX) for 60 year and benefits (costs of not having an OELV) for a static baseline with a static discount rate.

9.2 Multi-criteria analysis (MCA)

The multi-criteria analysis includes all the assessed impacts. The majority of the relevant and significant impacts are quantified. Hence, the quantification provides overview of the main impacts.

Overall, incremental benefits and costs are the same order of magnitude given the uncertainties attached to the assessment. The main benefits are for the reduction of the cases of peripheral neuropathy. The benefit range included in the table illustrates the uncertainty on the monetary valuation of the reduced number of cases of peripheral neuropathy.

The estimated compliance costs are very small compared to industry activities. The estimated compliance costs are in a level below 0.5% of industry turnover per exposed worker. Therefore no market effects are expected.

The impacts on public authorities are limited. They comprise the costs transposition for MS that currently have no OELV for inorganic arsenic compounds including arsenic acid and its salts.

Table 9-8: Inorganic arsenic compounds. Multi-criteria analysis				
Impact	**Stakeholders affected**	**Reference OELV A: 10 µg/m³**	**Reference OELV B: 25 µg/m³**	**Reference OELV C: 50 µg/m³**
Economic impacts				
Compliance costs	Companies exposing their workers	€ 21.2 million	€11 million	€1.6 million
Transposition costs	Public sector	€0.4 million	€0.4 million	€0.4 million
Benefits from reduced ill health	Reduction in number of cancer cases	3	2	1
	Reduction in numbers of non-cancer cases	574	468	393
	Employers avoided costs	€2.8 million	€2.3 million	€1.9 million
	Public sector avoided costs	€1.3 million	€1.1million	€0.9 million
Single-market: competition		Limited impact - no closures expected		
Single-market: consumers		No impact	No impact	No impact
Single-market: internal market	Companies. Positive impact: level playing field	Reduction of highest OEL/lowest OEL ratio from 71 to 4	Reduction of highest OEL/lowest OEL ratio from 71 to 9	Reduction of highest OEL/lowest OEL ratio from 71 to 18
International competitiveness		No impact	No impact	No impact
SMEs		No or very limited impact	No impact	No impact
Specific MS/regions	MS that would have to change OELs Companies that might be impacted	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, BG, HR, CZ, EE, FR, EL, HU, IT, LT, LU, MT, PT, SK, SI, UK	AT, HR, CZ, FR, EL, HU, IT, LU, MT, PT, SK, SI, UK
Social impacts				
Ill health avoided – lung cancer and peripheral neuropathy (incl. intangible costs)	Workers & families	€9 to €34 million	€7 to €28 million	€5 to €23 million
Other health points	Workers & families	Additional ill-health from other types of cancer and non-cancer endpoints not included in the assessment (expected to be lower than the assessed endpoints)		
Employment	Workers	No impact	No impact	No impact
Environmental impacts				
Environmental releases		No impact (expected that ventilation air is cleaned before released to the environment)		
Recycling – loss of business	Recycling companies	No impact		
Recycling – durability of consumer goods, etc.		No impact		

10 Sensitivity analysis

The assessment of benefits and costs are sensitive to a number of uncertainties.

Benefits:

- **Cancer and non-cancer effects; endpoints not quantified -** The sensitivity of the benefits assessment to the derived ERR and DRR for cancer and non-cancer effects, respectively, is discussed in detail in Section 4.7.2. As concluded in the section, a quantitative sensitivity analysis is not feasible, but it may be concluded that the reference to only lung cancers tends to underestimate total number of cancer cases to be expected after occupational exposure to inorganic arsenic compounds. Similarly, a quantitative sensitivity analysis is not feasible for the non-cancer cases, but it may be concluded that the reference to only peripheral neurotoxicity tends to underestimate total number of cases of disease to be expected after occupational exposure to inorganic arsenic compounds.
- **Cases after the 60-years period -** Due to the applied latency time of 10 years, a significant part of the cancer cases induced by the exposure to inorganic arsenic compounds during the 60 years assessment period will occur after this period. This systematically underestimates the long-term benefits of introduction of the OELV. Using a
- **Non-confirmed processes and exposed workforce** - Both benefits and costs estimates are sensitive to the estimate on number of exposed workforce. It has for the estimations been assumed that arsenic trioxide is still used in some small-scale production of domestic glass, which has not been confirmed. As the exposure levels are expected to be high, the total number of cases of ill health may be overestimated in case this application in fact has ceased (represents about 20% of the estimated future burden). The costs would be reduced accordingly. The number of workers exposed at levels above the assessed OELVs in the power sector and in ferrous basic metal production has not been confirmed and may result in an overestimation of both benefits and costs. A high number of workers are exposed to inorganic arsenic compounds at relatively low levels. The actual number is very uncertain which has influence on the baseline. However, the exposure concentrations for this group are considered to be well below the lowest of the assessed OELVs and consequently the uncertainty has no influence on the estimated benefits and costs of establishing an OELV.
- **Processes not included in the estimations** - A high number of workers may potentially be exposed to low levels of arsenic (typically below the detection limit of the analytical methods and not reported). The number of workers exposed at low levels could be considerably higher compared to the approximately 10,000 workers included in the assessment. The exclusion of workers exposed at low levels may lead to an underestimation of the baseline, but would not influence the estimates of the benefits of establishing an OELV.
- **Determinations of exposure concentration distributions** - For the main exposure groups separate exposure distributions have been established. As different parameters have been reported from stakeholder and in the literature it has for some sectors been necessary to establish the distributions form general experience from other sectors regarding e.g. the AM/90th percentile ratio. Compared to the uncertainty related to the adjustment for RPE the uncertainty from the conversion into exposure concentrations distributions is considered to be relatively low.

- **Changes in exposure concentrations -** It is assumed that the exposure concentrations will decrease by a 1% (-1% increase) p.a. in the future whereas the past trend is estimated at -8%. This reflects information obtained from stakeholder consultations indicating that for some of the main sectors the focus is much on reducing the total exposure, e.g. by better hygiene and rotation. If the decreases in exposure concentrations is higher than the 1% (-1% increase), the benefits as compared to the baseline may be overestimated.

Costs:

- **Copper sector -** The assumptions regarding the need for additional LEV and the costs of this are highly uncertain. It should be noted that the need for additional LEV, if the workplace concentration in the smelter should be on a level where no RPE was needed, would be much higher. The need for additional LEV is considered as the necessary measure to reach a similar level of other smelters in the EU complying with national OELs at 10 µg/m3 or lower. It cannot be excluded that none of the three companies would need installation of tertiary fume collection or other additional LEV and that this cost element would be 0. On the other hand, it cannot be excluded that the primary smelter would need to establish some tertiary fume collection, which based on experience from other smelters could be an investment in the magnitude of €6-10 million (which over the 60-years period could results in costs of OPEX and replacement of approximately 6 times this investment). It is reported that it would be difficult to implements such measures in existing buildings and consequently the costs could be even higher. Without specific estimates from the companies it will be difficult to provide a more certain estimate. Regarding costs of better RPE and organisational measures it is considered very likely that the costs will be at the indicated size but with an uncertainty of a factor of 2. The need for LEV for the copper smelters is considered to represent the main uncertainty for the cost estimate.
- **Domestic glass sector** - The current use of diarsenic trioxide for the domestic glass sector has not been confirmed and the estimated costs are sensitive to this assumption. The actual costs may be 0 if the use has ceased in all MS. However, the benefits would also decrease accordingly. As specific information on current workplace concentrations and current RMMs has not been obtained, the costs are estimated with high uncertainty and are considered to represent a worst case estimate.
- **Other sectors** - The actual exposure levels, use of RPE and the number of companies with high arsenic levels in the other assessed known. Therefore, both the costs and the benefits estimates are highly uncertain, but linked. The costs estimate is based on the assumption that current exposure levels would be below the actual OEL levels in the MS, but that additional measures would be needed in order to comply with an OELV below the national OELs. The estimated costs for these sectors are relatively small compared to the total estimated costs, rendering the total estimated costs not very sensitive to the estimate from these sectors.

General:

- **Discount rate** – The assessment has been done using a constant discount rate at 4% as recommended in the Better Regulation Guidance. The assessment is not very sensitive to using an alternative discount rate profile where the discount rate is reduced to 3% after 20 years. Using the declining discount rate will increase the estimated monetary value of the benefits by around 8%. The estimated compliance costs will also increase, but only by 5%. Overall, the choice of discount rate has limited impact on the result.

11 Key Issues for the Outcome of the CBA

Baseline number of cancer cases - As discussed in 3.13.2, the number of cancer cases is relatively low as compared to estimates based on other approaches. The estimates are based on ERR established by RAC, number of workers and exposure concentrations. For the exposure concentrations of the baseline, the average concentration used for the estimated 60,000 workers exposed at lower levels is important and the baseline could be higher if the actual average concentration would be higher. However, this is not considered to influence the estimates of reduced cases of introduction of the assessed OELVs. It is considered that the study reflects the current knowledge of applications with higher exposure levels, and that the copper sector represents a significant part of workers exposed at higher level. For some applications, where the available data indicates the possibility of exposures at high, but current exposures have not been confirmed by the stakeholder consultation, some estimates have been undertaken to investigate the possible influence of these sectors on the costs and benefits.

Sectors impacted - The data still indicate that the main impacted sector would be the copper sector. Within this sector, a primary smelter in Bulgaria, and two secondary smelters in Slovakia and Austria, respectively, will be affected by establishing an OELV at the assessed levels (the smelter in Bulgaria would not be affected by an OELV at 50 µg/m^3). The affected companies have not been able to provide estimates of actual costs, but have indicated that better RPE, monitoring, and possibly better local ventilation could be necessary. The costs have been estimated on the basis of knowledge on the RMMs implemented in other smelters in order to comply with an OELV of 10 µg/m^3. As mentioned before, the smelters can only comply with OELs at that level by use of RPE in parts of the smelters with high exposure concentrations e.g. in the furnace areas. The highest uncertainty is linked to the estimated CAPEX for better ventilation. On one hand it may not be necessary (or possible) for any of the smelters to install better ventilation, on the other hand experience shows that better ventilation, if it should have a measureable effect on workplace concentration, may result in costs significantly above the estimated costs. Smelters with ventilation considered BAT still have workplace concentrations in some areas where the 90th percentile is well above the 10 µg/m^3. The primary smelter would, like all other primary smelter in the EU, face increasing arsenic content of concentrates in the future which may result in RMM costs beyond those estimated in this study.

No other sectors have provided specific information demonstrating that they would be impacted if an OELV at the assessed level is established. For the intentional use of arsenic information has been received for all uses except the possible use in domestic glass. The major use of diarsenic trioxide in the domestic glass sector took place in Northern Italy and has been prohibited in recent years, but it cannot be excluded that some activities take place in some Member States.

For other non-ferrous metal production than copper, it cannot be excluded that a few companies could be impacted (none has been identified), but the total costs are considered to be small compared to the costs to the copper sector.

Benefits assessment - The benefits assessment consists of an estimate of the benefits of avoided cases of lung cancer and an estimate of avoided cases of peripheral neuropathy. The monetization of lung cancers follows well established methods. For the benefits of avoided cases of peripheral neuropathy, very limited data on the actual costs of the cases have been available. The estimates are bases on information from the literature describing the cases. Of importance for the valuation is the information indicating that the effects are irreversible, but not lethal. Furthermore information has been obtained from a medical doctor supervising workers in a primary copper smelter. Due to the high number of cases, the benefits of avoided cases of peripheral neuropathy, is significantly higher than the benefits of avoided cancer cases. As described before, due to the zero-effect threshold at 5 µg/m^3

for the peripheral neuropathy, establishing an OELV has a more pronounced effect on reducing the number of case of peripheral neuropathy as compared to the effects on lung cancer cases. However, the estimates for peripheral neuropathy is considered highly uncertain. It should be noted that exposure to arsenic may also lead to other types of cancer and other types of non-cancer effects. Biomonitoring data of workers using RPE and other PPE in primary copper smelters shows that good work practice and hygiene is essential in keeping the total exposure to arsenic by all pathways at an acceptable level.

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Annex 1 Summary of consultation responses

Responses to consultation relevant to arsenic

There were a relatively larger number of questionnaire responses, interviews and site visits for arsenic due to its widespread use in a number of key sectors such as energy, metal processing, glass industry, chemical industry, etc. For key sectors arsenic is present as impurity in raw materials and data cannot be obtained from REACH registrations dossiers or authorisation dossiers.

Table 12-1: Number of responses relevant to arsenic	
Questionnaire responses	22
Interviews	18
Site visits	5
Total	**45**

Besides the general stakeholder consultation addressing a large number of stakeholders with a request for information across the six substances/substance groups, a number of organisations and companies were addresses directly with a request about inorganic arsenic compound. The organisations were generally requested to forward the questionnaire to member organisations and member companies, and asked some more general questions regarding the sector. Many og the organisations were contacted by phone and interview about the knowledge on use of and exposure to arsenic compounds in the sector.

The arsenic substances are covered by two REACH consortia: **Arsenic Consortium** (diarsenic trioxide, As metal, arsenic trichloride, GaAs, calcium arsenate) and the **Arsenic Acid Consortium** (arsenic acid). Both organisations forwarded the request to the member who all answered the questionnaire. One of the companies was subsequently visited. As arsenic metal is still not registered, limited information on the use of arsenic metal (apart from ultrapure arsenic) was obtained.

Eurometaux and the sector associations: the **European Copper Institute** (ECI), the **Nickel Institute**, the **European Precious Metals Association** (EPMF), the **International Lead Association** (ILA), and the **International Zinc Association** (IZA) were contacted. Furthermore **the International Cadmium association** (ICdA) was contacted as part of the study on cadmium. Furthermore, the national associations **WirtschaftsVereinigung Metalle** (Germany) and **Alliance des Minerais, Minéraux et Métaux** (France) were contacted. The European Copper Institute (ECI) organised a reporting of the companies and the majority of the copper smelters in the EU responded directly to the questionnaire. The questionnaire responses were followed up with interviews and visits to three sites in the sector. From the order organisations various information on the sector was received, but very limited information on actual exposure to arsenic was available.

For collection of information on glass, **GlassAlliance Europe** and the sector associations **European Domestic Glass Committee, International Crystal Federation** (EDG/ICF) and **European Special Glass Association** (ESGA) were contacted. The associations provided general information on the sectors and the use of arsenic compounds and assisted in contacts the companies. The contact was supplemented with contact to the national associations **Bundesverband Glasindustrie e.V.** (Germany); **Assovetro**

(Italy), and **Association of the Glass and Ceramic Industry of the Czech Republic**. A conference call was set up with representatives of the ESGA, EDG, Bundesverband Glasindustrie e.V, an Italian research centre and two major producers of special glass in Germany and France. One special glass company was visited. The contact was supplemented with contact to the **European Insulation Manufacturers Association** (EURIMA).

The **European Steel Association** (EUROFER) and **European Association of Mining Industries, Metal Ores & Industrial Minerals** (Euromines) forwarded the request to members but no responses were obtained.

The **European Semiconductor Industry Association** (ESIA) provided a description of the use of arsenic and the occupational exposure in the semiconductor industry.

Contact to the International lead association was supplemented with contact to the **Association of European Automotive and Industrial Battery Manufacturers** (EUROBAT) and **Association of European Manufacturers of Sporting Ammunition** (AFEMS). No questionnaire responses were obtained from the lead sector.

In order to investigate the use in power plant, the **Union of the Electricity Industry** (EURELECTRIC) was contacted but had no data. Furthermore power companies in Denmark, the Czech Republic and Slovakia were contacted but limited data on actual exposure concentrations was obtained.

The European Sulphuric Acid Association forwarded the request to member companies and one response was obtained.

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