Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbes-tos)

Final report for lead and its compounds

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List of abbreviations and acronyms

ACGIH	American Conference for Governmental Industrial Hygienists
AGS	Committee for Hazardous Substances (Ausschuss für Gefahrstoffe)
AM	Arithmetic mean
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food Safety, Environment and Labor, France)
APF	Assigned Protection Factor (indicating how much RPE are reducing air-borne exposure)
ASA	ASA Register (of occupational exposure hazards and procedures in Finland)
BAT	Best Available Technique
BEI	Biological Exposure Indices
BGV	Biological Guidance Value
BLL	Blood lead level
BLV	Biological Limit Value
BPb	Blood lead, lead concentration in blood
BREF	Best available techniques reference document
CAREX	Carcinogen Exposure
CAD	Chemical Agents Directive
CAS	Chemicals Abstracts Service
CBA	Cost Benefits Analysis
CMD	The Carcinogens and Mutagens Directive
CNS	Central nervous system
COLCHIC	Occupational exposure to chemical agents database
CSR	Chemical Safety Report
DALY	Disability Adjusted Life Years
DFR	Draft Final Report
DG	Directorate General
DRR	Dose Response Relationship
EC	European Commission
ECHA	European Chemicals Agency
ELV	End-of-Life Vehicle
EPRD	Office for Economic Policy and Regional Development
ERR	Exposure Risk Relationship
ETUI	European Trade Union Institute
EU	European Union
FoBiG	Forschungs- und Beratungsinstitut Gefahrstoffe, German Consultancy Com-panys
GDP	Gross Domestic Product
GESTIS	Database Internationale Grenzwerte für chemische Substanzen (International limits for chemical substances)
HHI	Herfindahl-Hirschman Index, indicator of market concentration in economics
HSE	Health & Safety Executive, United Kingdom
IA	Impact Assessment
IARC	International Agency for Research of Cancer
IED	Industrial Emissions Directive

IFA	Institute for Occupational Safety and the German Statutory Accident Insurance (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung)
ILA	International Lead Association
INRS	The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases
IOM	Institute of Occupational Medicine
IPPC	Integrated Pollution Prevention and Control
ISO	The International Organization for Standardization
JRC	Joint Research Centre
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
MaxEx	The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase)
MinEx	The minimum exposure duration required to develop the endpoint
MCA	Multi-Criteria Analysis
NACE	"nomenclature statistique des activités économiques dans la Communauté européenne" or the Statistical Classification of Economic Activities in the European Community
NIOSH	National Institute for Occupational Safety and Health
OEHHA	Office of Environmental Health Hazard Assessment of California Environmental Protection Agency
OEL	Occupational Exposure Limit
OR	Odds Ratio
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration (US)
PbA	Pb in Air, Lead concentration level in air
PbB	Pb in Blood, Lead concentration level in blood
PBPK	Physiologically-based Pharmacokinetic (PBPK) Model to estimate worker PbB concentrations as a result of inhalation exposure to lead (without respiratory protection)
PNEC	Predicted No Effect Concentrations
PPE	Personal Protective Equipment
R&D	Research and Development
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RoHS directive	The Restriction of Hazardous Substances Directive 2002/95/EC, short for Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment
RPA	Risk & Policy Analysts
RPE	Respiratory Protection Equipment
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Committee for Socio-Economic Analysis
SEG	Similar Exposure Group
STEL	Short-Term Exposure Limits
STP	Sewage Treatment Plant
SUMER	Surveillance médicale des expositions aux risques professionnels (Medical Monitoring Survey of Professional Risks)
SVHC	Substance of Very High Concern
TLV	Threshold Limit Value

TWA	Time Weighted Average
UK	United Kingdom
VRAR	Voluntary Risk Assessment Report
WCS	Worker Contributing Scenarios
WEEE	The Waste and Electrical & Electronic Equipment Directive (2002/96/EC)
WWTP	Wastewater treatment plant
WHO	World Health Organisation

Executive summary

The Chemical Agents Directive (Directive 98/24/EC) protects workers from the risks related to chemical agents at work. The aim of this study is to support the European Commission's Impact Assessment (IA) of lowering the existing limit values for lead and its compounds. The Chemical Agents Directive currently specifies an Occupational Exposure Limit value (OEL) of 150 µg/m³ and a Biological Limit Value (BLV) of 700 µg/L.

Fifteen sectors with occupational lead exposure are analysed.

The costs and benefits (relative to the baseline) estimated in this report for six different BLV options are summarised in the table below.

Two estimates of the cost savings (benefits) from ill health avoided under the different BLV options (Methods 1 and 2) are presented in this report. These estimates rely on two different monetisation approaches. Both monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect (productivity/lost earnings[1]) impacts. However, they use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.). The results of both approaches should be considered together and treated as indicative of the general order of magnitude of the cost savings. A detailed explanation of these approaches is provided in the Methodological note.

For the benefits, there is a substantial increase in benefits going from the highest BLV option of 300 to 200 µg/L. Going stepwise from 200 to 45 µg/L, further increases in benefits become less significant.

The costs are for the present value (PV) over 40 years with a static discount rate of 4%. They assume a 5% turnover in staff. There is a substantial increase in compliance costs going from the BLV option of 100 to 45 µg/L. Compared to companies' turnover, compliance costs are generally of limited significance for most companies in most sectors for the BLV options ≥ 150 µg/L. This reflects the fact that the current EU BLV is regarded as outdated, and most companies are compliant with lower national BLVs and/or pursue voluntary industry targets. This also means that many measures for compliance with limit values below the current 700 µg/L are already in place, meaning the cost of implementing additional measures would be limited.

A significant part of the compliance cost at the BLV options ≤ 100 µg/L is caused by discontinuations. The modelled discontinuation costs have to be interpreted with care, as companies most often would find alternative ways of reaching compliance rather than discontinue their operations.

The RAC recommended a BLV of 150 µg/L.

Table 1-1 Cost-Benefit of the BLV options

Impact	BLV options					
	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Total benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million	€ 0
Total benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million	€ 0

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

Impact	BLV options					
	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Total costs	€ 6,300 million	€ 1,800 million	€ 750 million	€ 350 million	€ 130 million	€ 0
Cost benefit ratio M1	20	6.0	2.9	1.7	1.6	0
Cost benefit ratio M2	14	4.3	2.1	1.2	1.08	0

Source: study team's calculation

The table below summarises both the monetised and qualitative impacts.

Table 1-2 Multi-criteria analysis (all impacts over 40 years and additional to the baseline)

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Direct costs - compliance							
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€6,300 million	€1,800 million	€750 million	€350 million	€130 million	€0
Monitoring (sampling and analysis)	Companies	€0	€0	€0	€0	€0	€0
Direct costs - administrative burdens							
Company cost of additional administration	Companies	€0	€0	€0	€0	€0	€0
Direct costs - total							
Compliance and monitoring costs per company	Companies	€300,000	€82,000	€31,000	€15,000	€6,000	€0
Direct costs - enforcement costs							
Transposition costs	Public sector	€520,000	€520,000	€500,000	€480,000	€460,000	€0
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0
Indirect costs - other							
Firms exiting the market - No. of company closures	Companies	29	3	0	0	0	0
Employment – Jobs lost	Workers & families	1,800	130	0	0	0	0
Employment – Social cost	Workers & families	€150 million	€10 million	€0	€0	€0	€0
International competitiveness	Companies	Substantial negative impact	High negative impact	Moderate negative impact	Limited negative impact	Limited negative impact	No impact
Consumers	Consumers	Limited impacts expected					
Internal market	Companies	Lowest/ highest BLV from 45 to 45	Lowest/ highest BLV from 100 to 100	Lowest/ highest BLV from 100 to 150	Lowest/ highest BLV from 100 to 200	Lowest/ highest BLV from 100 to 300	Lowest/ highest BLV from 100 to 700
Specific MSs/regions - MSs that would have to change BLVs	Public sector	All MS	All MS	All MS except DE	All MS except DE, DK	All MS except DE, DK, FI	Only EE (not transposed)
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited					
Direct benefits – improved well-being - health							
Reduced cases of ill health (all endpoints, excl. developmental toxicity)	Workers & families	12,000	11,000	10,000	8,100	3,200	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€200 - 310 million	€190 - 300 million	€160 - 250 million	€130 - 200 million	€52 - 80 million	€0
Avoided costs	Companies	€6 million	€6 million	€5 million	€4 million	€2 million	€0
Avoided costs	Public sector	€130 million	€120 million	€100 million	€90 million	€40 million	€0

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free environment					
Direct benefits – improved well-being - environmental							
Environmental releases	All	No impact/limited impact					
Direct benefits – market efficiency							
Level playing field	Companies	A harmonisation of the BLVs leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases with the stringency of BLVs					
Indirect benefits							
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are sectors 1, 2, 3, 6, and 15.					
Synergy	Companies	Synergies in terms of exposure reduction to other chemical substances used in production sectors may occur. The specific substances will vary between sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.					
Corporate Social Responsibility	Companies	Work with lead may be less perceived as a risky line of work associated with health issues. As a result of such an improved public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.					
No cost of setting BLV (saving for MS for developing lower national BLVs)	Public sector	Benefit (MS would expectedly not implement lower BLV)		Small benefit (some MS would consider implementing lower BLV)	Limited benefit (many MS would consider the BLV too high)		No benefit

Notes: All costs/benefits are incremental to the baseline (PV over 40 years). Internal market shows the ratio of highest BLV to lowest BLV before and after implementing the BVL option.

Source: study team's calculation

The relationship between airborne and blood lead levels, as well as the interdependency of OELs and BLV have been investigated in this study.

Blood lead concentrations are recognized as the main exposure metric in assessing occupational exposures of lead. The present study includes a full quantitative impact assessment of all BLV reference options as outlined in chapter 3. The assessment of the OEL options could not be performed in a corresponding manner due to missing and uncertain data regarding health effects related to airborne exposures. Relationships between lead in air (PbA) and lead in blood (PbB) depend on various factors within an occupational settings and unambiguous correlation methods are not available. The recognized best available method for estimating PbB based on exposure to airborne lead is the conversion method developed by the California Office for Environmental Health Hazard Assessment (OEHHA). This method has been applied by the RAC to derive the proposed OEL based on the proposed BLV. The conversion method showed to have limited value for the calculation of ill health cases in this study, as the validated conversion range and conversion values do not reflect relevant PbB and PbA concentrations of current occupational settings (section 4.16). For that reason, the steering group agreed that the study should evaluate the BLV quantitatively and the OEL qualitatively in relation to the BLV options. Data on compliance cost with OEL options have been collected during stakeholder consultation. Most companies focus on PbB management and found it challenging to provide data on PbA management. The OEL assessment has been conducted in a qualitative manner. Available data indicate the OEL option of 50 µg/m³ as an achievable level.

The development of future exposure concentrations has a significant impact on the benefits estimate and a less significant impact on the costs estimate. Available data do not allow for clear conclusion on the development of future trends under the baseline scenario. The available data show that blood lead levels have reduced drastically during the past decades, while the trend appears to have stagnated in recent years. Continuous efforts within the main lead producing and processing sectors indicate that further reductions are likely, however, these are not reflected in the exposure concentration trends data of the most recent years. Available information does not suggest exposure concentration reduction in sectors other than the main lead producing and processing sectors for the recent years. Since May 2021, companies in Germany, which represent a significant proportion of the European lead industry, must comply with a BLV of 150 µg/L. No data are available yet to show the extent to which the newly introduced German BLV impacts the baseline and the benefits estimation. Future changes in exposure concentrations are therefore included as a variable in the sensitivity analysis. Future reductions in exposure concentrations result in a larger decrease of the benefits estimates compared to the decrease in cost estimates for the BLV options.

Differentiated susceptibilities to lead and its compounds between different groups within the working population are recognized. The BLV of 150 µg/L, recommended by RAC, is recognized as not being protective for "Women of childbearing age". Instead, a biological guidance value of 45 µg/L is recommended for women of childbearing age. It has not been a subject of this study to elucidate the relationship between setting protective limit values and gender equality. Data on adverse health effects of lead in women of childbearing age, exposure concentrations and numbers of female employees of childbearing age have been included in the study, as well as information on how exposure of women is currently managed in the industry.

1. Introduction

Ensuring a safe and healthy work environment for over 200 million workers in the EU is an ongoing strategic goal for the European Commission according to the Communications from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020[2] and 2021 - 2027[3].

Cancer and other work-related health problems caused by exposure to carcinogenic and other hazardous chemical substances at the workplace leads to suffering of workers and their caring families. It reduces the length, quality, and productivity of the working lives of European workers.

It is important to ensure that risks to workers' health that arise from exposure to carcinogenic and other hazardous chemicals at the workplace are effectively controlled including, where appropriate, by the use of limit values.

The present study is concerned with lead and its compounds.

Lead and its compounds are key occupational reprotoxicants[4]. The objective of the present study is to provide the Commission with the most recent, updated and robust information on exposure to lead and its compounds with the view to support the European Commission in future work to revise the current occupational exposure limit value (OEL) and biological limit value (BLV) for these substances.

1.1 Chemical Agents Directive (CAD)

The Chemical Agents Directive (98/24/EC) applies to hazardous substances other than carcinogens (C1A and 1B) and mutagens (M1A and 1B) and lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemicals.

It sets out requirements for determining and assessing the risks associated with hazardous chemical agents in the workplace, as well as measures for preventing risks, dealing with accidents, incidents and emergences, and informing and training workers.

The legislation provides for occupational exposure limit values (OEL), as well as biological limit values (BLV) and health surveillance measures. Member States can set Limit Values that are lower/stricter than the level set by the Commission but must not exceed them/be less stringent.

Under Annex I of the CAD 'binding occupational exposure limit values' are established, while under Annex II 'binding biological limit values and health surveillance measures' are established. To date only one binding occupational exposure limit value and one binding biological limit value have been set under the CAD, both for 'inorganic lead and its compounds' (0.15 mg/m^3 and 70 µg Pb/100 ml blood, respectively).

Under Annex II medical surveillance is also carried out if:

- exposure to a concentration of lead in air is greater than 0.075 mg/m^3, calculated as a time-weighted average over 40 hours per week, or
- blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.

[2] Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN

[3] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0323&qid=1626089672913#PP1Contents

[4] https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

Furthermore, this directive states that standardised methods for the measurement and evaluation of workplace air concentrations in relation to occupational exposure limit values must be developed.

1.2 The study

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

The four reports are:

- Methodological note incl. summary of stakeholder consultation (lead editor: RPA);
- Report for asbestos (lead editor: COWI/RPA);
- Report for lead and its compounds (lead editor: COWI);
- Report for di-isocyanates (lead editor: RPA).

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 98/24/EC. The four reports are supplemented with a baseline report for inorganic lead and its compounds.

The objective of this specific report is to assess the impacts of lowering the current OEL and BLV for lead and its compounds.

The methodology used for study and a summary of the stakeholder consultation are described in detail in the separate methodological note.

1.3 Study scope

1.3.1 Existing limit values

Lead and its compounds are already subject of a legally binding OEL and BLV under the Directive 98/24/EC (CAD). Annex I of the CAD specifies an OEL and a BLV for "inorganic lead and its compounds" of 0.15 mg/m^3 and 70 µg Pb/100 ml blood, respectively.

1.3.2 Selection of the relevant measures

This report assesses the impacts of changing the existing OEL and BLV for lead and its compounds. The assessment in this report does not include the introduction of a short-term exposure limit (STEL) or 'notations'.

1.4 Structure of the report

The report is organised as follows:

- Chapter 1 is this introduction;
- Chapter 2 sets out the problems and objectives;
- Chapter 3 sets out the options;
- Chapter 4 sets out the baseline;
- Chapter 5 sets out the benefits of the relevant measures;

- Chapter 6 sets out the costs of the relevant measures;
- Chapter 7 summarises the market effects;
- Chapter 8 describes the distribution of any impacts;
- Chapter 9 describes the environmental impacts;
- Chapter 10 provides an overview of the limitations and the sensitivity analysis; and
- Chapter 11 compares the options and provides the conclusions.

This report is complemented with three Annexes.

2. Problems and objectives

This chapter comprises the following subsections:

- Section 2.1: Need for action as assessed by Committee of Risk Assessment (RAC), Scientific Committee on Occupational Exposure Limits (SCOEL), and Advisory Committee of Safety and Health at Work (ACSH).
- Section 2.2: Summary of epidemiological and experimental data.
- Section 2.3: Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects).
- Section 2.4: Objectives.

2.1 Need for action as assessed by RAC, SCOEL and ACSH

2.1.1 RAC

In the recent opinion of the Committee for Risk Assessment (RAC 2020a), RAC proposes an Occupational Exposure Level (OEL) of 4 µg lead/m^3 and a Biological Limit Value (BLV) of 150 µg lead/L blood for lead and its inorganic compounds.

RAC notes that neither the proposed BLV of 150 µg/L blood and the proposed air limit value of 4 µg/m^3 for lead and its inorganic compounds protects from developmental toxicity. Therefore, RAC recommends to state in the Chemical Agents Directive (CAD) a recommendation for Groups at Risk, special considerations applying to women of childbearing age, as is shown in the table below.

According to RAC, short-term increases in inorganic lead air levels would not be expected to drastically increase blood-lead levels due to the long half-life. Therefore, no short-term limit value for lead and its inorganic compounds is proposed, since acute toxicity is observed only at considerably higher blood-lead levels, starting above 400 µg/L, and representing particularly high air levels.

In addition to the BLV, RAC derives a Biological Guidance Value (BGV) of 45 µg lead/L. The BGV relates to background exposure of the general population of the same age group not occupationally exposed to lead. RAC notes that blood-lead levels vary throughout Europe, with mean values around 30 to 35 µg/L. BGVs usually relate to the 95th percentile of background exposure; therefore, RAC establishes the value of 45 µg/L. Blood lead levels above this value would indicate occupational exposure. According to RAC, due to a continuous decline in environmental lead exposure levels, this value should be revisited about every five to ten years.

Table 2-1 Derived limit values developed by RAC and recommended statement (RAC, 2020a)

Derived limit value	**Concentration**
OEL as 8-hour TWA	4 µg lead/m^3 (inhalable fraction) for lead and its inorganic compounds None for organic lead compounds (=0.004 mg lead/m^3)
STEL	No STEL proposed
BLV	150 µg lead/L (= 15 µg lead/100mL) None for organic lead compounds
BGV	45 µg lead/L blood (= 4.5 µg lead/100mL)

Derived limit value	**Concentration**
Recommended statement in the CAD	*Exposure of fertile women to lead should be avoided or minimised in the workplace because the BLV for lead does not protect offspring of women of childbearing age. The blood lead level in women of childbearing age should not exceed the (95 percentile) reference values of the general population not occupationally exposed to lead in the respective EU country. Higher blood lead levels are an indicator of potentially exceeded occupational exposure and should be followed up by an occupational hygiene expert. When national reference levels are not available, blood lead levels in women of childbearing age should not exceed the Biological Guidance Value (BGV) of 45 µg/L, the maximal European reference value.*

Note: National OELs and monitoring data are most often expressed in µg lead/100mL.

RAC notes that "*In practice, exposure occurs through multiple routes and even if the OEL for lead in air is not exceeded, internal levels may still exceed the BLV. On the other hand, in most cases, air levels in particular are regularly monitored to prevent adverse health effects of chemicals at the workplace. In the case of lead and its compounds, however, there is usually a poor correlation between concurrent external and internal blood lead levels which can be explained by several specific factors. The most important aspects are:*

- *It is generally accepted that internal lead levels are critical for the occurrence of adverse health effects.*
- *Lead accumulates in the body, which contributes to the poor correlation between blood lead levels and air lead levels.*
- *Background (non-occupational) exposure has dropped considerably over the last years and as a consequence, results from older studies on the correlation between air levels to blood lead levels are not representative for the current situation anymore.*
- *Personal hygiene in the work environment greatly affects lead uptake and only through inhalation (e.g., hand to mouth contact, smoking, etc.), complicating generalisation regarding the contribution of air exposure. The respective contributions of air exposure and hand-mouth uptake are likely to differ in different industries and/or workplaces.*
- *Exposure towards different lead compounds may lead to different internal lead levels. thus, internal exposure may be driven considerably by uptake from surfaces and not only through inhalation (e.g., hand to mouth contact, smoking, etc.), complicating generalisation regarding the contribution of air exposure. The respective contributions of air exposure and hand-mouth uptake are likely to differ in different industries and/or workplaces.*
- *Exposure towards different lead compounds may lead to different internal lead levels.*

RAC understands that for practical reasons of continuity with current limits an air limit value is required, but it should be ensured that the BLV of 150 µg/L should not be exceeded in the majority of workers; i.e. at least at the 95th percentile level."

In line with other international and national bodies proposing occupational limit values since the SCOEL (2002) recommendation, RAC recognizes the biological limit value (BLV), more specifically PbB, as the relevant exposure metric, although measurement of Pb concentration in the air is important to control occupational exposure.

RAC states that "*proposing an OEL value for air is more complicated than for other compounds as the derivation of the OEL is based on a correlation to the established BLV. Lead* *is unique in this regard as for most substances with a national and international BLV, the BLV is derived from the OEL.*"

The developed BLV of 150 µg/L PbB corresponds an air concentration of 3.9 µg/m³ (95th percentile) based on the correlation between BLV and OEL derived by the Office of Environmental Health Hazard Assessment of California Environmental Protection Agency (OEHHA). Thus, an OEL (8 h TWA (time-weighted average)) of 4 µg Pb/m³ is recommended by RAC.

For organic lead compounds, due to data limitations, no quantitative scientific evaluation of the organic lead compounds is possible and thus no limit values are proposed by RAC. For the current study it is of importance that the organic lead compounds may contribute to the concentration of lead in the air (measured as elemental lead) and to the blood lead levels (measured as elemental lead). Consequently, companies with workers exposed to organic lead compounds would also be affected by the suggested new OEL and BLV values. The organic lead compounds can be divided into two groups: the organolead compounds (mainly tri- and tetraalkyllead) and organic lead salts (mainly various PVC additives). Both types of compounds may to some extent be metabolised to inorganic lead in humans (RAC, 2020b) and thereby contribute to the blood-lead levels. When released to the air in occupational settings, the organic lead salts would contribute to the air concentrations of lead as measured by the conventional analytical methods for lead and its inorganic compounds (such as ISO 8518 and ISO 15202 (the International Organization for Standardization)). Many of the organolead compounds such as tetraethyllead are gaseous and are not measured by these methods; therefore, organolead compounds would in general not contribute to the measured air concentrations.

2.1.2 SCOEL

SCOEL published an evaluation of lead and its inorganic compounds in 2002.

A BLV of 30 µg/100 ml was recommended. SCOEL notes that "*It should be kept in mind that the recommended BLV is not seen as being entirely protective of the offspring of working wom-en. No threshold for potential central nervous system effects in new born and infants can be identified at present. The exposure of fertile women to lead should therefore be minimised.*" (SCOEL, 2002).

SCOEL (2002) recommended an OEL of 0.1 mg/m³. SCOEL notes that "*Only part of the occupational exposure occurs by inhalation and a considerable portion is incorporated after oral ingestion. Lead ingestion varies as a function of personal hygiene of the individual and the over-all cleanliness of the work environment. In consequence, the setting of an OEL for airborne lead is more difficult than for other compounds.*" Based on field studies on lead battery workers and using the preferred values approach of SCOEL, an OEL for airborne exposure of 0.1 mg/m3 was recommended as consistent with the above biological limit value.

Table 2 1 Recommended limit values for lead and its inorganic compounds proposed by SCOEL (2002).

Limit value	Concentration
OEL as 8-hour TWA	0.1 mg/m³ for inorganic lead (lead fumes and dusts of < 10 µm)
STEL	Not established
BLV	30 µg/100 ml

2.1.3 ACSH

In a supplementary opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace, the ACSH states *"In addition, as a large percentage of exposures to repro-toxic substances are to inorganic lead and lead compounds, and as the existing EU binding occupational and biological limits for these substances are known to be not sufficiently protective of health, these limits should be reviewed and amended as soon as possible.*" (ACSH, 2013).

2.2 Summary of epidemiological and experimental data

The literature on health effects of lead is excessive. In the current report concise summaries are provided. For more detailed reports see for example the newest ATSDR document (ATSDR, 2020) or the documentation by RAC (RAC, 2020b, RAC, 2020a).

As for all relevant endpoints a broad epidemiological database is available, which is then used for deriving dose-response relationships, the following summary focusses on human data.

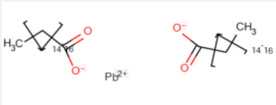
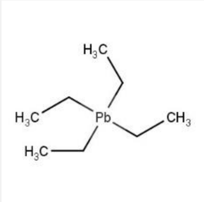
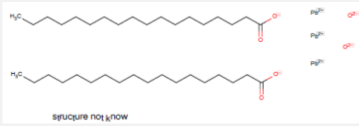
2.2.1 Identity and classification

The identification and physico-chemical properties of lead and four inorganic lead compounds are described in the following Table 2-2. In Table 2-2 data are presented for three organic lead compounds (RAC, 2020a).

Table 2-2 Identity and physico-chemical properties of lead and four inorganic lead compounds (RAC, 2020a).

	Lead	**Lead monooxide**	**Tetralead trioxide sulphate**	**Pentalead tetraoxide sulphate**	**Orange lead**
CAS No.	7439-92-1	1317-36-8	12202-17-4	12065-90-6	1314-41-6
EC No.	231-100-4	215-267-0	235-380-9	235-067-7	215-235-6
Molecular formula	Pb	PbO	$Pb_4O_3(SO_4)$	$Pb_5O_4(SO_4)$	Pb_3O_4
Physical state	solid	solid	solid	solid	solid
Density [g/cm³ at 20 °C]	11.45	9.96	6.84	7.15	8.93
Melting point [°C]	326	888	>500	>600	>550
Water solubility [mg/L]	3.2 (pH 6, 24 h) 185 (pH 11)	70 (pH 11) 0.1 (pH 8.4)	102 (pH 8)	32.7 (pH 8.7)	67.3 (pH 10.8)

Table 2-3 Identity and physico-chemical properties of organic lead compounds (RAC, 2020a).

	Fatty acids, C16-18, lead salts	Tetraethyllead	Dioxobis(stearato)trilead
CAS No.	91031-62-8	78-00-2	12578-12-0
EC No.	292-966-7	201-075-4	235-702-8
Structure			
Physical state	solid	liquid	solid
Density [g/cm³ at 20 °C]	1.46	1.7	1.95
Melting point [°C]	101 - 105	-134	290 (decomp.)
Water solubility [mg/L]	10.4 (pH 7.8)	< 2.35	1.76 (pH 9.3)

A harmonised classification according to Annex VI of the CLP Regulation (9th ATP) is available for lead powder (particle diameter < 1mm) and lead massive (particle diameter ≥ 1 mm). Further, for "lead compounds with the exception of those specified elsewhere in Annex VI (Index No 082-001-00-6)" harmonised classifications in Annex VI of the CLP Regulation are available. Since the four inorganic lead compounds considered by RAC are not specified in the Annex they fall under entry No 082-001-00-6.

The organic lead compounds considered here, also fall under the entry "lead compounds with the exception of those specified elsewhere in Annex VI", except for tetraalkyllead which falls in the category "lead alkyls" and has a higher acute toxicity.

Table 2-4 Harmonised classification of lead powder, lead massive , "lead compounds with the exception of those specified elsewhere in Annex VI" and alkyl lead (RAC, 2020a)

Substance	Classification
Lead powder [particle diameter < 1 mm]	Repr. 1A (H360FD: C ≥ 0,03%) Lact (H362)
Lead massive [particle diameter ≥ 1 mm]	Repr. 1A (H360FD) Lact (H362)
lead compounds with the exception of those specified elsewhere in Annex VI	Repr. 1A (H360-Df, Repr. 2; H361f: C ≥ 2.5%) Acute Tox. 4* (H332) Acute Tox. 4* (H302)

Substance	Classification
	STOT RE 2* (H373**, STOT RE 2; H373: C ≥ 0,5 %) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
lead alkyls	Repr. 1A (H360-Df, Repr. 1A; H360D: C ≥ 0.1%)* Acute Tox. 2* (H330) Acute Tox. 1 (H310) Acute Tox. 2* (H300) STOT RE 2* (H373**, STOT RE 2; H373: C ≥ 0,05 %) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

The use of lead is regulated extensively at national, European Union and global levels. Numerous legal requirements apply, for example Directive 98/24/EC, Directive 2004/37/EC or Safety of toys Directive 2009/49/EC.

2.2.2 General toxicity profile, critical endpoints and mode of action

2.2.2.1 Toxicokinetics (RAC, 2020a)

Metallic lead has the oxidation state of 0, lead compounds exist with oxidation states of +2 and +4. Lead in the environment is primarily found in the +2 state in inorganic compounds, the +4 state is only formed under strongly oxidizing conditions.

Absorption

Relevant exposure routes are oral and inhalation. After inhalation most inorganic lead compounds appear to be almost completely absorbed. The toxicokinetic behaviour in the respiratory tract depends on particle characteristics (e.g., particle size) and the physico-chemical properties of the lead compound. Compounds with low solubility (e.g., lead sulphide) tend to accumulate in the lung. Gastrointestinal absorption of lead is relatively poor in adults and depends on particle size, shape, time spent in the gastrointestinal tract, food intake etc. The following table summarizes representative uptake rates for lead.

Table 2-5 Representative lead uptake rates (RAC, 2020a)

Intake route	Adults	Children
Oral (food)	10%	50%
Oral (soil)	6%	30%
Dermal	<0.01%	<0.01%
Air (deep lung deposition)	100%	100%
Air (upper airway deposition)	Variable	Not available

Distribution

Once lead is absorbed inorganic lead is distributed to both soft tissue (e.g., blood, liver kidney) and mineralising systems (bones, teeth). Under steady state conditions lead in blood is found primarily in the red blood cells (96 – 99%) where it is bound mostly to ALAD (δ-aminolevulinic acid dehydrase). In adults more than 90% of the total amount of accumulated lead ends up in bone, while in children 75% is accumulated in bones. Redistribution from this large depository might lead to elevated blood lead levels long after cessation of exposure. Lead can easily be transferred to the foetus via the placenta. The blood brain barrier is also permeable for lead ions.

Metabolism

Lead in the form of Pb^{2+} is not further metabolised in the body.

Excretion

Lead is mainly excreted via the urine (75 - 80%) and the gastrointestinal tract. Excretion routes like hair, nails or sweat cover less than 8% of the total excretion. Breast-feeding women excrete relevant amounts via the milk. Lead elimination from the body is slow: After the end of exposure the blood lead levels decrease in the first phase with a half-life of 29 - 36 days. The following elimination phases take much longer due to counterbalancing from soft tissue and the bone compartments (half-life up to 13 years).

Organic lead compounds show different toxicokinetic properties compared to lead and its inorganic compounds. Part of the organic lead is metabolised to inorganic lead (Pb2+). Organic lead is not further discussed in this chapter since inorganic lead compounds are used in greater quantities (> 99%) then organic compounds and are the relevant lead forms at most workplaces.

2.2.2.2 Target organs and key toxicological endpoints (RAC, 2020a)

Toxicological effects after lead exposure are diverse and affect a multitude of organ systems.

Target organs of lead and its inorganic compounds after repeated exposure comprise the nervous system, kidneys, the cardiovascular system, the haematological system, and the reproductive system including the developing organism. For all endpoints epidemiological studies are available.

Lead and its inorganic compounds are carcinogenic to experimental animals (kidney tumours), while epidemiological data concerning carcinogenicity are inconsistent (see section 2.2.3.).

2.2.2.3 Mode of action (RAC, 2020a)

Lead ions (Pb^{2+}) are the critical species for toxic effects. The interference with the calcium homeostasis is the relevant mode of action of the neurotoxic and haematological effects. Nephrotoxic effects are mainly based on the formation of intranuclear inclusion bodies in the renal proximal tubule. The cardiovascular effects, mainly the effect of lead on blood pressure, is based on an interference with the Na-K system (natrium-kalium system), cAMP (cyclic adenosine monophosphate), Ca^{2+}-mediated signalling and the renin angiotensin system. The mechanism of the reproductive effects is not completely understood. Direct effects on the reproductive organs are possible as well as effects on the endocrine control of reproduction.

The genotoxic and carcinogenic activity might most likely be mediated via an indirect genotoxic mechanism involving the induction of oxidative stress, the interaction with DNA repair and the deregulation of cell proliferation.

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

Numerous studies on carcinogenic effects of lead have been published. The epidemiological evidence is considered as inconsistent. This is mainly due to confounding factors and uncertainties regarding quantification of exposure (absence of blood lead levels) in the studies. IARC (International Agency for Research of Cancer) concluded that the evidence for carcinogenicity of inorganic lead compounds in human data is limited (IARC, 2006).

In one of the most recent evaluations Steenland et al. (2019) reported results from a Finnish and a UK cohort of lead-exposed workers. Increased risks were calculated for lung cancer and for brain tumours in the Finnish cohort. No correlations were found for kidney or stomach tumours. However, the risk estimates were not adjusted for smoking or for workplace exposures other than lead.

Extensive experimental evidence showed that various water-soluble and –insoluble lead compounds in high doses can induce tumours in rodents at various sites. Several animal studies showed the induction of kidney tumours in male rats and also brain gliomas were induced after oral exposure to lead in rats. IARC concluded that the evidence for carcinogenicity in experimental animals is sufficient.

As outlined in the previous section (“mode of action”) it is assumed that the carcinogenic activity of lead is based on indirect genotoxicity. According to this premise, several institutions have derived occupational exposure limits for lead, e.g., American Conference for Governmental Industrial Hygienists (ACGIH (2017)), Committee for Hazardous Substances (AGS (2017)), National Agency for Food Safety, Environment and Labor, France (ANSES (2017)) and Safe Work Australia (2014).

2.2.3.1 Genotoxicity (RAC, 2020a)

Various studies reporting clastogenic activity of lead are available. Studies with exposed workers could show DNA damage, increased frequency of micronuclei (MN) and chromosomal aberrations (CA) in exposed groups with mean blood lead levels above 300 µg/L (e.g. Chinde et al., 2014). Confounding in the form of co-exposure to other carcinogens however, cannot be excluded. Studies in workers with lower mean blood lead levels (<300 µg/L) showing increased DNA damage and DNA repair and increased MN frequency are more rarely found (Kasuba et al., 2012). Due to the limited number of available studies investigating clastogenic effects in workers below 300 µg/L and due to methodological limitations RAC considered the database in the mean exposure range below 300 µg/L to be too uncertain for a conclusion.

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

2.2.4.1 Neurotoxicity

Numerous epidemiological studies involving workers are available for the endpoint “neurotoxicity of lead”. NOAEL and LOAEL values for different endpoints of chronic lead neurotoxicity were derived, with subtle neurotoxic effects reported at blood lead levels of about 180 µg/L (Schwartz et al., 2001), (Schwartz et al., 2005)). In the meta-analysis by Krieg et al. (2008) LOAELs for peripheral nerve conducting velocity of 330 to 640 µg/L depending on the nerve are reported, LOAELs for subtle neurobehavioral deficits are reported lying between 370 and 520 µg/L (Seeber et al., 2002). LOAELs for changes in cognitive and sensomotoric parameters in lead exposed workers with mean blood lead concentrations of 340±140 µg/L are also available (Vlasak et al., 2019).

RAC (2020a), RAC (2020b) concluded on a NOAEL of 180 µg/L for neurotoxicity which is considered the most critical endpoint in RACs assessment.

RAC followed the assessment of SCOEL (2002) who considered the "impairment of performance in neurobehavioral tests as the leading toxic effect of lead in males and females". A LOAEL of 400 µg/L was established by SCOEL in 2002.

ANSES (2017) also concluded on a NOAEL of 210 µg/L and a NOAEL of 180 µ/L blood lead for neurobehavioral effects based on the studies by Schwartz et al. (2001) and Schwartz et al. (2005).

The study by Krieg et al. (2008) is a meta-analysis of 49 studies which investigated the effect of lead on peripheral nerve conduction velocity mainly in workers. In the meta-analysis data from 2825 exposed subjects and over 1500 controls are incorporated. The mean duration of exposure was 7.7 years. The conduction velocity in median, ulnar and radial nerves in arms and legs was found to be reduced in lead-exposed subjects in a dose-dependent manner. The lowest concentration at which a relationship with blood lead could be detected was 330 µg/L for the nerve conduction velocity of the median sensory nerve. This is the concentration where the relationship became consistently statistically significant. The authors declare that this is not a threshold for lead induced effects. The study by Krieg et al. (2008) was selected for the derivation of the dose-response relation in section 2.3.3.1.

2.2.4.2 Haematotoxicity

Several studies show that lead inhibits enzymes of haem synthesis in a dose-dependent manner (e.g., δ-aminolevulinic acid dehydrase (ALAD)). However, the clinical significance of these effects is uncertain. ALAD inhibition is known to start at blood lead levels of 100 to 200 µg/L. However, the biosynthesis of haem is not reduced until the action of ALAD is restricted by 80 - 90%, which takes place at a higher concentration of lead of about 550 µg/L in blood (RAC, 2020a, RAC, 2020b). In 2002 SCOEL concluded that subclinical changes in parameters of haem synthesis may occur below 400 µg/L blood lead, but these are not regarded as being adverse (SCOEL, 2002).

Two relevant studies (Khan et al. (2008), Karita et al. (2005)) of workers reporting a dose-dependent reduction in haemoglobin concentrations after lead exposure are reported by (RAC, 2020b). The reduced haemoglobin concentrations result in an increased risk of developing lead-induced anaemia. One of these studies (Khan et al., 2008) is a cross-sectional study in 87 lead smelter workers and 61 non-exposed controls in Pakistan. The authors reported a slight, statistically significant reduction in the haemoglobin concentration of exposed workers compared to controls. The study by Khan et al. (2008) was used for the derivation of a dose response relation in section 2.3.3.2.

RAC (2020a), RAC (2020b) report a $BMDL_{05}$ (considered as a NOAEL by RAC) of 195 µg/L based on an" increased probability for abnormal haemoglobin" (according to the authors calculated from the K-Power model set at an abnormal probability of 5% in unexposed workers and an excess risk of 5% in exposed workers) from the study of Karita et al. (2005).

2.2.4.3 Nephrotoxicity

ATSDR (2020) noted that various epidemiologic studies in adults show that exposure to lead can cause altered kidney function and contribute to the development of chronic kidney disease (CKD). However, studies on chronic kidney disease morbidity and mortality in workers do not lead to clear conclusions.

Ekong et al. (2006) reviewed epidemiological studies on lead exposure and nephrotoxic effects in humans (workers, CKD patients and general populations). Compared to the studies in the general population, the results in studies with workers are less consistent and the correlations between blood lead levels and nephrotoxic effects showing a clinical outcome are less distinct. RAC (2020a), RAC (2020b) discusses as possible reasons the generally smaller sample size in occupational studies, the "healthy worker effect" and exclusion criteria for workers in epidemiological studies like hypertension or diabetes. RAC states that these conditions might result in an "*obscuring of actual associations*".

In a recent publication by Steenland et al. (2017) including more than 88 000 workers the risk of death from kidney disease was not statistically significantly increased at any lead exposure level. In addition, no increased risk of severe kidney disease was observed in this study. Therefore, an early biological effect marker of nephrotoxicity, the increase of urinary excretion of N-acetyl-β-D-glucosamidase (NAG), was used as critical endpoint for the derivation of a DRR (Dose Response Relationship) in section 2.3.3.3.

In a cross-sectional study in 135 storage battery workers (mean PbB 422 µg/L, mean age 29 years) and 143 mechanics without occupational lead exposure (mean PbB 119 µg/L, mean age 27 years) in northern China, Lin and Tai-Yi (2007) measured changes in urinary total protein, urinary ß2-microglobulin and urinary NAG. The changes were most prominent regarding the NAG concentration in urine. Lin and Tai-Yi (2007) selected the 90th percentile of the control group as indicative for renal dysfunction.

RAC (2020a), RAC (2020b) also acknowledges a $BMDL_{10}$ (considered as a NOAEL) of 253 µg/L blood lead for sub-clinical effects in renal parameters (BMR 10% for the increase in NAG coming from a study by Lin and Tai-Yi (2007)) as the lowest NOAEL for nephrotoxicity.

2.2.4.4 Cardiovascular effects

Recent epidemiological studies provide indications for an association of past exposure to lead and cardiovascular mortality in workers (e.g. Steenland et al., 2017). The effect was seen at levels above 200 - 400 µg/L. However, it has to be noted that Steenland et al. and other epidemiological studies did not adjust for potential confounding factors (e.g. smoking). RAC (2020a), RAC (2020b) noted that the “healthy worker effect” and potential confounding by lifestyle risk factors may be a problem for the interpretation of epidemiological data from workers especially for cardiovascular morbidity and mortality in occupationally exposed populations.

Several cross-sectional studies investigated effects of lead exposure at workplaces and elevation of systolic and diastolic blood pressure (e.g., Dongre et al. (2013), Xie et al. (2019), Nomiyama et al. (2002)). The study by Dongre et al. (2013) was selected for the derivation of a DRR in section 2.3.3.4. Male workers in battery manufacture in India were selected for the study. The exposure duration is given with “one to 20 years” and workers were divided in three groups depending on the duration of lead exposure: Group 1 with 1 – 5 years exposure, group 2 with 6 - 10 years of exposure and group 3 with more than 10 years of exposure. Dongre et al. (2013) observed an increase of the systolic and diastolic blood pressure with increasing lead-exposure duration (systolic blood pressure: 116 (control), 123 (group 1), 127 (group 2) and 131 mmHg (group 3)).

RAC (2020a), RAC (2020b) noticed that small changes in blood pressure at the population level may be associated with considerable increase in numbers of hypertensive individuals. They considered a value of about 300 µg/L blood lead to be associated with a small increase in systolic and diastolic blood pressure. At 200 – 400 µg/L blood lead RAC (2020a), RAC (2020b) reported increased cardiovascular mortality based on the study by Steenland et al. (2017).

2.2.4.5 Male fertility

SCOEL (2002) concluded that adverse effects on male reproduction appear consistently at blood lead levels above 400 µg/L. RAC (2020a), RAC (2020b) supported this conclusion and referred to key studies by Bonde et al. (2002) and Kasperczyk et al. (2008) which showed adverse effects on sperm quality above a blood lead level of 400 µg/L.

For the derivation of a DRR, the study by Shiau et al. (2004) with the endpoint “reduced fecundability ratio” was selected. The reasons to deviate from the starting point selected by RAC is explained in section 2.3.3.5. Shiau et al. (2004) studied 153 currently employed and married male lead battery workers in Taiwan. The men were grouped according to the blood lead levels (<200, 200-290, 300-390, ≥400 µg/L). Indications for reduced fertility, measured as prolonged “Time-To-Pregnancy (TTP) in in the wife also called “reduced fecundability ratio", was reported with PbB levels ≥300 µg/L (fecundability ratio: 1.0 (control), 0.9, 0.72, 0.52, 0.4).

2.2.4.6 Female fertility

According to RAC (2020b), RAC (2020a) and SCOEL (2002) the data with regard to female fertility is too limited to draw any conclusion. However, RAC addressed this endpoint briefly and only described one study in a little more detail. In this study from Italy, Paredes Alpaca et al. (2013) observed a higher frequency of hypertension during pregnancy (RR: 1.34; 95% CI 1.07-1.68) and preeclampsia/eclampsia (RR: 1.47; 95% CI 1.08-2.00) in occupationally exposed women.

In a more recent meta-analysis Poropat et al. (2018) analysed eleven epidemiological studies with pregnant lead-exposed women with regard to the association between preeclampsia and lead poisoning. The authors concluded that an increase of 10 µg/L blood lead is associated with a 1.6% increase in the incidence of preeclampsia. This study was selected for the derivation of a DRR in section 2.3.3.6.

The meta-analysis by Poropat et al. (2018) states that "*women with BPb* [Lead concentration in blood] *levels greater than 5 µg/dL should be actively monitored for symptoms of preeclampsia*". This fits well to an effect level of 100 µg/L for hypertension during pregnancy as described in several recent reviews (e.g., ATSDR (2020)).

2.2.4.7 Developmental toxicity (effects on the foetus)

Lead can pass the placenta. During pregnancy lead deposited in maternal bones can be mobilised and elevate the exposure level of the foetus. SCOEL (2002) summarised that the blood lead concentration in the umbilical cord at birth is close to the blood lead level of the mother (80 to 90%).

SCOEL (2002) also noted that it is not possible to distinguish between the effects caused by maternal lead exposure during pregnancy and early childhood exposure due to other sources. However, there are toxicokinetic indications that neurological and psychomotoric developmental effects in the offspring are caused by prenatal exposure and/or lactation.

ATSDR (2020) summarised a large number of studies showing decrements in neurological function in children. The authors conclude that these studies indicate that lead affects cognitive function in children prenatally exposed to ≤ 50 µg/L blood lead and that no safe blood lead level in children has been identified.

RAC (2020a), RAC (2020b) specifically excluded pregnant women from the suggested BLV of 150 µg/L blood lead. RAC states: "*No threshold for potential central nervous system effects in new-borns and infants can be identified at present. The exposure of fertile women to lead should therefore be avoided or minimised.*"

For the derivation of a DRR in section 2.3.3.7 two studies were selected. Lanphear et al. (2005) in a pooled analyses of 1333 children from seven international prospective studies showed an association between the increase of the childhood blood lead level (24 to 100 µg/L) and the decline of 3.9 points in full-scale IQ. Increases from 100 to 200 µg/L and from 200 to 300 µg/L were associated with declines of 1.9 and 1.1 IQ points, respectively. Schnaas et al. (2006) analysed a cohort of 175 children in Mexico City. For this study, a similar dose response relationship for prenatal exposure in an exposure range close to potential occupational maternal exposure (i.e., at exposure levels > 50 µg/L PbB) was derived. As outlined in section 2.3.3.7 both studies have their limitations.

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

Several analytical methods are available for the measurement of blood lead. With these methods LOQs (level of quantification) of up to 0.015 µg lead/L blood (inductively coupled plasma / mass spectroscopy) can be reached (RAC, 2020a).

According to RAC, all international and national bodies proposing occupational limit values use lead measured in blood as the relevant exposure metric and derive biological limit values (BLV). If in parallel an OEL for workplace air is reported it is selected to correspond to the established BLV. As RAC points out, lead is unique in this regard since normally the BLV is derived from the OEL.

Biological limit values (BLV) in EU Member States and from selected non-EU countries are presented for lead, tetramethyl lead, and tetraethyl lead (status: 18.12.2020) in section 4.1.3, Table 4-3.

2.2.6 Group approach for lead compounds

Lead is a metal that can be found in organic and inorganic forms. The current document as well as the RAC documents (RAC, 2020b, RAC, 2020a) deal mostly with the inorganic lead form.

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

The BLV derived by RAC is only valid for lead and inorganic compounds. RAC explicitly states that due to data limitations, no quantitative scientific evaluation of organic lead compounds is possible and thus no limit values can be proposed.

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

2.3.1 Starting point

The starting point of the following quantitative considerations is the evaluation performed by RAC (2020a), RAC (2020b).

RAC proposed an 8-h TWA OEL of 4 µg lead/m³ which corresponds to a BLV of 150 µg lead/L blood (at the 95th percentile level). The Committee did not establish a STEL value since acute toxicity to lead is observed only at considerably higher blood levels. RAC states that "*the application of the BLV is to be preferred over the air limit value since internal lead levels are decisive for the chronic toxicity of lead and its inorganic compounds."* (RAC, 2020b). RAC further explains that the air limit value may not sufficiently protect from an exceedance of the BLV since additional exposure may occur due to ingestion (hand-to-mouth contact) which can have a relevant influence on the internal exposure. This OEL is considered to be protective for carcinogenic and non-carcinogenic effects. It is based on a NOAEL for subtle neurobehavioral effects in workers at 180 µg/L. Other also relevant effects started at higher concentrations.

Since the limit values are derived from human data, no interspecies factor is required. The database on human exposure to inorganic lead is extended. Therefore, the variability of workers is addressed adequately and an intraspecies factor could also be omitted.

RAC states, that the proposed BLV does not protect from developmental toxicity. Therefore, the exposure of fertile woman should be avoided.

A skin notation for lead is not recommended.

2.3.2 Exposure Risk Relationship (ERR) for carcinogenic effects

2.3.2.1 Approach

As outlined in section 2.2.3, there is sufficient evidence in experimental animals for the carcinogenic activity of lead compounds, but limited evidence, due to a contradictive and inconsistent database from human studies.

Apart from an older unit risk derivation by the Californian EPA (which is discussed in detail by AGS (2017)), the only known exposure-risk relationship was derived by the German AGS in the documentation leading to deriving a biological limit value of 150 µg/L (AGS, 2017). Using the rat study by Azar et al. (1973) with lead acetate and the incidence data for kidney tumours reported in this study, AGS derived a concentration of

24 mg/m^3 for an excess cancer risk of 4 : 1 000

2.4 mg/m^3 for an excess cancer risk of 4 : 10 000

0.24 mg/m^3 for an excess cancer risk of 4 : 100 000.

With these results AGS concluded that relevant cancer risks occur at concentrations above critical workplace concentrations and well above low effect concentrations for non-cancer endpoints. As detailed in section 2.2.3, RAC (2020b), RAC (2020a) found the epidemiological data on carcinogenicity of lead inconsistent and states that: “the original conclusions by IARC (2006) are still valid, i.e. that the evidence for the carcinogenicity of inorganic lead compounds in the human data is limited.” In the opinion document RAC discussed in some detail the recent study of Steenland et al. (2019), which reports incidence data for brain and lung cancer from two European cohorts. RAC noted that the results between the Finish and UK cohort were contradictive and the number of cases was low.

As the LOAEL for chromosomal effects was identified by RAC to be around 300 µg/L, the committee concluded that the proposed OEL would also be protective for clastogenicity and carcinogenicity. However, this does not exclude the possibility that carcinogenic effect might be relevant above the proposed OEL.

As described above, there is no consistent epidemiological database available, which could serve as a basis for a quantitative cancer risk estimation (see the summary in section 2.2.3). As results from individual epidemiological studies are partly contradictive, deriving an ERR based on the outcome of a single study would be highly uncertain. However, a new meta-analysis on brain tumours by Ahn et al. (2020) increases the suggestive evidence for this localisation and is used here for a semi-quantitative analysis on the relevance of carcinogenic effects in the exposure range above the OEL. However, the uncertainties of these calculations must be clearly acknowledged and taken into account in their interpretation. Obtained cancer risks are considered an upper limit of a range, which may include no excess cancer risks at all.

Input data:

Hazard ratios:

Ahn et al. (2020), by analysing 18 epidemiological studies passing the authors’ quality criteria, calculated a pooled, statistically significant odds ratio (OR) of **1.13** for malignant tumours of the brain and/or the central nervous system (CNS) (the OR for malignant plus non-malignant brain tumours was not statistically significantly elevated). Only 3 out of 18 studies on malignant brain tumours showed a statistically significant increase.

Exposure:

Blood lead measurements were available for only 5 cohorts included in the analysis (exposure information for the other studies consisted in job-exposure matrix information). Three of these recent cohorts come from the recent studies by Barry and Steenland (2019) and Steenland et al. (2019). The highest exposure group in these studies is given as > 400 µg/L. It is assumed here that higher workplace exposures potentially leading to increased cancer risk are in the region of **500 µg/L**.

Background cancer rate:

The ECIS - European Cancer Information System[5] gives background rates for malignant "brain and other CNS" tumours from 18 EU-27 member states plus 5 other European countries. The total range reported is 0.3 to 1.1%, for EU-27 countries 0.4 to 1.1%. The average for EU-27 member states is 0.66% (some countries (ES, DE, IT, FR) are overrepresented, due to a higher number of individual values included in the list; however, the error is considered acceptable as the values over all countries are very homogeneous).

Using the simple

Equation 2-1: Calculation of excess cancer risk for malignant brain/CNS tumours

$$ER = \frac{(RR - 1) * P(0)}{x}$$

With

ER = excess cancer risk

RR = relative risk as observed in the meta-analysis

P(0) = background risk for dying of malignant brain and/or CNS tumours, according to ECIS

x = blood lead concentration (µg/L)

Further steps to derive an ERR:

Step 1:

This relationship given in Equation 2-1 is used to calculate the excess cancer risk at a blood lead level of 500 µg/L.

This formula results in an ER of 8.6×10^{-4} at 500 µg/L.

Step 2:

We derive a linear ERR, using this datapoint and a second datapoint defined by RAC's OEL proposal, which assumes 0 risk at the OEL of 150 µg/L (i.e., we follow RAC's conclusion that there is no carcinogenic risk at the proposed OEL of 150 µg/L). In the following Figure 2-1 this correlation is shown graphically:

[5] https://ecis.jrc.ec.europa.eu/

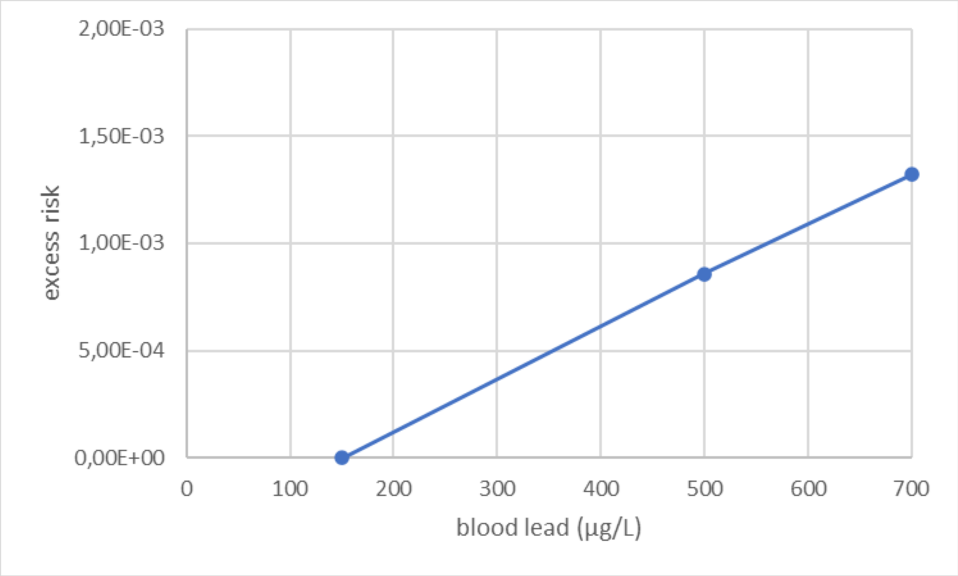


Figure 2-1: ERR for malignant brain and/or CNS tumours

The algorithm to calculate the excess cancer risk is given in Equation 2-2:

Equation 2-2: Tentative ERR for excess cancer risk for malignant brain/CNS tumours caused by lead expsoure

$$\mathrm{ER} = -3.69 * 10^{-4} + 2.46 * 10^{-6}\ [1/\mu\mathrm{g/L}] * \left(c_{blood_{lead}}\right)\ [\mu\mathrm{g/L}]$$

with c ranging from 150 to 700 µg/L.

No information on the maximum exposure duration (MaxEx) or minimum exposure duration (MinEx)[6] is available. The studies evaluated in the meta-analysis of Ahn et al. (2020) comprised several case-control and cohort studies with long-term occupational exposures, which can be expected to vary between studies and individuals included in these studies. No information on latency is available. Default values are applied for the impact modelling.

2.3.2.2 Discussion

As explained above this tentative ERR should be considered a conservative approach to give an indication for possible cancer risks, under the assumption that the evidence for brain tumours as shown in the meta-analysis of Ahn et al. (2020) is further substantiated. Individual studies included in this meta-analysis vary largely in their results: whereas many do not support an association with lead exposure, some (e.g. Barry and Steenland (2019) and Steenland et al. (2019)) calculated high relative risks in the range between 1.5 and 2.

It is also noted that other tumour localisations such as lung cancer would lead to higher excess risks (due to the higher background rates) if the calculated relative risks in individual studies would prove to be a realistic description of the tumour induction by lead. However, RAC in their analysis made clear that when considering the evidence from all studies, for lung cancer the overall database is inconsistent, as there are at least as many negative as positive studies. The same conclusion was drawn by RAC for brain tumours, but for this location we make use of the new meta-analysis not considered by RAC, which concludes on an overall slightly increased cancer risk, considering all studies of sufficient quality.

It should also be noted that the ERR derived by AGS (2017) based on animal data (for kidney tumours) lead to risks in the relevant workplace exposure ranges, which are orders of magnitude lower. If the linear correlation derived by AGS (2017) as shown above is

[6] MaxEx - The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase). MinEx - The minimum exposure duration required to develop the endpoint

extended to the 1 : 100 000 risk level, the corresponding concentration would be 60 µg/m³. So, acceptable concentrations derived from this ERR would be far above currently discussed concentrations for OEL setting. The comparison with the ERR based on the rat study also shows that if the tentative ERR based on human data would be substantiated, a considerably higher sensitivity of humans regarding carcinogenic effects of lead would become evident.

In this project we will use the tentative ERR for risks for malignant brain tumours but will critically compare and discuss its impact in relation to the other relevant non-cancer health endpoints associated with lead exposure (see below).

2.3.3 Dose Response Relationship (DRR) for non-carcinogenic effects (biomonitoring)

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

- Neurotoxicity
- Haematotoxicity
- Nephrotoxicity
- Cardiovascular effects
- Male fertility
- Female fertility
- Developmental toxicity (effects on the foetus)

DRRs for each of these endpoints will be discussed in the following subsections. The current chapter deals with DRRs derived for blood lead levels (PbB). In section 2.3.4 a conversion of the PbBs to concentrations in air is performed and an equation for the correlation between air lead concentrations and blood lead concentrations is given.

The following approach was applied for the derivation od DRRs:

- It is accepted that PbB may be influenced by non-occupational sources of lead exposure (e.g., food, drinking water),
- it is accepted to use NOAELS, LOAELS based on studies from the general population with no occupational exposure, because identical sensitivity of workers is assumed (relevant for the endpoints female fertility and developmental toxicity),
- it was avoided to rely on study results from experimental animals, because of significant additional uncertainties of species extrapolation for lead compounds, considering tissue accumulation, species-specific biological half-life, and toxicodynamics,
- assessment results from RAC were used as starting points for identifying critical endpoints and key studies.

To derive DRRs, studies identified by RAC as relevant for the endpoints under consideration are used as often as possible. If these studies do not provide dose-response data sufficient to determine the dose-response relationship, further reliable studies were exploited. For all endpoints (except female fertility and developmental toxicity) zero effect was assumed at the OEL proposed by RAC and the dose-dependent effect size above was estimated using data from the studies.

A member of the steering group of the study questioned this approach and requested that the endpoint-specific NOAELs reported by RAC were used as the doses with zero effect. According to e.g., the European Food Safety Agency the NOAEL is the highest dose that does not produce statistically significant effects (EFSA, 2017) and thus depends on the sensitivity of the study and the statistical methods applied (WHO, 2020). For experimental animal studies, EFSA (2017) concludes that "*The NOAEL is therefore not necessarily a 'no adverse effect' dose, although it is often interpreted as such. Indeed, as the review studies …, the size of the estimated effect at the NOAEL is, on average over a number of studies, close to 10% (quantal responses) or 5% (continuous responses).*" Considering the design and the size of the human studies used for the various endpoints below, effect sizes in the single-digit percent range can also be expected for these studies and where actually confirmed for some of them where authors calculated benchmark doses (see below for more details).

To clarify this controversy, RAC was requested to provide their opinion. The ECHA OEL support team responded to this request by emphasizing the uncertainty associated with the NOAELs and that these NOAELs are not set by RAC but result directly from the studies scrutinized. In an additional ad-hoc meeting to further clarify the controversy the following conclusions on the subject of the NOAEL interpretation, adopted by all participants, were drawn:

"Following on from the morning meeting of the Steering Group on Thursday 27th May [2021] to discuss the progress report for lead and its compounds, a small group had a further call in the afternoon to discuss a specific question. The group included: Alick Morris (DG EMPL), Martin Wieske (EIG), and Sophie Garrett and Klaus Schneider of the study team.

The specific question was about the linear extrapolation of the DRR for the cardiovascular and nephrotoxicity effects endpoints below the NOAEL. MW was unhappy in principle that the DRR did not have a threshold at the NOAEL, and concerned that this led to cases, and particularly costs of ill-health for cardiovascular effects that did not seem realistic. KS strongly believed that the extrapolation used in the DRR was the only sensible assumption.

After some discussion, it was agreed that the DRR and the number of cases should be kept as they are, but that the specific attributes of a cases should be investigated further to ensure that the cost variables used in the benefits model for methods 1 and 2 sensibly reflect a case. The definition of the case should indicate what cardiovascular effect (e.g., increased blood pressure) constitutes a case and the source of this information. It was felt that the costs of a case are probably too high because a case has been taken to mean a substantial increase in blood pressure, which may not be correct. …"

Following these conclusions, the principal approach and the definition of NOAELs (as a dose possibly associated with small effect sizes) was kept, but the definition of cases with cardiovascular effects (increased blood pressure) was scrutinized again and compared to how the benefit model handles the cases. In consequence the criterion for defining cases of increased blood pressure was increased to 140 mm Hg, which substantially reduced the number of cases (see below).

2.3.3.1 Neurotoxicity

Approach

Epidemiological studies showing neurotoxic effects of lead were evaluated considering the endpoints "reduced nerve conduction velocity" and "neurobehavioral effects".

RAC (2020a), RAC (2020b) also considered these two endpoints, concluding that data derived from workers exposed to lead provide NOAELs and LOAELs for different neurological effects. Based on studies by Krieg et al. (2008), Seeber et al. (2002), Meyer-Baron and Seeber (2000), Schwartz et al. (2001) and Schwartz et al. (2005) RAC anticipated 180 µg/L blood lead as NOAEL for neurotoxicity in these studies, not clearly referring to one of the above mentioned endpoints. RAC did not derive a DRR for neurotoxicity.

In the study by Schwartz et al. (2001) results from an older, extensive study on cognitive functions in lead workers by Stollery et al. (1989) were confirmed: "*sensory and motor (rather than cognitive) requirements of the neurobehavioral tests were most affected by lead*"

(Schwartz et al., 2001). Studies by Bleecker et al. (2005) and Bleecker et al. (2007) also confirmed these findings. In their 2007 publication, Bleecker et al. observed that the cognitive reserve protects from the effect of chronic lead exposure, however, the motor performance is impaired. Bleecker et al. (2005) observed effects of lead exposure on sensory peripheral nerve fibres in exposed workers.

Since the endpoint "reduced nerve conduction velocity" seems to be the most sensitive endpoint for neurological effects of lead the derivation of a DRR was based on the study by Krieg et al. (2008). This study is a meta-analysis investigating the effects of lead exposure on nerve conduction velocity in exposed workers.

Reduced nerve conduction velocity is an indication for neuropathy. Motor neuropathy may cause impaired balance and coordination or muscle weakness. Symptoms of sensory neuropathy are numbness to touch and vibration, reduced position sense causing poorer coordination and balance, reduced sensitivity to temperature change and pain, spontaneous tingling or burning pain.

In a meta-analysis by Krieg et al. (2008) 49 studies which investigated the effect of lead on peripheral nerve conduction velocity mainly in workers are reported. The conduction velocity in median, ulnar and radial nerves in arms and legs was found to be reduced in lead-exposed subjects in a dose-dependent manner. The reduction of the conduction velocity of the median motor nerves in the arm was selected for the derivation of the DRR since a) most studies (28) were evaluated for this endpoint and b) a high slope of -6.05 was calculated by the authors in the mixed model analysis. The data are shown in the following table.

Table 2-6 Blood lead concentrations and corresponding median motor nerve conduction velocity in control and exposed workers reported in the study by Krieg et al. (2008)

Blood lead concentration [µg/L, mean]	**Median motor nerve conduction velocity (mean ± SD) [m/sec]**
Control: 157	59.1 ± 2.2
Exposed: 530	55.9 ± 2.9

From the data reported in Table 2-6 no direct information on the fraction of affected individuals can be derived. Therefore, a transformation was performed, which allows to estimate the affected fraction (% individuals of total exposed). To this end,

1. Median motor nerve conduction velocity below 50 m/sec in the arm were considered as adverse. Reference values for median motor nerve conduction velocity in the upper extremities of healthy individuals are often defined as being >50 m/sec[7]. Therefore, a median nerve conduction velocity below 50 m/s was considered as adverse and associated with the clinical picture of peripheral neuropathy.

2. It was assumed that median nerve conduction velocity within an investigated exposure group are normally distributed (Naik et al., 2014; Schuhfried et al., 2017).

1. With this assumption and the standard deviation (SD) given in the publication all percentiles of the distribution can be calculated from mean and SD. The fraction

[7] https://www.racgp.org.au/download/documents/AFP/2011/September/201109huynh.pdf, https://books.publisso.de/en/publisso_gold/publishing/books/overview/49/40, https://www.aanem.org/getmedia/c58afeb5-4164-47f2-b7a4-519ff08a26e6/Chen_et_al-2016-Muscle_-_Nerve.pdf

of individuals with median motor nerve conduction velocity below 50 m/sec was calculated in Excel®, an overview is given in Table 2-7.

The following table for evaluation was generated in Excel®:

Table 2-7 Mean values for median motor nerve conduction velocity and standard deviation used to calculate percentage of individuals exceeding the cut-off of a normal distribution. For calculation of affected individuals, a cut-off criteria of <50 m/sec was set.

Mean blood lead [µg/L]	Median motor nerve conduction velocity [m/sec] mean	Median motor nerve conduction velocity [m/sec] SD	Affected individuals [%]	Affected individuals above control [%]
157	59.1	2.2	0.002	0
530	55.9	2.9	2.095	2.093

The “affected individuals above control group” (considered as individuals who suffer from neuropathy) were plotted against the mean blood lead level and the result is presented in Figure 2-3. A trendline for these data is included, using the trendline function in Excel®.

Since RAC concluded on a BLV for humans of 150 µg/L, the linear equation is only valid starting from 150 µg/L blood lead. Due to the definition of the OEL by RAC the excess risk for neuropathy is zero at this point.

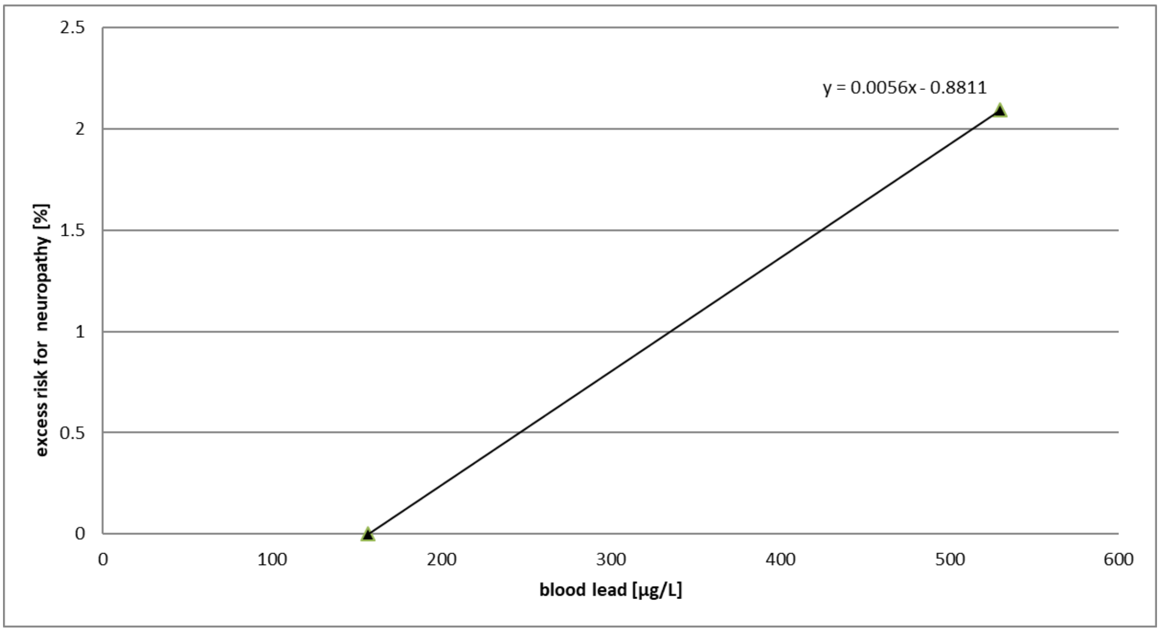


Figure 2-2: Trendline for excess risk of neuropathy in lead-exposed individuals based on the study by Krieg et al. (2008) .

The dose response relation for neuropathy can therefore be described with the following equation:

Equation 2-3: DRR for lead (endpoint neurotoxicity)

$$Excess\ Risk(neuropathy) = 0.0056 * (c_{blood_{lead}}) - 0.8811$$

With c ranging from >150 to 700 µg/L.The exposure duration in the metanalysis by Krieg et al. is given with 7.7 years ± 4.7 years (mean ± SD).

No information on the intensification of the effect is available. Therefore, MaxEx was estimated with 7 years. Due to the absence of data, the default value (0 years) is assumed for MinEx. No information on latency is available, therefore, no latency period is assumed.

Discussion

Krieg et al. also calculated the lowest concentration at which a relationship can be detected. They describe this as "*the concentration of blood lead at which the relationship becomes consistently statistically significant*". However, they emphasize that this is not an estimate of a threshold for lead to have an effect. The lowest value reported is 330 µg/L for median sensory conduction velocity. For median motor conduction velocity this value is 394.0 µg/L. This is in agreement with the assumption of absence of such effects at 150 µg/L.

2.3.3.2 Haematotoxicity

Approach

Epidemiological studies showing haematological effects of lead were evaluated considering the endpoints "anaemia" and "effects on enzymes involved in haem synthesis".

RAC (2020a), RAC (2020b) also considered these two endpoints, concluding that data derived from workers exposed to lead provide a $BMDL_{05}$ of 195 µg/L based on increased probability for abnormal haemoglobin (Karita et al., 2005). RAC refers to SCOEL (2002) concluding that the subclinical changes in parameters of haem synthesis (e.g. zinc protoporphyrin increase) below 400 µg lead/L blood are not considered as adverse. RAC did not derive a DRR for haematotoxicity.

Based on the conclusion by RAC and the availability of data for the endpoint "anaemia" it was decided to use the endpoint "anaemia" for the derivation of a DRR for the current project. This endpoint was preferred over the "effects on enzymes involved in haem synthesis" since the clinical relevance and the associated clinical picture is not clearly defined.

The study by Karita et al. (2005) does not report the haemoglobin concentrations in blood (or other parameters relevant for the manifestation of clinical anaemia) for control and exposure groups of workers. Due to the way how results are reported in the study, it is not possible to use the publication for the derivation of a DRR.

A second study reported by RAC on the endpoint anaemia is from Khan et al. (2008). Haemoglobin concentrations in 87 male workers and 61 controls are reported as means with standard deviations. The corresponding blood lead concentrations (mean values) are also given. It has to be noted that the haemoglobin concentrations are reported as g/L. Since reference values for haemoglobin concentrations in humans are between 13 and 18 g/dL for males (medizinische Fachredaktion Pschyrembel, 2018), it can be assumed with high certainty that the unit in Khan et al. is de facto g/dL (see the following Table 2-10, haemoglobin concentration given in in g/L but 10times higher than in the publication).

Table 2-8 Blood lead concentrations and corresponding haemoglobin concentrations in control and exposed workers reported in the study by Khan et al. (2008)

Blood lead concentration [µg/L]	Haemoglobin concentration ± SD [g/L]
Control: 83	156.2 ± 9.6
Exposed: 291	151.2 ± 12.4

From the data reported in

Table 2-8 no direct information on the fraction of affected individuals can be derived. Therefore, a transformation was performed, which allows to estimate the affected fraction (% individuals of total exposed). To this end,

- Haemoglobin concentration below 130 g/L blood was defined by the World Health Organization (WHO) as the borderline for considering a male individual as affected with anaemia[8],
- it was assumed that haemoglobin concentrations within an investigated exposure group are normally distributed (Tufts et al., 1985).
- With this assumption and the standard deviation (SD) given in the paper all percentiles of the distribution can be calculated from mean and SD; the fraction of individuals with haemoglobin concentrations below 130 g/L was calculated in Excel®, an overview is given in Table 2-11.

The following table for evaluation was generated in Excel®:

Table 2-9 Mean values for haemoglobin concentration in blood and standard deviation used to calculate percentage of individuals exceeding the cut-off of a normal distribution. For calculation of affected individuals, a cut-off criteria of <130 g haemoglobin / L blood was set.

Mean blood lead [µg/L]	Haemoglobin conc. in blood [µg/L] Mean	Haemoglobin conc. in blood [µg/L] SD	Affected individuals [%]	Affected individuals above control [%]
83	156.2	9.6	0.32	0.00
291	151.2	12.4	4.37	4.05

The "affected individuals above control group" (considered as individuals who suffer from anaemia) were plotted against the mean blood lead level and the result is presented in Figure 2-3. A trendline for these data is included, using the trendline function in Excel®.

Since RAC concluded on a BLV for humans of 150 µg/L, the linear equation is only valid starting from 150 µg/L blood lead. Due to the definition of the OEL by RAC the excess risk for anaemia is zero at this point.

[8] https://www.who.int/vmnis/indicators/haemoglobin.pdf

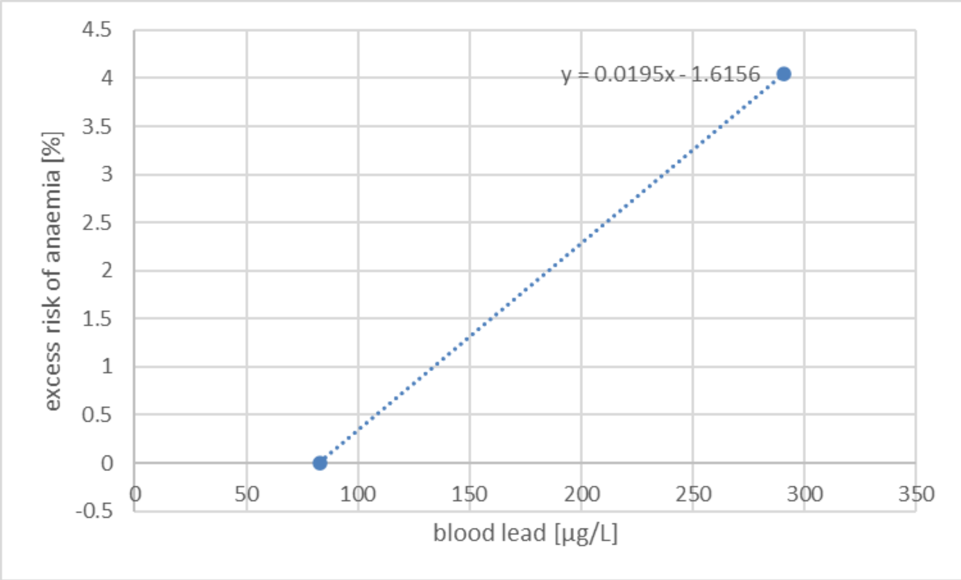


Figure 2-3: Trendline for excess risk of anaemia in lead-exposed individuals based on the study by Khan et al. (2008).

The dose response relation for anaemia can therefore be described with the following equation:

Equation 2-4: DRR for lead (endpoint anaemia)

$$Excess\ Risk(anaemia) = 0.0195 * (c_{blood_{lead}}) - 1.6156$$

With c ranging from >150 to 700 µg/L.

The exposure duration in the study by Khan et al. is given with 3 – 24 years.

No information on the intensification of the effect with exposure time is available. Therefore, MaxEx was estimated with 10 years. Due to the absence of data the default value (0 years) is assumed for MinEx. No information on latency is available, therefore, no latency period is assumed.

Discussion

The DRR given above for the endpoint haematotoxicity is based on the study by Khan et al. (2008). Since only one exposure group is available in the study the results have to be considered cautiously and a proof of concept is performed considering the other study on anaemia reported in the RAC documentation by Karita et al. (2005).

Karita et al. report a the $BMDL_{05}$ of 195 µg/L blood lead for an “increased probability of abnormal haemoglobin”. The corresponding BMD_{05} reported by Karita et al. is 286.3 µg/L blood lead, associated with an incidence of the modelled effect of 5%. Our trendline as shown in Figure 2-3, predicts for a blood lead level of 286.3 µg/L an incidence of 3.97%, which we consider a high agreement between the two studies.

According to ATSDR (2020) decreased blood haemoglobin levels can be observed ≤100 µg/L blood, at higher blood lead levels further decreases in blood haemoglobin and loss of erythrocytes (resulting from increased membrane fragility) and anaemia can be observed. No dose response data above about 300 µg/L blood were identified in the context of the current evaluation. Based on the summary provided by ATSDR, a linear extrapolation of the straight line shown in Figure 2-3 up to 700 µg/L blood seems justified, however it is associated with high uncertainty due to the lack of data.

2.3.3.3 Nephrotoxicity

Approach

Epidemiological studies showing renal effects of lead were evaluated considering the end-point “parameters for kidney effects”. This includes changes in serum creatinine or serum urea concentrations or urinary excretion of N-acetyl-β-D-glucosamidase (NAG).

RAC (2020a), RAC (2020b) considered three endpoints for nephrotoxicity: “parameters for kidney effects”, “chronic kidney disease” and “mortality from kidney disease”.

Overall RAC considered a $BMDL_{10}$ (considered as a NOAEL) of 253 µg/L blood lead for sub-clinical renal parameters (increase in (NAG) coming from a study by Lin and Tai-Yi (2007) as the lowest NOAEL for nephrotoxicity. RAC did not derive a DRR for the endpoint nephrotoxicity.

Studies on chronic kidney disease and mortality from kidney disease reported by RAC did not lead to clear conclusions. It is obvious that nephrotoxicity is a relevant endpoint for lead toxicity, however, this is often not reflected in the epidemiological data when looking for late-stage effects. See also section 2.2.4.3. and the publication by Ekong et al. (2006) for possible explanations. In this situation the early event of an increase of NAG concentration in urine (summarised under “parameters for kidney effects”) was used as critical endpoint for the derivation of a DRR.

The study by Lin and Tai-Yi (2007) reported NAG concentrations in urine from several groups of workers exposed to lead. NAG is a high molecular-weight enzyme located in lysosomes where it is involved in the breakdown of glycoproteins. It cannot pass into glomerular ultrafiltrate due to its high molecular weight. However, NAG shows high activity in renal proximal tubular cells and a low level of NAG is found in normal urine. NAG concentration in urine is enhanced when renal proximal tubular epithelial cells are damaged. This effect is considered as one of the first indicating renal damage after lead exposure.

The study by Lin and Tai-Yi (2007) was used for the derivation of a DRR. In the following Table 2-10 the data as given in the publication from Lin and Tai-Yi (2007) (first two columns) are presented. In the third column the excess risk of “renal dysfunction” (see below) above the control group (i.e., observed prevalence minus prevalence in control group) is given in percent and was calculated for the current evaluation.

Lin and Tai-Yi (2007) selected the 90th percentile of the control group as the discriminative criterion for renal dysfunction, which corresponded to a NAG concentration of 17.47 U/g creatinine. It should be noted that column two of Table 2-10 reports prevalence but not incidence data. This is set equal to incidence for calculating excess risks over a worker’s lifetime (see discussion below).

Table 2-10 Blood lead concentrations, prevalence of renal dysfunction based on NAG above 17.47 U/g creatinine and excess risk for renal dysfunction based on elevated NAG as reported in the study by Lin and Tai-Yi (2007)

Blood lead concentration [µg/L]*	Prevalence of renal dysfunction (NAG above 17.47 U/g creatinine**) in %	Excess risk above control for early renal dysfunction [%]
55 (control)	5.77	0
160	10.39	4.62
260	21.62	15.85
360	13.64	7.87
460	22.86	17.09
560	41.82	36.05

**concentrations averaged from the values given in the publication*

***cut-off point of 17.47 U/g creatinine defined by the 90th percentile in the control group*

From the data presented above in Table 2-10 (column one and three) the graph shown in Figure 2-4 was created. A trendline for these data is included, using the trendline function in Excel®. For the cost-benefit analysis, early renal dysfunction was equated to CKD stage 1[9]. This is the mildest of five stages of CKD.

Since RAC concluded on a BLV for humans of 150 µg/L, the linear equation is only valid above 150 µg/L blood lead. Due to the definition of the OEL by RAC the excess risk for nephrotoxicity is zero at this point.

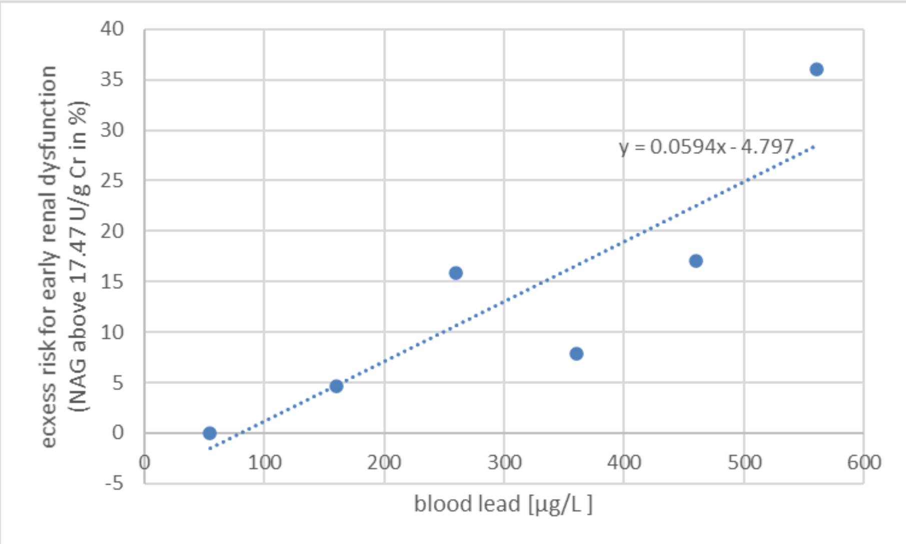


Figure 2-4 Trendline for excess risk of early renal dysfunction in lead-exposed individuals based on the study by Lin and Tai-Yi (2007)

The dose response relation for early renal dysfunction can therefore be described with the following equation:

[9] https://www.kidneyfund.org/kidney-disease/chronic-kidney-disease-ckd/stages-of-chronic-kidney-disease/

Equation 2-5: DRR for lead (endpoint nephrotoxicity)

$$Excess\ Risk(renal\ dysfunction) = 0.0594 * (c_{blood_{lead}}) - 4.797$$

With c ranging from >150 to 700 µg/L.

In the study from Lin and Tai-Yi (2007) the highest exposure group is given with 510 µg/L blood lead and above. Therefore, a linear extrapolation of the straight line shown in Figure 2-4 up to 700 µg/L blood seems justified.

The exposure duration in the study by Lin and Tai-Yi (2007) is given with 5.8 ± 4.4 years.

No information on the intensification of the effect is available. Therefore, MaxEx was estimated with 5 years. Due to the absence of data the default value (0 years) is assumed for MinEx. No information on latency is available, therefore, no latency period is assumed.

Discussion

Concerning the nephrotoxic effects ATSDR (2020) states that "*adverse renal effects of Pb are well-established in numerous epidemiological studies. Studies show consistent evidence of renal damage and reduced renal function associated with a wide range of PbB (≤100–500 µg/L)*". They further elaborate: "*At higher PbB (>300 µg/L), Pb-induced nephrotoxicity is characterized by proximal tubular nephropathy, glomerular sclerosis, interstitial fibrosis, and tubular necrosis.*" Therefore, early renal dysfunction is associated with blood lead levels of 150 – 300 µg/L blood whereas nephropathy, glomerular sclerosis, interstitial fibrosis, and tubular necrosis is expected to occur at blood lead concentrations of 300 – 700 µg/L blood.

The DRR given above for the endpoint nephrotoxicity is based on the study by Lin and Tai-Yi (2007). The $BMDL_{10}$ from the same study and the same endpoint (renal dysfunction due to increased levels of NAG in urine) is 253.4 µg/L blood, the BMD_{10} 299.4 µg/L (as given in the publication). Our trendline as shown in Equation 2-5 predicts for a blood lead level of 299.4 µg/L an incidence of 12.9%. This shows a good agreement of our evaluation and the one made by the authors.

Sun et al. (2008) also calculated a BMD (and BMDL) for NAG in urine from workers exposed to lead. However, the BMD was calculated on a 5% level and is therefore not comparable to the one calculated by Lin and Tai-Yi. Using Equation 2-5 and a blood lead level of 122.4 µg/L (BMD_{05}) of the Sun study an excess risk of about 2.5% can be calculated. This indicates a reasonable agreement of the results by Sun et al. with the DRR derived.

It hast to be noted that the study by Lin and Tai-Yi reports prevalence data not incidence data for renal dysfunction. Therefore, the DRR derived above is potentially an underestimation of the "real" cases that would have been counted if incidence data were collected (which would include affected workers leaving the workplace). However, since NAG elevation is an early effect of renal dysfunction this uncertainty seems acceptable in the current context.

2.3.3.4 Cardiovascular effects

Approach

Epidemiological studies showing cardiovascular effects of lead were evaluated considering the endpoint "effects on systolic blood pressure".

RAC (2020a), RAC (2020b) considered two endpoints for cardiovascular effects of lead: "effects on blood pressure" and "cardiovascular disease and mortality". Overall RAC considered a value of ca. 300 g/L blood lead to be associated with a small increase in systolic and diastolic blood pressure based on the studies by Glenn et al. (2006) and Weaver et al. (2008) (cited in RAC, 2020b). At 200 – 400 µg/L blood lead RAC reported increased cardiovascular mortality based on the study by Steenland et al. (2017). However, this study did not adjust for potential confounding by non-occupational risk factors (e.g. smoking). RAC did not derive a DRR for the endpoint cardiovascular effects.

Several studies are available that report elevated systolic and diastolic blood pressure in lead exposed workers with dose-response data (e.g., Dongre et al. (2013), Xie et al. (2019), and Nomiyama et al. (2002)). This endpoint was selected for the derivation of a DRR since effects on blood pressure are a risk factor for cardiovascular and cerebrovascular diseases.

Elevation of systolic blood pressure in lead-exposed workers was selected as the relevant endpoint for the derivation of a DRR. The studies by Glenn et al. (2006) and Weaver et al. (2008) which were used by RAC for the derivation of a LOAEL are not suitable for the derivation of a DRR. Therefore, studies by Dongre et al. (2013), Xie et al. (2019) and Nomiyama et al. (2002) (all these studies are also listed in Annex 1 of the RAC opinion) were evaluated and the study by Dongre et al. selected for the derivation of a DRR. All three studies reported an increase in systolic blood pressure with increasing blood lead concentrations. The exposure duration in the study by Dongre et al. (2013) is given with "one to 20 years". Workers were divided in three groups depending on the duration of lead exposure: Group 1 with 1 – 5 years exposure, group 2 with 6 - 10 years of exposure and group 3 with more than 10 years of exposure. In the following Table 2-11 the data reported for the three exposure groups are presented. The exposure duration given above correlated with increased blood lead concentrations. However, the blood lead concentrations in the three exposure groups show only small differences (584 – 655 µg/L). If cumulative exposure to lead is considered, clear differences appear (exposure duration 1 - > 10 years as given above).

Compared to the studies by Xie et al. (2019) and Nomiyama et al. (2002) the study by Dongre et al. (2013) resulted in the highest slope and was therefore selected. It has to be noted that in the study by Nomiyama et al. (2002) only female workers were evaluated.

In the following Table 2-11 the data from the study by Dongre et al. (2013) are shown.

Table 2-11 Blood lead concentrations and corresponding systolic blood pressure in control and exposed workers reported in the study by Dongre et al. (2013)

Blood lead concentration [µg/L]	Mean systolic blood pressure [mm Hg] ± SD
Control: 102	115.83 ± 10.5
Exposure group 1 (1-5 years of exposure): 583.7	123.53 ± 9.43
Exposure group 2 (6-10 years of exposure): 625.2	127 ± 12.41
Exposure group 3 (>10 years of exposure): 655	130.8 ± 10.5

From the data reported in Table 2-11 no direct information on the fraction of affected individuals can be derived. Therefore, a transformation was performed, which allows to estimate the affected fraction (% individuals of total exposed). To this end,

- Systolic blood pressure above 140 mm Hg was defined as the borderline for considering an individual as affected with high systolic blood pressure.
  According to the "2018 ESC/ESH Guidelines for the management of arterial hypertension" (Williams et al., 2018) systolic blood pressure ≥ 140 mm Hg is

considered as hypertension grade 1[10] and has to be treated by a physician in most cases.

- It was assumed that the systolic blood pressure of individuals is normally distributed (Döring, 1959), and

- with this assumption and the standard deviation given in the paper the fraction of individuals with systolic blood pressure above 140 mm Hg can be estimated in an Excel® calculation, an overview is given in Table 2-12.

The following table for evaluation was generated in Excel®:

Table 2-12 Mean values for systolic blood pressure and standard deviation used as basis for a normal distribution. For calculation of affected individuals, a cut-off criterion of >140 mm Hg was set.

Mean blood lead [µg/L]	Systolic blood pressure [mm Hg] Mean	Systolic blood pressure [mm Hg] SD	Affected individuals [%]	Affected individuals above control [%]
102.0	115.83	10.50	1.07	0.00
583.7	123.53	9.43	4.04	2.97
625.2	127.00	12.41	14.74	13.68
655.0	130.80	10.50	19.05	17.98

Considering the above-described discrepancy between the small differences in blood lead concentrations in the three exposure groups and the cumulative exposure, we conclude that the differences in exposure duration between the three groups cannot be ignored. Therefore, the data points at 583.7 and 625.2 µg/L blood lead were excluded for the calculation of a DRR and a more conservative DRR with a steeper slope as shown in the following Figure 2-5 was selected.

The “affected individuals above control group” for the highest exposure group were plotted against the mean blood lead level and the result is presented in Figure 2-5. A trendline for these data is included, using the trendline function in Excel®.

[10] Classification of blood pressure and definition of hypertension grades according to Williams et al., 2018: “Optimal”, “Normal”, “High normal”, “Grade 1 hypertension”, “Grade 2 hypertension”, “Grade 3 hypertension” and “Isolated systolic hypertension”. Grade 1 hypertension is lowest grade of hypertension from 140 – 159 mm Hg systolic blood pressure.

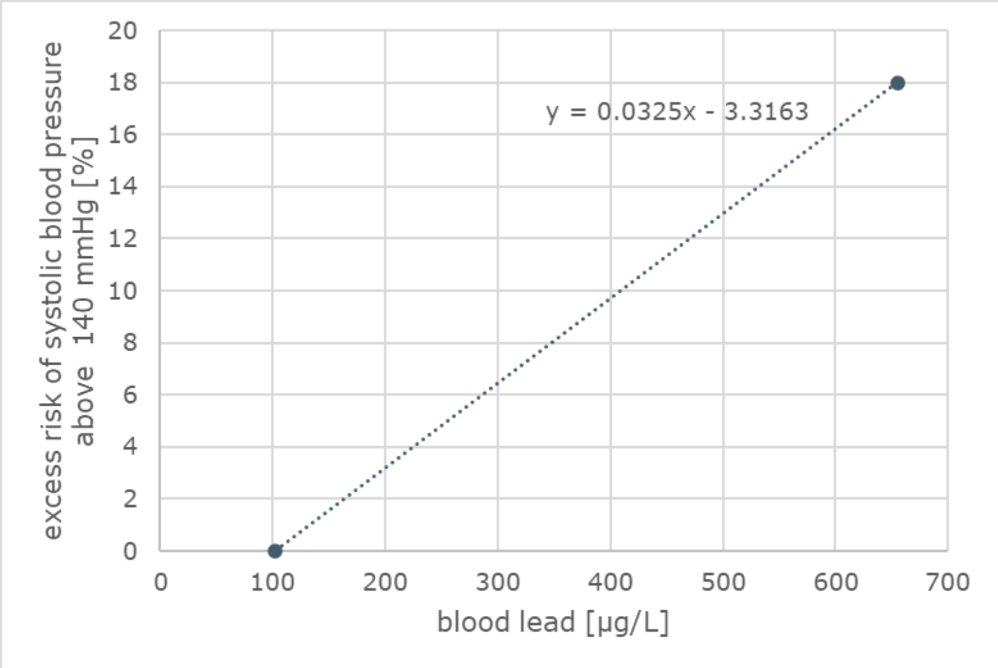


Figure 2-5: Trendline for excess risk of systolic blood pressure above 140 mm Hg in lead-exposed individuals based on the study by Dongre et al. (2013), excluding group 1 and 2

Since RAC concluded on a BLV for humans of 150 µg/L, the linear equation is only valid starting from 150 µg/L blood lead. Due to the definition of the OEL by RAC the excess risk for elevated systolic blood pressure is zero at this point.

The dose response relation for systolic blood pressure above 140 mm Hg can therefore be described with the following equation:

Equation 2-6: DRR for lead (endpoint cardiovascular effects)

$$Excess\ Risk(high\ systolic\ blood\ pressure) = 0.0325 * \left(c_{blood_{lead}}\right) - 3.3163$$

With c ranging from >150 to 700 µg/L.

Since the highest exposure group in the study by Dongre et al. (2013) had mean blood lead levels of 655 µg/L, the straight line can be extended up to 700 µg/L blood lead.

Due to the information given in the publication by Dongre et al. MaxEx was estimated with 10 years. Due to the absence of data the default value (0 years) is assumed for MinEx. No information on latency is available, therefore, no latency period is assumed.

Discussion

Analysis of the data from Xie et al. (2019) and Nomiyama et al. (2002) showed a linear correlation between blood lead levels and elevation of systolic blood pressure, however, with a lower slope compared to Dongre et al. (2013). Using the data from Dongre et al. (2013) is conservative, as the observed slope is higher than the one coming from the other studies. Nomiyama et al. investigated groups of exposed women. In this study the absolute change in mm Hg in the highest exposure group (>=600 µg/L blood lead) compared to the control group is about 10 mm Hg. Dongre et al. report changes of about 15 mm Hg at comparable blood lead levels. It has to be considered that (at least younger) women have a generally lower blood pressure compared to men, the cut-off criteria (140 mm Hg selected for the Dongre study only performed with male workers) would probably have to be adapted to females. The study by Xie et al. reports changes of systolic blood pressure of about 5 mm Hg between controls (67% male) and the highest exposure group (714 µg/L blood, only men exposed). There are indications by the authors that workers in the highest exposure group “worked longer” (no further details are provided). Statements on the potential cumulative exposure cannot be drawn from this publication. Overall, selection of the study by Dongre et al. seems reasonable and conservative.

RAC states that no studies are available that assess specifically in workers the long-term predictive value of small blood pressure increases for cardiovascular morbidity or mortality.

Steenland et al. (2017) reported results from three cohorts from Europe and the US (including 88000 workers) with clearly increased hazard ratios for ischaemic heart disease in lead exposed workers. As outlined above, elevated blood pressure is a risk factor for cardiovascular and cerebrovascular diseases and is therefore a relevant endpoint for the derivation of a DRR for the endpoint cardiovascular effects.

2.3.3.5 Male fertility

Approach

RAC (2020a), RAC (2020b) refers to adverse effects on sperm quality above a blood lead level of 400 µg/L based on key studies by Bonde et al. (2002) and Kasperczyk et al. (2008). Table 37 in the Annex of the RAC document (RAC, 2020b) reports a number of studies indicating impaired sperm quality and/or sperm count, male exposure related longer time-to-pregnancy and/or decreased hormonal levels in males and concludes: “*Exposure of male workers to lead may affect semen quality and sperm DNA integrity that could lead to reduced fertility and miscarriages or preterm birth in the partner. Recent data in lead-exposed workers support the conclusion from SCOEL (2002) that adverse effects on male reproduction could appear at PbB levels above 400 µg/L”* (RAC, 2020a). RAC does not derive a DRR for male fertility effects.

Most of other assessments (e.g. ACGIH (2017), Safe Work Australia (2014), US EPA (2013)) do not provide a clear-cut threshold and discuss significant uncertainties linked to their effect potency. Therefore, recent assessment reports demonstrate some range of potential thresholds for effects on male fertility in the area of 100 to 450 µg/L PbB. In addition, we tried to identify a study reporting effects (adverse effect closely correlated to “male fertility impairment”), which could be translated into a) a quantal outcome (fraction affected), and b) allowing for monetization. Fertility impairment is the crucial endpoint with respect to male reproductive endpoints addressed by the RAC-assessment.

RAC (2020a), RAC (2020b) selected studies with an assumed threshold in their assessment addressing “adverse effects on sperm quality” (Bonde et al. (2002) and Kasperczyk et al. (2008)) above 400 µg/L PbB. For the current assessment the study by Shiau et al. (2004) with the endpoint “reduced fecundability ratio[11]” which is also termed “delayed conception from paternal exposure” or “delayed time to pregnancy” (TTP)” was selected. The reasons to deviate from the starting point selected by RAC can be summarized:

- The addressed endpoint (“fecundability ratio”) is more closely linked to “impairment of fertility” than is a moderate change in sperm quality parameters, as detected in the studies by Bonde et al. (2002) or Kasperczyk et al. (2008). Effects on sperm count and quality (measured as, e.g., continuous decrease of sperm counts, or increase of morphologically changed sperms or the like) are difficult to translate into a pathological endpoint or a disease, which can be used in the impact assessment.
- The authors, Bonde et al. (2002), emphasize in their discussion of the study: “*Besides the statistical uncertainties, it should be acknowledged that the threshold of 45 µg/dL found in this study is based on a group average, which is unlikely to protect all workers from the reproductive toxicity of lead. More research is*

[11] Fecundability ratio measures the odds of a conception among the exposed divided by the odds among those not exposed (according to Shiau et al. (2004))

needed to clarify whether subgroups of men are more vulnerable to the disruptive effects of lead."

- In a more recent review, Bonde (2010) refer to the study by Shiau et al. (2004) and state: "*exposure to inorganic lead that reduce sperm counts at exposure levels above 40 µg dL-1 blood …and possibly impairs fertility at considerably lower levels*".
- Several recent assessments on sperm quality impairment due to lead exposure by knowledgeable committees selected a lower threshold for this effect parameter, e.g. NTP (2012) or ACGIH (2017). From these assessments, a threshold of 200 µg/L can equally be justified. This is also confirmed by a recent assessment by ATSDR (2020) based on extensive literature search with more studies covered.
- RAC refers to a cross sectional study by Hsu et al. (2009) stating an effect level of 400 µg/L. This study was cited by RAC from NTP (2012). However, NTP further comments on the Hsu et al. study: "*Hsu et al. (2009) reported a threshold for increased abnormal sperm morphology at blood Pb levels ≥45 µg/dL in Pb battery workers, relative to workers with blood Pb <25 µg/dL. However, the extent of DNA denaturation per cell was significantly increased at lower blood Pb levels, among workers in both the mid-Pb group (25-45 µg/dL) and high-Pb group (>45 µg/dL) workers*" (NTP, 2012). We regard a control group with blood lead levels up to 250 µg/L as no suitable group for threshold quantifications and we conclude that sperm DNA denaturation may possibly also be regarded as an adverse effect with potential consequences for male fertility. This is supported by a recent study by Wijesekara et al. (2020), who found a close link between lead induced sperm DNA-fragmentation and infertility with otherwise insignificant impact of lead exposure on other sperm parameters.
- The endpoint of "semen quality" is difficult to handle in terms of the "severity of effect"-outcome, which needs to be translated into a fraction affected with respect to male fertility.
- The study of Shiau et al. (2004) provides data to establish a DRR directly. Despite the many existing studies on sperm quality due to lead exposure, almost all those studies provide insufficient data to be used for deriving a DRR.
- RAC (2020a) questioned the results by Shiau et al. (2004) by reference to conflicting evidence from other studies: *"However, in a larger cross-sectional study (Joffe et al., 2003) in 638 men occupationally exposed to lead (292±98 µg/L up to 372±155 µg/L) from 4 countries and 22 companies, no consistent association of Time To Pregnancy with current PbB levels was found in any of the exposure models applied.*" However, in a more recent systematic review by Snijder et al. (2012), the authors demonstrate that various study data on "time to pregnancy" including the study by Joffe et al. (2003) provide sufficient evidence for a threshold close to 200 µg/L and a dose response relationship at higher lead blood levels.
- Finally, "delayed conception from paternal exposure" does not contradict the overall suggested threshold for occupational exposure to lead by RAC (2020a), RAC (2020b) which is 150 µg/L PbB.

Based on considerations explained above, the study by Shiau et al. (2004) was selected as a key study for a starting point (no or insignificant risk for fertility impairment due to occupational exposure to lead). This study also provides data to establish a DRR (see Table 2-13):

Table 2-13 Blood lead concentrations and corresponding fecundability ratio in control and exposed workers reported in the study by Shiau et al. (2004)

Blood lead concentration [µg/L]	Fecundability ratio (95% confidence interval)
Non-exposed	1.0
< 200	0.9 (0.61-1.34)
≥ 200 - 290	0.72 (0.46-1.11)
< 300- 390	0.52 (0.35-0.77)
≥ 400	0.4 (0.27-0.59)

No adequate data was obtained to estimate the impact of lead exposures at higher exposure levels. However, it is suggested to extrapolate linearly to up to 700 µg/L.

The “fecundability ratio” was plotted against the blood lead concentrations (assuming 150 µg/L for the non-exposed control group (=OEL proposed by RAC), 200, 245, 345 and 400 µg/L) and the result is presented in Figure 2-6. A trendline for these data is included, using the trendline function in Excel®.

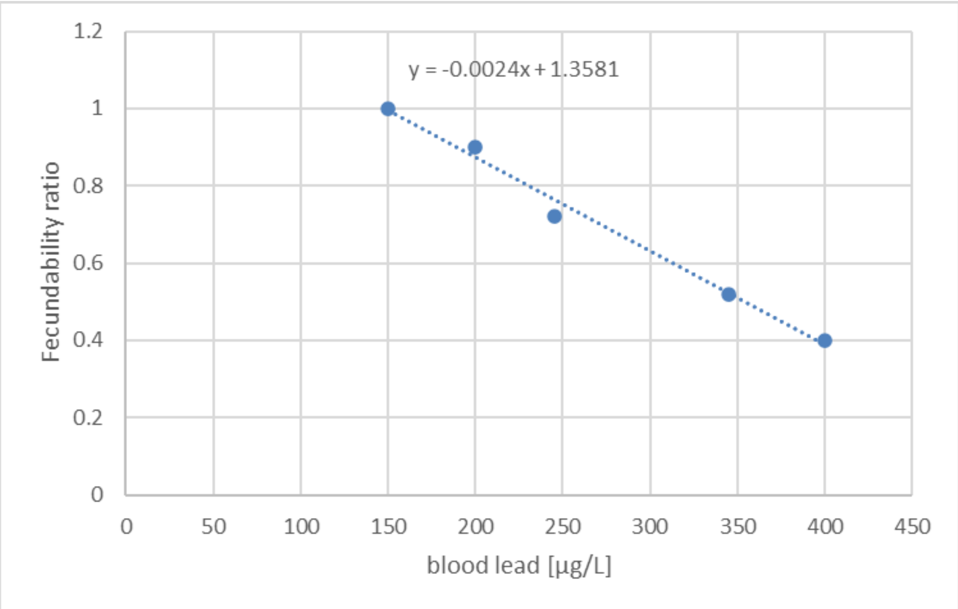


Figure 2-6 Trendline for decrease in fecundability ratio in couples with lead-exposed males based on the study by Shiau et al. (2004)

RAC concluded on a BLV for humans of 150 µg/L. This fits well with the observations of the current study. Therefore, the linear equation is only valid starting from 150 µg/L blood lead.

The dose response relation for the fecundability ratio can therefore be described with the following equation:

Equation 2-7: DRR for lead (endpoint male fertility)

$$fecundability\ ratio = -0.0024 * \left(c_{blood_{lead}}\right) + 1.3581$$

With c ranging from 150 to 700 µg/L.

The men included in the study by Shiau et al. were working in the lead industry between 2.7 and 3.7 years (mean value). MaxEx was estimated with 3 years. Due to the absence of data the default value (0 years) is assumed for MinEx. No information on latency is available, therefore, no latency period is assumed.

Discussion

Using an epidemiological study, which addressed "fecundability ratio" as critical toxicological endpoint, is apparently more closely linkable to male fertility impairment than quality characteristics of sperm parameters. Moreover, this study by Shiau et al. (2004) is the only one detected in an extensive literature search which provides an adequate number of exposure levels in relation to odds ratios, which permit the establishment of a dose-response relationship. As outlined above, the studies by Bonde et al. (2002) or Kasperczyk et al. (2008) which are mentioned by RAC report effects on sperm count or quality that are difficult to translate into an endpoint or disease, which can be used in the impact assessment. The excess risk of sperm quality reducing by a specific amount could be determined, but it would be difficult to assess how many exposed workers would then experience fertility problems due to this reduced sperm quality. Most men would have no fertility issues with a small reduction in sperm quality, but they could not tolerate larger reductions (the scientific literature does not provide a uniform opinion on where to set such a limit). This means that there would be considerable uncertainty in the estimates when selecting this endpoint.

However, relevant inconsistencies of the various studies on TTP are to be acknowledged. As stated by RAC (2020a), RAC (2020b), the results of this study are not in full accordance to another extended study Joffe et al. (2003). Moreover, effects in the Shiau et al. study may have been influenced by earlier higher exposure to lead, not measured in concurrent blood lead levels.

However, the results by Shiau et al. (2004) are supported by further studies, e.g., Apostoli et al. (1998), Sallmén et al. (1995), Sallmén et al. (2000) and only differ from Joffe et al. (2003) significantly at high PbB-levels (> 400 µg/L). Only few persons had been exposed at this high lead blood level in the Joffe et al. (2003) study. The data by Sallmén et al. (2000) point to an even lower threshold (100 µg/L PbB). Similarly, the recent LIFE – study (Buck Louis et al., 2016) points to even stronger effects of lead exposure on TTP.

Therefore, despite of those uncertainties, the derived DRR apparently provides a plausible approach to address dose dependent effects on male fertility from occupational lead exposure.

2.3.3.6 Female fertility

Approach

RAC (2020a), RAC (2020b) does not address quantitatively female reproductive toxicity in the respective opinion document. In the Annex to the RAC opinion, female reproductive toxicity is only briefly addressed, referring to an SCOEL assessment from 2002 with no data on the respective toxicological endpoint. In addition, RAC only mentions a single study by Paredes Alpaca et al. (2013) addressing female reproductive toxicity. In this Italian study, women occupationally exposed to lead showed, among a number of other adverse outcomes, a higher frequency of hypertension during pregnancy (RR: 1.34; 95% CI 1.07-1.68) and preeclampsia/eclampsia (RR: 1.47; 95% CI 1.08-2.00). Because this was the only retrieved study, RAC summarised: "*With regard to female fertility the database is too limited to draw any conclusion.*"

As most prior assessments found no convincing quantitative threshold for female reproductive impairments due to lead exposure, recent original studies, meta-analyses and systematic reviews were evaluated for this endpoint.

It is well established that exposure to lead leads to hypertension (see section 2.3.3.4). Hypertension can also lead to the development of preeclampsia or eclampsia during pregnancy, placing both mother and child at risk of further complications[12]. "*It has been estimated that 5 – 6% of pregnancies are complicated by hypertension and preeclampsia can occur in as high as 10% of pregnancies*" (Kennedy et al., 2012).

Therefore, hypertension during pregnancy and/or direct data on preeclampsia were considered as a potential critical endpoint for female reproductive toxicity. This effect was also observed in the Italian study by Paredes Alpaca et al. (2013), which is documented in the Annex of the recent RAC-opinion on occupational exposure to lead with respect to female fertility impact.

Poropat et al. (2018) provide such a recent meta-analysis and conclude: "*Blood lead concentrations in pregnant women are a major risk factor for preeclampsia, with an increase of 1 µg/dL associated with a 1.6% increase in likelihood of preeclampsia*." For this effect, the meta-analysis provides a no adverse effect level of 5 µg/100 ml (PbB). This meta-analysis is based on 11 original studies. Therefore, the meta-analysis by Poropat et al. (2018) is selected as key study for the current DRR assessment.

There are several other original studies (Musa Obadia et al. (2018), Wells et al. (2011), Disha et al. (2019) and Bayat et al. (2016) and a systematic review by Kennedy et al. (2012) to support the relevance of this endpoint and the threshold effect level. Kennedy et al. evaluated 9 study reports on gestational hypertension or preeclampsia (with only partial overlap to the 11 studies covered by Poropat et al.). Six of the nine studies included found a significant association between blood lead concentrations and gestational hypertension or preeclampsia.

La-Llave-León and Salas-Pacheco (2020) conclude: "*In women, prenatal exposure to lead, even at very low levels of exposure, has shown to be harmful for both the mother and the foetus. Thus, any level of lead exposure could be associated with adverse reproductive outcomes. Lead has been associated with a wide range of adverse outcomes, including …pregnancy hypertension, preeclampsia, …".* The authors also provide insight into a possible mode of action: "*Some possible mechanisms have been suggested to explain the role of lead in the development of this pregnancy disorder. It is considered that lead increases the circulating levels of endothelin, a vasoactive substance that causes constriction of the blood vessels, leading to the increase of blood pressure... Lead also interferes in the increase of reactive oxygen species reducing the serum levels of nitric oxide (NO) and other vasodilator substances…. From the molecular point of view, lead causes inhibition of membrane adenosine triphosphatases (ATPases), which produces vasoconstriction due to the increase of intracellular calcium ions*."

The meta-analysis by Poropat et al. (2018) states that "*women with BPb levels greater than 5 µg/dL should be actively monitored for symptoms of preeclampsia*". This fits well to an effect level of 100 µg/L for hypertension during pregnancy as described in several recent reviews (e.g., ATSDR (2020)).

From these considerations we suggest assuming a starting point of **45 µg/L** (a value indicated by RAC to represent the 95th percentile of background PbB, (RAC, 2020b)) to be used within this report for further analysis.

The study by Poropat et al. (2018) can be used to provide a DRR for this endpoint where an increase of 10 µg/L is associated with a 1.6% increase in the incidence of preeclampsia

[12] **Pre-eclampsia** is a disorder of pregnancy characterized by the onset of high blood pressure and often a significant amount of protein in the urine… In severe disease there may be red blood cell breakdown, a low blood platelet count, impaired liver function, kidney dysfunction, swelling, shortness of breath due to fluid in the lungs, or visual disturbances. Pre-eclampsia increases the risk of poor outcomes for both the mother and the baby…. If left untreated, it may result in seizures at which point it is known as eclampsia…. Risk factors for pre-eclampsia include obesity, prior hypertension, older age, and diabetes mellitus (cited definition according to wikipedia; https://en.wikipedia.org/wiki/Pre-eclampsia; visited December, 17, 2020)

starting from 45 µg/L (see Table 2-14, blood lead levels selected arbitrarily between 45 and 695 µg/L). With the limited given data, this DRR is assumed to be linear, leading, e.g., to an assumed 16% extra incidence beyond the global background incidence of preeclampsia at 145 µg/L (PbB).

Table 2-14 Blood lead concentrations and corresponding excess risk for preeclampsia above the control for lead-exposed women based on the information provided by Poropat et al. (2018)

Blood lead concentration [µg/L]	Excess risk for preeclampsia above the control [%]
45	0
145	16
295	40
395	56
495	72
595	88
695	104

The "excess risk for preeclampsia above the control [%]" was plotted against the blood lead concentrations and the result is presented in Figure 2-7. The equation for this linear function is given in Excel®.

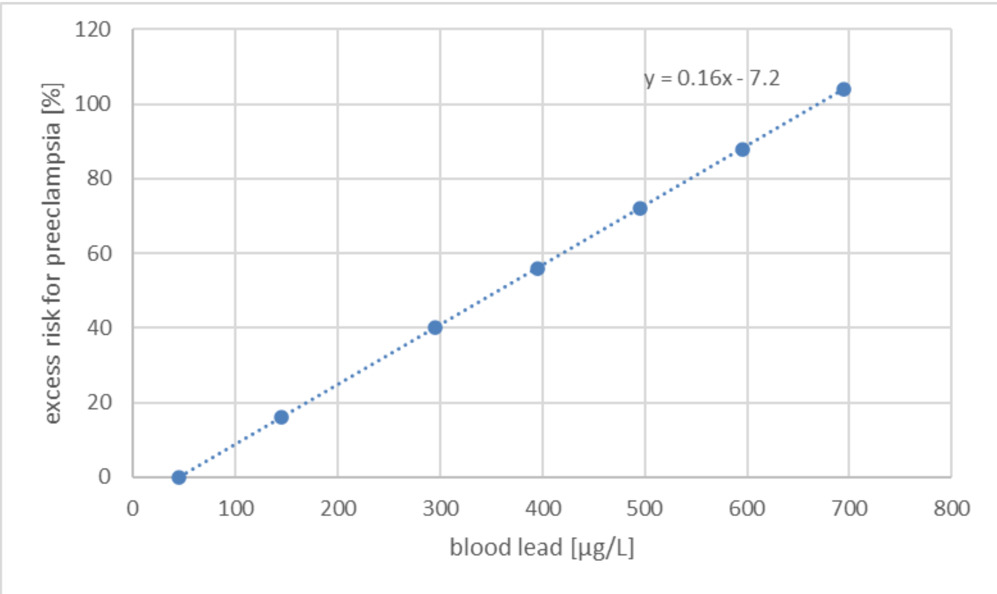


Figure 2-7 Straight line for excess risk of preeclampsia based on the study by Poropat et al. (2018)

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

Equation 2-8: DRR for lead (endpoint female fertility)

$$Excess\ Risk(preeclampsia) = 0.16 * (c_{blood_{lead}}) - 7.2$$

With c ranging from >45 to 700 µg/L.

The women included in studies from the meta-analysis by Poropat et al. (2018) were not generally exposed at work. No information is provided on exposure duration of these women. Therefore, estimation of MaxEx is not possible. The approximate length of a pregnancy is used as best estimate (1 year). Due to the absence of data the default value (0 years) is assumed for MinEx. No latency period is assumed.

Discussion

Using the data from the study by Poropat et al. (2018) results in an excess risk for preeclampsia of about 100% at 695 µ/L blood lead. In other words, this means that all pregnant women that would be exposed against 700 µg/L would suffer from this condition. To our understanding, it is the common procedure to remove pregnant women from workplaces with high exposure to lead. Therefore, the number of pregnant women with blood lead levels that high should be limited.

RAC considered the database too limited for the endpoint female fertility. However, RAC only analysed the study by Paredes Alpaca et al. (2013). Other relevant studies including the one from Poropat et al. (2018) which is used for the current derivation of a DRR are not mentioned. The endpoint preeclampsia is considered relevant. Therefore, the derivation of a DRR is necessary to fully describe the toxicological effects caused by lead.

2.3.3.7 Developmental toxicity (effects on the foetus)

Approach

RAC (2020a), RAC (2020b) reminds that "*neither the proposed BLV of 150 µg/L blood and the proposed air limit value of 4 µg/m^3 for lead and its inorganic compounds protect from developmental toxicity…. Exposure of fertile women to lead should be avoided or minimised in the workplace because the BLV for lead does not protect offspring of women of childbearing age… When national reference levels are not available, blood lead levels in women of childbearing age should not exceed the Biological Guidance Value (BGV) of 45 µg/L, the maximal European reference value*." In the Annex attached to this opinion, RAC refers to a draft version of the most recent ATSDR assessment (ATSDR, 2020), and their conclusion: "*ATSDR considered that collectively, these studies support the concept that Pb affects cognitive function in children prenatally exposed to PbB levels ≤ 100 µg/L, with numerous studies providing evidence for effects at PbB levels ≤ 50 µg/L.*" In summary, RAC emphasises: "*It is noteworthy that maternal bone is catabolised during pregnancy to produce the fetal skeleton and as lead passes the placenta, lead release from the maternal bone has the potential to be stored in the fetal bones. This means that lead from occupational exposure accumulated in the bones of a woman in childbearing age has the potential to influence the IQ development of the newborn during the years of childhood. This does not apply only to lead accumulated during pregnancy, but throughout the whole working career until the pregnancy. Based on the above it is considered that it does not seem possible to directly identify a maternal PbB that would exclude the possibility of any effect on cognitive function development of the newborn*."

All major assessments on neurological developmental toxicity of children prenatally exposed to lead conclude that a no-effect level for reproductive toxicity of lead may not be established. Most of the assessments conclude that "*some" adverse neurodevelopmental effect would already occur at (maternal) exposure levels of 50 µg/L or below*" (e.g., ATSDR (2020), ACGIH (2017) and WorkSafe New Zealand (2017)). Apparently, this opinion is also shared by RAC, who requests that blood lead levels in women of childbearing age should not exceed 45 µg/L, a value that RAC proposes as Biological Guidance value (BGV) for EU countries (if national reference levels are not available). The BGV is presumably adopted from ANSES (2017) and based on the 95th percentile from data of the French general population aged 18 – 74 years. This concentration representing the current population background level should not be confused with a threshold for this effect. On the contrary, some recent studies suggest that even lower prenatal exposures to lead may be associated with intellectual impairments later in children's development (Desrochers-Couture et al. (2018), Tatsuta et al. (2020)). Therefore, 45 µg/L PbB (maternal blood) was selected as a starting point. Any discrimination between cord-blood, maternal blood or infant blood lead level could not be provided as this level of precision is not possible from the provided data.

Establishing a DRR is inevitably linked to several uncertainties. As mentioned above already the starting point is, by no means, an exact figure. The most accepted study to establish a dose response for IQ development in relation to lead exposure is an assessment by Lanphear et al. (2005). In the pooled analyses of 1,333 children enrolled in 7 international prospective studies, an increase from 24 to 100 µg/L in childhood blood lead level was associated with a decline of 3.9 points in full-scale IQ, whereas increases from 100 to 200 µg/L and from 200 to 300 µg/L were associated with declines of 1.9 and 1.1 points, respectively. However, this study relates to early childhood and concurrent blood lead levels in children and may therefore be misleading to assess prenatal lead exposure. However, this large and important key study on postnatal developmental toxicity of lead demonstrates an interesting feature, i.e., a supralinear dose response between exposure level (PbB) and IQ deficits. There has been extended discussions on the validity of this curved slope, but even most recent assessments tend to accept this result of the data regression.

To our knowledge, there is only one study trying to establish a similar dose response for prenatal exposure in an exposure range close to potential occupational maternal exposure (i.e., at exposure levels > 50 µg/L PbB). This is the study by Schnaas et al. (2006). Surprisingly, this regression provided a similar supralinear dose response for children's IQ in correlation to prenatal lead blood levels (3rd trimester maternal blood). The absolute loss of IQ points per exposure unit in the two studies is quite different, but this may be attributed to the different test strategies applied to measure IQ.

These different IQ scoring methods is one major uncertainty when comparing study results. Moreover, the limited quality of the regression in the Schnaas et al. study demonstrates that, most probably, some of the postnatal children's lead exposures may have influenced the IQ score to an unknown degree. Results from full scale IQ assessments (Wechsler Intelligence Scale for Children (WISC) as applied by Schnaas et al.) may differ from, e.g., the result in the mental development index (MDI), which is applied in many of such studies in early postnatal assessments.

Moreover, results from longitudinal studies are derived at different ages and are not directly comparable. Van Landingham et al. (2020) discuss that maternal IQ, HOME score, socio-economic status, parental education, birth weight, smoking, and race are "characteristic variables which may have interaction effects". Even though Lanphear et al. (2005) controlled their study for some of these parameters, not all relevant covariates may have been considered. The authors did for example not examine the influence of maternal depression.

Furthermore, most recent assessments provide some evidence that there may be significant differences in IQ impairment between boys and girls, with boys being much more vulnerable (Desrochers-Couture et al. (2018), Tatsuta et al. (2020)). This possible difference was disregarded as there are no data to reflect respective effects at elevated exposure levels at PbB > 50 µg/L.

With these conditions, the following approach was suggested:

45 µg/L PbB was adopted as the starting point of an effect level, as suggested in most international recent assessments.

The supralinear slope suggested from the Lanphear et al. (2005) study was adopted also for the dose response for prenatal exposure.

A simple regression equation of the type $y = a \ln(x) + b$ was established, with plausible parameters for a and b, which does not pretend to be precise on the one (Lanphear et al.) or the other (Schnaas et al.) data background and which may not be calculated from aggregated or weighted original study data to derive a plausible slope for this DRR. Parameters were selected in a way that the equation takes into account the Lanphear et al. study (blue dotted line) and the Schnaas et al. study (grey dotted line). In both cases a regression based on an evaluation by the authors of the current document of graphical data in the publications was performed. The following figure presents this plausible DRR (red dotted line) and the other DRRs for comparison. This red line DRR estimate is largely parallel to the Schnaas et al. line but shifted to the right because of the other IQ-scale regarded as more reliable.

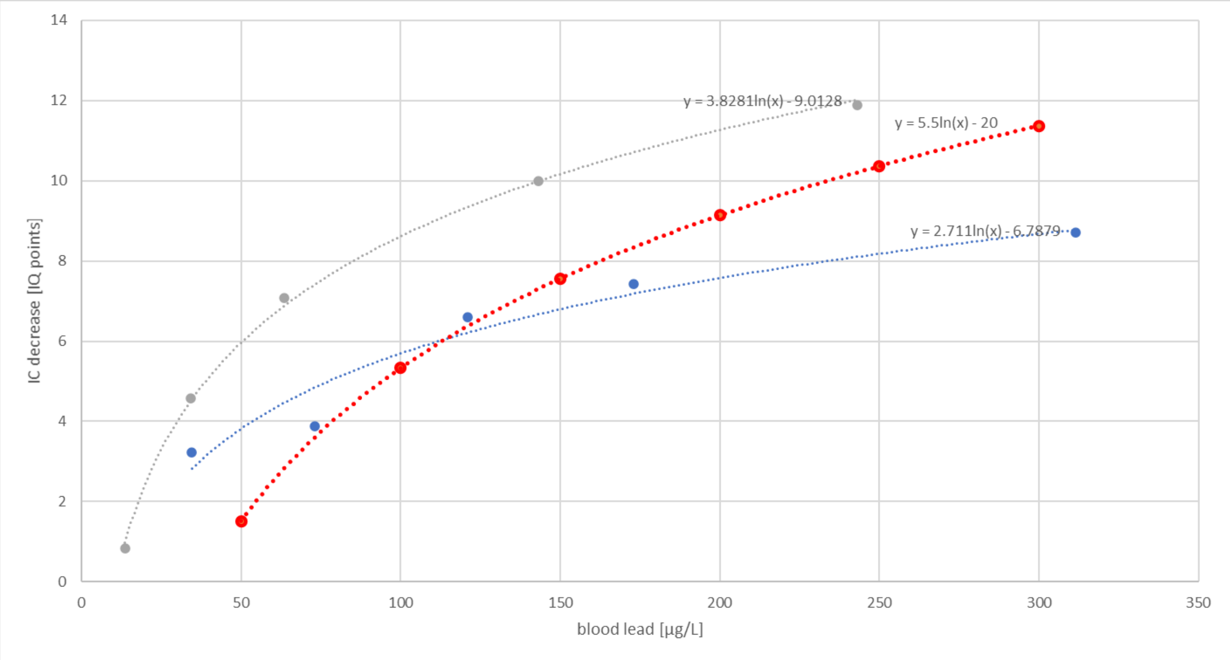


Figure 2-8 Logarithmic graphs for the study from Lanphear et al. (2005) (blue dots) and Schnaas et al. (2006) (grey dots). In red the study team's evaluation (for explanation see text above) is depicted. The data points from the Lanphear and Schnaas studies were generated based on figures presented in the original publications.

The highly significant uncertainties of this DRR are acknowledged, but we suggest here a pragmatic solution to reflect the heterogeneous assessment results of the various knowledgeable national or international expert committees in a “weight of evidence” as a compromise, without providing a pseudo-exact estimate.

The DRR is regarded as being valid in a range **from 45 to 300 µg/L PbB**,

with a lower end at which first impairments of neurodevelopmental effects from prenatal lead exposure were observed in the offspring and an upper end, which is given from the database (highest assessed exposures in the Schnaas et al. (2006) study). We assume that additional factors will influence the slope beyond 300 µg/L. Therefore, it is not possible to quantify the impact of higher exposures on developmental health in the range >300 to 700 µg/L PbB.

The dose response relation for the IQ decrease can therefore be described with the following equation:

Equation 2-9: DRR for lead (endpoint developmental toxicity)

$$Decrease\ in\ IQ\ points = 5.5 * \ln\left(c_{blood_{lead}}\right) - 20$$

With c ranging from 45 to 300 µg/L.

No information on MaxEx is available. Since the maternal blood lead level is crucial for the developmental effects regarded in this evaluation, MaxEx is considered with 1 year. Due to the absence of data the default value (0 years) is assumed for MinEx. No latency period is assumed.

Discussion

It is emphasised that the DRR derived for this endpoint is associated with a large number of uncertainties. None of the available studies seemed reliable enough to be selected as sole basis for the DRR derivation. The regression equation selected (marked in red in Figure 2-8) is a weight-of-evidence conclusion form the studies by Lanphear et al. and Schnaas et al. Due to the limited reliability of this DRR an extrapolation above the blood lead concentrations given in the studies (about 300 µg/L) cannot be advised.

2.3.4 Conversion of blood lead to an air concentration of lead

As outlined in section 2.2.5 ("Biological monitoring") all international and national bodies proposing occupational limit values refer to biological limit value (BLV) measured in the form of blood lead. If, in parallel, an OEL for lead in workplace air is reported, it is selected to correspond to the established BLV.

The findings on the relationship between blood lead levels and air lead concentrations vary according to various studies (AGS, 2017). The conversion of blood lead concentrations to corresponding air concentrations is associated with large uncertainties (as summarised in (AGS, 2017) because:

a) the background exposure to lead via food and from air (gasoline lead) in the last few decades has decreased so that older measured values can no longer be correctly transferred,

b) there are strong fluctuations, which depend, among other things, on the hygiene behaviour at workplaces (parallel oral intake of lead and to a limited extent via the skin can have a relevant influence),

c) different occupational activities with different lead compounds lead to different transfer from air to blood,

d) smoking also has a relevant influence on the blood lead value.

For these reasons, all conversions are only rough approximations.

RAC (2020b) noted that if an air limit is required, it should be ensured that the BLV is not exceeded in the majority of workers (meaning the 95th percentile in this case). ANSES (2017) and Safe Work Australia (2014) used measured historical correlations between blood lead and air concentrations observed in a number of industrial settings. ANSES correlated a BLV of 180 µg/L with an 8 h TWA of 30 µg/m³, while Safe Work Australia correlated blood lead concentrations of 200 – 300 µg/L with an 8 h TWA of 50 µg/m³.

An assessment from the California Environmental Protection Agency (OEHHA, 2013) is available and provides a basis to estimate air lead concentration from blood lead levels using a pharmacokinetic model. The estimate is based on the non-linear variant of the model by Leggett (1993) (Leggett +) taking into account some corrections based on more recent work (including O'Flaherty (1995)). The modelling was validated with some data sets (including Griffin et al. (1975)), whereby the influence of different particle sizes was also taken into account. The model used was adjusted for several parameters:

- blood, bone, and urine clearance parameters (to fit available data from workers and the general population)

- TWA breathing rate of 26 m³/day

- transfer rate of 30% of inhaled lead to blood

Using this adjusted model, OEHHA (2013) predicted the constant air concentrations resulting in worker blood lead levels in the range of 23–300 µg/L (50th percentile) after 40 years of workplace exposure. From those values, the 90th and 95th percentile blood lead levels were calculated (see Table 2-15).

Table 2-15 Air concentrations at the workplace (PbA) and assigned blood lead values (PbB) according to PBPK modelling by (OEHHA, 2013)

Air lead (8 h TWA; µg/m^3)	Predicted PbB (50th percentile; µg/L)	Predicted PbB (90th percentile; µg/L)	Predicted PbB (95th percentile; µg/L)
0.5	23	40	50
0.8	27	50	60
2.1	46	80	100
2.4	50	90	110
2.8	55	100	120
3.9	69	130	**150**
5.0	82	150	180
6.0	93	170	200
6.5	100	180	220
7.5	110	200	240
10.4	140	250	300
11.5	150	270	320
12.6	160	300	350
17.6	200	370	430
25.0	250	460	540
34	300	550	650

Based on the OEHHA estimate RAC (2020a), RAC (2020b) transferred the BLV of 150 µg/L to an OEL (using the 95th percentile) of 4 µg lead /m³.

According to RAC there is considerable uncertainty on the correlation of air lead levels and blood lead levels under given workplace conditions. Given the available data and the fact that extrapolating lead air concentrations to blood lead concentrations in the low dose range is beyond the experimental data included by Safe Work Australia and may underestimate the increase in internal lead concentrations, the PBPK (Physiologically-based Pharmacokinetic) modelling approach of OEHHA (2013) is considered a more appropriate approach to determine a correlation between air and blood lead concentrations.

From the data presented above in Table 2-15 (column one and four) the graph shown in Figure 2-9 was created for the current report. A trendline for these data is included, using the trendline function in Excel®. The trendline "polynomial grade 2" was selected as best fit.

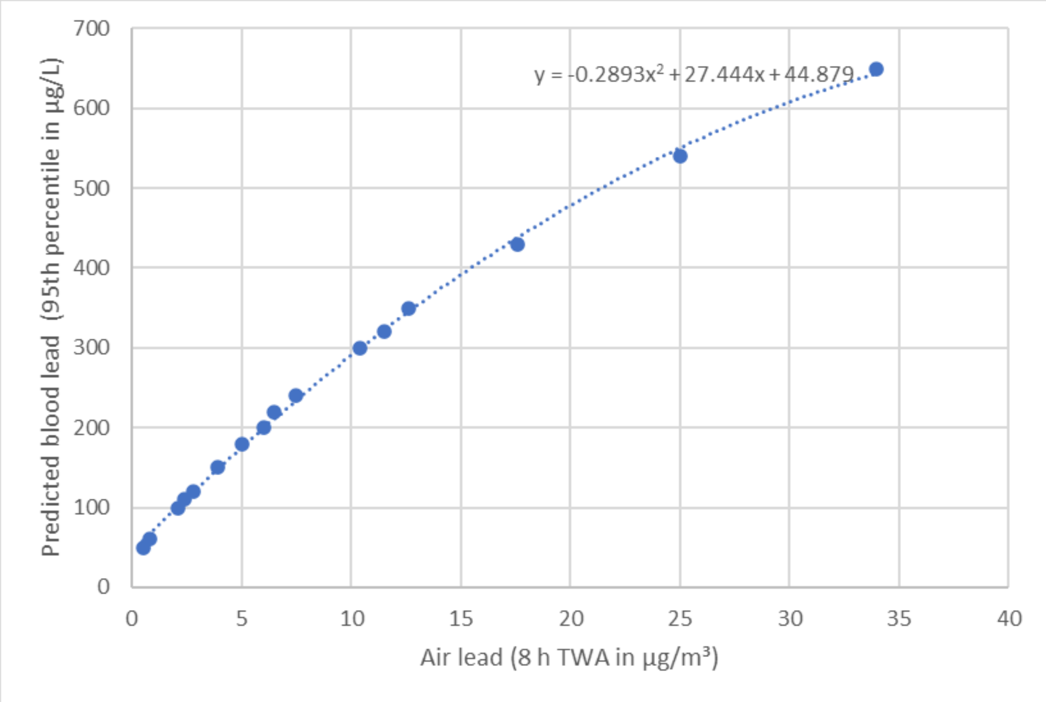


Figure 2-9 Correlation between 8 h TWA air lead concentrations and the 95th percentile of the predicted blood lead concentration in µg/L (according to OEHHA, 2013).

It was assessed that the equation for the relationship between air and blood lead concentrations can be considered as valid from 45 up to 700 µg/L blood lead.

The transformation of air lead concentrations to blood lead concentrations can therefore be described with the following equation:

Equation 2-10: Transformation of air lead concentrations to blood lead concentrations according to OEHHA model

$$Predicted\ blood\ lead\ (95th\ percentile\ in\ \mu g/L) = -0.2893\left(c_{air_{lead}}\right)^2 + 27.444\left(c_{air_{lead}}\right) + 44.879$$

With predicted blood lead concentrations valid from 45 to 700 µg/L.

2.4 Objectives

The objective of the present study is to provide the Commission with the most recent, updated and robust information on exposure to lead and its compounds with the view to support the European Commission in future work to revise the OEL and BLV for these substances.

3. Options

The study is to provide a comparison of the costs and benefits for a range of potential OELs and BLVs. The ranges start at the values proposed by RAC, encompass the values in the SCOEL opinion and end at the current limit values.

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

Throughout the analysis of benefits and costs, the following reference levels have been chosen as the options of the assessment (Table 3-1 and Table 3-2).

To alleviate the burden of participation in the surveys for the stakeholders, the BLV options of 200 and 100 µg/L and the OEL option of 100 µg/m³ have been omitted in the survey. The detailed analysis of costs concerns lowering the BLV to 700, 300, 150 and 45 µg/m³, whereas the costs of lowering the level to 200 and 100 µg/L has been interpolated from the costs estimates for the four previous mentioned BLV levels. The OEL options have been evaluated in relationship to the BLV options.

Please note, that baseline analysis (chapter 4) provides concentration data in the commonly used units mg/m³ (airborne lead concentration) and µg/100ml (blood lead levels), corresponding to the limit value options in the second column in the tables below.

The analysis of benefits and costs refers to the limit value options in the units as written in the first column of the below tables.

Table 3-1 OEL options for lead and its compounds

Level, µg/m³	Level, mg/m³	Reason for inclusion
150	0.15	Existing EU level in the Chemical Agents directive
100*	0.10*	Intermediate level of current OELs in EU Member States as agreed by the steering group of this study.
50	0.05	Lowest OEL in EU Member States (Bulgaria, Czech Republic, Denmark, Estonia, Latvia, Poland, Sweden)
20	0.02	Intermediate level between lowest national OEL and the level proposed by RAC as agreed by the steering group of this study.
4	0.004	OEL at the level proposed by RAC

** marked options are included in the impact assessment, but not part of the stakeholder consultation survey*

Table 3-2 BLV options for lead and its compounds

Level, µg/L	Level, µg/100 mL	Reason for inclusion
700	70	Existing EU level in the Chemical Agents directive
300	30	Intermediate level of BLV in EU Member States
200*	20*	Lowest national BLV in EU Member States for all workers (Denmark). Voluntary target of International Lead Association.
150	15	BLV at the level proposed by RAC

Level, µg/L	Level, µg/100 mL	Reason for inclusion
100*	10*	The ILA voluntary programme recommendation for females of reproductive capacity (defined as ≤45 years of age or as agreed by the company medical advisor) based on DNEL set under REACH. Included as agreed by the steering group of this study.
45	4.5	Biological guidance value related to background exposure of the general population. Applies to women of child-bearing age (under 50 years of age). Included following agreement of the steering group of this study

** marked options are included in the impact assessment, but not part of the stakeholder consultation survey*

4. The baseline analysis

4.1 Existing national limits

4.1.1 Lead and inorganic lead compounds

Existing limit values for lead and inorganic lead compounds are shown in the table below.

Table 4-1 OELs (mg/m³, 8-h TWA) and STELs (mg/m³, 15 min) in EU Member States and selected non-EU countries for lead and inorganic compounds, as Pb (status: 28.06.2021)

Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
Austria[1,2,3]	0.1 (I)	-for lead compounds except alkyl lead compounds; R1, L	0.4 (I)	-for lead compounds except alkyl lead compounds; R1, L
Belgium[1,2,4]	0.15		-	
Bulgaria[5]	0.05		-	
Croatia[6, 29]	0.15†	- except lead chloride fluoride iodide; R1	-	
Cyprus	-		-	
Czech Republic[7]	0.05	-for lead compounds except alkyl lead compounds	0.2	-for lead compounds except alkyl lead compounds
Denmark[1,2,8]	0.05 (I)†		0.1 (I)	
Estonia[9]	0.1 (T) 0.05 (R)	-R -R	-	
Finland[1,2,10]	0.1†		-	
France[1,2,11]	0.1 (I)	- restrictive statutory limit value; K, R	-	
Germany[1,12, 29]	0.15 (I)† 0.1	-R1, L - reference value*; R1, L	-	
Greece	-		-	
Hungary[13]	0.10 0.05 (R)		-	

Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
Ireland[1,2,14]	0.15†	-R1	-	
Italy[1,2,15]	0.15		-	
Latvia[16]	0.05		0.1	
Lithuania[17]	0.15 (I) 0.07 (R)	- except lead sulphide; R -except lead sulphide; R	-	
Luxembourg[18]	0.15		-	
Malta[19]	0.15†		-	
Netherlands[2,20]	0.15 (I)†		-	
Poland[1,2,21]	0.05 (I)	-except lead arsenate and lead chromate	-	
Portugal[22]	0.15		-	
Romania[1,2,23,29]	0.15		-	
Slovakia[24]	0.5 (R) 0.15 (I)		-	
Slovenia[25,29]	0.1 (I)	-R1	0.4 (I)	-R1
Spain[1,2,26]	0.15 (I)	-R1	-	
Sweden[1,2,27]	0.1 (I) 0.05 (R)	-R	-	
European Union[1,29]	0.15 (I)†		-	
RAC[2]	0.004 (I)		-	
Non-EU countries				
Australia[1,30]	0.05	-dusts and fumes	-	
Brazil[31]	0.1		-	
Canada, Ontario[1,32]	0.05	-elemental, inorganic and organic compounds of lead, except tetraethyl lead	-	

Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
Canada, Québec[1,33]	0.05	-K	-	
China[1]	0.05 (I) 0.03 (R)		-	
India[34]	0.15	-dusts and fumes	-	
Japan[35]	0.05		-	
Japan - JSOH[1,36]	0.03	-for lead compounds except alkyl lead compounds; K, R1	-	
Norway[1,37]	0.05†	-dusts and fumes; except lead acetate, lead phosphate, lead chromate and lead subacetate; R		
Russia[38]	0.05	-aerosol		
South Korea[1,39]	0.05	-K,R1	-	
Switzerland[1,2,340]	0.1 (I)	-except alkyl lead compounds; K2,R1	0.8 (I)	
Turkey[1,41]	0.15			
United Kingdom[1,2,28]	0.15	-except alkyl lead compounds	1	
USA, ACGIH[42]	0.05	-K	-	
USA, NIOSH[**,1,2,43]	0.05 (T)		-	
USA, OSHA[1,2,44]	0.05 (T)		-	

Notes:
RAC = Committee for Risk Assessment
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
(I) = inhalable fraction/aerosol
(R) = respirable fraction/aerosol
(T) = total dust
K = carcinogenicity notation assigned
K1 = assigned as Carc. Category 1A or 1B

Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL

K2 = assigned as Carc. Category 2

R = notation as reproductive toxin assigned

R1 = assigned as Repr. Category 1A or 1B

L = notation for effects on or via lactation assigned

- no value available

* reference value that represents the state of the art. Individual measures are related to this limit value.

† binding limit value, if explicitly stated by the member state

** NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.

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Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL

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Country	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
35: Japan (2020) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 18.12.2020				
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4.1.2 Tetramethyl lead and tetraethyl lead

Table 4-2 OELs (mg/m³, 8-h TWA) and STELs (mg/m³, 15 min) in EU Member States and selected non-EU countries for tetramethyl lead and tetraethyl lead (status: 28.06.2021)

Country	OEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of OEL	STEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of STEL
Austria[1,2,3]	0.05 / 0.05	-Sk,R1 / Sk,R1	0.2 / 0.2	-Sk,R1/ Sk,R1
Belgium[1,2,4]	0.15 / 0.1	-D / D	- / -	
Bulgaria[5]	0.075 / 0.05		- / -	
Croatia[6]	- / -		- / -	
Cyprus	- / -		- / -	
Czech Republic[7]	0.05 / 0.05	-Sk / Sk	0.1 / 0.1	-Sk / Sk
Denmark[1,2,8]	0.05 (0.007) / 0.05 (0.007)	-Sk / Sk	0.1 (0.014) / 0.1 (0.014)	-Sk / Sk
Estonia[9]	0.05 / 0.05	-Sk,R / Sk,R	0.2 / 0.2	-Sk,R / Sk,R

Country	OEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of OEL	STEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of STEL
Finland[1,2,10]	0.075 / 0.075	-Sk,R1/ Sk,R1	0.23 / 0.23	-Sk,R1/ Sk,R1
France[1,2,11]	0.15 / 0.1	-Sk,R1/ Sk,R1	- / -	
Germany[1,2,12]	0.05 / 0.05	-Sk,R1 / Sk,R1	0.1 / 0.1	Sk,R1 / Sk,R1
Greece	- / -		- / -	
Hungary[1,2,13]	0.05 / 0.05	-Sk / Sk	0.2 / 0.2	-Sk / Sk
Ireland[1,2,14]	0.15 / 0.1	-Sk,R1 / Sk	- / -	
Italy[15]	- / -		- / -	
Latvia[1,2,16]	- / 0.005		- / -	
Lithuania[17]	0.05 / 0.05	-Sk,R / Sk,R	0.2 / 0.2	-Sk,R / Sk,R
Luxembourg[18]	- / -		- / -	
Malta[19]	- / -		- / -	
Netherlands[20]	- / -		- / -	
Poland[1,2,21]	- / 0.05	- / Sk	- / 0.1	- / Sk
Portugal[22]	- / -		- / -	
Romania[1,2,23]	- / 0.01	- / Sk	- / 0.03	- / Sk
Slovakia[24]	0.05 / 0.05	-Sk / Sk	0.2 / 0.2	-Sk / Sk
Slovenia[25]	0.05 / 0.05	-Sk,R1 / Sk,R1	0.1 / 0.1	-Sk,R1 / Sk,R1
Spain[1,2,26]	0.15 / 0.1	-Sk,R1 / Sk,R1	- / -	
Sweden[1,2,27]	0.05 / 0.05	-Sk,R1 / Sk,R1	0.2 / 0.2	-Sk,R1 / Sk,R1
European Union	- / -		- / -	
RAC[2]	- / -		- / -	
Non-EU countries				
Australia[1,29]	0.15 / 0.1	-Sk / Sk	- / -	
Brazil[30]	/		- / -	
Canada, Ontario[1,31]	- / 0.1		- / 0.3	
Canada, Québec[1,32]	0.05 / 0.05	-Sk / Sk	- / -	

Country	OEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of OEL	STEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of STEL
China[1]	- / 0.02		- / -	
India[33]	- / 0.1	- / Sk	- / -	
Japan[34]	- / -		- / -	
Japan - JSOH[1,35]	- / 0.075	- / Sk	- / -	
Norway[1,36]	0.075 / 0.075	-Sk, R / Sk, R	- / -	
Russia[37]	- / 0.005	-vapours and/or gases	- / -	
South Korea[1,2,38]	0.075 / 0.075	-Sk,K / Sk,K	- / -	
Switzerland[1,2,39]	0.05 / 0.05	-Sk / Sk	0.1 / 0.1	-Sk / Sk
Turkey[40]	- / -		- / -	
United Kingdom[1,28]	0.1 / 0.1	-applies to total alkyl lead	- / -	
USA, ACGIH[41]	0.15 / 0.1	-Sk / Sk,K	- / -	
USA, NIOSH[**1,2,42]	0.075 / 0.075	-Sk / Sk	- / -	
USA, OSHA[1,2,43]	0.075 / 0.075	-Sk / Sk	- / -	

Notes:

RAC = Committee for Risk Assessment

JSOH = Japan Society for Occupational Health

ACGIH = American Conference of Governmental Industrial Hygienists

OSHA = Occupational Safety and Health Administration

NIOSH = National Institute for Occupational Safety and Health

Sk = skin notation assigned

D = absorption of the agent through the skin, mucous membranes or eyes is an important part of the total exposure. It can be the result of both direct contact and its presence in the air.

K = carcinogenicity notation assigned

R = notation as reproductive toxin assigned

R1 = assigned as Repr. Category 1A or 1B

- no value available

** NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.

Sources:

Country	OEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of OEL	STEL Tetramethyl lead/ tetraethyl lead [mg/m³, (ppm)]	Specification of STEL

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4.1.3 Biological limit values (BLVs)

Table 4-3 Biological limit values in EU Member States and selected non-EU countries for lead, tetramethyl lead, and tetraethyl lead (status: 28.06.2021)

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification
Austria[1,2]	70 µg Pb/100 ml 45 µg Pb/100 ml	-men, women >50 years -women <50 years	-	
Belgium[1]	70 µg/100 ml		-	
Bulgaria[1,3]	400 µg/l 300 µg/l	 -women <45 years	-	
Croatia[1,4]	400 µg/l 300 µg/l	 -women <45 years	-	
Cyprus[1]	70 µg/100 ml		-	
Czech Republic[1,5]	400 µg/l		-	
Denmark[1,6]	20 µg/100 ml		-	
Estonia	-		-	
Finland[1,10]	290 µg/l (1.4 µmol/l)		20.7 µg/l urine	-action limit for tetramethyl and tetraethyl lead

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification
France[1,9,10]	400 µg/l 300 µg/l 180 µg/l	-male -female -recommended value by ANSES	-	
Germany[1,11]	150 µg/l		50 µg total Pb/l urine / 25 µg diethyl lead/l urine; 50 µg total Pb/l urine	-also valid for mixtures with tetraethyl lead -for tetraethyl lead, calculated as Pb -also valid for mixtures with tetramethyl lead
Greece[1]	70 µg/100 ml		-	
Hungary[12]	300 µg/l (1.5 µmol/l) 200 µg/l (1.0 µmol/l)	-men, women >45 years -women <45 years	-	
Ireland[13]	70 µg/100 ml	-health surveillance for workers at > 40 µg/100 ml	-	
Italy[14]	60 µg/100 ml 40 µg/100 ml	-health surveillance for workers at > 40 µg/100 ml -women at childbearing age	-	
Latvia[15]	60 µg/100 ml	-health surveillance for workers at > 40 µg/100 ml	-	
Lithuania[1,16]	70 µg/100 ml		-	
Luxembourg[1,17]	70 µg/100 ml		-	
Malta[1,18]	70 µg/100 ml		-	
Netherlands[1,19]	60 µg/100 ml		-	
Poland[1]	50 µg/100 ml		-	

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification
Portugal[1,20]	70 µg/100 ml		-	
Romania[1,21]	70 µg/100 ml	-health surveillance for workers at > 40 µg/100 ml	- / 50 µg total Pb/l urine; 25 µg diethyl lead/l urine	-for tetraethyl lead
Slovakia[1,22]	400 µg/l[#] 100 µg/l[#]	 -women <45 years	50 µg total Pb/l urine / 25 µg diethyl lead/l urine	-also valid for mixtures with tetraethyl lead -for tetraethyl lead
Slovenia[1,23]	400 µg/l 300 µg/l	 -women <45 years	50 µg total Pb/l urine / 25 µg diethyl lead/l urine	-also valid for mixtures with tetraethyl lead -for tetraethyl lead
Spain[1,24]	70 µg/100 ml	-mandatory health surveillance for workers at > 40 µg/100 ml	-	
Sweden[1,25]	311 µg/l (<1.5 µmol/l) 104 µg/l (<0.5 µmol/l	-men, women >50 years -women <50 years	-	
European Union[1,27]	70 µg/100 ml	-mandatory health surveillance for workers at > 40 µg/100 ml	-	
RAC[1]	150 µg/l 45 µg/l[##]	-for lead and its in-organic compounds -women of childbearing age	-	
Non-EU countries				
Australia[28]	30 µg/100 ml	-men and women not of reproductive capacity	-	

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification
	10 µg/100 ml	-women of reproductive capacity		
Brazil[29]	-		-	
Canada, Ontario[30]	-		-	
Canada, Québec[31]	-		-	
China	-		-	
India[32]	-		-	
Japan[33]	-		-	
Japan - JSOH[34]	15 µg/100 ml	-except alkyl compounds	-	
Norway[35]	0.5 µmol/l 1.5 µmol/l	-women of childbearing age other workers	-	
Russia[36]	-		-	
South Korea[37]	-		-	
Switzerland[38]	400 µg/l 100 µg/l	-men, women >45 years -women <45 years	-	
Turkey[39]	70 µg/100 ml		-	
United Kingdom[1,26]	60 µg/100 ml 30 µg/100 ml	-men -women of reproductive capacity	-	
USA, ACGIH[40]	200 µg/l		-	
USA, NIOSH[41]	60 µg/ 100 g		-	
USA, OSHA[1,42]	50 µg/ 100 g		-	

Notes:

RAC = Committee for Risk Assessment

JSOH = Japan Society for Occupational Health

ACGIH = American Conference of Governmental Industrial Hygienists

OSHA = Occupational Safety and Health Administration

NIOSH = National Institute for Occupational Safety and Health

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification

- no value available/found

 # value from RAC is cited as a value of 400 mg/l or 300 mg/l is given in the list of limit values of Slovakia, which presumably may be a typo

Biological Guidance Value (BGV), relates to the 95th percentile of background exposure

Sources:

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Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification

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26: United Kingdom (2020) List of limit values. Available at: https://www.hse.gov.uk/pubns/priced/eh40.pdf and https://www.hse.gov.uk/pubns/priced/l132.pdf, accessed on 17.12.2020

27: European Union, Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0024, accessed on 16.12.2020

28: Australia (2020) Lead (inorganic) health monitoring. Available at: https://www.safeworkaustralia.gov.au/system/files/documents/2002/health_monitoring_guidance_-_lead.pdf, accessed on 18.12.2020

29: Brazil List of limit values. Available at: http://www.guiatrabalhista.com.br/legislacao/nr/nr15_anexoXI.htm, accessed on 18.12.2020

30: Canada, Ontario (2020) List of limit values. Available at: https://www.ontario.ca/laws/regulation/900833, accessed on 18.12.2020

31: Canada, Québec (2020) List of limit values. Available at: http://legisquebec.gouv.qc.ca/en/showdoc/cr/S-2.1,%20r.%2013, accessed on 18.12.2020

32: India (2020) List of limit values. Available at: https://dgfasli.gov.in/book-page/permissible-levels-certain-chemical-substancesin-work-environment, accessed on 18.12.2020

33: Japan (2020) List of limit values. Available at: https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpcLst?slIdxNm=&slScNm=RJ_04_061&slScCtNm=&slScRgNm=&ltCatFl=&slMdDplt=0&ltPgCt=200&stMd, accessed on 18.12.2020

34: Japan - JOSH (2020) List of limit values. Available at: https://www.sanei.or.jp/images/contents/310/OEL.pdf, accessed on 18.12.2020

35: Norway (2021) List of limit values. Available at: https://www.arbeidstilsynet.no/globalassets/regelverkspdfer/forskrift-om-tiltaks--og-grenseverdier, ac-cessed on 28.06.2021

36: Russia (2021) List of limit values. Available at: http://publication.pravo.gov.ru/Document/View/0001202102030022?index=21&rangeSize=1, accessed on 28.06.2021

Country	Lead (as Pb) in blood	Specification	Tetramethyl lead/ tetraethyl lead	Specification
37: South Korea (2020) List of limit values. Available at: https://www.moel.go.kr/skin/doc.html?fn=202001141546O202ae79b648784733aac25448f202f783.hwp&rs=/viewer/BBS/2020/, accessed on 18.12.2020				
38: Switzerland (2019) List of limit values. Available at: https://www.suva.ch/de-CH/material/Richtlinien-Gesetzestexte/erlaeuterungen-zu-den-grenzwerten, accessed on 18.12.2020				
39: Turkey (2013) List of limit values. Available at: https://www.resmigazete.gov.tr/eskiler/2013/08/20130812-1.htm, accessed on 28.06.2021				
40: ACGIH, American Conference of Governmental Industrial Hygienists (2020), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.				
41: USA, NIOSH (2020) List of limit values. Available at: https://www.cdc.gov/niosh/index.htm, accessed on 18.12.2020				
42: USA, OSHA (2020) List of limit values. Available at: https://www.osha.gov/dsg/annotated-pels/tablez-1.html, accessed on 18.12.2020				

4.2 Groups at Extra Risk

Due to specific toxicity mechanisms, certain groups within a population may be at extra risk. The extra risks may be related to intrinsic properties such as sex, age and/or genetic variations.

In the RAC opinion on lead and its compounds, RAC proposes a BLV and an OEL, but notes that neither the proposed BLV or the proposed OEL for lead and its inorganic compounds protects from developmental toxicity: "*Considering the workplace, women of childbearing capacity and pregnant women require specific considerations. Neither the proposed BLV of 150 µg/L blood nor the proposed air limit value of 4 µg/m³ for lead and its inorganic compounds protects from developmental toxicity. No threshold for potential central nervous system effects in new-borns and infants can be identified at present. The exposure of fertile women to lead should therefore be avoided or minimised*" (RAC, 2020b).

In recognition of the gender-differentiated toxicity action of lead, RAC recommends adding a qualitative statement in the CAD, as outlined in section 2.1.1, supporting the use of Biological Guidance values derived from population background exposure levels as upper limits for female exposure. The maximum European reference value, as the 95th percentile, is 45 µg/L, although lower background concentrations levels exist in many Member States or regions.

RACs recommended statement (see section 2.1.1) is not part of the assessment in this impact study. However, the Biological Guidance Value (BGV) of 45 µg/L is included as a BLV option (see chapter 3. Options).

It should be noted that the Biological Guidance Value (BGV) of 45 µg/L cannot be regarded as a 'safe' level with respect to effects from developmental toxicity. The BGV has been derived as the 95th percentile of the maximal background concentration within the EU population. A 'safe' level, i.e. a threshold protecting the offspring from developmental effects, could not been derived in recent reviews (e.g. RAC, 2020b).

The establishment of a limit value accounting for developmental effects under the CAD may not harmonise with the intention of the CAD, as limit values under the CAD (as long as limit values are set at the level of the lowest threshold for all the relevant effects) suggest ‘safe levels of exposure’ not requiring further measures of exposure minimisation once the limit values are complied with. This is in contrast with the provisions of the CMD (The Carcinogens and Mutagens Directive), which always require exposure minimisation.

It is not within the scope of this study to investigate whether occupational limit values protecting the offspring of women of childbearing age should be encompassed within the CAD, the CMD or other legislation.

It is also noted that the "Pregnant Workers Directive" does not provide sufficient protection from developmental effects, as it only contains provisions for pregnant workers (from the moment they have notified their employer, typically three months within pregnancy) and workers who have recently given birth or are breastfeeding. Lead absorbed in skeletal tissue (bones, teeth) is mobilised during pregnancy. Therefore, exposures long before pregnancy may cause health effects in offspring.

In principle, there are three options, with the following consequences, for setting limit values intended for the protection of workers of different risk groups:

1 Setting one (the lowest) limit value for all workers irrespective of risk group, thus aspiring safe levels of protection for the most sensitive group(s) of workers and 'overprotection' of workers in less sensitive groups. For lead, this option would support an occupational limit value corresponding to the 95th percentile of the background concentration within a population. Specifically for this impact assessment study, the scenario of a BLV of 45 µg/L has a relatively low impact on the benefits assessment, because there are rather few women contributing with the relevant health endpoints of developmental effects and effects on female fertility to the benefits estimate. In the cost assessment, a BLV of 45 µg/L applying to all workers has a significant impact as many additional technical and organisational risk management measures (RMMs) are needed and company discontinuations are caused by reducing the exposure of all workers to this BLV;

2 Setting differentiated limit values according to the most sensitive toxic effect for each risk group of workers, thus aspiring equal protection of all workers. This approach may lead to preferred employment of less sensitive groups and may thus encourage discrimination in employment. Specifically for this impact assessment study, the inclusion of a low BLV for workers of childbearing capacity (45 µg/L) will expectedly have limited impacts on both the benefits and the cost assessment, as only minor fractions of women are employed in most sectors with lead exposure and because the preferred risk management measures (RMM) for preventing/reducing exposures of workers of childbearing capacity are relatively inexpensive (e.g. increased rotation or relocation);

3 Setting one limit value and encouraging additional measures to protect worker groups at extra risk. This approach corresponds to the current situation. Some Member States have implemented differentiated limit values for men and women (see section 4.1 Existing national limits). Furthermore, some companies use differentiated risk management measures to achieve lower exposures of women of childbearing age (stakeholder consultation, 2021).

Within the lead industry, awareness of increased sensitivity of workers of childbearing capacity is prevailing. The awareness is reflected in lower trigger values for surveillance in national and/or company surveillance programmes and additional organisational risk management measures.

ETUI (European Trade Union Institute) has at an early stage of this study raised awareness about "*the discriminatory character of the proposed BLV for women at the workplace and the risks of litigation in front of the European Court of Justice should the proposed BLV* [by RAC] *be adopted in the CAD*", as the BLV proposed by RAC is not protective of the offspring of women of childbearing age (ETUI, 2020). In this note, ETUI also refers to the "Directive 2006/54/EEC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment in occupation" providing that there shall be no direct or indirect discrimination on grounds of sex in relation to working conditions.

It is not within the scope of this study to define, whether the BLV as proposed by RAC is directly or indirectly discriminatory.

For this study, the impact assessment considers the options listed in chapter 3, which were agreed at the inception meeting of the 7th of December 2020.

4.3 Impact of OELs for other substances

In the copper smelting sector, exposures to both lead and **arsenic compounds** are of concern, as both elements occur in varying amounts in the raw materials used for copper smelting. Exposure to arsenic dusts and aerosols may take place at all stages in the copper production process but at different exposure levels (CMD 3). An OEL for arsenic acid and its salts, as well as inorganic arsenic compounds, has been introduced with Directive (EU) 2019/983 in the 3rd round of CMD amendments, and has been set at 0.01 mg/m^3 for the inhalable fraction. It was recognized that the copper smelting sector would have difficulties in complying with a limit value of 0.01 mg/m^3. A transitional period of four years (until 11 July 2023) for the copper smelting was therefore be introduced. Risk managements measures for achieving compliance with the OEL for arsenic comprise organisational measures (amongst others cleaning, procedures to reduce/limit dust formation, restricted entrance to certain areas, hygiene routines and clean cloth services) and improving local exhaust ventilation. These measures will also have a positive effect on reducing airborne and blood lead concentrations. Therefore, the number of cases of ill-health associated with lead exposure in the copper smelting sector may decrease independently of the introduction of limit values for lead. Furthermore, the compliance costs for the copper sector may be overestimated, as some measures for reducing lead exposure should already be in place to achieve compliance with the arsenic OEL.

Chromium VI is emitted in certain welding processes during stainless steel welding. Lead exposure related to welding can occur if lead has also been added to the alloy. Lead exposure due to welding may also occur in situations, where chromium VI exposure would not be expected, e.g. vehicle radiator repair (where lead is present due to use of lead solders) or welding of (lead-painted) carbon steel. In the CMD, the OELV for chromium VI (for welding or plasma cutting processes or similar work processes that generate fume) is currently 0.025 mg/m^3 for the inhalable fraction and is being reduced to 0.005 mg/m^3 (inhalable fraction) over a transition period ending in 17 January 2025. Therefore, new risk management measures are likely to be introduced for stainless steel welding in many companies. These may cause a reduction of lead exposure levels and the associated cases of ill-health for a limited fraction of welding processes, regardless of the introduction of limit values for lead and its compounds.

Within the demolition and renovation sector, workers may be exposed to multiple hazardous substances in buildings, including **asbestos** and lead. A study for assessing the impacts of the OEL for asbestos is undertaken in parallel with this study. At the begin of demolition and renovation works, a screening of hazardous substances is typically performed. This screening includes tests for asbestos, PCB (polychlorinated biphenyls), chlorinated paraffins, heavy metals (lead, cadmium, mercury, hexavalent chromium) and PAH (polyaromatic hydrocarbons). Many of the applied RMMs (in particular the organisational measures) would reduce exposure to all the substances. However, typically asbestos and lead containing components would be removed separately, and building materials containing asbestos would not contain lead. Exposure to lead in renovation and demolition works would typically be by removal of paint (decorative and anticorrosive) and by handling of lead metal, e.g. lead pipes, lead windows or lead roofing materials. The technical measures to reduce dust may be the same (e.g. wetting and use of LEV) but asbestos and paint removal are typically not undertaken simultaneously. Asbestos insulation around e.g. lead pipes may occur, but typically the asbestos would be removed before the pipes. The introduction of a lowered limit value for asbestos is therefore expected to have no or a limited impact on the cost and benefit assessment for lead and its compounds.

4.4 Impact of COVID-19

In the consultation for this study, stakeholders were asked about the impact of the COVID-19 pandemic on their business. A few stakeholders reported temporarily reduced production due to failure raw material delivery. In most cases, production could be maintained or brought back to normal levels after some weeks' time as most production staff could be maintained on-site. Office staff were temporarily sent home for work. Information on whether improved risk management measures such increased use of PPE protect employees against COVID19 has not been obtained. One company notes slightly reduced production levels ongoing in 2021, however, these are not related to the pandemic but to the unavailability of workers.

Several stakeholders indicated that most recent exposure data (from 2020) are either not available or may not be representative, as their companies have had a lower production or regular measurements were disturbed due to provisions related to the pandemic.

Visits on-site in selected companies with exposures to the substance in question usually provide a valuable input to the impact assessment. However, such site visits could not be organised in the current OEL impact assessment for lead and its compounds due to the various and quickly changing restrictions in the Member States. During the previous OEL study (the preliminary study for lead and its compounds) two site visits were conducted (at a primary lead producer and a manufacturer of lead products), and the information from these visits are integrated in the current study. Attempts of organising virtual site visits have not been successful for companies with lead exposure, as most companies do not allow visual recording equipment in the production facilities due to safety and/or confidentiality reasons. The missing input from the site visits has been compensated by an increased number of one-to-one interviews with lead companies.

4.5 Relevant sectors, uses, and operations

Occupational exposure to lead and its compounds may take place by the following processes:

1. Production and intentional use of the substances within the scope of the study (focus on registered substances)
2. Formation of lead or lead compounds by processes involving lead compounds not within the scope (focus on registered substances)
3. Releases of lead or lead compounds by thermal processes where lead is present as unintentional impurity in raw materials or waste products (e.g. by copper production)
4. Management of articles and materials with lead or lead compounds due to former use of the substances in articles and materials.

4.5.1 Summary of REACH registration data

The registered substances are in the ECHA 2019 Scientific Report (ECHA 2019) divided into three groups:

- Metallic lead and inorganic lead compounds (30 listed substances)
- Organic lead compounds (nine listed substances)
- Various complex substances containing lead used mainly in the production of secondary lead such as lead matte and lead dross (33 listed substances)

In Table 4-4, each of the tree groups are ordered by registered tonnage. The tonnages are based on the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) registered substances factsheets on ECHA's website. For some of substances the tonnage indicated at the website differs from the ranges are indicated in the ECHA 2019 Scientific

Report. According to ECHA' secretariat for OELs (personal communication, January 2021), tonnages are regularly updated and the tonnages indicated at ECHA's website are considered the most up-to-date. Registered tonnages used as intermediate are based on the ECHA 2019 Scientific Report as information of tonnages used as intermediate are not public available at ECHA's website.

Most of the inorganic and organic lead compounds have a common harmonised classification under the entry "lead compounds with the exception of those specified elsewhere in this Appendix (Index No 082-001-00-6)". The exposure is mainly monitored by measuring lead in the workplace air or measuring lead in the blood or other biomarkers. For some lead compounds such as lead chromates or lead arsenate, with carcinogenic properties of the compounds due to the presence of hexavalent chromium or arsenate, monitoring may include the entire compounds and specific OELs have been established in some Member States. However, the focus in this study will be on possible effects of lead.

The 33 substances of complex and variable composition are mainly used for the manufacture of secondary lead and its compounds. The 33 substances are mostly generated as waste products from various, mainly metallurgical processes. These substances include other constituents than lead compounds. The focus of this study will be on the lead content and the total exposure to lead by production of secondary lead and in the industries generating the wastes.

In addition to the registered substances, workers may be exposed to formerly used lead stabilisers in PVC, e.g. in recycling of PVC, and formerly used lead siccatives in paints, e.g. in demolition works.

Table 4-4 Registered lead compounds and lead containing residues. For each group ordered by registered tonnage

Substance (REACH registration name) *	EC Number *	CAS Number *	Registered tonnage, t/year full registration *	Registered tonnage, t/year intermediate **
Lead metal and inorganic lead compounds				
Lead	231-100-4	7439-92-1	1,000,000 - 10,000,000	10,000-100,000
Lead monoxide	215-267-0	1317-36-8	100,000 - 1,000,000	10,000-100,000
Tetralead trioxide sulphate	235-380-9	12202-17-4	100,000 - 1,000,000	10,000-100,000
Pentalead tetraoxide sulphate	235-067-7	12065-90-6	10,000 - 100,000	10,000-100,000
Orange lead	215-235-6	1314-41-6	10,000 - 100,000	-
Lead dinitrate	233-245-9	10099-74-8	1,000 - 10,000	-
Trilead dioxide phosphonate	235-252-2	12141-20-7	1,000 - 10,000	-
Lead sulfochromate yellow	215-693-7	1344-37-2	1,000 - 10,000	-
Lead chromate molybdate sulfate red	235-759-9	12656-85-8	1,000 - 10,000	-
Lead dichloride	231-845-5	7758-95-4	1,000 - 10,000	10-1,000
Reaction product of lead chloride	931-722-2	#NA	-	1,000-10,000

Substance (REACH registration name) *	EC Number *	CAS Number *	Registered tonnage, t/year full registration *	Registered tonnage, t/year intermediate **
or lead sulphate with alkaline solution				
Lead titanium zirconium oxide	235-727-4	12626-81-2	100 - 1,000	-
Lead oxide sulfate	234-853-7	12036-76-9	100 - 1,000	-
Lead carbonate	209-943-4	598-63-0	-	10 - 1,000
Lead hydroxide	243-310-3	19783-14-3	-	10 - 1,000
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5	10 - 100	-
Lead cyanamidate	244-073-9	20837-86-9	10 - 100	-
Trilead diarsenate	222-979-5	3687-31-8	-	10 - 1,000
Lead telluride	215-247-1	1314-91-6	-	10 - 1,000
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8	10 - 100	-
Lead titanium trioxide	235-038-9	12060-00-3	10 - 100	-
Lead sulphide	215-246-6	1314-87-0	-	10-1,000
Lead selenide	235-109-4	12069-00-0	-	10-1,000
Lead diazide	236-542-1	13424-46-9	10 - 100	-
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	10 - 100	-
Lead dioxide	215-174-5	1309-60-0	1 - 10	-
Silicic acid, lead salt	234-363-3	11120-22-2	0 - 10	-
Lead Bullion, Platinum Group Metals rich	931-607-7	#NA	0 - 10	-
Lead sulphate	231-198-9	7446-14-2	-	< 10
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7	-	-
Organic lead compounds				
Fatty acids, C16-18, lead salts	292-966-7	91031-62-8	1,000 - 10,000	-
Tetraethyllead	201-075-4	78-00-2	1,000 - 10,000	-
Dioxobis(stearato)trilead	235-702-8	12578-12-0	1,000 - 10,000	-
Lead 2,4,6-trinitro-m-phenylene dioxide	239-290-0	15245-44-0	10 - 100	-

Substance (REACH registration name) *	EC Number *	CAS Number *	Registered tonnage, t/year full registration *	Registered tonnage, t/year intermediate **
Lead di(acetate)	206-104-4	301-04-2; 6080-56-4	10 - 100	-
Trilead bis(carbonate) dihydroxide	215-290-6	1319-46-6	10 - 100	not included in ECHA, 2021
Copper lead resorcylate salicylate complex	614-455-3	68411-07-4	1 - 10	-
Acetic acid, lead salt, basic	257-175-3	51404-69-4	1 - 10	10 - 1,000
Phthalate [phthalato(2-)]dioxotrilead	273-688-5	69011-06-9	-	-
Lead tetraacetate	208-908-0	546-67-8	-	-
Various complex substances containing lead, mainly used in the production of secondary lead				
Slags, copper refining	266-970-4	67711-94-8	100,000 - 1,000,000	>100 000
Matte, copper	266-967-8	67711-91-5	100,000 - 1,000,000	>100 000
Flue dust, zinc-refining	273-760-6	69012-63-1	-	>100 000
Leach residues, zinc ore, lead-contg.	293-314-4	91053-49-5	100,000 - 1,000,000	10,000-100,000
Slags, lead smelting	273-825-9	69029-84-1	100,000 - 1,000,000	>100 000
Lead, bullion	308-011-5	97808-88-3	100,000 - 1,000,000	>100 000
Slags, lead reverbatory smelting	273-800-2	69029-58-9	100,000 - 1,000,000	10,000-100,000
Wastes, lead battery reprocessing	305-445-7	94551-99-2	10,000 - 100,000	>100 000
Calcines, lead-zinc ore conc.	305-411-1	94551-62-9	-	>100 000
Matte, lead	282-356-9	84195-51-7	10,000 - 100,000	10,000-100,000
Flue dust, lead-refining	273-809-1	69029-67-0	10,000 - 100,000	10,000 - 100,000
Lead, dross, copper-rich	273-925-2	69227-11-8	10,000-100,000	10,000-100,000
Slimes and sludges, copper electrolytic	266-972-5	67711-95-9	10,000 - 100,000	10,000 - 100,000
Lead alloy, base, Pb,Sn, dross	273-701-4	69011-60-5	10,000 - 100,000	1,000 - 10,000

Substance (REACH registration name) *	EC Number *	CAS Number *	Registered tonnage, t/year full registration *	Registered tonnage, t/year intermediate **
Slimes and Sludges, precious metal refining	308-516-0	98072-61-8	10,000 - 100,000	1,000 - 10,000
Lead, dross	273-796-2	69029-52-3	1,000-10,000	10,000-100,000
Zinc, desilverizing skims	273-802-3	69029-60-3	1,000 - 10,000	1,000 - 10,000
Residues, zinc smelting	273-824-3	69029-83-0	-	10,000-100,000
Lead, dross, antimony-rich	273-791-5	69029-45-4	1,000 - 10,000	10,000-100,000
Speiss, lead	282-366-3	84195-61-9	1,000 - 10,000	1,000 - 10,000
Lead, dross, bismuth-rich	273-792-0	69029-46-5	1,000 - 10,000	1,000 - 10,000
Slimes and Sludges, battery scrap, antimony- and lead-rich	310-061-8	102110-60-1	-	1,000-10 000
Lead, antimonial, dross	273-795-7	69029-51-2	1,000 - 10,000	1,000 - 10,000
Concentrates of lead and zinc compounds with sulfur resulting from hydrometallurgy (hot acid leaching, super-hotacid leaching and flotation)	936-276-2	#NA	1,000 - 10,000	-
Matte, precious metal	308-506-6	98072-52-7	1,000-10,000	<10
Slimes and Sludges, zinc sulfate electrolytic	273-742-8	69012-43-7	-	1,000 - 10,000
Leach residues, zinc ore-calcine, zinc cobalt	273-769-5	69012-72-2	-	1,000 - 10,000
Waste solids, lead silver anode	305-449-9	94552-05-3	-	1,000 - 10,000
Flue dust, precious metal refining	308-496-3	98072-44-7	100-1,000	10-1,000
Slags, tellurium	273-828-5	69029-86-3	-	1,000 - 10,000
Residues, precious metal refining cementation	310-051-3	102110-50-9	100-1,000	10-1,000
Residues, copper speiss acid leaching	309-643-4	100656-54-0	-	10-1,000
Leach residues, tellurium	273-814-9	69029-73-8	-	10-1000

*Sources: * Tonnages as indicated in the registrations database at ECHA's website; accessed 10 February 2020. For some substances the tonnages differ from the tonnages reported in ECHA (2019). ** Registered tonnage used as intermediate as indicated in ECHA (2019). Tonnages of substances used as intermediate are not public available at ECHA's website and it has not been assessed to what extent the indicated tonnages are up-to-date.*

4.5.2 Mining and manufacture of lead

Mining of lead ore takes place in eight Member States as shown in the table below. According to the Euromines (2020), the total lead content of the mined ores increased from 197,000 tonnes in 2008 to 282,000 tonnes in 2018. The two main mining countries are Sweden and Poland. There as 7 active lead mines in Sweden, while in Poland exploitation is currently carried out from three deposits (ECHA, 2019).

The total refined lead production in the EU is about 2.7 million t/year, meaning that the mining within the EU in 2018 only accounts for about 10%. The remaining ca. 90% of lead concentrate used for the primary production of lead was imported from countries outside the EU.

The production of refined lead is distributed all over the EU and refining takes place in 18 Member States. The major Member States in terms of production of refined lead are Germany (24.2% of total), Spain (9.8%), Italy (9.5%), Poland (8.8%), and Belgium (7.9%). These figures are from 2014, where the UK contributed with 15.8% of the EU refined lead production. The balance between primary and secondary production has shifted since 1998, and in 2011 secondary sources accounted for more than 77% of EU production (BREF, 2017). Lead-acid batteries are the main source of scrap for secondary refining.

The distribution of lead mining and refined lead production (primary and secondary) can be used as a rough indication of the distribution of workers exposed to lead within these sectors.

Table 4-5 Mining production and production of refined lead (primary and secondary) by Member State in EU-27 (from 2020)

	Mining production in 2008, t/year*	Mining production in 2018, t/year*	Production of refined lead in 2014, t/year**	Percentage of total production of refined lead
Austria	-	-	37,122	2.6%
Belgium	-	-	133,252	9.4%
Bulgaria	14,600	24,200	92,000	6.5%
Czech Republic	-	-	44,000	3.1%
Estonia	-	-	8,588	0.6%
France	-	-	72,000	5.1%
Germany	-	-	408,000	28.7%
Greece	16,100	15,300	6,000	0.4%
Ireland, Rep. of	50,300	16,700	17,200	1.2%
Italy	-	-	160,000	11.3%
Netherlands	-	-	31,000	2.2%
Poland	47,900	40,200	149,000	10.5%
Portugal	-	-	5,000	0.4%
Romania	-	-	12,000	0.8%

	Mining production in 2008, t/year*	Mining production in 2018, t/year*	Production of refined lead in 2014, t/year**	Percentage of total production of refined lead
Slovenia	-	-	11,000	0.8%
Slovakia	1,800	100	-	-
Spain	2,400	20,300	166,000	11.7%
Sweden	63,500	64,800	68,708	4.8%
Total	**196,600**	**181,600**	**1,420,870**	**100%**

* *Source: Euromines (2020) at: http://www.euromines.org/mining-europe/production-mineral#Lead. Rounded figures.*

** *Source: USGS, 2017. Mining production expressed as lead content of concentrate. The 2017 publication is the most recent Minerals Yearbook for lead.*

4.5.2.1 Primary production of lead

The production rate of lead and its compounds in the EU is in excess of 10 million tonnes per year. Occupational exposure of workers happens primarily in industries that produce or recycle lead or use large quantities of lead or lead compounds (such as lead battery production). Exposure also occurs in the ceramics and lead crystal glass sectors and PVC processing[13].

Lead is registered in the tonnage band 1,000,000 – 10,000,000 tonnes per annum. Its registered uses are:

- Lead battery production
- Lead sheet production
- Lead powder production
- Use of lead metal in the production of a range of lead articles (e.g. cast, rolled and extruded products, ammunition, lead shot)
- Use of lead metal in the production of leaded steels
- Use of lead metal in lead oxide production and use of lead oxide in stabiliser production

The registered tonnage of manufacture and import of lead compounds and various complex substances containing lead is shown in Table 4-5 in the previous chapter. Further information on the consumption of lead for various applications is provided in section 4.5.3.

4.5.2.2 Secondary production of lead

The complex waste products used for the production of secondary lead may provide indications of processes, where exposure to lead can occur when generating the wastes. The substances listed in the following table account for 97.5% of REACH registered tonnage used in the secondary manufacture of lead (ECHA, 2019).

[13] SUBSPORT Specific Substances Alternatives Assessment – Lead and its inorganic compounds, March 2013 accessed at https://www.subsportplus.eu/subsportplus/_Downloads/SUBSPORT-Lead.pdf?__blob=publicationFile on 19 January 2021.

Table 4-6 Substances used in the secondary manufacture of lead (ECHA, 2019)

EC number	Name	Description
266-970-4	Slags, copper refining	Mainly copper, copper oxides, some oxides of lead and minor metals, skimmed from the anode furnace and returned to the converter.
266-967-8	Matte, copper	Product of smelting roaster calcines concentrates or cement copper with flux in reverberatory or electric furnaces. Composed primarily of copper and copper, iron and lead sulfides with minor sulfides of other metals.
273-760-6	Flue dust, zinc-refining	By-product of refining of zinc ores consisting primarily of zinc, lead and iron.
273-825-9	Slags, lead smelting	Insoluble substance obtained during dissolution of zinc ores or concentrate in sulfuric acid for the production of zinc sulfate solutions after physical separation such as flotation and filtration.
293-314-4	Leach residues, zinc ore, lead-contg.	Insoluble substance obtained during dissolution of zinc ores or concentrate in sulfuric acid for the production of zinc sulfate solutions after physical separation such as flotation and filtration.
308-011-5	Lead, bullion	nan
305-445-7	Wastes, lead battery reprocessing	Material obtained during the recycling of exhausted lead storage batteries. Consists primarily of oxides and sulfates of lead and lead alloys.
273-809-1	Flue dust, lead-refining	By-product of refining lead ores obtained from baghouse and electrostatic precipitator and as slurry from scrubbers.
305-411-1	Calcines, lead-zinc ore conc.	A thermally agglomerated substance formed by heating a mixture of metal sulfide concentrates, limestone, sand, furnace dross, miscellaneous zinc, lead and copper bearing materials, together with already roasted material to a temperature of 1000°C to 1200°C (538°F to 649°F).
273-800-2	Slags, lead reverbatory smelting	By-product from the smelting of lead ores, scrap lead or lead smelter dross. Consists primarily of oxides and silicates of antimony and lead.
282-356-9	Matte, lead	Substance resulting from the smelting of lead and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Composed primarily of iron and lead (mainly in sulfide form) and may contain other residual non-ferrous metals and their compounds.
273-796-2	Lead, dross	nan

Note: The table combines information from Table 18 (EC number and name) and Table 40 (description). "Nan" is not explained in the report (ECHA, 2019).

4.5.3 Consumption of lead

This section provides an overview of the consumption of lead by application area. A more detailed description of the processes is provided in section 4.6.2 'Exposure concentrations by main sectors'.

“First application” is defined as the first application after refining for which a metal is used. As an example, the first application may be the manufacture of lead compounds, which are later used for various applications such as manufacturing plastics, paints or ceramics. From 2000 to 2015, the trends in the consumption of lead by first applications are shown in Table

4-7. The data for 2000, 2005 and 2015 have been obtained from the Lead REACH Consortium (2019) and represent 14 Member States and Norway. The 2015 data represent 94% of the total use of lead for first use in EU28 and EFTA countries. The data include consumption volumes from the UK. The breakdown of data per Member State is not available, the data have therefore not been recalculated to reflect the EU-27 as per 2020. The percentage may be lower or higher for individual applications.

For 2000, also the data from the Voluntary Risk Assessment for Lead are shown (LDAI, 2008). The data represent first applications in EU15. In 2000, lead additives for gasoline, which are organolead compounds, accounted for about 1% of the total use of lead. The gasoline additives for the 2005 and 2015 datasets are included under lead compounds.

The consumption for batteries has been increasing during the period, whereas the consumption for rolled and extruded products has been decreasing.

The decrease in the consumption of lead for the latter three application areas may be used as an indication of a decrease in the number of workers exposed when working with the lead containing products (the decrease in the number of workers may be even higher than the decrease in the lead consumption).

The following includes a short description of the uses of lead metal. Further details on the different applications are provided in section 4.6 on exposure concentrations. Uses of lead compounds are further described in the next section.

Rolled and extruded products. These products consist of lead plates, sheets, strips, bars, wires and tubing produced through a combination of rolling, drawing and extruding. Lead sheet accounts for the majority of lead used in this category and 85% of lead sheet is used in construction applications, with the remainder used in various medical, nuclear, defence and industrial applications (Lead REACH Consortium, 2019). Due to differences in architectural style and building techniques, the use of lead sheet varies considerably among Member States. During the period 2005-2015, UK has accounted for approximately half of the use of lead in rolled and extruded products. This is of importance for the interpretation of data on the number of exposed workers related to the building sector.

Shot and ammunition. The consumption of lead for the production of ammunition has been stable during 2000-2015 (Table 4-7). Lead shot accounts for an estimated 75% of the lead used in non-military shot/ammunition, while lead pellets and bullets account for the remaining 25% (Lead REACH Consortium, 2019). Major civilian ammunition manufacture in Europe is concentrated in Italy, followed by Germany, Spain, the UK, Sweden, the Czech Republic and France.

Miscellaneous. Lead is used as an alloying additive to other metals, typically to improve castability, finishing and plating characteristics. Lead is used as an alloying element for tin, steel, copper (brasses and bronzes) and aluminium alloys. The total consumption for miscellaneous applications has decreased markedly from 67,000 t/year in 2000 to 10,000 t/year in 2015. Lead was widely used in white metal and pewter (tin-lead alloys) models, ornaments and jewellery. Lead solders, the alloys used to create metallurgical bonds between two or more metal surfaces to achieve an electrical and/or physical connection, once dominated both electronic and industrial applications. The use of lead solders in electrical and electronic equipment (EEE) has been banned since 2006, with some exemptions, but the exemptions gradually expire and are often not renewed. According to the Lead REACH Consortium (2019), there is also a move away from the use of lead solder in industrial applications, such as in the joins to copper or brass heat exchangers and the solder for joining copper, brass and zinc in roofing, and rainwater furniture.

Table 4-7 Consumption of lead by first use application

Application area (sector numbering according to this study)	Consumption of lead for first use (1000 tonnes)				% of total in 2015
	2000**	2000*	2005*	2015*	
Batteries, automotive (3)	1,009	971	1,033	809	53%
Batteries, industry (3)				460	30%
Rolled and extruded products (4)	242	205	200	95	6%
Shot and ammunition (4)	57	53	50	57	4%
Cable sheathing (4)	31	17	13	18	1%
Gasoline additives [out of scope of study]***	19	202	110	68	4%
Pigments and other lead compounds*** (6)	201				
Miscellaneous (including alloys and solders) (4, 5)	78	67	52	10	1%
Total	**1,677**	**1,515**	**1,458**	**1,517**	**100%**

** Data from Lead REACH Consortium (2019). Data represent the first applications consumption in 14 EU Member States and Norway[14]. The total represents about 94% of the total use of lead for first use in EU28 and EFTA countries. Consumption volumes have not been adjusted to reflect EU-27 (2020), as national data for UK have not been available. The percentage may be different for the individual applications. The total is similar to the total indicated in the proposal for identifying lead as a SVHC (Substance of Very High Concern) (Swedish Chemicals Agency, 2018) but the distribution between applications is slightly different.*

***Data from the voluntary risk assessment for lead (LDAI, 2008). Represents the consumption in EU15.*

**** Consumption of lead compounds are not differentiated into applications for gasoline additives, pigments and other for 2000 -2015 in the data from Lead REACH Consortium (2019). However, the use of lead compounds has gasoline additives is restricted to diminishing amounts in special applications.*

4.5.4 Consumption of lead compounds

The consumption of lead compounds is shown in

Table 4-8 and the uses are briefly described below. Please note that the total quantities are higher than indicated under “Pigments and other lead compounds” in the previous section, as a major part of the quantities indicated as first uses of lead for batteries are in fact use of lead compounds.

Batteries. Lead-acid battery manufacture is the largest application for lead and lead compounds in Europe: lead oxides are pressed, cured, hydrated and then reacted with sulphuric acid to produce porous metallic lead negative electrode pastes (Lead REACH Consortium, 2019). Lead sulphates can be used as seeding material for the lead dioxide, the active material at the positive electrode. Lead-acid batteries are the leading rechargeable battery technology, at over 90% of the rechargeable battery market in terms of energy stored. Key countries for lead-based battery manufacture in Europe include the Czech Republic, France, Germany, Italy, Spain, Poland and the United Kingdom (ECHA, 2019). About 99% of lead monooxide tonnage used in the EU (500,000 tonnes) and about 80% of lead tetraoxide tonnage (36,000 tonnes) is used in battery manufacture. They are transformed in the course of the battery manufacturing process into pentalead tetraoxide sulphate and

[14] Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Spain, Sweden, the United Kingdom

tetralead trioxide sulphate, which are themselves ultimately transformed within the battery into lead metal and lead dioxide (ECHA, 2019).

Plastic stabilisers. Lead stabilisers based on lead sulphates, phthalates and stearates have traditionally been added to both rigid and flexible PVC to improve their physical properties and durability. As of the end of 2015 under the VinylPlus voluntary commitment, all lead-based PVC stabilisers have been completely replaced in formulations for PVC applications sold in the EU28. The alternatives are predominantly calcium-based stabilisers. In 2005, approximately 60,000 tonnes lead were used for PVC stabilisers in the EU15. The consumption has gradually decreased from 2005 to 2015. Although lead stabilisers are no longer used in virgin PVC in the EU28, some lead stabilisers are still produced in Europe for export to other regions. According to the Annex to the Restriction on the use of lead compounds to stabilise PVC (ECHA, 2018), the European Stabiliser Producers Association (ESPA) representing more than 95% of PVC stabiliser industry across EU indicated that in 2016 that there was only one European company producing lead stabilisers for export to non-EU countries. The Annex also notes that approximately 30% of EU produced lead stabilisers are exported outside the EU, which means that 70% remains within the EU. According to the proposed REACH restriction of the use of lead stabiliser, PVC with lead stabilisers may still be recycled for certain uses.

Pigments. The major lead pigments are lead chromates, which are subject to authorisation (due to the content of hexavalent chromium in the compounds). The total authorised quantities are 3,000 t/year. According to the Lead REACH Consortium (2019), pigments based on lead carbonates (white) and lead oxide (red) are used now only in niche applications such as paint for restoring or maintaining works of art or historic buildings. For the vast majority of uses in the EU, lead pigments have been replaced with other pigments such as titanium dioxide. For red lead oxide, there is only one professional use of the substance in paints included in the joint registration dossier, which is for rust-inhibiting priming paints applied directly to iron and steel (mainly ships) because of its anti-corrosion properties.

Glasses. Leaded glass typically contains 54-65% of SiO_2, 24-30% PbO (lead oxide), 13-15% Na_2O or K_2O and various minor components (Lead REACH Consortium, 2019). Leaded glass has a higher density and refractive index than most other glasses and is used in decorative applications e.g. wine glasses, tableware and decanters. Lead crystal production has historically been concentrated in Europe and has declined steeply over the last decade (Lead REACH Consortium, 2019). France, Germany, Ireland, the Czech Republic and Slovakia still have some lead glass production remaining and the lead use in crystal glass in European countries has been estimated at 3,000 - 5,000 t/year (Lead REACH Consortium, 2019). In the EU, only glass products containing at least 24% of PbO may be referred to as "lead crystal". Products with less lead oxide must be labelled "crystalline" or "crystal glass" (ECHA, 2019).

Lead glass is also used for various types of optical and filter glasses e.g. camera and microscope lenses. Lead glass has been granted an exemption under the RoHS (Restriction of Hazardous Substances) Directive (Directive 2011/65/EU) until 2021.

Frits (ceramics). Frits, a term for the coloured precursors to ceramic glazes and glass colouring, can contain lead compounds. Overall, the use of lead in frits and pigments is decreasing due to the availability of lead-free alternatives and the costs associated with ensuring regulatory compliance when using lead-containing compounds in a workplace (Lead REACH Consortium, 2019).

Table 4-8 Summary of lead compounds and their main uses

Lead compound (REACH registration name)	EC Number	Main applications	Approx. share	Approx. amount in Europe (t/year)
Compounds covered by Lead REACH Consortium (2019) * (consumption figures concern ca. 2008)				
Lead monoxide	215-267-0	Lead-acid batteries	95%	540,000
		Plastic stabiliser production	4%	
		Speciality & crystal glasses	1%	
		Other (frits, rubber protection and explosives)	<1%	
Orange lead (lead tetraoxide)	215-235-6	Lead-acid batteries	81%	45,000
		Frits	12%	
		Speciality & crystal glasses	7%	
		Other (industrial absorbents, rubber protection and explosives)	<1%	
Lead oxide sulfate	234-853-7	Coatings and inks for mirror backing	no data	no data
Tetralead trioxide sulphate	235-380-9	Lead-acid batteries	Major use	>370,000
		Plastic stabiliser	Minor use (replaced)	
		Other (mirror backing)	Minor use	
Pentalead tetraoxide sulphate	235-067-7	Lead-acid batteries	Major use	>39,000
		Plastic stabiliser	Minor use	
Lead dichloride	231-845-5	Pigments	No EU use	100 - 1,000
		Ceramics and speciality glasses	(export only)	
Dibasic lead phthalate	273-688-5	Plastic stabiliser	100%	100 – 1,000 (replaced)
Trilead dioxide phosphonate	235-252-2	Plastic stabiliser	100%	Unknown (replaced)
Fatty acids, C16-18, lead salts	292-966-7			

Lead compound (REACH registration name)	EC Number	Main applications	Approx. share	Approx. amount in Europe (t/year)
Dioxobis(stearato)trilead	235-702-8			
Dibasic lead sulphite	263-467-1	Plastic stabiliser	Major use	(replaced)
		Mirror backing	Minor use	
Other lead compounds				
Lead chromate molybdate sulfate red	235-759-9	Pigments	100%	According to the authorisation decision, the total amounts used should not exceed 900 t/year
Lead sulfochromate yellow	215-693-7	Production of pyrotechnical delay devices	100%	According to the authorisation decision, the total amounts used should not exceed 2,100 t/year
Lead chromate	231-846-0	Pigments	100%	Not registered, no indication of quantities authorised

** Based on REACH registration dossiers (ca. 2008) (data provided by Lead REACH Consortium, 2019). Data by Member States are not available and therefore include consumption volumes of the UK.*

4.5.5 Sectors with exposure to lead and its compounds

Exposure to lead and its compounds may take place within many different sectors at all life-cycle stages. The following table provides an overview illustrating the complexity of the exposure situations.

Potentially relevant sectors identified from literature review and stakeholder consultation are listed in Table 4-9. The designation of NACE (the Statistical Classification of Economic Activities in the European Community) codes is done on the basis of the authors' understanding of the relevant activities. To make the NACE codes as useful as possible, the codes are identified at the three-digit level that are most likely to cover most of the activities.

Some activities, which could cause to exposure to lead, may take place within sectors covered by other codes, but these activities are considered to account for only a limited part of the activities within the aggregated codes (e.g. C27 - Manufacture of electrical equipment) and activity data for these codes is therefore not useful for the assessment.

The Voluntary Risk Assessment Report (LDAI, 2008) includes 31 different occupational exposure scenarios. The scenarios are listed in Table 4-9 below for each of the sectors assessed in this study.

For some of the subsectors under "15. Other", there is limited information available about the actual processes, but the subsectors are indicated in national databases on exposures.

Table 4-9 Sectors, subsectors and uses of lead and its compounds

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
1. Primary lead production and mining	Primary lead production	Production of metallic lead from lead ore concentrates for use in metals	C24.4.3 - Lead, zinc and tin production B07.29 - Mining of other non-ferrous metal ores	1: Primary production of lead metal
2. Secondary lead production (including lead battery recycling)	Lead battery recycling	Separation of the component parts of batteries; smelting and refining of the lead components	C24.4.3 - Lead, zinc and tin production E38.3.2 - Recovery of sorted materials G46.7.7 - Wholesale of waste and scrap	2: Secondary production of lead metal
	Other recycling of metallic lead	Smelting and refining of the lead articles		
	Recovery of lead from residues	Smelting and refining residues from other metal industry		
3. Lead battery production	Lead battery production	Use in automobile starting, lighting and ignition (SLI) batteries; emergency lighting; traction (propulsion) batteries	C27.2.0 - Manufacture of batteries and accumulators	4: Battery production
4. Production of articles of metallic lead	Lead sheet and tubes production	Production of rolled and extruded products for use in machinery and vehicles; radiation shielding; roofing and flashing; soundproofing; coating of steel	C25.1.1 - Manufacture of metal structures and parts of structures C25.5.0 - Forging, pressing, stamping and roll-forming of metal; powder metallurgy C25.9.9 - Manufacture of other fabricated metal products n.e.c.	3: Production of lead sheet
	Production of cables	Extrusion of lead for cable sheathing	C27.3.2 - Manufacture of other electronic and electric wires and cables	-
	Production of lead keels, sinkers and other cast lead articles	Smelting of lead for production of keels, sinkers, cast articles for radiation protection	C24.5.4 - Casting of other non-ferrous metals C30.1.2 - Building of pleasure and sporting boats	-

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
	Production of ammunition	Smelting of lead for production of shot and other ammunition	C25.4.0 - Manufacture of weapons and ammunition	-
	Production of leaded steel	Smelting of lead for production of leaded steel sheet	C25.9.9 - Manufacture of other fabricated metal products n.e.c.	-
5. Foundries and production of articles of leaded alloys	Non-ferrous foundries	Production of moulded articles of alloys with lead (e.g. steel, aluminium, brass and bronzes)	C24.5.3 - Casting of light metals C24.5.4 - Casting of other non-ferrous metals	10.1: Bronze & brass foundries
	Machining of non-ferrous alloys	Production of other articles of alloys with lead (e.g. steel, aluminium, brass and bronzes)	C25.6.2 - Machining	
	Production and use of leaded steel	Production of steel lead alloy Turning and other processing of leaded steel	C24.1 - Manufacture of basic iron and steel and of ferro-alloys C24.3.3 - Cold forming or folding C25.6.2 - Machining	Production and use of leaded steel
6. Production of lead compounds and lead frits	Lead oxide and lead frit production for glass and ceramics	Intermediates in the manufacture of lead special glass and lead crystal glass	C20.1.3 - Manufacture of other inorganic basic chemicals	5: Production of lead oxides and stabiliser compounds
	Manufacture of PVC stabilisers	Historic, the use phased out from 2016	C20.1.3 - Manufacture of other inorganic basic chemicals C20.1.4 - Manufacture of other organic basic chemicals	
	Manufacture of pigments and colours	Pigments for restoration paints, traffic paints	C20.1.2 - Manufacture of dyes and pigments	10.6: Pigment manufacturing
7. Production of glass	Lead crystal glass production	Production of decorative glass; cutting and etching	C23.1.9 - Manufacture and processing of other glass, including technical glassware C23.13.12.20 Drinking glasses (including stemware drinking glasses), other	6: Production of lead crystal glass
	Lead special glass production	Production of special glass e.g. for filters and camera lenses		

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
			than of glass ceramics, of lead crystal, gathered by hand; 23.13.12.40: Drinking glasses (including stemware drinking glasses), other than of glass ceramics, of lead crystal, gathered mechanically;	
8. Ceramic ware production and enamelling	Ceramic ware production	Use in ceramic glazes on earthenware, porcelain and glazed tiles; potteries, glazers and transfers	C23.3.1 - Manufacture of ceramic tiles and flags C23.4 - Manufacture of other porcelain and ceramic products	7: Production of ceramic ware 10.17: Enamelling
	Jewellery making and enamelling	Casting/extrusion; badge and jewellery enamelling and other vitreous enamelling Remark: Restricted with some exemption	C32.1.2 - Manufacture of jewellery and related articles	
9. Manufacture and use of plastics and paints	Manufacture of PVC and other plastics	Historic, the use phased out from 2016	C22.2.1 - Manufacture of plastic plates, sheets, tubes and profiles C22.2.3- Manufacture of builders' ware of plastic C22.2.4- Manufacture of other plastic products	7: PVC processing
	Manufacture and use of paints with lead compounds	Use of lead paints and coatings on steel structures, road markings, and in consumer products (e.g. spray-painting of automobiles)	C20.3 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics C25.6.1 - Treatment and coating of metals F43.3.4 - Painting and glazing [buildings]	10.22: Printing and paint manufacturing 10.11: Paint spraying
10. Work with metallic lead	Plumbing	Plumbing of lead sheets and tubes; soldering of building materials	F43.2.2 - Plumbing, heat and air-conditioning installation	10.18: Soldering of electronic circuit boards 10.14: Engine reconditioning 10.5: Opticians

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
	Manufacture of computer, electronic and optical products, electrical equipment	Solder used in electrical and electronic industries for certain applications which are out of scope of the RoHS Directive *	C26 - Manufacture of computer, electronic and optical products Main activities probably in: C26.1 - Manufacture of electronic components and boards C27 - Manufacture of electrical equipment	10.4: Capacitator manufacturing
	Construction work with lead sheets	Cutting lead sheet, soldering, etc.	F43.9.1 - Roofing activities	10.9: Radiotherapy shield manufacturing
	Construction work with leaded steel	Cutting leaded sheet	F43.9.9 - Other specialised construction activities n.e.c.	-
	Stained glass workshops	Working with lead rods and solders	C25.1.2 - Manufacture of doors and windows of metal	10.2: Stained glass workshops
	Tyre fitting	Tyre fitting using lead balance weights	G45.2.0 - Maintenance and repair of motor vehicles	10.21: Tyre fitters
11. Shooting	Shooting	Use of lead ammunition on shooting ranges e.g. by the police	O84.2.2 - Defence activities O84.2.4 - Public order and safety activities	10.3: Occupational exposure related to the use of lead shot/ammunition
12. Recycling of PVC and other plastics	Recycling of PVC	Melting of PVC Remark: planned restriction exempt lead stabilisers in PVC for recycling	C22.2.1 - Manufacture of plastic plates, sheets, tubes and profiles C22.2.3 - Manufacture of builders' ware of plastic C22.2.4- Manufacture of other plastic products	7: PVC processing
	Recycling of other plastics	Melting of plastics		-
13. Demolition, repairing and scrap industry	Ship repairing and breaking	Welding, hot cutting and other processes on steel with lead containing coatings	C33.1.5 - Repair and maintenance of ships and boats E38.3.1 - Dismantling of wrecks	10.19: Shipyard workers 10.10: Welding fumes

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
	Paint removal and other renovation operations	Blast removal and burning of old lead paint; stripping of old lead paint from doors, windows etc	F43.1.1 – Demolition F43.3.3 – Floor and wall covering	10.15: Carpenters 10.12: Construction workers
	Welding and cutting	Welding and cutting of bridges and other steel structures with lead containing coatings	F43.1.1 - Demolition	10.13: Iron workers (exposure situation unclear)
	Handling of lead scrap	Separation of component parts which may include lead	E38.3.2 - Recovery of sorted materials G46.7.7 - Wholesale of waste and scrap	9: Exposure in demolition and scrap industries
	Recycling of waste electrical and electronic equipment (WEEE)		E38.3.2 - Recovery of sorted materials E39 - Remediation activities and other waste management services	-
14. Other waste handling and remediation	Glass recycling	Including TV or computer monitors containing cathode ray tubes (CRT)	C23.1 - Manufacture of glass and glass products	-
	Hazardous waste handling		E38.2.2 - Treatment and disposal of hazardous waste	-
	Incineration plants		E38.2 - Waste treatment and disposal	10.8: Incineration plants
	Non-hazardous waste handling		E38.2.1 - Treatment and disposal of non-hazardous waste	10.20: Garbage handling
	Soil remediation	Remediation of lead contaminated soils	E39 - Remediation activities and other waste management services	10.7: Soil remediation
15. Other	Mining	Mining and production of lead ore concentrates	B7.2.9 - Mining of other non-ferrous metal ores	-
	Use of alkyllead as fuel additive	Very limited use in closed systems for formulation of fuel additives for aviation fuel	None identified	-

Sector	Subsector	Uses and/or activities	NACE codes	Exposure scenarios in the Voluntary RAR, LDAI (2008)
	Production of copper	No information	C24.4.4 - Copper production	-
	Primary steel production, blast furnace	No information	C24.1.0 - Manufacture of basic iron and steel and of ferro-alloys	-
	Manufacture of explosives	Various lead compounds use to manufacture explosives	C25.4.0 - Manufacture of weapons and ammunition	-
	Laboratory uses	Lead and/or lead monoxide used as a laboratory agent in chemical analysis (fire assay)	M71.2.0 - Technical testing and analysis	-
	Printing	Lead has historically been used for typesetting	C18.1 - Printing and service activities related to printing	10.22: Printing and paint manufacturing
	Electroplating	No information	C25.6.1 - Treatment and coating of metals	-
	Manufacture of friction lining	No information	C23.9.1 - Production of abrasive products	-
	Gravestone inscription writers	Exposure by lead in the dust	-	0.16: Monumental masonry workers
	Others		-	10.23: Others

Sources: Various information collected for the study, among these: ECHA (2019; 2020), SUBSPORT (2013), Health and Safety Executive, HSE (2012, 2016), European Commission (2019), LDAI, 2008) and stakeholder consultation.

The primary routes of occupational exposure is by inhalation and by ingestion (by hand-to-mouth behaviour due to insufficient personal hygiene and housekeeping). Dermal absorption of inorganic lead is considered to be minimal. The significant exposure by ingestion and the importance of this exposure route for the toxicological endpoints result in a particular focus on organisational risk management measures with regard personal hygiene and housekeeping.

The following table provide an overview of the life-cycle stages and examples of exposure situations. A detailed description of the exposure situations and exposure levels is provided in Chapter 7, which will be further developed during the implementation of the study.

Table 4-10 Examples of exposure situations with occupational exposures to lead and its compounds

Life cycle stage	Processes, sector number used in this study	Examples of exposure situations
Mining	1. Lead mining	Excavation (exposure to lead containing dust) Production of concentrates - handling of concentrates
	1. Mining of other non-ferrous metals	Production of concentrates - handling of concentrates
Manufacture of metallic lead and lead alloys	1. Primary lead production	Raw material handling Smelting Refining and casting Internal logistics
	2. Secondary lead production (linked to the recycling phase)	
Production of lead compounds	6. Manufacture of PVC stabilisers	Loading into reaction vessels Grinding/milling Bagging/drumming operations Internal logistics
	6. Lead oxide and lead frit production for glass and ceramics	
	6. Manufacture of pigments and other lead compounds	
Production of lead-containing articles	3. Lead battery production	Plate manufacturing and treatment Assembly Battery formation Internal logistics
	4. Production of lead sheet and tubes	Raw material handling Smelting and refining Extruding Milling, sawing and slitting Storage and shipment
	4. Production of cables	
	4. Production and use of ammunition, lead keels, sinkers, balance weights and other lead articles	
	4. Production and use of leaded steel	
	5. Non-ferrous foundries and machining of non-ferrous alloys	Furnace (casting), cutting, grinding, pour-ing
	7. Lead glass production	Raw material handling Forming, cutting, polishing
	8. Ceramic ware production	Production of frits Production and handling of pigments Lithography Decoration Glazing of ceramic
	8. Jewellery making and enamelling	Production of enamels

Life cycle stage	Processes, sector number used in this study	Examples of exposure situations
	9. Manufacture of PVC and other plastics	Handling of pigments and stabilisers
	10. Production of stained glass	Smelting, forming, cutting
Production and use of lead-containing mixtures	9. Manufacture of paints, enamels and glazes	Handling of pigments powder or paste Handling of paint, enamels or glazes
	9. Use of lead-pigmented paint	Spaying and other application of the paints Application of hotmelt roadmarking
	12. Production of leaded petrol	Mixing of alkyllead and petrol
Use of lead-containing articles	10. Use of lead solder for manufacture of electrical and electronic equipment and other uses of solder	Handling of lead metal Heating of lead metal
	10. Use of lead solder for plumbing	
	10. Construction work with lead sheets and lead pipe	
	10. Construction work with leaded steel	
Demolition, shipbreaking, recycling, etc.	13. Recycling of PVC and other plastics	Shredding and grinding Compounding, converting
	14. Ship repairing and breaking	Heating up surfaces treated with lead-containing coatings
	14. Paint removal and other renovation operations	Heating up surfaces treated with lead-containing coatings Grinding
	14. Handling of lead scrap	Welding and cutting Handling of lead metal Heating up surfaces treated with lead-containing coatings
	14. Welding and cutting	Heating up surfaces treated with lead-containing coatings
	15. Glass recycling	Crushing of glass Heating up glass with content of lead
	15. Hazardous waste handling	Handling ESP dust form waste incinerators
Research and development	16 Use of lead compounds in laboratories	Handling of lead compounds

4.6 Exposure concentrations

Exposure concentrations are available from various sources: the consultation survey of the current study, the previous consultation survey of the previous OEL study (confidential data, study undertaken by Lassen et al., 2019), surveys undertaken by the Lead REACH Consortium, Member State surveillance programmes, scientific papers, the IARC monograph, the Voluntary Risk Assessment for Lead (LDAI, 2008) and the German MEGA database. The data are presented by main sectors; including data from the consultation surveys and data from the literature review.

Data from large datasets covering many sectors are also listed by source and described in the Appendix B to this report.

4.6.1 Units

Different units are used in various sources and have been converted into the units used in this report. The most commonly used unit for lead concentration is air is mg/m³. The most used unit for lead levels in blood is µg/100 ml. The following conversions have been undertaken:

- Airborne concentrations
  1 µg/m³ = 0.001 mg/m³
- Blood levels
  1 µg/dl = 1 µg/100 ml
  1 µg/l = 0.1 µg/100 ml
  1 µmol/l = 20.72 µg/100 ml

Please note that the proposed limit values by RAC are set out in the units µg/l (blood lead level) and µg/m³ (airborne concentration). The OEL and BVL options assessed in this study are listed in two sets of units (Table 3-1 and Table 3-2) in order to facilitate the comparison of the provided exposure concentration data with the OEL and BLV options.

4.6.2 Exposure concentrations by main sectors

These sections include for each sector the information from the consultation survey of the current study and the consultation survey of the previous OEL study, from stakeholder consultation and from the literature, including data from IARC (2006) and the VRAR – Voluntary Risk Assessment Report (LDAI, 2008).

Companies were asked to provide data in the consultation survey of the current study, if they had not participated in the survey of the previous OEL study (Lassen et al., 2019) or more updated data were available. Some companies provided updated data in the survey of the current study. Therefore, survey data from both surveys are presented.

The collection of data from companies only serves the purpose to support the information base for the impact assessment. The provided information on exposure concentrations cannot be used to assess a company's regulatory compliance with current national or EU limit values.

The Lead REACH Consortium has provided data for entire sectors and by workplace (Lead REACH Consortium, 2019; Grewe and Vetter, 2019). The workplace names and description of the operations are included in the sector specific descriptions of the risk management measures in section 4.8.2. The VRAR for lead (LDAI, 2008) includes data on exposure levels and blood-lead levels by workplace categories, but the data are collected in the period 1998-2001 and must be considered as outdated. However, they still provide useful information for the section on trends.

Most companies report concentrations for four workplaces and have apparently chosen the workplaces/activities with the most significant exposures. The standard number of activities for reporting exposure concentrations in the survey questionnaire was four. Only a few companies provided two questionnaires, allowing for data from five to eight activities. This means that data for workplaces with less significant exposures are represented to a lesser degree.

Data from the VRAR for lead (LDAI, 2008) and IARC (2006) are reported only for sectors where limited newer data are available. Only well documented datasets with an indication of country and years have been included.

Data reported in ECHA (2019) and Annex I to the RAC opinion (RAC, 2020b) are included if the data sources are less than 10 years old or if only limited newer data are available.

Concentration data to be taken forward in the cost benefit assessment and comparison between sectors are provided in the section 4.6.6 "Summary of exposure concentrations".

4.6.2.1 Primary lead production

In primary lead metal production, several different processes can be used to extract metallic lead bullion from the ore concentrate. The two major processes are: traditional two-stage pyrometallurgical processing, which involves sintering and blast furnacing (main process); and hydrometallurgical (electrolytic) processing (LDAI, 2008). Most lead smelters today use a variable percentage of secondary lead raw materials; the distinction between primary and secondary producers is described in the next section.

Occupational exposure by primary production takes place in the following processes (REACH Lead Consortium, 2019):

- **Raw material handling**: Ore/concentrate delivery, loading/unloading and furnace feed, mixing
- **Sintering**: Feeding/unloading, sinter plant operation
- **Smelting**: Furnace operation
- **Refining and casting**: Decopperisation, softening (arsenic, antimony and tin removal), silver separation, zinc distillation, casting of lead ingots/slabs or lead alloy ingots
- **Internal logistics**: Storage and shipment of finished goods, intra-facility transport
- **Other**: Repair, cleaning, and maintenance, quality control, and engineering

The main exposure route is by inhalation and hand-to-mouth contact, but some dermal exposure may take place at some processes.

The datasets from France and Finland both include a sector “Production of lead, zinc and tin” (Appendix B). As primary production of lead does not take place in these Member States, the data are included under secondary lead production.

The airborne exposure concentrations provided in the report by Grewe and Vetter (2019) for the International Lead Association (ILA) document that average lead concentrations in air range from 0.05 – 1.63 mg/m³ and commonly exceed the current OEL. As workers are wearing RPE (Respiratory Protection Equipment) during these activities, exposure concentrations have been recalculated, taking the filter class and assigned protection factors (APF) of RPE into account. Information on RPE has been provided by the companies for each workplace and APFs have therefore been considered on a site-by-site and workplace-by-workplace basis. The calculated P95 concentrations inside RPE exceed the currently lowest national OELs of 0.05 mg/m³ for the workplaces raw material handling, sintering and smelting.

P90 values for the reported lead concentrations in blood (PbB) range from 22.5 – 34.8 µg/100 ml and are below the current EU BLV of 70 µg/100 mL but exceed the RAC proposed BLV of 15 µg/100 ml. Four primary smelters provided data for this survey, and data for three of them is included here. Their data does not seem to deviate from the Lead REACH Consortium survey data.

Table 4-11 Exposure concentrations (inhalable fraction, mg Pb/m³) in primary lead production from published sources and stakeholder consultation.

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Primary lead producers (personal, outside RPE)	182	0.39	0.10	1.04	2.21	4.15	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	9	0.61	-	1.24	2.39	3.55		
W2 - sintering	11	1.63	-	2.41	2.68	2.94		
W3 - smelting	16	0.68	-	1.79	2.43	3.59		
W4 - refining and casting	85	0.30	-	0.58	0.89	3.44		
W5 - internal logistics	11	0.09	-	0.11	0.28	0.45		
W6 - others	36	0.05	-	0.07	0.10	0.99		
JR - job rotation	14	0.62	-	2.71	3.83	4.15		
Primary lead producers (personal, inside RPE)*	**182**	**0.01**	**<0.01**	**0.03**	**0.06**	**0.10**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	9	0.02	-	0.03	0.06	0.09		
W2 - sintering	11	0.04	-	0.06	0.07	0.07		
W3 - smelting	16	0.02	-	0.04	0.06	0.09		
W4 - refining and casting	85	0.01	-	0.01	0.02	0.09		
W5 - internal logistics	11	<0.01	-	<0.01	0.01	0.01		
W6 - others	36	<0.01	-	<0.01	<0.01	0.02		
JR - job rotation	14	0.02	-	0.07	0.10	0.10		
Company K (furnace work), personal	19	0.17	0.14	-	0.35	0.36	EU MS	Consultation survey
Company K (Lead refining), personal	19	0.04	0.05	-	0.07	0.09	EU MS	Consultation survey
Company K	19	0.02	0.02	-	0.06	0.08	EU MS	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
(Lead casting), personal								
Company K (Material handling), personal	3	0.02	0.01	-	0.028	0.03	EU MS	Consultation survey
Company Y (Production of crude lead), personal	136	0.049	0.013	-	0.202	0.65	EU MS, 2020	Consultation survey
Company Y (Material handling), personal	750	0.019	0.0046	-	0.08	0.95	EU MS, 2020	Consultation survey
Company AG (Smelting), personal	22	0.62	0.146	-	2.18	2.36	EU MS, 2019	Consultation survey
Company AG (Raw material handling), personal	17	0.18	0.060	-	0.69	0.92	EU MS, 2019	Consultation survey
Company AG (refining), personal	17	0.047	0.024	-	0.12	0.13	EU MS, 2019	Consultation survey
Company AG (Other), personal	96	0.016	0.012	-	0.037	0.052	EU MS, 2019	Consultation survey

** Concentrations have been calculated based on the assigned protection factors of RPE used at the workplaces.*

Table 4-12 Blood-lead level (µg Pb/100 ml) in primary lead production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Primary lead producers	8,487	14.2	12.0	27.0	-	62	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Raw material handling	318	15.9	13.3	30.0	-	-		
Sintering	48	28.5	29.0	34.8	-	-		
Smelting	3,250	14.4	12.3	27.0	-	-		
Refining and casting	1,546	17.5	16.2	29.2	-	-		
Internal logistics	334	15.1	13.9	28.4	-	-		
Others	2,889	11.6	10.0	22.5	-	-		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Smelting, refining, alloying and casting *	2,654	12.8	11.0	-	32	60-69	UK, 2015-2018	Based on HSE, 2019*
Company K (furnace and refining work)	98	10.86	11.0	-	18.63	21.7	EU MS, 2020	Consultation survey
Company K (Lead casting)	8	14.9	14.9	-	17.18	17.6	EU MS, 2020	Consultation survey
Company K (Material handling)	9	18.0	16.8	-	26.91	30.0	EU MS, 2020	Consultation survey
Company Y (Production of crude lead)	45	-	-	-	-	15.0 – 29.9	EU MS, 2020	Consultation survey
Company Y (Material handling)	577	-	-	-	-	45.0 – 49.9	EU MS, 2020	Consultation survey
Company AG (Primary lead smelters)	70	29.9	31.5	-	48.4	66	EU MS, 2020	Consultation survey
Company AG (Raw material handling)	21	18.5	18.8	-	32.2	36.2	EU MS, 2020	Consultation survey
Company AG (lead raffinery)	61	22.5	21.2	-	37.6	64.4	EU MS, 2020	Consultation survey
Company AG (Other technical worker)	386	10.39	7.92	-	29.54	48.79	EU MS, 2020	Consultation survey

**May include primary lead production together with other activities*

4.6.2.2 Secondary lead production - recycling

Secondary lead manufacturers use feed materials containing spent lead batteries (i.e. lead metal, lead sulphate), lead scrap, and/or other lead-containing materials usually metallic or oxidic lead compounds, but potentially also other lead compounds (e.g. lead sulphide and lead sulphate) where the recycler is processing lead-containing dusts, slags/drosses or other industrial residues.

Occupational exposure by secondary production takes place in several processes - some of the processes (e.g. desulphurisation) may depend on feed material and only be relevant for some companies (REACH Lead Consortium, 2019):

- **Raw material handling**: Storage, transport and handling of batteries and other lead scrap

- **Shredding and sorting**: For batteries, separation of sulphuric acid, shredding (breaking), grid-separation, elution of lead oxide paste, also sorting of other lead scrap
- **Desulphurisation**: Sulphur removal from lead oxide paste
- **Melting and smelting**: Melting of grids, smelting and reduction of paste
- **Refining and casting**: Refining of lead, casting of ingots
- **Storage, shipment and transport**: Storage and shipment of finished goods, intra-facility transport
- **Others**: Repair, cleaning, and maintenance

The main exposure route is by inhalation and hand-to-mouth contact, but some dermal exposure may take place by some processes if proper gloves are not used.

Data from the questionnaires are included in the tables below. As the companies report about different processes, it is not possible to analyse the data across the questionnaires. To maintain confidentiality, the Member State is not indicated, and the processes are described in general terms.

Six questionnaires in the stakeholder consultation for the previous OEL study (Lassen et al., 2019) were from companies involved in recovery of lead from various waste materials. The companies were apparently not included in the Lead REACH Consortium survey (2019). Zinc is typically recovered from the same materials e.g. secondary steel production dust and may be the main metal recovered. Different companies indicate slightly different processes: this is an example from a company handling lead/zinc containing residues:

- Concentrate receive and preparation
- Roaster (smelting), operator of roaster and operator of boiler
- Leach product handling
- Anode casting

In the consultation survey, concentration data was provided for 18 facilities within secondary smelting. Some companies, with facilities in several Member States or at several locations submitted questionnaires for each facility. For confidentiality reason, each facility is reported as a separate company in the tables below.

The exposure data from the companies and the ILA survey (Grewe and Vetter, 2019) without RPE show that mean airborne concentrations range from 0.03 – 0.23 mg/m³ for the different workplaces and commonly exceed the current OEL of 0.05 mg/m³. Taking RPE into account, the P95 values generally comply with the current lowest national OELs (0.05 mg/m³), apart from data for raw material handling.

Most companies reported data from stationary samples. The concentration data are generally in range with the data from the ILA survey. Considerable differences in exposure concentrations are reported for different companies/facilities, e.g. for shredding and sorting between Company A and B in the table below, the differences are so large that they also appear to include some differences in sampling and/or possibly mistakes in calculations (correct units have been double checked).

For the blood-lead levels, the survey data from the Lead REACH Consortium summarises more than 11,000 samples. Median values (10.6 – 16.9 µg/100 ml) are relatively close to the BLV proposed by RAC (15 µg/100 ml), while the P90 for alle workplaces reaches 28 µg/ 100 ml.

Most of the data provided by companies indicate lower levels than given in the large datasets from the Lead REACH Consortium survey (2019) and the UK data (HSE, 2019); this may partly be reflecting the bias that often the best performing companies have resources for participating in these kind of surveys.

Table 4-13 Exposure concentrations (mg Pb/m³) in secondary lead production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Secondary lead producers (personal, outside RPE)	**369**	**0.16**	**0.03**	**0.42**	**0.79**	**5.18**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	48	0.19	-	0.27	0.93	3.44		
W2 - shredding and sorting	44	0.11	-	0.32	0.42	1.18		
W3 - desulphurisation	0	n.a.	-	n.a.	n.a.	n.a.		
W4 - melting and smelting	190	0.14	-	0.28	0.60	5.18		
W5 - refining and casting	111	0.23	-	0.63	1.13	2.50		
W6 - storage, shipment and transport	12	0.03	-	0.05	0.06	0.07		
W7 - others	49	0.11	-	0.25	0.54	1.18		
JR - job rotation	27	0.07	-	0.04	0.09	1.34		
Secondary lead producers (personal, inside RPE)*	**369**	**<0.01**	**<0.01**	**0.01**	**0.02**	**0.13**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	48	0.01	-	0.03	0.09	0.24		
W2 - shredding and sorting	44	<0.01	-	0.01	0.02	0.04		
W3 - desulphurisation	0	n.a.	-	n.a.	n.a.	n.a.		
W4 - melting and smelting	190	<0.01	-	0.01	0.02	0.13		
W5 - refining and casting	111	0.01	-	0.02	0.03	0.06		
W6 - storage, shipment and transport	12	<0.01	-	<0.01	<0.01	<0.01		
W7 - others	49	<0.01	-	0.01	0.01	0.03		
JR - job rotation	27	<0.01	-	<0.01	<0.01	0.03		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Metallurgy of lead, zinc or tin	1259	0.505	0.071	-	2.38	18.2	France, 2009-2017	INRS, 2018b
Company A (shredding and sorting), stationary	46	13.7	1.99	-	93.3	248	Europe, non-EU, 2017-2018	Consultation survey
Company A (Smelting), stationary	26	0.22	0.15	-	0.640	1.01	Europe, non-EU, 2017-2018	Consultation survey
Company A (Smelting), stationary	19	0.19	0.07	-	0.84	1.39	Europe, non-EU, 2017-2018	Consultation survey
Company A (Melting and alloying), stationary	16	0.03	0.03	-	0.068	0.06	Europe, non-EU, 2017-2018	Consultation survey
Company B (Melting and casting), stationary	9	0.089	0.057	-	0.23	0.23	EU MS, 2000, 2003, 2011	Consultation survey
Company B (shredding and sorting), stationary	10	0.039	0.03	-	0.094	0.094	EU MS, 2000, 2003, 2011	Consultation survey
Company B (Lead coating), stationary	5	0.40	0.13	-	1.6	1.6	EU MS, 2000, 2003, 2011	Consultation survey
Company C (Raw material handling), stationary	2	1.5	1.5	-	-	2.7	EU MS, 2019	Consultation survey
Company C (melting and smelting), stationary	15	0.8	0.14	-	2.49	3.66	EU MS, 2019	Consultation survey
Company C (Refinery), stationary	11	1.2	0.16	-	3.52	4	EU MS, 2019	Consultation survey
Company C (Others), stationary	10	0.0048	0.002	-	0.013	0.017	EU MS, 2019	Consultation survey
Company D (Others), stationary	18	0.029	0.028	-	0.066	0.079	EU MS, 2015-2020	Consultation survey
Company D (sampling), stationary	6	0.021	0.020	-	0.035	0.037	EU MS, 2015-2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company D (material handling, smelting), stationary	34	0.198	0.173	-	0.512	0.61	EU MS, 2015-2020	Consultation survey
Company D (material handling, casting), stationary	31	0.064	0.047	-	0.121	0.46	EU MS, 2015-2020	Consultation survey
Company E (shredding and sorting), stationary	2	0.085	-	-	-	0.12	EU MS, 2020	Consultation survey
Company E (raw material handling, smelting cleaning), stationary	6	0.09	-	-	-	0.23	EU MS, 2019/20	Consultation survey
Company F (casting, material handling), personal	-	-	-	-	-	3.91	EU MS, 2020	Consultation survey
Company F (raw material handling), personal	-	-	-	-	-	0.50	EU MS, 2020	Consultation survey
Company F (raw material handling, maintenance), personal	-	-	-	-	-	0.45	EU MS, 2020	Consultation survey
Company F (material handling), personal	-	-	-	-	-	0.08	EU MS, 2020	Consultation survey
Company G (Smelting), personal	2	-	-	-	-	1.17	EU MS, 2020	Consultation survey
Company G (Refining), personal	2	-	-	-	-	0.55	EU MS, 2020	Consultation survey
Company G (Maintenance), personal	2	-	-	-	-	0.25	EU MS, 2020	Consultation survey
Company G (others), personal	2	-	-	-	-	0.33	EU MS, 2020	Consultation survey
Company H (raw material handling), personal	76	0.064	0.032	-	0.298	0.57	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company H (smelting), personal	167	0.027	0.016	-	0.082	0.29	EU MS, 2020	Consultation survey
Company H (refining and casting), personal	143	0.103	0.048	-	0.34	2.08	EU MS, 2020	Consultation survey
Company H (intra-facility transport), personal	41	0.018	0.0049	-	0.047	0.26	EU MS, 2020	Consultation survey
Company H (repair, maintenance), personal	54	0.034	0.0083	-	0.13	-	EU MS, 2020	Consultation survey
Company H (Others), personal	127	0.0091	0.0034	-	0.032	-	EU MS, 2020	Consultation survey
Company M (raw materials handling), stationary	10	0.025	0.006	-	0.096	0.11	EU MS, 2020	Consultation survey
Company M (material handling), stationary	108	0.095	0.056	-	0.302	0.39	EU MS, 2019-2021	Consultation survey
Company M (refining and casting), stationary	144	0.084	0.054	-	0.22	0.38	EU MS, 2019-2021	Consultation survey
Company T (melting and smelting), personal	3	0.052	0.045	-	0.085	0.085	EU MS, 2016	Consultation survey
Company T (Other works), personal	2	0.19	-	-	0.24	0.24	EU MS, 2020	Consultation survey
Company T (Refining), personal	6	0.12	0.057	-	0.089	0.30	EU MS, 2019	Consultation survey
Company Z (Lead refining), personal	25	0.047	0.030	-	-	0.26	EU MS, 2020-2021	Consultation survey
Company Z (Production of copper matte), personal	32	0.033	0.023	-	-	0.14	EU MS, 2020-2021	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AD (material handling), stationary	1	0.74	0.74	-	0.74	0.74	EU MS, 2018	Consultation survey
Company AD (Cleaning and maintenance), stationary	2	0.81	0.81	-	0.85	0.85	EU MS, 2020	Consultation survey
Company AD (Refining and casting), stationary	1	0.98	0.98	-	0.98	0.98	EU MS, 2020	Consultation survey
Company AE (Refining and casting), stationary	9	0.089	0.057	-	0.23	0.23	EU MS, 2000, 2003, 2011	Consultation survey
Company AE (material handling), stationary	10	0.039	0.03	-	0.094	0.094	EU MS, 2000, 2003, 2011	Consultation survey
Company AE (Production of lead articles), stationary	5	0.40	0.13	-	1.6	1.6	EU MS, 2000, 2003, 2011	Consultation survey
Company AM (Smelting), personal	11	0.18	0.16	-	0.32	0.55	EU MS, 2018-2020	Consultation survey
Company AM (Refining), personal	16	0.13	0.081	-	0.29	0.54	EU MS, 2018-2020	Consultation survey
Company AM (Sampling), personal	18	0.012	0.052	-	0.12	0.42	EU MS, 2018-2020	Consultation survey
Company AQ (Smelting), stationary	6	0.58	-	-	-	1.76	EU MS	Consultation survey
Company AQ (Lead refining), stationary	6	0.18	-	-	-	0.29	EU MS	Consultation survey
Company AQ (Casting), stationary	11	0.20	-	-	-	0.40	EU MS	Consultation survey
Company AQ (Other), stationary	10	0.23	-	-	-	0.81	EU MS	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AR (Shredding and sorting), personal	6	2.53	0.50	-	6.16	6.79	EU MS, 2017-2020	Consultation survey
Company AR (Smelting), personal	5	1.41	1.79	-	2.61	2.8	EU MS, 2017-2020	Consultation survey
Company AR (Lead Refining), personal	17	0.32	0.16	-	1.025	1.47	EU MS, 2017-2020	Consultation survey
Company AR (Casting), personal	5	0.027	0.027	-	0.059	0.067	EU MS, 2017-2020	Consultation survey
Company AW (smelting), personal	4	0.13	0.13	-	0.17	0.17	EU MS, 2020	Consultation survey
Company AW (refining)	5	0.067	0.058	-	0.10	0.0073	EU MS, 2020	Consultation survey
Company AW (Shredding and sorting)	4	0.049	0.031	-	0.035	0.085	EU MS, 2020	Consultation survey
Company AW (Others (maintenance)	4	0.015	0.015	-	0.015	0.015	EU MS, 2020	Consultation survey
Company AAA (Smelting), stationary	1	1.91	-	-	-	-	EU MS, 2020	Consultation survey
Company AAA (Refinery), stationary	1	1	-	-	-	-	EU MS, 2020	Consultation survey
Company AAA (Casting), stationary	1	0.05	-	-	-	-	EU MS, 2020	Consultation survey
Company AAA (Shredding and sorting), stationary	1	0.005	-	-	-	-	EU MS, 2020	Consultation survey
Company 1, smelting *	13	0.046	-	-	-	0.309	2018	Lassen et al. (2019)
Company 2, smelting	24	0.015	0.0075	-	0.035	-	2019	Lassen et al. (2019)
Company 3, loading/storage	1	0.010	-	-	0.010	0.010	2019	Lassen et al. (2019)

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Refer-ence
Company 3, smelt-ing	3	0.051	-	-	0.027	0.027	2019	Lassen et al. (2019)
Company 3, product handling	1	0.008	-	-	0.001	0.001	2019	Lassen et al. (2019)
Company 3, leach-ing	1	0.022	-	-	0.023	0.023	2019	Lassen et al. (2019)
Company 4, smelt-ing	6	0.023	-	-	0.08	0.098	2017	Lassen et al. (2019)
Company 4, casting	1	0.011	-	-	-	0.011	2017	Lassen et al. (2019)
Company 4, mainte-nance	3	0.002	-	-	0.004	0.004	2017	Lassen et al. (2019)
Company 4, material handling	9	0.13	-	-	0.66	1.05	2017	Lassen et al. (2019)
Company 5, logistics	8	0.03	-	-	-	0.11	2018	Lassen et al. (2019)
Company 5, smelt-ing	37	0.45	-	-	-	1.20	2018	Lassen et al. (2019)
Company 5, refining	28	0.38	-	-	-	0.63	2018	Lassen et al. (2019)
Company 6, smelt-ing	12	0.04	-	-	-	0.20	2018	Lassen et al. (2019)
Company 6, machin-ing	3	0.05	-	-	-	0.07	2018	Lassen et al. (2019)
Company 6, material handling	9	0.012	-	-	-	0.004	2018	Lassen et al. (2019)

**These measurements are for special working places, using part-time workers.*

Table 4-14 Blood-lead level (µg Pb/100 ml) in secondary lead production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Secondary lead pro-ducers	**11,478**	**16**	**14**	**28**	**-**	**61**	EU-wide, 2013-2016	Lead REACH Consortium, 2019*
Raw material handling	893	14.6	13.4	-	-	-		
Shredding and sorting	1,423	15.4	14.2	27.0	-	-		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Desulphurisation	300	7.5	10.6	-	-	-		
Melting and smelting	2,664	17.8	16.7	-	-	-		
Refining and casting	2,104	18.1	16.9	-	-	-		
Storage, shipment and transport	409	13.6	12.9	-	-	-		
Others	2,862	13.8	12.4	-	-	-		
Production of lead, zinc and tin	311	8.3	6.2	-	20.7	31.7	Finland, 2000-2014	FIOH, 2017
Smelting, refining, alloying and casting	2,654	12.8	11	-	32	60-69	UK, 2015-2018	Based on HSE, 2019**
Lead battery recycling	1,949	13.6	14	-	23	40-49	UK, 2015-2018	Based on HSE, HSE, 2019**
Recovery of lead from car batteries	77	32.8	-	-	-	-	Romania, 2018	Negru et al., 2020
Company A (Sinter crushing, shredding, loading)	20	9.8	-	-	15	17	Europe, non-EU, 2020	Consultation survey
Company A (Smelting)	43	9.3	-	-	19	20	Europe, non-EU, 2020	Consultation survey
Company A (Smelting 2)	16	9.3	-	-	19	20	Europe, non-EU, 2020	Consultation survey
Company A (Melting and alloying)	19	9.5	-	-	16.3	19	Europe, non-EU, 2020	Consultation survey
Company B (Melting and casting)	15	10.9	11.1	-	21.7	21.7	EU MS, 2020	Consultation survey
Company B (Shredding etc.)	33	8.2	7.9	-	18.7	22.2	EU MS, 2020	Consultation survey
Company B (Lead coating)	24	10.5	7.8	-	20	22	EU MS, 2020	Consultation survey
Company C (Raw material handling)	10	12	12	-	17	23.8	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Company C (Melting)	87	9.6	9	-	20	26	EU MS, 2020	Consultation survey
Company C (Refinery)	74	12	11	-	20	22	EU MS, 2020	Consultation survey
Company C (Others)	95	8	7	-	22	22	EU MS, 2020	Consultation survey
Company D (control)	6	10.5	10.4	-	14.9	15.6	EU MS, 2020	Consultation survey
Company D (control and sampling)	5	8.3	7.4	-	12	13.1	EU MS, 2020	Consultation survey
Company D (material handling)	18	12	17.5	-	20	22	EU MS, 2020	Consultation survey
Company D (material handling and casting)	17	13.8	14	-	22	22	EU MS, 2020	Consultation survey
Company E (shredding and sorting)	8	11.4	-	-	-	17.7	EU MS, 2020	Consultation survey
Company E (raw material handling and maintenance)	17	9.6	-	-	-	16.9	EU MS, 2020	Consultation survey
Company E (Maintenance)	16	9.9	-	-	-	17.3	EU MS, 2020	Consultation survey
Company F (casting, internal logis-tics)	-	-	7.8	-	-	23.3	EU MS, 2020	Consultation survey
Company F (Loading)	-	-	8.7	-	-	20.6	EU MS, 2020	Consultation survey
Company F (Material handling, maintenance)	-	-	11.2	-	-	18.2	EU MS, 2020	Consultation survey
Company F (Material handling, Loading)	-	-	8.7	-	-	20.6	EU MS, 2020	Consultation survey
Company G (Smelting)	18	8.1	7	-	14.6	22	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Company G (Refining)	15	8.5	8.1	-	14.1	14.7	EU MS, 2020	Consultation survey
Company G (Maintenance)	6	7.1	6.1	-	10.8	11.2	EU MS, 2020	Consultation survey
Company G (others)	11	6.2	6.8	-	13.2	15.4	EU MS, 2020	Consultation survey
Company H (raw material handling)	232	10.7	9.3	-	22.3	33.6	EU MS, 2020	Consultation survey
Company H (smelting)	215	13.5	12.8	-	16.1	29.9	EU MS, 2020	Consultation survey
Company H (refining and casting)	133	15.3	13.8	-	31.2	38.8	EU MS, 2020	Consultation survey
Company H (intra-facility transport)	94	10.8	10.4	-	18.5	29.5	EU MS, 2020	Consultation survey
Company H (repair, maintenance)	150	11.0	10.1	-	22.2	27.8	EU MS, 2020	Consultation survey
Company H (Others)	317	6.5	5.1	-	16.1	28.5	EU MS, 2020	Consultation survey
Company M (raw material handling)	5	14.7	14.2	-	19.1	19.7	EU MS, 2020	Consultation survey
Company M (Smelting)	23	9.4	9.2	-	18.12	18.5	EU MS, 2020	Consultation survey
Company M (refining)	11	19.1	18.9	-	24	24.3	EU MS, 2020	Consultation survey
Company Z (refining)	189	20.0	20.3	-	29.8	38.9	EU MS, 2020	Consultation survey
Company Z (Production of copper matte)	439	13.7	12.8	-	25.9	47.9	EU MS, 2020	Consultation survey
Company AD (material handling)	8	18.3	17.8	-	-	27.0	EU MS, 2020	Consultation survey
Company AD	8	18.3	17.8	-	-	27.0	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
(Cleaning and maintenance)								
Company AD (Refining and casting of lead)	8	18.3	17.8	-	-	27.0	EU MS, 2020	Consultation survey
Company AD (Maintenance)	2	30.5	30.5	-	-	36	EU MS, 2020	Consultation survey
Company AE (Refining and casting)	15	10.9	11.1	-	21.7	21.7	EU MS, 2020	Consultation survey
Company AE (material handling)	33	8.2	7.9	-	18.7	22.2	EU MS, 2020	Consultation survey
Company AE (Production of lead articles)	24	10.5	7.8	-	20.0	22.0	EU MS, 2020	Consultation survey
Company AM (Smelting)	262	15.7	15.5	-	29.0	36.0	EU MS, 2020	Consultation survey
Company AM (Refining)	202	7.89	7.0	-	15.0	18.0	EU MS, 2020	Consultation survey
Company AM (Sampling)	147	9.37	8.0	-	21.4	36.0	EU MS, 2020	Consultation survey
Company AQ (Smelting)	166	13.9	13.7	-	-	29.0	EU MS, 2020	Consultation survey
Company AQ (Lead refining)	84	16.8	18.7	-	-	37.3	EU MS, 2020	Consultation survey
Company AQ (Casting)	71	8.7	7.7	-	-	41.4	EU MS, 2020	Consultation survey
Company AQ (Other)	72	8.9	7.0	-	-	24.9	EU MS, 2020	Consultation survey
Company AR (Shredding and sorting)	30	24.51	26.75	-	35.24	46.8	EU MS, 2020	Consultation survey
Company AR (Smelting)	64	16.62	18.2	-	32.58	36.9	EU MS, 2020	Consultation survey
Company AR (Lead Refining)	54	18.8	18.6	-	34.8	38.1	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Company AR (Casting)	17	15.38	20.9	-	34.0	34.0	EU MS, 2020	Consultation survey
Company AW (smelting)	31	14.9	14.03	-	20.6	23.9	EU MS, 2020	Consultation survey
Company AW (refining)	27	16.2	16.6	-	25.3	28.1	EU MS, 2020	Consultation survey
Company AW (Shredding and sorting)	11	16.4	15.9	-	23.2	24.1	EU MS, 2020	Consultation survey
Company AW (Others (maintenance)	11	18.5	18.5	-	24.4	24.9	EU MS, 2020	Consultation survey
Company AAA (Furnace), stationary	-	13	-	-	-	17.6	EU MS, 2020	Consultation survey
Company AAA (Refinery), stationary	-	14	-	-	-	16.5	EU MS, 2020	Consultation survey
Company AAA (Casting), stationary	-	14	-	-	-	16.5	EU MS, 2020	Consultation survey
Company AAA (Shredding and sorting), stationary	-	15	-	-	-	16.8	EU MS, 2020	Consultation survey
Company 1, smelting	70	10.7	-	-	-	19.6	2018	Lassen et al. (2019)
Company 2, smelting	47	8.06	-	-	-	17.9	2019	Lassen et al. (2019)
Company 3, load-ing/storage	6	8.1	-	-	-	-	2019	Lassen et al. (2019)
Company 3, smelting	16	9.9	-	-	-	-	2019	Lassen et al. (2019)
Company 3, final prod-uct collection	5	10.5	-	-	-	-	2019	Lassen et al. (2019)
Company 3, leaching	6	11.9	-	-	-	-	2019	Lassen et al. (2019)
Company 4, smelting	1	-	-	-	-	<2	2017	Lassen et al. (2019)
Company 4, casting	8	9.5	6.1	-	23.3	27	2017	Lassen et al. (2019)

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Company 4, anode maintenance	38	1.6	1.0	-	3.3	9.7	2017	Lassen et al. (2019)
Company 4, leach residue handling	12	2.7	3.0	-	5.1	5.6	2017	Lassen et al. (2019)
Company 5, logistics	-	20.5	-	-	-	32.2	2018	Lassen et al. (2019)
Company 5, smelting	-	15.1	-	-	-	25.0	2018	Lassen et al. (2019)
Company 5, refining	-	23.0	-	-	-	32.4	2018	Lassen et al. (2019)
Company 5, maintenance	-	14.2	-	-	-	14.2	2018	Lassen et al. (2019)
Company 6, smelting	2	17.9	-	-	-	24.0	2018	Lassen et al. (2019)
Company 6, machining	2	9.8	-	-	-	13.3	2018	Lassen et al. (2019)
Company 6, handling of lead pieces	2	13.3	-	-	-	27.0	2018	Lassen et al. (2019)
Company 6, office work	2	6.7	-	-	-	10.5	2018	Lassen et al. (2019)

** P90 values were provided for all workplaces but are not reported here, if they were lower than median values.*

***Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.3 Lead battery production

The production process of lead acid batteries usually includes the following steps: grid casting, lead oxide production, mixing and pasting, curing operations, formation (including plate treatment), assembly, quality control, packaging and shipment (LDAI, 2008).

Key countries for lead-based battery manufacture in Europe include the Czech Republic, France, Germany, Italy, Spain, Poland and the United Kingdom (ECHA, 2019).

Lead battery producers use various lead species as input material: lead metal, lead monoxide, tetralead trioxide sulphate, pentalead tetraoxide sulphate, and some will additionally use lead tetroxide.

Occupational exposure by lead battery production takes place in the following processes (REACH Lead Consortium, 2019):

- **Plate manufacturing**: Casting/production of grids, oxide production, mixing, pasting and curing operations
- **Plate treatment**: Jar/tank formation, plate washing, drying and cutting
- **Assembly**: Stacking, assembly, welding and joining operations
- **Battery formation**: Acid filling, formation (wet batteries) and finishing

- **Internal logistics**: Storage of raw materials and finished goods, intra-facility transport and shipment
- **Others**: Cleaning and maintenance

The main exposure route is by inhalation and hand-to-mouth contact, but some dermal exposure may take place by some processes if proper gloves are not used.

The exposure concentrations provided by Grewe and Vetter (2019) show that P95 lead concentrations in air exceed the current OEL (0.15 mg/m³) in most processes (values ranging from 0.04 – 0.41 mg/m³). Taking the use of RPE into account, the calculated P95 concentrations are still in close vicinity to the current OEL for these three processes.

Blood lead data summarised from more than 40,000 samples by the Lead REACH Consortium show elevated median (range 15 – 19.8 µg/100 ml) and P90 levels (29.8 – 33.5 µg/100ml) for the processes where lead is not enclosed yet (plate manufacturing, plate treatment, assembly). Data for the other processes show lower exposures.

Most recent data (from 2019, 2020 and 2021) are provided for ten facilities participating in the survey, which is about 1/3 of battery manufacturing facilities in the EU. Looking at all processes, the median data provided by companies are well in line with the range of median values provided by the Lead REACH Consortium, with just a few values being smaller or larger. The same applies to average values. The maximum value reported by the Lead REACH Consortium is with 85 µg/100 ml above the current EU BLV. Maximum values reported by companies do not exceed 39 µg/100 ml.

Table 4-15 Exposure concentrations (mg Pb/m³) in lead battery production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead battery producers (personal, outside RPE)	**1,546***	**0.07**	**0.03**	**0.15**	**0.25**	**3.68**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - plate manufacturing	606	0.08	-	0.17	0.29	3.68		
W2 - plate treatment	84	0.13	-	0.18	0.41	2.04		
W3 - assembly	708	0.06	-	0.15	0.23	1.74		
W4 - battery formation	40	0.04	-	0.10	0.12	0.46		
W5 - internal logistics	40	0.01	-	0.02	0.04	0.11		
W6 - others	68	0.05	-	0.08	0.13	1.63		
JR - job rotation	7	0.06	-	0.10	0.11	0.12		
Lead battery producers (personal, inside RPE)*	**1,546**	**0.03**	**<0.01**	**0.07**	**0.12**	**1.63**	EU-wide, 2015-2018	Grewe and Vetter, 2019

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
W1 - plate manufacturing	606	0.03	-	0.08	0.16	0.79		
W2 - plate treatment	84	0.04	-	0.10	0.14	0.17		
W3 - assembly	708	0.02	-	0.06	0.11	0.73		
W4 - battery formation	40	<0.01	-	0.01	0.01	0.05		
W5 - internal logistics	40	0.01	-	0.02	0.04	0.11		
W6 - others	68	0.03	-	0.02	0.03	1.63		
JR - job rotation	7	0.06	-	0.10	0.11	0.12		
Manufacture of batteries and accumulators	879	0.135	0.041	-	0.568	4.912	France, 2009-2017	INRS, 2018b
Lead accumulators, nickel cadmium batteries	364	-	0.072	-	0.90	-	Germany 2000-2009	IFA, 2010
Manufacture of batteries	-	-	-	-	-	0.167	Romania, 2018	Negru et al., 2020
Company AC (Plate manufacture), personal	-	0.01	-	-	-	-	EU MS, 2014-2015	Consultation survey
Company AC (Plate treatment), personal	-	0.06	-	-	-	-	EU MS, 2014-2015	Consultation survey
Company AC (Assembly), personal	-	0.05	-	-	-	-	EU MS, 2014-2015	Consultation survey
Company AH (Plate manufacturing), personal	27	0.035	0.025	-	0.027	0.10	EU MS, 2020	Consultation survey
Company AH (Assembly), personal	56	0.057	0.035	-	0.084	0.084	EU MS, 2020	Consultation survey
Company AI (Plate manufacturing), personal	27	0.038	0.028	-	0.080	0.10	EU MS, 2020	Consultation survey
Company AI (Plate treatment), personal	27	0.038	0.028	-	0.080	0.10	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AI (Cleaning and maintenance), personal	26	0.059	0.037	-	0.085	0.086	EU MS, 2020	Consultation survey
Company AJ (Plate Production), personal	69	0.047	-	-	-	0.33	EU MS, 2019	Consultation survey
Company AJ (Assembly), personal	102	0.048	-	-	-	0.21	EU MS, 2019	Consultation survey
Company AJ (Finish), personal	39	0.0025	-	-	-	0.0054	EU MS, 2019	Consultation survey
Company AJ (Others), personal	27	0.0025	-	-	-	0.0049	EU MS, 2019	Consultation survey
Company AN (plate production and treatment), stationary	-	-	-	-	-	0.25	EU MS	Consultation survey
Company AN (assembly and formation), stationary	-	-	-	-	-	0.16	EU MS	Consultation survey
Company AS (Grid), personal	8	0.02	-	-	-	0.31	EU MS, 2020	Consultation survey
Company AS (Plate), personal	16	0.16	-	-	-	0.29	EU MS, 2020	Consultation survey
Company AS (Assembly), personal	74	0.07	-	-	-	0.23	EU MS, 2020	Consultation survey
Company AS (Other), personal	4	0.08	-	-	-	0.13	EU MS, 2020	Consultation survey
Company AU (Plate Manufacture), personal	44	0.12	0.083	-	0.36	0.54	Europe, non-EU, 2019	Consultation survey
Company AU (Battery Assembly), personal	68	0.12	0.054	-	0.41	0.84	Europe, non-EU, 2019	Consultation survey
Company AX (plate manufacture), personal	109	0.050	0.037	-	0.12	0.14	Other, 2020	Consultation survey
Company AX (Assembly), personal	126	0.047	0.034	-	0.12	0.13	Other, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AX (formation, logistics), personal	33	0.0062	0.0092	-	0.013	0.016	Other, 2020	Consultation survey
Company AX (Offices, laboratories), personal	30	0.017	0.0091	-	0.055	0.071	Other, 2020	Consultation survey
Company AY, personal	95	0.067	0.051	-	0.14	0.16	Other, 2020	Consultation survey
Company AY (Assembly), personal	162	0.052	0.041	-	0.12	0.20	Other, 2020	Consultation survey
Company AY (formation, logistics), personal	26	0.0095	0.0096	-	0.016	0.016	Other, 2020	Consultation survey
Company AY (Laboratories, offices), personal	18	0.022	0.016	-	0.052	0.064	Other, 2020	Consultation survey
Company AZ (Plate manufacturing), personal	120	0.060	0.060	-	0.098	0.12	EU MS, 2019	Consultation survey
Company AZ (Plate treatment), personal	48	0.079	0.086	-	0.099	0.102	EU MS, 2019	Consultation survey
Company AZ (Assembly), personal	192	0.046	0.045	-	0.076	0.095	EU MS, 2019	Consultation survey
Company AZ (Others), personal	56	0.069	0.064	-	0.102	0.103	EU MS, 2019	Consultation survey

* *Not the sum of the number of samples from the single workplaces. Possibly, the workplace "job rotation" has been omitted.*

Table 4-16 Blood-lead level (µg Pb/100 ml) in lead battery production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead battery producers	**43,173**	**14**	**12**	**29**	**-**	**85**	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Plate manufacturing	7,520	19.0	17.9	33.5	-	-		
Plate treatment	1,708	20.1	19.8	32.9	-	-		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Assembly	12,101	16.7	15.0	29.8	-	-		
Battery formation	7,358	11.3	9.0	22.5	-	-		
Internal logistics	4,090	10.9	8.3	22.7	-	-		
Others	6,517	12.3	9.0	27.9	-	-		
Lead battery manufacture	1,002	14	12	-	24	40-49	UK, 2015-2018	Based on HSE, 2019*
Manufacture of car batteries, men	524	16.0	-	-	-	-	Romania, 2018	Negru et al., 2020
Manufacture of car batteries, women	90	3.5	-	-	-	-	Romania, 2018	Negru et al., 2020
Company AC (Plate manufacturing)	-	-	21.8	-	-	-	EU MS, 2020	Consultation survey
Company AC (Plate treatment)	-	-	21.8	-	-	-	EU MS, 2020	Consultation survey
Company AC (assembly)	-	-	21.8	-	-	-	EU MS, 2020	Consultation survey
Company AH (Plate manufacturing)	70	15	15	-	18	35	EU MS, 2020	Consultation survey
Company AH (Assembly)	100	15	15	-	19	39	EU MS, 2020	Consultation survey
Company AH (Cleaning and maintanence)	30	22	20	-	30	44	EU MS, 2020	Consultation survey
Company AI (Plate manufacturing)	120	12	13	-	25	30	EU MS, 2020	Consultation survey
Company AI (Plate treatment)	10	12	13	-	25	30	EU MS, 2020	Consultation survey
Company AI (Cleaning and maintenance)	144	14	14	-	25	39	EU MS, 2020	Consultation survey
Company AI (Assembly)	33	24	23	-	28	45	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AJ (Plate Production)	150	14.4	-	-	-	32	EU MS, 2019	Consultation survey
Company AJ (Assembly)	19	9.6	-	-	-	21	EU MS, 2019	Consultation survey
Company AJ (Finish)	36	4.8	-	-	-	21	EU MS, 2019	Consultation survey
Company AJ (Others)	185	7.4	-	-	-	25	EU MS, 2019	Consultation survey
Company AT (Plate manufacturing)	104	21.49	21.01	-	28.78	32.81	Other, 2020	Consultation survey
Company AT (Assembly)	90	22.39	22.38	-	32.45	33.52	Other, 2020	Consultation survey
Company AT (Formation)	40	15.21	16.46	-	16.66	24.75	Other, 2020	Consultation survey
Company AT (Maintenance)	30	17.20	16.82	-	16.78	24.64	Other, 2020	Consultation survey
Company AU (Plate Manufacture)	127	16.69	20	-	26	30	Europe, non-EU, 2019	Consultation survey
Company AU (Battery Assembly)	144	18.99	19	-	24	26	Europe, non-EU, 2019	Consultation survey
Company AU (Maintenance)	55	19.20	20	-	24	39	Europe, non-EU, 2019	Consultation survey
Company AX (Plate manufacturing)	389	13.02	12.63	-	21.92	26.88	Other, 2020	Consultation survey
Company AX (Assembly)	567	11.62	10.92	-	21.17	27.19	Other, 2020	Consultation survey
Company AX (Formation)	337	6.48	5.20	-	13.94	19.46	Other, 2020	Consultation survey
Company AX (Offices, laboratories)	317	5.95	4.57	-	15.30	18.69	Other, 2020	Consultation survey
Company AY (Plate manufacturing)	209	16.67	16.66	-	24.90	30.32	Other, 2021	Consultation survey
Company AY (Assembly)	433	14.73	14.50	-	24.80	32.48	Other, 2021	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AY (Formation)	460	7.66	6.69	-	15.19	23.15	Other, 2021	Consultation survey
Company AY (Offices, laboratories)	145	11.43	11.23	-	18.90	23.85	Other, 2021	Consultation survey
Company AZ (Plate manufacturing)	147	12	10	-	25	26	EU MS, 2019	Consultation survey
Company AZ (Plate treatment)	9	11	13	-	16	16	EU MS, 2019	Consultation survey
Company AZ (Assembly)	220	15	17	-	24	29	EU MS, 2019	Consultation survey
Company AZ (Others)	122	15	19	-	22	23	EU MS, 2019	Consultation survey

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.4 Production of articles of lead metal

Producers of articles of lead metal will use lead metal as raw material, but many recover the lead metal from secondary sources so various lead compounds may be present before/during the process. For the production of cables, in addition to the use of lead metal for sheathing, lead pigments may be used in the plastic insulation materials.

The main activities are considered to be:

- **Lead sheet and tubes production**. The lead is melted and formed into lead sheets and tubes by rolling and extrusion.
- **Production of cables.** Lead is melted and extruded to form a lead sheathing for high-voltage and medium-voltage cables used for certain applications such as some underground cables, fire resistant cables and sub-sea cables.
- **Production of lead keels, sinkers, balancing weights, diving weights, organ pipes, etc**. The lead is melted and cast into lead keels for yachts and other small boats, fishing sinkers, balancing weights for vehicles and a number of minor lead metal applications.
- **Production of lead shot and bullets**. The lead is melted and formed into small shot or cores of bullets. Exposure to lead can occur during manufacture of bullet capsules/cartridges, due to handling of and filling the cartridges with lead containing explosives and during product testing (shooting).
- **Production of lead articles for radiation shielding**. Comprises many different articles with various production processes used for radiation shielding within health

services, research, energy production and industry, e.g. leaded panels, lead shields, lead glass vials, lead wool.

The exposure from the application of the lead articles is further described in section 4.6.2.10 and 4.6.2.11.

Occupational exposure by production of articles of lead takes place in several processes, as illustrated below for production of lead sheets (REACH Lead Consortium, 2019):

- **Raw material handling**: Delivery, sorting and furnace loading
- **Smelting and refining**: Melting, drossing and refining
- **Milling**: Milling operations
- **Sawing and slitting**: Sawing and slitting operations
- **Storage and shipment**: Internal logistics, storage and shipment of finished goods
- **Others**: Repair, cleaning and maintenance

The processes to produce cables with lead sheathing vary: in the stakeholder consultation for of the previous study (Lassen et al., 2019), the industry association Europacable (2019) summarised the processes given in the questionnaire responses by six cable manufacturers as follows:

- Melting lead to produce the sheathing
- Extruding plastics with lead compounds used as pigments (not a use of metallic lead)
- Cleaning tools.

It is likely that some of the processes indicated for producing lead sheets such as raw material handling, storage and shipment are also relevant to the production of lead cables.

A questionnaire response from a lead foundry producing keels, weight and sinkers indicates the following processes:

- Melting
- Machining
- Handling of pieces of lead
- Office work

The main exposure route is by inhalation and hand-to-mouth contact, but some dermal exposure may take place by some processes such as handling the pieces of lead and final articles.

Small-scale smelting of lead. Smelting of lead may take place in artisanal and small-scale settings e.g. for manufacture of fishing sinkers. The sub-scenario 10.9: "Radiotherapy shield manufacturing" of the VRAR for lead describe occupational exposure to lead during radiotherapy shield manufacturing, which was monitored in three hospitals (locations not stated). The tasks involved melting and casting of radiotherapy shields from special lead alloys (27% Pb) with a melting point of only 70°C. Full-shift personal and static sampling was conducted, but no further details on the sampling methodology were reported. Only two out of a total of 16 samples contained lead at detectable levels: one personal sample had 2 µg/m³, and one static sample taken over a melting pot had a value of 47 µg/m³. The blood-lead levels of two block makers at one of the three sites were stated by the authors to be "normal", i.e. within a range of 0-35 µg/100 ml blood, but the exact values were not given (DeMeyer et al., 1986 cited by LDAI, 2008). Whereas local casting of radiotherapy shield may not take place in the EU now, it cannot be assumed that other small-scale casting of lead and lead alloys does not take place. COWI (2004) reported that the only identified companies of a certain size (>20 employees), which have manufacturing of lead sinkers as their main activity, were situated in Eastern Europe. According to information from the stakeholder consultation for the previous OEL study, lead sinkers are nowadays usually imported from Asia.

In the survey, nine companies have provided data on airborne exposure concentrations, six of these did also provide blood lead measurements. These companies comprise manufacturers of ammunition, cables and radiation shielding.

The most comprehensive data set is from France (INRS, 2018b) comprising data from 2009-2017. Median (range 0.001 – 0.085 mg/m³) and P95 (range 0.022 – 3.115 mg/m³) values for airborne concentrations are usually well below the current OEL of 0.150 mg/m³ with the only exception of the P95 for cold rolling of sheets (3.115 mg/m³).

Few median and P95 values for the survey have been reported but those available lie generally within the INRS median range with few exceptions. Data for lead sheet producers provided by the Lead REACH Consortium indicate higher airborne lead concentrations for lead sheet producers compared to manufacturers of other lead articles.

The most comprehensive data sets for blood lead levels have been available from the Lead REACH Consortium for lead sheet and ammunition producers. Median values range from 9 – 30 µg/100 ml, while P90 range from 26 -39 µg/100 ml. The Finnish data (FIOH, 2017) for ammunition manufacturers are corresponding, cable manufacturers appear to have lower levels.

Table 4-17 Exposure concentrations (mg Pb/m³) in production of articles of lead metal from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead sheet producers (personal, outside RPE)	**13**	**0.30**	**0.10**	**1.00**	**1.48**	**1.90**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	2	0.28	-	0.36	0.37	0.38		
W2 - melting and refining	10	0.37	-	1.28	1.59	1.90		
W3 - milling	2	0.01	-	0.01	0.01	0.01		
Lead sheet producers (personal, inside RPE)*	**13**	**<0.01**	**<0.01**	**0.01**	**0.02**	**0.13**	EU-wide, 2015-2018	Grewe and Vetter, 2019
W1 - raw material handling	2	0.01	-	0.01	0.01	0.01		
W2 - melting and refining	10	0.02	-	0.06	0.08	0.10		
W3 - milling	2	0.01	-	0.01	0.01	0.01		
Cold rolling of sheets	111	0.665	0.085	-	3.115	12.18	France, 2009-2017	INRS, 2018b
Manufacture of other plumbing fixtures	20	0.036	0.017	-	0.139	0.287		
Cold wire drawing	55	0.047	0.007	-	0.134	0.867		

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Refer-ence
Manufacture of other metal articles	110	0.048	0.009	-	0.105	2.862		
Arms and ammunition manufacturing	36	0.02	0.013	-	0.060	0.091		
Manufacture of other electronic or electric wires and cables	105	0.009	0.002	-	0.036	0.116		
Manufacture of metal structures and parts of structures	36	0.006	0.001	-	0.022	0.098		
Company I (Melting), personal	3	0.008	0.008	-	0.011	0.011	EU MS, 2020	Consulta-tion sur-vey
Company I (Sorting), personal	1	0.021	0.021	-	0.021	0.021	EU MS, 2020	Consulta-tion sur-vey
Company I (storage), personal	3	0.006	0.006	-	0.008	0.008	EU MS, 2020	Consulta-tion sur-vey
Company I (machin-ing), personal	3	0.005	0.005	-	0.009	0.009	EU MS, 2020	Consulta-tion sur-vey
Company J (Raw ma-terial handling), per-sonal	3	0.054	-	-	-	0.081	EU MS, 2019	Consulta-tion sur-vey
Company J (Product testing), personal	3	0.003	-	-	-	0.004	EU MS, 2019	Consulta-tion sur-vey
Company J (Manu-facture), personal	3	0.009	-	-	-	0.014	EU MS, 2019	Consulta-tion sur-vey
Company L (Product handling), stationary	11	0.16	-	-	-	0.63	EU MS, 2020	Consulta-tion sur-vey
Company L (melting), stationary	3	0.006	-	-	-	0.018	EU MS, 2019	Consulta-tion sur-vey
Company L (Product testing), stationary	4	0.12	-	-	-	0.40	EU MS, 2016	Consulta-tion sur-vey
Company L (machin-ing), stationary	3	0.01	-	-	-	0.03	EU MS, 2018	Consulta-tion sur-vey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Refer-ence
Company N (Raw material handling), personal	4	0.14	0.14	-	0.18	0.18	EU MS, 2018	Consulta-tion sur-vey
Company N (Smelt-ing), personal	4	0.48	0.23	-	1.21	1.21	EU MS, 2018	Consulta-tion sur-vey
Company N (Refin-ing), personal	4	0.62	0.23	-	1.90	1.90	EU MS, 2018	Consulta-tion sur-vey
Company N (Dross Handling), personal	4	0.10	0.11	-	0.14	0.14	EU MS, 2018	Consulta-tion sur-vey
Company P (Loading cartridges), personal	2	-	-	-	-	0.0082	EU MS, 2020	Consulta-tion sur-vey
Company P (production), personal	2	-	-	-	-	0.0081	EU MS, 2020	Consulta-tion sur-vey
Company Q (Loading cartridges), personal	4	-	-	-	-	0.002 **	EU MS, 2019	Consulta-tion sur-vey
Company Q (Product testing), stationary	2	-	-	-	-	0.005 **	EU MS, 2019	Consulta-tion sur-vey
Company Q (Raw material handling), personal	1	-	-	-	-	<0.001 **	EU MS, 2019	Consulta-tion sur-vey
Company U (Manufacture), per-sonal	3	-	-	-	-	68	EU MS, 2017	Consulta-tion sur-vey
Company U (Product testing), per-sonal	4	-	-	-	-	3	EU MS, 2017	Consulta-tion sur-vey
Company AA, personal	-	0.078	-	-	-	0.11	EU MS	Consulta-tion sur-vey
Company AB (Lead extrusion), per-sonal**	6	0.00007	0.00008	-	0.00013	0.00014	EU MS, 2020	Consulta-tion sur-vey

** Concentrations have been calculated based on the assigned protection factors of RPE used at the workplaces.*

** *very low concentrations, possible erroneous data*

Table 4-18 Blood-lead level (µg Pb/100 ml) in production of articles of lead metal from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Lead sheet produc-ers, all*	**(1,438)**	**(14)**	**(16)**	**(30)**	**-**	**(52)**	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Raw material handling	26	29.5	30.0	38.9	-	-		
Smelting and refining	222	20.6	19.0	31.7	-	-		
Milling	98	19.2	16.9	30.8	-	-		
Sawing and slitting	514	18.2	17.6	28.0	-	-		
Storage and shipment	151	15.6	15.2	29.0	-	-		
Others	161	16.6	15.4	29.3	-	-		
Ammunition producers	750	12	9	26	-	-	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Manufacture of cord-age, rope, twine and netting	11	23.6	19.7	-	38.7	38.7	Finland, 2000-2014	FIOH, 2017
Manufacture of weap-ons and ammunition	291	11.4	9.7	-	26.3	42.3	Finland, 2000-2014	FIOH, 2017
Manufacture of other electronic and electric wires and cables	89	5.2	3.9	-	13.5	22	Finland, 2000-2014	FIOH, 2017
Manufacture of articles of metal wire	97	-	-	-	-	54.5	Romania, 2019	Negru et al., 2020
Company I (melting), personal	11	13.9	-	-	-	-	EU MS, n. y.	Consulta-tion survey
Company I (sorting), personal	7	9.1	-	-	-	-	EU MS, n. y.	Consulta-tion survey
Company I (storage), personal	7	12.6	-	-	-	-	EU MS, n. y.	Consulta-tion survey
Company I (machin-ing),	5	10.5	-	-	-	-	EU MS, n. y.	Consulta-tion survey
Company L (material handling),	10	6.7	4	-	18.9	26	EU MS, 2019	Consulta-tion survey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Loca-tion, year	Reference
Company L (melting), stationary	8	14	14	-	25.6	25	EU MS, 2015; 2016; 2017	Consulta-tion survey
Company L (Product testing, shooting)	39	7.6	4	-	22.2	48	EU MS, 2015; 2016; 2017	Consulta-tion survey
Company L (material handling)	105	9.5	7	-	19.9	29	EU MS, 2015; 2016; 2017	Consulta-tion survey
Company N (Scrap In-take)	2	26.5	26.5	-	27	27	EU MS, 2020	Consulta-tion survey
Company N (Smelt-ing), personal	2	9	9	-	9	9	EU MS, 2020	Consulta-tion survey
Company N (Refining), personal	2	10.5	10.5	-	11	11	EU MS, 2020	Consulta-tion survey
Company N (Dross Handling)	2	26.5	26.5	-	27	27	EU MS, 2020	Consulta-tion survey
Company Q (Catridge loading)	29	11.8	10.5	-	25.18	33.79	EU MS, 2020	Consulta-tion survey
Company Q (Product testing, shooting)	1	-	-	-	-	9.12	EU MS, 2020	Consulta-tion survey
Company Q (Raw ma-terial handling)	3	-	-	-	-	9.50	EU MS, 2020	Consulta-tion survey
Company U (Bullet Manufacture)	13	-	-	-	-	10	EU MS, 2018	Consulta-tion survey
Company U (Proof Range)	4	-	-	-	-	7	EU MS, 2018	Consulta-tion survey
Company AB (Lead extrusion)	14	5.8	4.9	-	11.6	12.4	EU MS, 2020	Consulta-tion survey
Company AB (Soldering)	10	3.0	2.6	-	5.6	6.2	EU MS, 2020	Consulta-tion survey
Company AB (Cutting / Sawing)	9	1.2	1.0	-	2.2	2.5	EU MS, 2020	Consulta-tion survey

** n of samples from the different processes does not add up to n of all processes, and median and mean values appear to low.*

4.6.2.5 Foundries and production of articles of alloys

Lead is used as alloying element for the production of articles of some types of steel, tin alloys, aluminium, brass and bronzes (copper compounds). Lead is added to the alloys to improve castability, finishing and plating characteristics.

The European Foundry Association (CAEF, 2019a) inform that in Europe (mainly in Germany, Italy, France, Portugal and Poland), a large number of non-metal-ferrous foundries process lead-containing copper and aluminium alloys for the following applications:

- taps and fittings for water, gas and sanitary installations
- sliding materials (bearing bushes and shells)
- structural material for certain purposes, e.g. ship propellers, water turbines and pumps
- electrical conductors, switches, power supply lines etc.

As part of the stakeholder consultation for the previous OEL study (Lassen et al., 2019), completed questionnaires were returned by five foundries. In the survey, three additional foundries provided exposure concentration data. Occupational exposure in foundries takes place in a number of processes as indicated in questionnaire responses (most responses indicate casting only):

- Casting
- Shake out
- Grinding

According to the VRAR for lead (LDAI, 2008) exposure may take place by the following processes:

- Cutting
- Furnace (casting)
- Grinding
- Pouring

Additionally, exposure may occur during melting of the lead-containing alloys or during the machining of castings (CAEF, 2019a).

The most recent French data set, (INRS, 2018b) indicates generally low airborne exposure concentrations with median values ranging from 0.001 – 0.02 mg/m³ and P95 not exceeding 0.093 mg/m³. Data from two companies lie within this range. A questionnaire response has been obtained from a company involved in cold rolling of leaded steels. The data are included in the tables below.

For the blood lead levels (Table 4-20) comprehensive data are available from the UK (HSE, 2019) and Finland (FIOH, 2017). Median values range from 3 – 25 µg/100ml and P95 range from 6 - 65 µg/100ml. Median and P95 are thus below the current BLV of 70 µg/100ml, but some of the reported maximum values exceed the current BLV. The few reported company data from the OELs survey are within these ranges.

It is reported that RPE (HEPA masks) is used in melting/casting, but not in the other processes.

In an investigation of blood-lead levels in 17 workers of a bronze (lead-tin, 0-20% Pb) foundry in Germany (Schirmberg, 2004), repeated measurements were made after a blood-lead reduction programme was initiated and the work conditions were periodically monitored. Blood lead levels were reduced during 1 year after initiation of the program. The data are included in Table 4-20 below.

The VRAR concluded that the data available from the public domain indicate that lead inhalation exposure of brass foundry workers may occur to a relevant extent and that the particle size distribution of aerosols for some of the tasks may be associated with a high degree of alveolar deposition.

Table 4-19 Exposure concentrations (mg Pb/m³) in foundries from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Foundry	177	-	0.024	-	0.320	-	Germany, 2000-2009	IFA, 2010
Aluminium metallurgy	58	0.001	0.001	-	0.002	0.010	France, 2009-2017	INRS, 2018b
Light metals foundry	24	0.001	0.001	-	0.001	0.002	France, 2009-2017	INRS, 2018b
Steel foundry	21	0.017	0.003	-	0.093	0.093	France, 2009-2017	INRS, 2018b
Foundry of other non-ferrous metals	34	0.018	0.020	-	0.037	0.050	France, 2009-2017	INRS, 2018b
Cold rolling of leaded steels, manual operation	2	0.031	-	-	-	0.055	Germany, 2017	Lassen et al. (2019)
Company W (Casting), personal	8	0.03	0.005	-	0.12	0.08	EU MS, 2019	Consultation survey
Company X (Foundry, brass alloys), stationary	-	-	-	-	-	0.008	EU MS, 2018	Consultation survey

Table 4-20 Blood-lead level (µg Pb/100 ml) in foundries from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Brass foundry, CNC-operators	7	13.7	7.7		31.9	33.2	Sweden, no year	Julander et al., 2020
Manufacture of bearings, gears, gearing and driving elements	31	20.3	8.5	-	64.9	76.7	Finland, 2000-2014	FIOH, 2017
Casting of iron	201	19.9	11.2	-	55.1	109.2	Finland, 2000-2014	FIOH, 2017

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Reference
Casting of other non-ferrous metals	599	25.3	25.1	-	43.9	66.9	Finland, 2000-2014	FIOH, 2017
Moulding of light al-loy	54	11.4	11.2	-	21.5	23.8	Finland, 2000-2014	FIOH, 2017
Manufacture of basic iron and steel and of ferro-alloys	160	6.4	5.6	-	14.9	25.9	Finland, 2000-2014	FIOH, 2017
Manufacture of other taps and valves	109	4.8	4.4	-	8.9	15.3	Finland, 2000-2014	FIOH, 2017
Manufacturing of locks and hinges	70	3.1	2.9	-	7.5	8.1	Finland, 2000-2014	FIOH, 2017
Other non-ferrous metal production	26	3.5	3.1	-	6	13.3	Finland, 2000-2014	FIOH, 2017
Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	17	6.4	5	-	16.8	16.8	Finland, 2000-2014	FIOH, 2017
Smelting, refining, alloying and casting	2,654	12.8	11	-	32	60-69	UK, 2015-2018	Based on HSE, 2019*
Bronze casting, af-ter initiation of lead red. programme	17	30	31	-	-	38	Germany, 2001	Schirmberg, 2004, cited in LDAI, 2008
Bronze casting, 1 year later	17	24	23	-	-	34	Germany, 2002	Schirmberg, 2004, cited in LDAI, 2008
Foundry 1 - melt-ing/casting	44	11.2	10.3	-	20.7	22.8	Sweden 2017-2019	Lassen et al. (2019)
Foundry 1 - ex-trude/manufacture	30	12.4	10.3	-	26.7	33.1	Sweden 2017-2019	Lassen et al. (2019)
Company 3 Cold rolling of leaded steels, manual oper-ation	56	-	-	-	-	>40	EU MS, 2017	Lassen et al. (2019)
Foundry 2, casting and machining	48	16.6	-	-	-	40	Germany, 2018	Lassen et al. (2019)
Company V Foundry	30	-	-	-	-	0.15	EU MS, 2020	Consultation survey
Company V (Machining)	20	-	-	-	-	0.13	EU MS, 2019-2020	Consultation survey
Company V	6	-	-	-	-	0.074	EU MS, 2016-2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Reference
(Maintenance)								
Company W (Foundry)	80	5.8	6	-	13	17	EU MS, 2019	Consultation survey

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.6 Production of lead compounds and lead frits

Various lead compounds are produced using lead oxides as intermediates. All industrial manufacturing of lead oxides uses ingots of highly refined lead metal (99.9%) as raw material. The process is an oxidation of lead with atmospheric oxygen. Both the oxidation products and the final products are powders.

Occupational exposure due to the production of lead compounds and lead frits takes place in a number of processes as illustrated below for lead oxide and lead stabiliser production (REACH Lead Consortium, 2019):

- **Lead oxide production**: Production of "crude" oxide, further oxidation/calcination, grinding/milling and packaging
- **Lead stabiliser production (wet process)**: Loading of lead oxide into reaction vessels, slurry formation by addition of water, catalysts and acid compounds, centrifuge operation, drying process and bagging/drumming operations
- **Lead stabiliser compound production (dry/melting process)**: Loading of lead oxide into reaction vessels, feeding of molten acid compound to reaction vessels, process control, cooling and forming of tablets, flakes etc., drying process and bagging/drumming operations
- **Mixing/blending of formulated stabiliser products**: Material loading (manual or automated handling), operation of mixing/blending equipment and packaging operations
- **Internal logistics**: Storage (raw materials, finished goods) and shipment of finished goods
- **Others**: Repair, cleaning and maintenance, quality control, and engineering

Information on airborne concentrations levels in this sector are available from the ILA survey, France, Germany and two companies answering the survey. The most recent data from the ILA survey show with a median and P95 level of 0.04 and 0.64 mg/m^3 higher levels compared to the older French and German data, possibly because the ILA survey comprises dedicated lead oxide producers, while the national data are from pigment producers handling lead compounds amongst other things. The most recent data from the companies are both below the ILA survey data. The airborne exposure levels in these companies differs by appr. one order of magnitude.

With respect to the blood lead levels, comprehensive data covering 1,540 samples from lead oxide and stabilisers producers are available from the Lead REACH Consortium with mean and P90 levels of 11-21 and 25-33 µg/100ml, respectively. Again, data provided by the companies appear in range or slightly lower. The difference in blood lead levels between the two companies is not as pronounced as for the airborne concentration levels, showing the blood levels only partly depends on airborne lead concentrations.

Table 4-21 Exposure concentrations (mg Pb/m³) due to the production of lead compounds and lead frits from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Reference
Lead oxide and stabiliser producers (personal, outside RPE)	20	0.18	0.04	0.49	0.64	1.85	EU-wide, 2015-2018	Grewe and Vetter, 2019
Lead oxide and stabiliser producers (personal, in-side RPE)*	20	0.01	<0.01	0.01	0.02	0.05	EU-wide, 2015-2018	Grewe and Vetter, 2019
Manufacture of other or-ganic basic chemicals	23	0.001	0.001		0.001	0.002	France, 2009-2017	INRS, 2018b
Manufacture of dyes and pigments	24	0.044	0.034		0.095	0.120	France, 2009-2017	INRS, 2018b
Chemical industry	54	-	0.006 5	-	0.480	-	Germany 2000-2009	IFA, 2010
Company AV (Production), personal	2	0.135	0.135	-	0.152	0.154	EU MS, 2019	Consultation survey
Company AV (Packaging), personal	2	0.114	0.114	-	0.129	0.131	EU MS, 2019	Consultation survey
Company AAB (Production), stationary	10	0.019	-	-	-	0.049	EU MS, 2019	Consultation survey
Company AAB (Logistics), stationary	4	0.02	-	-	-	0.031	EU MS, 2019	Consultation survey
Company AAB (Mainte-nance), stationary	16	0.018	-	-	-	0.049	EU MS, 2019	Consultation survey
Company AAB (Laboratory), stationary	2	0.009	-	-	-	0.017	EU MS, 2019	Consultation survey

* *Concentrations have been calculated based on the assigned protection factors of RPE used at the workplaces.*

Table 4-22 Blood-lead level (µg Pb/100 ml) due to the production of lead compounds and lead frits from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead oxide and sta-biliser producers	**1,540**	**16**	**14**	**28**	**-**	**58**	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Lead oxide production	331	21.7	21.4	31.0	-	-		
Lead stabiliser pro-duction (wet process)	53	19.6	18.5	32.6	-	-		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead stabiliser compound production (dry/melting process)	205	16.9	14.1	29.4	-	-		
Mixing/blending of formulated stabiliser products	334	12.9	10.8	24.9	-	-		
Internal logistics	75	14.9	14.0	26.2	-	-		
Others	377	14.5	12.1	27.7	-	-		
Manufacture of pigments and colours	65	6.4	<10	-	17	60-69	UK, 2015-2018	Based on HSE, 2019*
Manufacture of inorganic or organic lead compounds (including lead salts, fatty acids)	790	9	<10	-	23		UK, 2015-2018	Based on HSE, 2019*
Production and sale of dyes and additives for plastics	38	5.2	-	-	-	14.5	Romania, 2012	Negru et al., 2020
Company AV (Internal Logistics)	4	15.2	15.2	-	16.2	16.3	EU MS, 2020	Consultation survey
Company AV (Production, Operation)	6	12.8	13.5	-	16.7	17.0	EU MS, 2020	Consultation survey
Company AV (Production, Supervision)	6	9.91	9.91	-	10.3	10.3	EU MS, 2020	Consultation survey
Company AV (Packaging)	10	17.5	11.2	-	25.0	28.9	EU MS, 2020	Consultation survey
Company AAB (Production)	22	10.7	-	-	-	15.2	EU MS, 2020	Consultation survey
Company AAB (Logistics)	4	11.1	-	-	-	19	EU MS, 2020	Consultation survey
Company AAB (Maintenance)	9	18.3	-	-	-	25	EU MS, 2020	Consultation survey
Company AAB (Laboratory)	12	6.6	-	-	-	13.2	EU MS, 2020	Consultation survey

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.7 Production of glass

Leaded glass is used in decorative applications (lead crystal glass) such as wine glasses, tableware and decanters and for various types of optical and filter glasses e.g. camera and micro-scope lenses. The starting materials for the production of leaded glass are lead oxides (predominantly red lead oxide, but also lead oxide). Lead glass contains typically 18–40% (by weight) lead oxide (PbO), while modern lead crystal, historically also known as flint glass due to the original silica source, contains a minimum of 24% lead oxide. In the EU, only glass products containing at least 24% of lead oxide may be referred to as "lead crystal". Products with less lead oxide, or glass products with other metal oxides used in place of lead oxide, must be labelled "crystalline" or "crystal glass" (ECHA, 2019).

Key countries for lead crystal glass manufacture are Belgium, Czech Republic, France, Germany, Italy, Hungary, Ireland, Slovenia, Poland, UK and Portugal (ECHA, 2019).

Occupational exposure by production of glass takes place in the following processes as described for lead crystal glass (REACH Lead Consortium, 2019):

- **Raw material handling**: Raw material delivery, batch formulation, pot filling and melting
- **Forming processes**: Manual operation of multi-pot systems or semi-automated cold-top furnace and blowing operations
- **Cutting processes**: Finishing, manual and automated cutting operations
- **Polishing processes**: Acid polishing
- **Others:** Storage and shipment of finished goods, repair, cleaning and maintenance, quality control, and engineering.

The main exposure route is by inhalation. In the raw material and forming processes exposure is primarily due to lead oxides, whereas in the cutting and polishing processes, some lead exposure may be to leaded glass.

The blood-lead levels reported by the Lead REACH Consortium are generally corresponding to the data from the HSE in the UK. Data from Finland on “Shaping and processing of flat glass” show significantly lower concentrations. The data from Finland may include non-leaded glass, as flat glass would usually not contain lead. IARC (2006) notes that production of leaded glass has been associated with high lead exposure, with AM blood-lead concentrations in excess of 50 µg/100 ml in all studies. The actual AM levels in the Lead REACH Consortium and UK HSE data are approximately at 20% of the concentrations reported in the older studies quoted by IARC (2006).

Table 4-23 Exposure concentrations (mg Pb/m³) in glass production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Manufacture of glasses	57	0.001	0.001	-	0.003	0.006	France, 2009-2017	INRS, 2018b
Shaping and processing of flat glass	5	0.056	0.030	-	0.185	0.480	France, 2009-2017	INRS, 2018b
Manufacture of other glass articles, including technical glass	129	0.026	0.005		0.094	0.625	France, 2009-2017	INRS, 2018b
Hollow glass manufacturing	144	0.096	0.002		0.081	6.03	France, 2009-2017	INRS, 2018b
Hollow glass and flat glass, technical glass	273	-	0.026	-	0.560	-	Germany, 2000-2009	IFA, 2010

Table 4-24 Blood-lead level (µg Pb/100 ml) in glass production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Lead crystal glass production	**1.047**	**11**	**12**	**24**	**-**	**48**	Across EU, 2013-2016	Lead EACH Consortium, 2019
Lead oxide production	331	21.7	21.4	31.0	-	-		
Lead stabiliser production (wet process)	53	19.6	18.5	32.6	-	-		
Lead stabiliser compound production (dry/melting process)	205	16.9	14.1	29.4	-	-		
Mixing/blending of formulated stabiliser products	334	12.9	10.8	24.9	-	-		
Internal logistics	75	14.9	14.0	26.2	-	-		
Glass making (including cutting and etching)	406	10.8	<10	-	28	40-49	UK, 2015-2018	Based on HSE, 2019*
Shaping and processing of flat glass	108	4.6	3.5	-	11.6	17	Finland, 2000-2014	FIOH, 2017

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.8 Ceramic ware production and enamelling

Used in appropriate amounts within silicate glazes, lead improves the chemical durability of glazes and colours on ceramic wares, helping them to withstand detergent attack and producing a smooth, durable surface that resists scratching and knife marking (LDAI, 2008). Lead lowers the surface tension and viscosity of silicate glasses to allow bubbles to escape efficiently from the glaze layer. Lead is introduced into glaze compositions as lead bisilicate frit, a fused vitreous mixture of two or more compounds, which is finally milled back to a powder. For example, lead monosilicate ($PbO{\cdot}0.67SiO_2$), which is considered one of the most economical methods for introducing lead into a glaze, contains 85% PbO (lead oxide) and 15% SiO_2 (LDAI, 2008). Glazes with lead are used for some earthenware, porcelain and glazed tiles.

Occupational exposure by production of ceramic ware with lead-containing glazes takes place in several processes (REACH Lead Consortium, 2019):

- **Production of frits**: Raw material handling, smelting, quenching and wet milling/grinding
- **Production and handling of pigments**: Weighing, ball milling and filling
- **Lithography**: Manual transfer of lithographs
- **Decoration**: Manual painting and artwork, and printing
- **Glazing of ceramic**: Dipping and spraying
- **Others**: Firing, cleaning and maintenance, and quality control

Limited data on recent airborne lead concentrations are available.

For blood-lead levels, data from the Lead REACH Consortium, Finland, UK and Romania indicate generally low median levels <13 µg/100ml and maximum levels not exceeding 39 µg/100ml.

Table 4-25 Exposure concentrations (mg Pb/m³) in ceramic ware production and enamelling from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Ceramic ware production (Personal, outside RPE)	3	0.02	0.02	0.03	0.03	0.03	EU-wide, 2015-2018	Grewe and Vetter, 2019
Ceramic ware production (personal, inside RPE)*	3	0.02	0.02	0.03	0.03	0.03	EU-wide, 2015-2018	Grewe and Vetter, 2019
Manufacture of ceramics for domestic or ornamental use	45	0.011	0.001	-	0.052	0.154	France, 2009-2017	INRS, 2018b
Porcelain, pottery, sanitary, tiles	334	-	0.004 *	-	0.230	-	Germany 2000-2009	IFA, 2010

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Manufacture of thermal ceramic products (terracotta)	-	-	-	-	-	0.12	Romania, 2018	Negru et al., 2020
Production of ceramic ware, all workplaces	1,152	-	0.033	0.103	-	0.958	Spain, 1998-2001	LDAI, 2008

* *Concentrations below largest LOQ or largest LOQ unknown.*

** *Concentrations have been calculated based on the assigned protection factors of RPE used at the workplaces*

Table 4-26 Blood-lead level (µg Pb/100 ml) in ceramic ware production and enamelling from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Ceramic ware production	**1,380**	**13**	**12**	**14**	**-**	**34**	EU-wide, 2013-2016	Lead REACH Consortium, 2019
Production of frits	557	11.0	12.2	13.8	-	-		
Production and handling of pigments	187	7.2	5.0	14.8	-	-		
Lithography	-	n/a	n/a	n/a	-	-		
Decoration	-	n/a	n/a	n/a	-	-		
Glazing of ceramic	79	12.7	12.7	14.2	-	-		
Others	557	12.6	12.7	14.2	-	-		
Manufacture of ceramic household and ornamental articles	275	3.9	3.3	-	8.9	14.7	Finland, 2000-2014	FIOH, 2017
Potteries, glazers and transfers	61	6.4	<10	-	19	10-19	UK, 2015-2018	based on HSE, 2019*
Manufacture of thermal ceramic products (terracotta)	26	-	-	-	-	38.9	Romania, 2018	Negru et al., 2020
Production of ceramic ware, all workplaces	13,391	-	18	23	-	84	Spain, 1998-2001	LDAI, 2008
Enamelling	14	10	-	-	-	-	Italy, 2003	Di Lorenzo et al. 2003 in LDAI, 2008

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.9 Manufacture and use of plastics and paints

Use of lead stabilizers for PVC has been phased out, but some lead pigments are still used in some plastics. Lead pigments are used for colouring or as anticorrosive in paints and coatings on steel structures, road markings, and in consumer products (e.g. vintage vehicles) in industrial or professional uses.

The three lead pigments (lead chromate, lead sulfochromate and lead molybdate chromate, colour range from yellow to orange to red) were subject to authorisation. CEPE (2021) estimates the use of lead pigment for paints as extremely low and for the restoration of historical buildings, the use should be zero.

Occupational exposure due to the manufacture and use of plastics and paints with lead pigments may occur in processes as indicated in the authorisation application for a pigment used for solvent based paints for non-consumer use (DCC Maastricht B.V, 2013a,b; 23 worker contributing scenarios (WCS) are here organised into groups):

- **Handling of pigment powder**: Distribution and mixing pigment powder in an industrial environment into solvent-based paints; delivery, storage and handling of closed bags with pigment powder; pigment powder quality control / lab work; manual and automatic dosing of pigment powder; and re-packaging of pigment powder

- **Handling of pigment paste**: Mixing of pigment paste; storage and transfer through closed piping; manual cleaning / scraping of mixing vessels, equipment and lids; cleaning of vessel with solvent; pigment paste testing by smearing; charging/discharging by gravity or manual handling or using a dedicated installation; and filling into drums/cans at a filling line;

- **Handling of pigmented paint by production:** Mixing colour paste in closed drum mixing machine with automated dosing of paste; mixing colour paste into paint in closed mixing vessel; filling into drums/cans; and charging/discharging;

- **Use of pigmented paint:** Equipment cleaning, scraping and brushing; dried pigment paint cleaning; spray testing of pigment paint in industrial booth; and pigment paint testing by brushing/rolling;

- **Laboratory operations:** Pigment paste or paint laboratory operations

The authorisation applications for a pigment used for hot-melt (plastics) road markings indicates the following processes with lead exposure (DCC Maastricht B.V, 2013a,b)

- Charging/discharging premix or pre-compound
- Storage and mixing of plastic compounds in an open vessel before application
- Application of hotmelt road marking (plastic compound) to road pavement
- Handling and manipulation of coloured road marking
- High energy manipulation/removal of coloured road marking using abrasive techniques like grinding, drilling or sanding

The main exposure route is inhalation of pigment dust and aerosols of leaded paints.

Available airborne concentration data do generally indicate low levels with AM values ≤0.066 mg/m³. The only exception is the French data for painting and glazing showing extremely high levels with AM of 2.1 mg/m³ and P95 of 10 mg/m³. It is not known, which kind of workplace characteristics cause the outlying data.

Blood lead level data from Finland, UK and a single company participating in the consultation survey indicate low blood levels with AM ≤ 9 and P95 ≤ 15 µg/100ml, with the exception of two uses (Manufacture of plastic plates, sheets, tubes and profile, and Artistic creation).

Table 4-27 Exposure concentrations (mg Pb/m³) in the manufacture and use of plastics and paints from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Fabrication of plates, sheets, tubes and profiles in plastics	37	0.003	0.001	-	0.007	0.056	France, 2009-2017	INRS, 2018b
Painting and glazing	84	2.084	0	-	10.035	62	France, 2009-2017	INRS, 2018b
Manufacture of paints, varnishes, inks and sealants	94	0.066	0.011	-	0.356	1.385	France, 2009-2017	INRS, 2018b
Manufacture of basic plastic materials	159	0.013	0.001	-	0.047	0.379	France, 2009-2017	INRS, 2018b
Processing and manufacture of plastics and rubber	105	-	0.0059*	-	0.17	-	Germany 2000-2009	IFA, 2010
Company AF (pigment packaging), personal	-	0.016	-	-	-	-	EU MS, 2019	Consultation survey
Company AF (production), personal	-	0.032	-	-	-	-	EU MS, 2019	Consultation survey
Company AF (pigment packaging, warehouse, tank loading/unloading), personal	-	0.005	-	-	-	-	EU MS, 2019	Consultation survey
Company AF (laboratory), personal	-	0.005	-	-	-	-	EU MS, 2019	Consultation survey

* *Concentration below largest LOQ or largest LOQ unknown.*

Table 4-28 Blood-lead level (µg Pb/100 ml) in the manufacture and use of plastics and paints from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Plastics:								
Manufacture of plastic plates, sheets, tubes and profiles **	116	8.7	6.2	-	23.4	40	Finland, 2000-2014	FIOH, 2017
Manufacture of build-ers' ware of plastic **	42	7.3	6.6	-	14.3	21.1	Finland, 2000-2014	FIOH, 2017
Manufacturing of other plastic products **	117	1.9	1.9	-	4.1	6.4	Finland, 2000-2014	FIOH, 2017
Construction of roads and motorways ***	110	3.1	2.3	-	8.7	28.2	Finland, 2000-2014	FIOH, 2017
Paints:								
Artistic creation *	15	8.1	6	-	18.9	18.9	Finland, 2000-2014	FIOH, 2017
Painting	21	5.2	4.6	-	8.7	14.1	Finland, 2000-2014	FIOH, 2017
Painting of buildings and vehicles	702	8.8	<10	-	22	40-49	UK, 2015-2018	HSE, 2019****
Company AF (Packaging)	21	0.78	0.59	-	1.94	2.04	EU MS, 2020	Consulta-tion survey
Company AF (Production)	21	0.78	0.59	-	1.94	2.04	EU MS, 2020	Consulta-tion survey
Company AF (Packaging and Logis-tics)	21	0.78	0.59	-	1.94	2.04	EU MS, 2020	Consulta-tion survey
Company AF (laboratory)	21	0.78	0.59	-	1.94	2.04	EU MS, 2020	Consulta-tion survey

* *Assumed the activity is use of paint*

** *Assumed use of road markings*

*** *May be exposure by production of articles of PVC with lead stabilisers, which are now phased out in virgin PVC.*

**** *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

4.6.2.10 Work with lead metal

Lead metal or lead alloys are used for various end applications in different sectors:

- Electrical and electronic industry: Use of solders for certain applications outside the scope of the RoHS Directive, e.g. in large-scale applications

- Building industry: Building and plumbing with lead sheets and tubes; cutting lead sheet, soldering, etc.; manufacture of leaded windows using with lead rods and solders
- Vehicle repair: Tyre fitting using lead balance weights; soldering of car radiators
- Fish equipment industry: Fitting of fishing nets using lead sinkers

Occupational exposure due to working with lead metal takes place by several processes:

- Use of lead solders: Handling of solder material, heating up lead solders
- Use of lead sheets: Handling of the sheets, cutting sheets, soldering sheets.
- Use of balance weights and sinkers: Handling of weights and sinkers.

Exposure is largely dermal and hand-to-mouth contact by handling of solder material, lead sheets, balance weights and sinkers. Inhalation exposure may occur as solder material is heated.

Solders. Typical solders contain 60% lead and the high temperatures involved in flame solder works make some of this lead volatile. Use of solders for electronics has decreased markedly but solders are still used for other purposes. According to IARC (2006), workers repairing vehicle radiators are exposed to lead dust during radiator cleaning in addition to lead fumes during flame soldering. Surveys on welding work in radiator-repair workers generally show mean (AM) blood-lead concentrations in the range of 10–35 µg/100 ml. A study of 56 mechanics working in radiator shops in the Boston area, USA, reported that 80% had blood-lead concentrations greater than 30 µg/100 ml and 16 had concentrations >50 µg/100 ml (Goldman et al., 1987 as cited by IARC, 2006). Relatively high blood-lead concentrations (up to 47 µg/100 ml) were also reported among women engaged in soldering in an electronics plant (IARC, 2006).

The VRAR for lead describes under scenario 10.5 “Opticians” how the use of a low-melting alloy containing lead (among other metals) during the processing of the glass for spectacles in a procedure designated as “blocking” has caused occupational exposure to lead dust to be monitored for opticians in Germany. The P95 of the data was 0.0067 mg/m³. The German Social Accident Insurance (DGUV) has published recommendations for risk assessments for the use of leaded solder alloys in the electronics industry (DGUV, 2018). The concentrations for soldering (Table 4-29) show a clear decreasing trend from the period 1986-1994 to 2006-2014. Lead exposure concentrations from manual disassembly works are either low or below the LOD. All concentrations from this study were well below the current OEL of 0.15 mg/m³.

Tyre fitting. Blood-lead levels were investigated in French tyre-fitters mounting inertia blocks used to equilibrate car wheels (Javelaud et al., 2004 as cited in LDAI, 2008), involving 36 fitters and 37 controls. Between mechanics and controls, the haematological or toxicological results showed no differences. Glove wearing significantly decreased the mechanics' blood-lead levels. Lead weights are still used for balancing, but zinc weights are more commonly used nowadays.

Use of lead sheets. The VRAR for lead (LDAI, 2008) does not include exposure to construction workers from the use of lead sheets, but the use is probably covered under "Roofing activities" in the Finnish data (FIOH, 2017).

Airborne lead concentration P95 values in works related to soldering and manufacture of technical or electrical equipment do not exceed the current OEL of 0.15 mg/m³.

Elevated blood lead levels (> 15 µg/100ml) have been observed in Finnish and US-American car mechanics and a few uses within soldering. Maximum values within roofing activities have been measured at 7.5 µg/100ml.

Table 4-29 Exposure concentrations (mg Pb/m³) by application of lead metal from published sources and stakeholder consultation

Activity	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
(Soft/iron) soldering in electronic industry	81	-	0.002	-	0.010	-	Germany 1986-1994	DGUV, 2018 *
	54	-	0.002	-	0.007	-	Germany 1995-2000	
	77	-	0.001	-	0.004	-	Germany 2001-2005	
	37	-	<0.008	-	0.004	-	Germany 2006-2014	
Manufacture of dissecting and electric control equipment	54	0.001	0.001	-	0.003	0.007	France, 2009-2017	INRS, 2018b
Manufacture of electric motors, generators and transformers	23	0.002	0.001	-	0.005	0.035		
Manufacture of electronic components	107	0.002	<0.001	-	0.005	0.095		
Scientific and technical instrumentation manufacturing	123	0.019	0.002	-	0.097	0.195		
Manufacture of medical-surgical and dental equipment	26	0.012	0.003	-	0.071	0.088		
Manufacture of other special machines	43	0.015	0.005	-	0.057	0.152		
Manufacture of other electrical equipment	34	0.018	0.014	-	0.053	0.09		
Manufacture of assembled electronic boards	120	0.007	0.001	-	0.051	0.111		
Assembling of electronic components	-	-	-	-	-	0.02	Romania, 2016	Negru et al., 2020
Other:								
Manufacture and re-threading of tires	27	0.001	0.001	-	0.003	0.007	France, 2009-2017	INRS, 2018b
Assembly work of metal structures	22	0.067	0.065	-	0.169	0.265		
Lead works	42	-	0.075	-	0.32	-	Germany 2000-2009	IFA, 2010

Activity	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company O (Welding/Brazing), personal	-	-	-	-	-	0.0029	EU MS, 2019	Consultation survey
Company O (Testing), personal	-	-	-	-	-	0.014	EU MS, 2018-2020	Consultation survey

* *Sampling was a combination of stationary and personal samples. The soldering work was mainly carried out while sitting. Sampling equipment was positioned in a breathing zone in the immediate vicinity of the employees.*

Table 4-30 Blood-lead level (µg Pb/100 ml) by application of lead metal from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Car repair: **								
Tyre fitting	16	5	5	-	-	15	France, 2004	Javelaud et al., 2004 in LDAI, 2008
Repair and maintenance of motor vehicles (excluding tires)	264	10.4	5.4	-	33.6	70.7	Finland, 2000-2014	FIOH, 2017
Radiator repair	63		29	-		94	USA, 1992	Dalton et al.1997, cited in IARC, 2006
Radiator repair	53	31.7	-	-		58	USA, 1986	Lussenhop et al., 1989 cited in IARC, 2006
Solders for electrical and electronic eq.:								
Manufacture of non-domestic cooling and ventilation equipment	12	15.3	16	-	31.3	31.3	Finland, 2000-2014	FIOH, 2017
Manufacture of communication equipment	28	4.4	2.5	-	11.6	12.2	Finland, 2000-2014	FIOH, 2017
Manufacture of electronic components	400	4.1	2.3	-	11.6	65.5	Finland, 2000-2014	FIOH, 2017
Manufacture of medical and dental instruments and supplies (excl. dentures)	10	5.2	4.1	-	9.9	9.9	Finland, 2000-2014	FIOH, 2017
Manufacture of electronic circuits	50	3.9	3.1	-	9.5	10.6	Finland, 2000-2014	FIOH, 2017

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Manufacture of electric motors, generators and transformers	41	4.1	3.1	-	8.9	15.1	Finland, 2000-2014	FIOH, 2017
Manufacturing of other electrical appliances	74	2.1	1.7	-	4.1	6.6	Finland, 2000-2014	FIOH, 2017
Manufacture of irradiation, electromedical and electrotherapeutic equipment	21	1.9	1.9	-	2.9	3.9	Finland, 2000-2014	FIOH, 2017
Other or undefined:								
Roofing activities	13	1.9	1.5	-	7.5	7.5	Finland, 2000-2014	FIOH, 2017
Work with lead metal and lead containing alloys	663	14.9	15	-	34		UK, 2015-2018	based on HSE, 2019*

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

** *Older data on general exposure of auto mechanics are not included as the main exposure sources probably was leaded petrol with alkyllead compounds.*

4.6.2.11 Shooting

Discharge of firearms at firing ranges may cause significant exposure to lead. According to IARC (2006), numerous exposure assessments have been performed at both indoor and outdoor firing ranges.

Several sources of airborne lead have been identified: fragmentation of lead bullets during firing; the explosive vaporization of the primer, which can contain both lead styphnate, lead azide and lead peroxide; and inadequate ventilation of the range (stakeholder consultation; IARC, 2006). Instructors are generally exposed to the highest concentrations of airborne lead and tend to have the highest blood-lead concentrations due to their regular duties, which include supervising the range, cleaning and test-firing weapons, and preparing training ammunition from commercially purchased components. A positive correlation was reported between exposure of firearms instructors to elemental lead at covered outdoor firing ranges and increased blood-lead concentrations. Concentrations of airborne lead can be significantly reduced (97 – 99%) by using a lead-free primer and bullets jacketed with nylon, brass or copper (IARC, 2006). Furthermore, exposure at shooting ranges can be reduced by improved cleaning techniques (e.g. vacuum cleaning instead of brushing) and use of ventilation during cleaning (AUVA, 2021).

The VRAR for lead (LDAI, 2008) quotes Fischbein et al. (1979) for reporting blood-lead levels among 81 members of law enforcement agencies with respect to their indoor shooting activities. The persons examined were divided into three different categories: 43 full-time fire-arm instructors, 23 police officers with lesser instruction activities than the former, and 15 members of law enforcement agencies with only sporadic shooting activities. Two blood-lead examinations were carried out: one before the indoor season and the other after the indoor season. Blood-lead levels were apparently found to be influenced by lead exposure during the indoor season, which was shown by monitoring the same sub-group of fire-arm instructors (n=23) both before and after the indoor season.

Vandebrook et al. (2019) measured blood-lead levels in four groups of workers in firing ranges; Shooting instructors, police officers, Special Forces, and maintenance staff members. Mean values for blood lead were markedly higher in the Special Forces (3.9 µg/100 ml), maintenance staff (5.7 µg/100 ml), and instructors (11.7 µg/100 ml) compared to police officers (1.4 µg/100 ml). Special Forces train weekly and thus more often than police officers. P90 and P95 values are not reported. One instructor exceeded the biological exposure index for blood lead in Belgium at 38.8 µg/100 ml.

The Austrian Employers' insurance association (AUVA) informs that the exposure of trainees at shooting ranges is not significant in contrast to instructors' exposure. The worst-case exposure at shooting ranges may exist for cleaners, as ventilation typically is turned off and dust may raise during cleaning (AUVA, 2021).

An investigation of risk factors for high blood lead concentrations in Danish indoor shooters found that almost 60% of the shooters had a blood lead concentration above 9.9 µg/100 ml (Grandahl et al., 2012). Independent significant associations with blood lead concentrations above 9.9 µg/100 ml were found for shooting at a poorly ventilated range, use of heavy calibre weapons, number of shots and frequency of stays at the shooting range (data not shown in the table, as the exposure was not occupational).

Data from CAREX (Carcinogen Exposure) Canada indicate that police officers are the largest group of exposed workers in Canada. The surveys from the UK and Romania do not include specific data on exposure of police officers or firearm instructors, but the German MEGA data include a group of “Sports association, police”, shown in the table below. The French SCOLA database includes some sectors such as “defence” and “activities of sports clubs”. It is, however, not specifically indicated that the source of lead exposure is shooting.

IARC (2006) includes data from a large number of studies from around the world; only data from EU Member States are included in the table below.

The proposed REACH restriction on lead in shot does not concern the use of lead ammunition in shooting ranges and thus would not influence the potential occupational exposure in indoor ranges.

Table 4-31 Exposure concentrations (mg Pb/m³) in shooting ranges from published sources and stakeholder consultation.

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Sports association, police	22		0.002 ***	-	0.320	-	Germany 2000-2009	IFA, 2010
Public order and security activities **	38	0.003	0.001	-	0.009	0.026	France, 2009-2017	INRS, 2018b
Defence**	131	0.063	0.023	-	0.238	0.397	France, 2009-2017	INRS, 2018b
Activities of sports clubs **	22	0.045	0.058	-	0.091	0.096	France, 2009-2017	INRS, 2018b
Indoor range for police officers	7	0.03–0.16*	-	-	-	-	UK, 1976	Smith, 1976 cited in IARC, 2008

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Soldiers	35	0.19 *	-	-	-	30	UK, 1983	Brown, 1983 cited in IARC, 2008
Company J (Product testing, shooting), personal	3	0.003	-	-	-	0.004	EU MS, 2019	Consultation survey
Company L (Product testing, shooting), stationary	4	0.12	-	-	-	0.40	EU MS, 2016	Consultation survey
Company Q (Product testing, shooting), stationary	2	-	-	-	-	0.005	EU MS, 2019	Consultation survey

* *Not known if the concentrations represent 8-h TWA.*

** *Assumes the activity is shooting*

*** *Concentration below largest LOQ or largest LOQ unknown*

Table 4-32 Blood-lead level (µg Pb/100 ml) in primary lead production from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Activities of sport clubs *	10	29.8	29.6	-	54.1	54.1	Finland, 2000-2014	FIOH, 2017
Police service *	69	6.8	4.6	-	16.0	31.5	Finland, 2000-2014	FIOH, 2017
National defence/military *	252	4.4	3.3	-	9.7	50.8	Finland, 2000-2014	FIOH, 2017
On- and off-duty police officers	75 men	5.0	-	-	-	18.2	Sweden, 1999	Löfstedt et al. 1999, cited in IARC, 2008
	3 women	3.7	-	-	-	-		
Indoor range for police officers	7	30-59	-	-	-	-	UK, 1976	Smith, 1976 cited in IARC, 2008
Soldiers	35	19				30	UK, 1983	Brown, 1983 cited in IARC, 2008

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company L (Product testing, shooting)	39	7.6	4	-	22.2	48	EU MS, 2015; 2016; 2017	Consultation survey
Company Q (Product testing, shooting)	1	-	-	-	-	9.12	EU MS, 2020	Consultation survey

* *Assumes the activity is shooting*

4.6.2.12 Recycling of PVC and other plastics

As of 2015, products made from virgin PVC resin by European converters no longer contains lead. However, lead may still be contained in post-consumer waste PVC.

Occupational exposure due to recycling may take place in the following processes (Fruijtier-Pölloth, 2016):

- Shredding of waste PVC material
- Micronisation of waste PVC material (grinding)
- Compounding
- Converting
- Sampling

As reported by Fruijtier-Pölloth (2016) "*PVC containing lead is retrieved from post-consumer waste by separating PVC from other parts, followed by shredding, grinding and/or micronising the PVC. Shredding produces particles of about 50 mm, grinding produces particles of around 5-10 mm, and micronizing particles of around 200 µm. Compounding refers to the mixing of PVC resin with additives. Converting refers to the manufacture of semi-finished or finished products from a PVC intermediate, normally as granulate, pellets, or profiles. Converting usually involves a number of operations such as pressure, heat and/or addition of chemicals, re-melting of the plastic; it may also involve extrusion and filtering".*

The Annex XV Restriction Report for lead compounds in PVC (ECHA, 2016) concludes that the data presented in the industry VRAR (LDAI, 2008), indicate that blood-lead concentration do not exceed the current BLV occurred during production of PVC articles. Furthermore, Annex XV reports that three studies prepared by:

- (i) Fruijtier-Pölloth (2016) concerning the health risk of occupational lead exposure in conventional PVC recycling and converting operations;
- (ii) Sleeuwenhoek and Tongeren (2016) study on exposure of workers to lead via the dermal route and
- (iii) Vangeluwe et al. (2016) study about PVC compounding and converting sites (dermal exposure to lead)

did not conclude significant health risk associated with lead exposure since they appear to be properly controlled by the specific requirements of the relevant OHSs acts (ECHA, 2016). None of the studies provide data on occupational exposure levels, but the study by Fruijtier-Polloth (2016) provides data on blood-lead levels and are described below.

No data on exposure concentrations by recycling of PVC have been identified.

Health risks of occupational lead exposure in conventional PVC recycling and converting operations have been studied by Fruijtier-Pölloth (2016) for Polymer Comply Europe SCRL (industry association). The report was provided as part of the stakeholder consultation of the previous OEL study. Whole blood samples for lead determination were taken from a total of 127 subjects (5 females, 93 males, for 29 sex was not reported; average age 45.6 years (range 25-65), average age in females 47.4 (range 27-56). The subjects were employees of 12 PVC recycling and/or converting plants. The location of the plants is not reported. Data from the study are shown in the table below. The report does not indicate the total number of workers exposed in the 12 companies (blood-lead levels are reported for 127 employees or an average of 10 employees per company) or the total number of companies involved in PVC recycling with lead stabilisers in the EU.

The VRAR (LDAI, 2008) does not include data for recycling of PVC, but reports data from nine companies producing virgin PVC with lead stabilisers. Data are reported for four processes. Two of the processes are specific for virgin PVC production (raw material handling and mixing operations), whereas the other processes are quite similar in virgin and recycled PVC production. The data are reported to represent 90% of the PVC producers in EU15. The total number of employees exposed in these companies is reported at 2,853; of these 1,704 (60%) were involved in production and 163 (6%) in medical.

Table 4-33 Blood-lead level (µg Pb/100 ml) in recycling or production of PVC from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Recycling operations, all data	**100**	**4.4**	**3.7**	**8.8**	**10.0**	**0.8 -13.0**	12 plants, Not reported, 2015	Fruijtier-Pölloth, 2016
Male workers	92	4.4	3.7	8.8	9.9	0.8-13.0		
Shredding	28	5.1	4.0	9.2	9.9	1.3-12.0		
Micronisation	29	5.4	4.1	9.2	11.9	2.3-13.0		
Shredding/ Micronisation only	10	6.4	5.9	10.7	11.1	2.9-12.0		
Compounding	41	4.0	3.9	8.2	8.8	3.1-9.8		
Converting	39	3.7	3.1	6.0	6.5	1.2-13.0		
Converting only	19	3.1	2.7	4.6	4.8	1.2-6.1		
Sampling	46	4.2	3.5	8.5	9.6	0.8-12.8		
Office work	2	1.7	1.7	2.1	2.2	1.0-2.3		
Virgin PVC production	419	-	16	33	-	2-48	9 plants, Not reported, 1998-2006	VRAR, LDAI, 2008
Raw material handling	90	-	19	39	-	2-44		

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Mixing operations	217	-	15	32	-	3-48		
Forming	27	-	12	25	-	5-46		
Others	50	-	11	19	-	7-32		

4.6.2.13 Demolition, renovation, repairing and scrap industry

Various processes in the demolition, repairing and scrap industry may cause exposure to lead. Any process in which lead-containing metals or lead-containing paints are heated with torches to high temperatures are potentially hazardous. Furthermore, processes that generate of lead-containing dusts such as removing leaded-paints or dismantling products of lead metal may cause significant exposure.

Exposure may be to lead metal, lead oxides, lead carbonates, lead sulphates and other lead compounds.

Lead has traditionally been used in siccatives (curing catalyst) and pigments in some paints. In addition, paints based on red lead oxide (Pb_3O_4) were widely used as corrosion inhibitor on ships and steel constructions. The use of lead carbonates and lead sulphates is now restricted under REACH, but other lead compounds may still be used in some paints.

Exposure may take place within the following sectors:

- Ship repairing and breaking
- Renovation and demolition of buildings and steel structures such as bridges
- Scrap dealers
- Recycling of waste electrical and electronic equipment (WEEE)

Occupational exposure may take place in number of processes (LDAI, 2008; study team's observations):

- Welding and cutting of steel coated with leaded paints
- Sanding, sand blasting and cutting of other surfaces coated with leaded paints
- Heating of lead paint before removal
- Handling of lead metal
- Dismantling of WEEE with lead-containing solders¨
- Cleaning and reconstruction

Inhalation, hand-to-mouth contact and dermal exposure may occur. Dermal contact may be caused by handling of lead metal.

Demolition and removal of paint. Application of leaded paint for buildings and other constructions, e.g. bridges, has been common decades ago. Data on blood-lead levels from the UK demolition and paint removal industries demonstrate relatively high levels. Similarly, data from the French SCOLA database show relatively high exposure levels by demolition work. The risk of high exposure by these activities is reflected in the fact that many Member State authorities and demolition industry associations have prepared guidelines for safe work with lead by renovation and demolition activities.

Welding. Welders are exposed to lead in the welding fumes generated by gas metal arc welding of carbon steel. However, in one study, lead concentrations in the welding fumes were found to range from 0.001 to 0.017 mg/m³, well below the established permissible exposure limit for the workplace (Larson et al., 1989 as cited by IARC, 2006).

The occupational exposure of welders was studied in a plant in southern France (Iarmarcovai, 2005, cited in LDAI, 2008), including biomonitoring of blood-lead. The study included 60 male welders divided into two groups: group 1 working without any collective protection device, and group 2 aided with smoke extraction systems. A control group (n = 30) was also included (data not presented). The blood concentration of lead given in the publication is included in the table below. The mean (AM) concentrations ranged from 11 to 15 µg Pb/100 ml (Table 4-34).

Dismantling of WEEE with lead-containing solders

Lead is part of the screen glass and is used to connect the front and cone glass in the form of glass solder. It is also contained in soft solders. The level of exposure during manual dismantling of screen devices depends on various parameters, e.g. age and degree of dirt of the devices, type and design of the protective technology, personal working habits. Pre-cleaning of screen devices in closed cleaning booths has resulted in overall lower exposure levels (IFA, 2001). Exposure occurs primarily via inhalation of dusts and oral uptake.

Cleaning within reconstruction. An acute case of lead poisoning has recently been reported from Czech Republic (Štěpánek et al. 2020). The worker was presented to the emergency department of a hospital with acute signs of lead poisoning after an approximately seven day clean-up of an old recreational firing range with large ammunition and dust deposits. After treatment, the worker continued surveillance. Over the subsequent nearly three year follow-up period, the worker's blood lead levels fluctuated and continued to be increased (fluctuating between 32 and 55 µg/100 ml after completion of treatment). Given the absence of other sources of lead exposure, the authors suspect the elevated PbB levels to be caused by mobilization of bone deposits. The authors suggest that the aforementioned short, yet extreme, exposure was sufficient to produce resistant deposits in the body (Štěpánek et al. 2020).

Table 4-34 Exposure concentrations (mg Pb/m³) demolition, repairing and scrap industry

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Dismantle wrecks	134	0.056	0.013	-	0.224	0.82	France, 2009-2017	INRS, 2018b
Demolition work	25	0.349	0.002	-	1.764	3.16	France, 2009-2017	INRS, 2018b
Cleaning of buildings, waste disposal	65	-	0.048	-	0.250	-	Germany 2000-2009	IFA, 2010
Cleaning af recreational firing range, acute exposure, before treatment	1	-	-	-	-	81.6	Czech Republic	Štěpánek et al. 2020
Cleaning af recreational firing range, within 3-year follow-up period	1	-	-	-	-	54.6	Czech Republic	Štěpánek et al. 2020
Dismantling of Waste Electrical and Electronic Equipment:								
Manual disassembly of screen and other electrical devices (with cleaning in closed cabin)	28	-	0.001		0.01		Germany <2001	IFA, 2001 *

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Disassembly of electronic waste (with cleaning in closed cabin)	24	-	0.002		0.009			
Dusting and ventilation of screen devices in closed cleaning cabin	10	-	0.001		0.003			
Dusting and ventilation of screen devices in closed cleaning cabin	5		-		-	0.003		
Manual disassembly of screen and other electrical devices without closed cabin	29	-	0.005		0.03			
Disassembly of electronic waste without closed cabin	89	-	0.007		0.061			
Manual disassembly of screen and other electrical devices with closed cabin	14		-		-	0.01		
Manual disassembly of screen and other electrical devices without closed cabin	26		-		-	0.02		
Manual disassembly of screen and other electrical devices	55		-		-	0.023		

* *Sampling type a combination of stationary samples and personal samples.*

Table 4-35 Blood-lead level (µg Pb/100 ml) in demolition, repairing and scrap industry from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Reference
Ship breaking:								
Dismantling of wrecks	32	10.8	10.4	-	23.6	27.8	Finland, 2000-2014	FIOH, 2017
Shipbuilding, repair-ing and breaking	255	5.6	<10	-	11	10-19	UK, 2015-2018	Based on HSE, 2019*
Welding:								
Welders (ranges for four groups) **	120	11-15	6-10	-	-	30-44	France, 2005	Iarmarcovai, 2005 cited in LDAI,2008
Demolition and renovation:								
Demolition industry	965	8.7	<10	-	23	>80	UK, 2015-2018	Based on HSE, 2019*
Paint removal	1,338	9.8	<10	-	23	60-69	UK, 2015-2018	Based on HSE, 2019*
Bridge painting contractors (removal of leaded paint)								
All work tasks (base-line)	289	10.9	8.0	-	-	41	USA, 2019	Guth et al., 2020
All work tasks (2 months after base-line)	283	14.9	11.0	-	-	-	USA, 2019	Guth et al., 2020
All work tasks (4 months after base-line)	141	15.0	12.1	-	-	-	USA, 2019	Guth et al., 2020
Scrap handling:								
Recycling of as-sorted material	56	5.6	3.1	-	15.5	28.2	Finland, 2000-2014	FIOH, 2017
Scrap industry (in-cluding pipes, flash-ing, cables)	1,412	9.5	<10	-	22	50-59	UK, 2015-2018	Based on HSE, 2019*

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

** *Not specifically indicated that the welding was at shipyard*

4.6.2.14 Other waste management and soil remediation

Other waste management operations where occupational exposure to lead may occur in-clude:

- Treatment of hazardous waste

- Soil remediation of soils with high level of lead contamination
- Treatment of non-hazardous waste including waste incineration and sewerage treatment
- Glass recycling

Soil remediation. According to sub-scenario 10.7 “Soil remediation” in the VRAR for lead, inhalation exposure of soil remediation workers during excavation and tilling activities was monitored at four different events and at two different sites, taking both personal and static samples. Airborne personal lead samples (inhalable fraction) were below 0.004 mg/m³ in all cases (Romine & Barth, 2002 cited in LDAI 2008). The French SCOLA database includes a category “Remediation and other waste management services”. It is not clear to what extent the reported exposure concentrations are due to soil remediation. The high levels with an AM of 2.1 mg Pb/m³ indicate that remediation of lead-containing sites may cause high exposure levels. For all other categories, the P95 is below the existing OEL of 0.15 mg Pb/m³.

Waste incineration. According to sub-scenario 10.8 “Incineration plants” of the VRAR for lead, workers in incineration plants in New York (USA) were found to be exposed to air lead levels as high as 2.5 mg/m³ while cleaning electrostatic filters (task frequency: 6-7 operations per year, and for short periods). The average blood-lead value of all incineration workers was 11.0 µg/100 ml (range 5.1-28.7 µg/100 ml) (Malkin, R. et al., 1992 as cited in LDAI, 2008). The VRAR for lead also describes two studies of incinerator workers in Germany and Italy. Two additional studies were identified with data from Spain and Germany from/before 1997 in Mauriello et al. (2017). The background blood-lead level at that time was generally higher than today. No newer data on lead exposure of incinerator workers has been identified.

Table 4-36 Exposure concentrations (mg Pb/m³) by other waste management from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Hazardous waste and remediation:								
Treatment and elimination of hazardous waste	103	0.002	0.001	-	0.01	0.055	France, 2009-2017	INRS, 2018b
Collection of hazardous waste	30	0.024	0.018	-	0.05	0.056	France, 2009-2017	INRS, 2018b
Remediation and other waste management services	111	2.129	0.023	-	15.439	49.226	France, 2009-2017	INRS, 2018b
Non-hazardous waste and sewerage								
Treatment and disposal of non-hazardous waste	634	0.025	0.001	-	0.015	3.731	France, 2009-2017	INRS, 2018b
Sorted waste recovery	769	0.037	0.003	-	0.112	3.52	France, 2009-2017	INRS, 2018b

Table 4-37 Blood-lead level (µg Pb/100 ml) by other waste management from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Me-dian	P90	P95	Max	Location, year	Reference
Hazardous waste and remediation:								
Treatment and disposal of hazardous waste	153	3.1	2.7	-	6.4	9.9	Finland, 2000-2014	FIOH, 2017
Remediation activities and other waste management services	41	4.8	2.7	-	8.7	42.5	Finland, 2000-2014	FIOH, 2017
Incineration workers at hazardous waste incinerators	28	4.1 ± 2.1					Spain, 1999	Domingo et al. 2001 cited in Mauriello et al., 2017
Incineration workers at hazardous waste incinerators	19	4.1 ± 2.0					Spain, 1999	Schuhmacher at al., 2002 cited in Mauriello et al., 2017
Incineration workers at hazardous waste incinerators	19	4.0 ± 2.0					Spain, 2000	Schuhmacher at al., 2002 cited in Mauriello et al., 2017
Incineration workers at hazardous waste incinerators	26	2.7 ± 1.4					Spain, 2002	Agramunt et al., 2003 cited in Mauriello et al., 2017
Non-hazardous waste and sewerage:								
Treatment and disposal of non-hazardous waste	44	2.9	2.1	-	5.6	11	Finland, 2000-2014	FIOH, 2017
Collection of non-hazardous waste	655	2.3	1.9	-	4.6	23	Finland, 2000-2014	FIOH, 2017
Sewerage	29	2.1	1.7	-	4.6	5.2	Finland, 2000-2014	FIOH, 2017
Incinerator workers	47		11	--		<25	Germany, 1985	Reimann & Bloedner, 1985 cited in LDAI, 2008
Incineration workers	9	-	28	41	-	43	Italy, n.y.	Lello & Nieri, 1998 cited in LDAI, 2008
Incineration workers at municipal waste incinerators	17		9.5**				Spain, 1995	Gonzales et al, 2001, cited in Mauriello et al., 2017

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Incineration workers at municipal waste incinerators	17		10**				Spain, 1997	Gonzales et al, 2001, cited in Mauriello et al., 2017
Incineration workers at industrial waste incinerators	45	6.3 ± 2.0					Germany, n.y	Wrbitzky et al., 1995 cited in Mauriello et al., 2017
Management workers at industrial waste incinerators	45	6.0 ± 2.8					Germany, n.y.	Wrbitzky et al., 1995 cited in Mauriello et al., 2017
Glass recycling:								
Glass recycling (including TV and monitors)	429	16.4	16	-	29		UK, 2015-2018	Based on HSE, 2019*

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

** *Geometric mean*

4.6.2.15 Other

Occupational lead exposure may take place by some other activities:

- Mining activities
- Production of copper
- Primary steel production, blast furnace
- Manufacture of explosives
- Gravestone inscription writers
- Printing
- Laboratory uses

Mining activities. Limited data are available on lead exposure by mining activities in the EU. Mining of lead and zinc ores and manufacturing of concentrate are the main activities with high occupational exposure to lead in the USA (data not shown). Some data on blood-lead levels for “Support activities for other mining and quarrying” are available from Finland, but mining of lead ore does not take place in Finland.

Use of alkyllead as fuel additive. Tetraethyllead, used as an antiknock agent in petrol, has historically contributed significantly to the background exposure of the general population. This use was phased out in the EU in the year 2000. According to REACH Registration data around 2,000 tonnes/year are still manufactured in the EU (ECHA, 2019). All the tetraethyllead tonnage is blended into an additive formulation at the production facility. Most of the formulated fuel additive is then immediately exported outside the EU to industrial fuel blenders and refineries for blending into fuels. A limited volume is supplied to 4 fuel blenders and refineries within the EU to further formulate into aviation fuel (at less than 0.1% wt), within dedicated blending equipment (closed systems). According to RAC (2020b) tetraethyllead (the only registered alkyllead) is used only in formulation (in 4 EU sites) and transfer operations, with estimated air exposures between 0.002 and 0.4 mg/m^3, with the lower levels associated with quality control and laboratory activities, and the upper levels associated with professional uses related to transfer activities (e.g. refuelling of aircraft). For professional uses, there is no direct contact but exposure is possible incidentally and infrequently by inhalation of gasoline vapours, for example when opening gasoline tanks. According to RAC (2020b) the formulation/blending activities occur in 4 EU sites, are carried out under mainly closed conditions, with trained blending operators wearing full PPE (including gas filter or air-supplied respirator, chemical clothing including apron, gloves, boots, etc), who are subject to routine occupational health monitoring. Workers who test above a specified level are restricted from working in tetraethyllead areas until their lead levels fall considerably. Because of the limited use, number of exposed workers and low exposures, this use is not further considered in the impact assessment.

Production of copper and primary steel production. Lead can occur in the raw material used for copper smelting and exposure occurs via dust and aerosols. Data for copper production are available from Finland, but it is not clear whether the source of exposure is due to lead in the raw materials only or people working with lead metal, soldering, welding or other processes described elsewhere. Three copper producers (where copper is the main production output) are included under primary lead producers as they produce lead from ores as a by-product. Other copper producers are likely to process copper ores with lead content although the lead concentrations in the ores and the exposure of workers may be lower. Four companies within copper production have provided survey responses. Median airborne levels are well below the current OEL of 0.15 mg/m³, but some of the P95 values exceed the current OEL in smelting and refining operations.

The Finnish data indicate medium blood exposure levels with a median level of 14.9 µg/100ml and P95 of 32.9 µg Pb/100 ml. Data provided by three of the four companies indicate corresponding or lower levels. One of the workers of the forth company (Company S) shows a markedly elevated blood lead level (41.9 µg Pb/100 ml).

Manufacture of explosives. Lead is contained in essential parts of explosives initiation systems, such as electric fuse heads, primary explosive charges and pyrotechnic delay charges. Substances used in the production of explosives are mainly lead diazide, lead styphnate, lead nitrate and several other lead compounds (FEEM, 2021).

An application of authorisation of lead chromate (CAS No 7758-97-6) concerns the use of the substances for "*manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection"* (Etienne Lacroix Tous Artifices Sa, 2014). The processes where lead exposure may take place are manufacturing explosive substance (including handling of raw materials), manufacturing explosive mixture, manufacturing articles, and testing. The main challenge in managing lead exposure is to conciliate the reduction of lead exposure with the safety requirements related to product characteristics and explosives manufacturing processes. All of the lead compounds used in explosives manufacture are extremely sensitive primary explosives. Therefore, commonly used measures such as extraction and ventilation systems cannot be used and manufactures rely mainly on PPE in order to control exposures. Currently, there are no alternatives that would meet all the essential requirements for safe operation of explosives initiation systems (FEEM, 2021). Survey questionnaires in the previous OEL study (Lassen et al. 2019) were completed by two producers of explosives. Data are shown in the tables below. Due to confidentiality, the producers' Member State are not given

Exposure to lead compounds from explosives is partly accounted for in production of ammunition and shooting (sector 4 and 11). Due to the limited number of companies and workers involved, the processes of explosive manufacture are not further considered in this impact assessment.

Monumental masonry workers. According to the VRAR Sub-scenario 10.16, a survey of lead exposure among UK gravestone inscription writers was undertaken in 12 firms involved in monumental masonry in London and one in the East Midlands (Baxter et al., 1989 cited in LDAI, 2008). The mean blood-lead concentration in the 25 men studied was 35 µg/100 ml, with six workers exceeding 40 µg/100 ml. The men were unaware of the risks of lead exposure and the importance of not smoking or eating in their workshops (LDAI, 2008).

Other sources for exposure of masonry workers have not been identified. Due to the limited significance of this use, it is not further considered in this impact assessment.

Printing. Lead has historically been widely used for typesetting in the printing industry (WHO, 1997). The VRAR for lead (LDAI, 2008) includes data on blood-lead levels in type-setters. It is assumed that lead types have now been phased out in all professional printing in the EU and historical exposure data are not presented. The use is not further considered in this impact assessment.

Laboratories. According to data from the Lead REACH Consortium, five laboratories in primary lead plants are undertaking fire assays which is used to determine the metal composition of raw materials. For this application, the exposure may occur to lead in the samples. Data on exposure concentrations are included in the data for primary lead production and not reported separately. The Finnish survey of blood lead levels includes data for various laboratory examinations, research and development and technical testing and analysis. The specific activities are not reported, and it is not clear to what extent this takes place in laboratories of sectors included in other sections. No major application of lead chemicals for laboratory tests have been identified (lead analytical standards are used) and the main exposure risk in laboratories is likely exposure to lead in the samples (ores, waste products, leaded paint, etc.).

As the reported levels are relatively low, or the uses are historical, the applications and exposure situations have not been further assessed apart from copper production.

Table 4-38 Exposure concentrations (mg Pb/m³) in other sectors from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Manufacture of explosives:								
Manufacture of explosive products	347	0.033	0.019	-	0.119	0.362	France, 2009-2017	INRS, 2018b
Formulation of explosive	3	0.025	-	-	-	0.039	France, 2013	Etienne Lacroix Tous Artifices SA (2014)
Company 1, manufacture of substance and mixture	3	-	0.037		-	0.091	2018	Lassen et al. (2019)
Company 1, manufacture of substance and mixture	24	-	0.022	-	-	0.083	2018	Lassen et al. (2019)
Company 1, manufacture articles	12	-	0.011	-	-	0.064	2018	Lassen et al. (2019)
Company 1, test	3	-	0.051	-	-	0.089	2018	Lassen et al. (2019)
Company 2, sieving	26	0.139	0.085		0.418	0.986	2017	Lassen et al. (2019)
Company 2, weighing	97	0.030	0.010		0.138	0.308	2014	Lassen et al. (2019)

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company 2, final product preparation	230	0.004	0.001		0.023	0.088	2014	Lassen et al. (2019)
Research and laboratories:								
Research and development in other physical and natural sciences	31	0	0	-	0.002	0.006	France, 2009-2017	INRS, 2018b
Analyses, tests and technical inspections	75	0.012	0.002	-	0.069	0.098	France, 2009-2017	INRS, 2018b
Other:								
Manufacture and treatment of friction lining (brake lining and clutch lining)	37	-	0.0023*	-	0.11	-	Germany 2000-2009	IFA, 2010
Blast furnaces, rolling mills	57	-	0.026	-	0.93	-	Germany 2000-2009	IFA, 2010
Electroplating	84	-	0.002*	-	0.33	-	Germany 2000-2009	IFA, 2010
Printing office	13	-	-	-	0.038	-	Germany 2000-2009	IFA, 2010
Copper production								
Company R (Production), stationary	2	0.00123	-	-	-	0.0014	EU MS, 2019	Consultation survey
Company R (Production), stationary	1	-	-	-	-	0.00012	EU MS, 2020	Consultation survey
Company R (Production), personal	1	-	-	-	-	0.00029	EU MS, 2020	Consultation survey
Company S (Raw material handling), personal	1	0.00081	-	-	-	-	EU MS, 2017	Consultation survey
Company S (Melting), personal	1	0.068	-	-	-	-	EU MS, 2019	Consultation survey
Company S (Casting), personal	1	0.029	-	-	-	-	EU MS, 2019	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AL (Smelting), personal	172	0.065	0.026	-	0.24	0.44	EU MS, 2019-2020	Consultation survey
Company AL (Lead refining), personal	41	0.048	0.016	-	0.14	0.27	EU MS, 2019-2020	Consultation survey
Company AL (Quality control & Sampling), stationary	21	0.038	0.036	-	0.102	0.15	EU MS, 2019-2020	Consultation survey
Company AL (Copper refining), personal	40	0.047	0.016	-	0.17	0.58	EU MS, 2019-2020	Consultation survey
Company AK (Melting Copper), personal	7	0.027	0.034	-	0.036	0.073	EU MS, 2020	Consultation survey
Company AP (Smelting and casting of lead-containing brass), personal	3	0.027	0.014	-	0.052	0.052	EU MS, 2019	Consultation survey

* *Concentration below largest LOQ or largest LOQ unknown*

Table 4-39 Blood-lead level (µg Pb/100 ml) in other sectors from published sources and stakeholder consultation

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Production of copper:								
Production of copper	1,626	14.9	13.1	-	32.9	57.2	Finland, 2000-2014	FIOH, 2017
Company S (Raw material sampling and handling)	2	-	-	-	-	11.3	EU MS, 2020	Consultation survey
Company S (Melting)	1	41.9	-	-	-	-	EU MS, 2020	Consultation survey
Company S (Casting)	1	26.1	-	-	-	-	EU MS, 2020	Consultation survey
Company R (Extrusion Production)	11	11.9	12.8	-	15.5	16	EU MS, 2020	Consultation survey

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Company AK (Melting Copper)	75	9.1	9.2	-	16	17	EU MS, 2020	Consultation survey
Company AL (Smelting)	123	13.2	12.3	-	22.8	26.4	EU MS, 2019	Consultation survey
Company AL (Lead refining)	25	13.5	11.9	-	23.0	26.8	EU MS, 2019	Consultation survey
Company AL (Quality control & Sampling)	20	10.5	8.4	-	19.3	24	EU MS, 2019	Consultation survey
Company AL (Copper refining)	27	5.1	4.3	-	9.2	18.2	EU MS, 2019	Consultation survey
Mining:								
Support activities for other mining and quarrying	98	1.7	1.2	-	3.9	6.4	Finland, 2000-2014	FIOH, 2017
Manufacture of explosives:								
Company 1, manufacture of substance and mixture	17	10	7	-	20	28	2018	Lassen et al. (2019)
Company 1, manufacture articles	38	10	16	-	20	28	2018	Lassen et al. (2019)
Company 1, test	10	8	7	-	12	23	2018	Lassen et al. (2019)
Company 2, handling and formulation	8	3.9	3.0		7.8	8.6	2016	Lassen et al. (2019)
Masonry workers	25	35	--	54	-	89	UK, 1989	Baxter et al., 1989 cited in LDAI, 2008
Printing:								
Other printing	13	3.7	2.5	-	8.9	8.9	Finland, 2000-2014	FIOH, 2017
Research and laboratories:								
Medical research and development	31	8.3	7	-	18	42.1	Finland, 2000-2014	FIOH, 2017

Sector/ occupation	n	Mean (AM)	Median	P90	P95	Max	Location, year	Reference
Private doctors, medical clinics and similar specialized medical services	391	4.4	2.5	-	15.1	66.1	Finland, 2000-2014	FIOH, 2017
Laboratory examinations	154	4.8	2.9	-	14.1	41.4	Finland, 2000-2014	FIOH, 2017
Research and development on other natural sciences	86	3.9	3.3	-	9.1	11.6	Finland, 2000-2014	FIOH, 2017
Other technical testing and analysis	78	2.5	1.9	-	7	9.9	Finland, 2000-2014	FIOH, 2017
Other: **								
Other processes	1,555	7.9	<10	-	19		UK, 2015-2018	Based on HSE, 2019*

* *Calculated approximately from original data from HSE (2019) see Table A3-15. Data represent highest measured value for each worker for each of three periods summarised.*

** *Appendix A includes additional data from a number of sectors where the actual exposure source is not clear.*

4.6.3 Differences in exposures for female workers and female workers of childbearing age

Data from the Lead REACH Consortium on exposure of female workers show that women are exposed to lower levels (Table 4-40). This can be to some extent explained by the circumstance that many companies either follow lower national limit values for female employees or lower voluntary targets for female employees based on a precautionary principle. Generally, there are fewer women employed in the relevant sectors. Compared to data from the 2013-2016 survey (see Table A3-3), exposures appear to be unchanged or lower. Notable is the reduction within the lead battery sector, where AM values were reduced from 9.4 and 9.9 µg/100 ml in 2013-2016 (see Table A3-3) to 5.9 and 5.4 µg/100 ml in 2015--2018 for female workers and workers of childbearing age, respectively.

Table 4-40 Blood lead concentrations for female workers from the Lead REACH Consortium survey 2015-2018 (Lead REACH Consortium, 2021), µg/100 ml

Sector (numbering with reference to this study)	Female workers				Workers of childbearing age*			
	N	AM	P75	P90	N	AM	P75	P90
1. Primary lead producers	67	4.6	5.0	7.6	51	3.9	5.0	6.0
2. Secondary lead producers	117	5.1	6.2	9.4	82	4.0	5.2	8.1
3. Lead battery producers	411	5.9	7.0	13.0	214	5.4	6.2	11.5
4. Lead sheet producers	13	3.9	4.2	5.0	5	3.3	4.0	5.0
6. Lead oxide and stabiliser producers	11	6.7	7.3	12.5	9	6.3	7.1	9.2
7. Lead crystal glass production	112	7	9.3	14.2	58	6.8	9.3	15.5
8. Ceramic ware production	14	12.2	13.3	13.8	12	12.1	13.3	13.8

** Workers of reproductive age are defined as being <46 years.*

4.6.4 Inhalable vs. respirable fraction

Data on air exposure concentrations are assumed to represent the inhalable fraction if nothing else is indicates. Analytical methods all use inhalable samplers and consequently measure the inhalable fraction. Respirable particulate fraction is the fraction of inhaled airborne particles that can penetrate beyond the terminal bronchioles into the gas-exchange region of the lungs.

The ratio of respirable particulate to inhalable fraction varies by emission source. Particle-size distributions of workplace airborne lead were monitored by personal sampling of Korean workers (n=117) in four different industry sectors: secondary smelting, as well as radiator, battery and lead powder production (Donguk and Nawmon, 2004). As shown in Table 4-41, the ratio of respirable to inhalable fraction varies significantly between the different operations.

The largest fraction of respirable particles have been found in battery production and lead powder packaging. This indicates that lead exposure in the lead battery sector (sector 3) and in production of lead compounds and frits (sector 6) has a larger potential of causing health risks.

*Table 4-41 Mass median aerodynamic diameter (MMAD) and concentration of total lead, respirable and inhalable fraction of lead by sector and operation (Donguk and Nawmon, 2004)**

Industry	n	Operation	MMAD, µm	PbA, total lead concentration	Inhalable fraction	Respirable fraction	Inhalable /respirable **
Secondary smelting	6	Furnace	1.6	759	646	447	1.4
		Scrap and furnace	14.5	437	324	98	3.3
Radiator reproduction	42	Dipping	2.5	12.9	11	5	2.2
		Soldering	1.4	20.4	17	9	1.9
		Soldering after leak test	0.1	25.1	22	16	1.4
Battery production	44	Casting	13.5	138	98	16	6.1
		Plate off-bear	16.6	257	60	9	6.7
		Paste	13.5	85	182	26	7.0
		Encapsulation	15.1	776	537	58	9.3
		Caste on strap	15.1	537	372	43	8.7
		Soldering	13.2	305	174	40	4.4
		Grinding	12.3	5,011	3,467	398	8.7
Lead powder production	25	Reaction	14.5	339	246	45	5.5
		Cracking	12.3	36	27	9	3.0
		Packing	22.4	389	269	24	11.2
Total	**117**		**5.8**	**118**	**89**	**22**	**4.0**

* *More parameters are available in the original paper.*

** *Calculated here on the basis of the data.*

Petito Boyce et al. (2017) investigated particle size distributions of lead measured in battery manufacturing and secondary smelter facilities and discussed the implications in setting workplace lead exposure limits. The collected data indicate that, in general, workers in the sampled facilities were exposed to predominantly larger particle sizes (with average Mass median aerodynamic diameters >15–20 µm). The average percent of lead mass particles < 1 µm ranged among the facilities from 0.44% (refining) to 6.1% (blast furnace) with a total average of 3.3%. The ratio of respirable to inhalable fraction is not reported.

4.6.5 Trends in exposure concentrations

4.6.5.1 Data from Lead REACH Consortium

The trends in airborne concentrations (personal sampling, outside RPE) and blood-lead levels for the seven sectors covered by the Lead REACH Consortium survey are shown in Table 4-42 and Table 4-43. Data for 1998-2001 are retrieved from the VRAR for lead (LDAI, 2008) whereas recent data has been obtained from Lead REACH Consortium as part of the stakeholder consultation.

Except for lead sheet producers, median **airborne concentrations** are either unchanged or lower in 2015-2018 compared to 1998-2001. The more recent P90 (2015-2018) values are higher than for the former period (1998-2001) for three of the sectors, most pronounced again for lead sheet producers.

The inhalation monitoring data do not reflect actual exposures, as workers wear RPE in many of the activities in these sectors. Also, more samples were submitted for the survey conducted in relation to the VRAR (1998-2001) compared to the recent survey for the period 2015-2018, limiting the comparability of the data, especially for the sectors with few samples (i.e. 4. Lead sheet producers, 6. Lead oxide and stabiliser producers, 8. Ceramic ware production)

For the **blood-lead levels**, the data appear more consistent and reflect the efforts of reducing exposure to lead among workers. Most median and P90 values have approximately halved over the ~15 year period in all sectors, corresponding to approximate annual decrease of 2.8%. Comparing the 2013/16 data with the most recent data from 2015/18, the most recent levels vary between 87% and 109% of the earlier period. There is an overlap of the years 2015 and 2016 between the two time periods which may level out any possible significant differences. Based on the available data, no significant trend during the recent years can be recognised.

Table 4-42 Trends in exposure concentrations (personal sampling, 8-hTWA) for all workers by sector across all samples reported for the period 2015-2018 in the Lead REACH Consortium survey (Grewe and Vetter, 2019) and 1998-2001 data from the VRAR for lead (LDAI,2008), mg/m3

Sector (numbering with reference to this study)	1998-2001			2015-2018			2015-18 levels in percentage of 1998-2001 level	
	N	Median	P90	N	Median	P90	Median	P90
1. Primary lead producers	388	0.10	0.66	182	0.10	1.04	100%	158%
2. Secondary lead producers	3,293	0.05	0.36	369	0.03	0.42	60%	117%
3. Lead battery producers	3,194	0.06	0.33	1546	0.03	0.15	50%	45%
4. Lead sheet producers	157	0.08	0.36	13	0.10	1.00	125%	278%
6. Lead oxide and stabiliser producers	108	0.20	1.50	20	0.04	0.49	20%	33%

Sector (numbering with reference to this study)	1998-2001			2015-2018			2015-18 levels in percentage of 1998-2001 level	
	N	Median	P90	N	Median	P90	Median	P90
7. Lead crystal glass production	258	0.03	0.24	0	n.a.	n.a.	-	-
8. Ceramic ware production	32	0.04	0.11	3	0.02	0.03	50%	27%

Table 4-43 Trends in blood-lead levels for all workers by sector across all samples reported in the Lead REACH Consortium 2015-2018 and 2013-2016 survey, and 1998-2001 data from the VRAR for lead (LDAI, 2008), µg/100 ml

Sector (numbering with reference to this study)	1998-2001		2013-2016		2015-2018		2015/18 levels in percentage of 1998-2001 level		2015/18 levels in percentage of 2013-2016 level	
	Median	P90	Median	P90	Median	P90	Median	P90	Median	P90
1. Primary lead producers	28	40	12	27	13.1	27.4	47%	69%	**109%**	**101%**
2. Secondary lead producers	28	46	14	28	14.3	25.2	51%	55%	**102%**	**90%**
3. Lead battery producers	28	47	12	29	12.6	25.2	45%	54%	**105%**	**87%**
4. Lead sheet producers	30	49	16	30	15.2	26.0	51%	53%	**95%**	**87%**
6. Lead oxide and stabiliser producers	31	51	16	28	14.4	27.0	46%	53%	**90%**	**96%**
7. Lead crystal glass production	18	35	12	24	13.0	24.0	72%	69%	**108%**	**100%**
8. Ceramic ware production	14	30	12	14	10.8	14.2	77%	47%	**90%**	**101%**

4.6.5.2 Germany

In Germany, the industry associations WVMetalle (German umbrella organisation of the metal associations) and GDMB (Association of the German Non-ferrous Metal Industry) have been conducting yearly surveys of blood lead levels of male and female workers within the industry since 2008.

In the 2020 survey, 14 companies, representing 1,849 employees (male and female) participated. Between 2008 and 2019, approximately 2,000 to 4,000 employees are represented in the yearly statistics.

Figure 4-1 shows the fraction of companies with employees having elevated blood lead levels (>300 and >400 µg/L) since 2013. The fraction of 400 µg/L has been stable at a low level of 0.2% (±0.2%) from 2013 to 2020. The fraction of 300 µg/L has been decreasing from 2013 to 2016 (from 7.1% to 2.1%), but since appears to be slightly increasing. From 2019 to 2020, an apparent decrease from 3.3% to 1.4% can be seen. The small changes in the figures from 2016 – 2020 are, according to WVMetalle, caused by changes in companies participating in the survey, e.g. a major data contributor (representing approximately a quarter of the employees represented in the previous years of the survey) did not participate in the 2020 survey. Specific information about reduced production during 2020 due to the pandemic, with the potential of causing lower levels in 2020, were not available. However, the WVMetalle association regards a relationship between exposure concentration levels in 2020 and the pandemic as unlikely.

Data analysed per fractions of male employees having blood levels of >300 and >400 µg/L (data not shown here) show the same dynamics as the data for the fractions of companies in Figure 4-1.

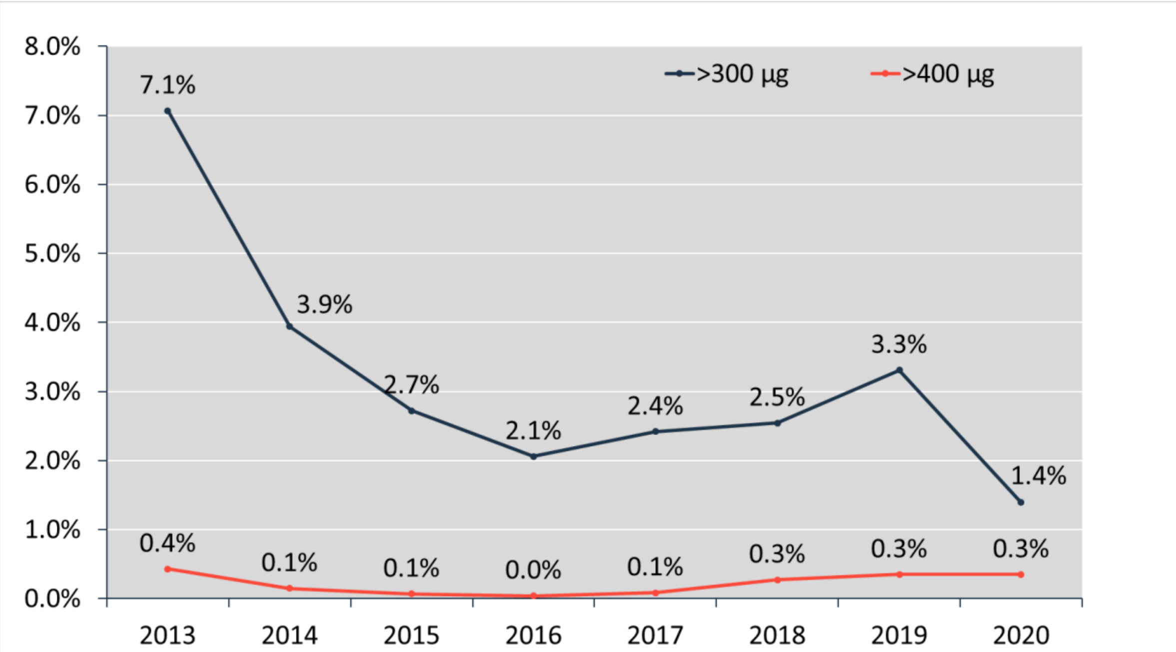


Figure 4-1 Fractions of German companies since 2013 with blood lead levels of employees exceeding 300 and 400 µg/L, respectively (figure modified from WVMetalle, 2021).

The bar charts of Figure 4-2 and Figure 4-3 below show the development of blood lead levels for specific working areas and the sum of working areas since 2015.

For many, but not all, working areas, the most recent data from 2020 show lower concentrations than the previous years, the 2019 values are in range or even larger than the values of the previous years. Significance statistics or exact figures on exposure concentrations were not provided along with the data. From the visual evaluation of the data, no significant trend in increasing or decreasing exposure concentrations can be concluded for the 6-year period. Most of all, the data appear stable with reasonable fluctuations as explained above, resulting in the sum of P50 concentrations of 100 (±20) µg/L and P90 concentrations of 225 (±25) µg/L.

With the 2021 update of the German BLV to 150 µg/L (see section 4.1), a decrease in exposure concentrations can be expected the coming years.

The German data are derived from companies producing and processing lead and can be compared with the summarised European data for sectors 1 and 2. The German P50 concentration (100 ±20 µg/L) appears slightly lower than the European summarised estimates for sectors 1 and 2, P50 of 131 and 143 µg/L, respectively. Also, the German P90 concentration (225 ±25 µg/L) appears slightly lower than the European summarised estimates for sectors 1 and 2, P90 of 274 and 252 µg/L, respectively (compare section 4.6.5.1). Since the German data is a significant proportion of the European estimates, it can be anticipated that the German exposure concentrations will be lower than in many other Member States. This notion is also supported by industry stakeholders with activities in several Member States.

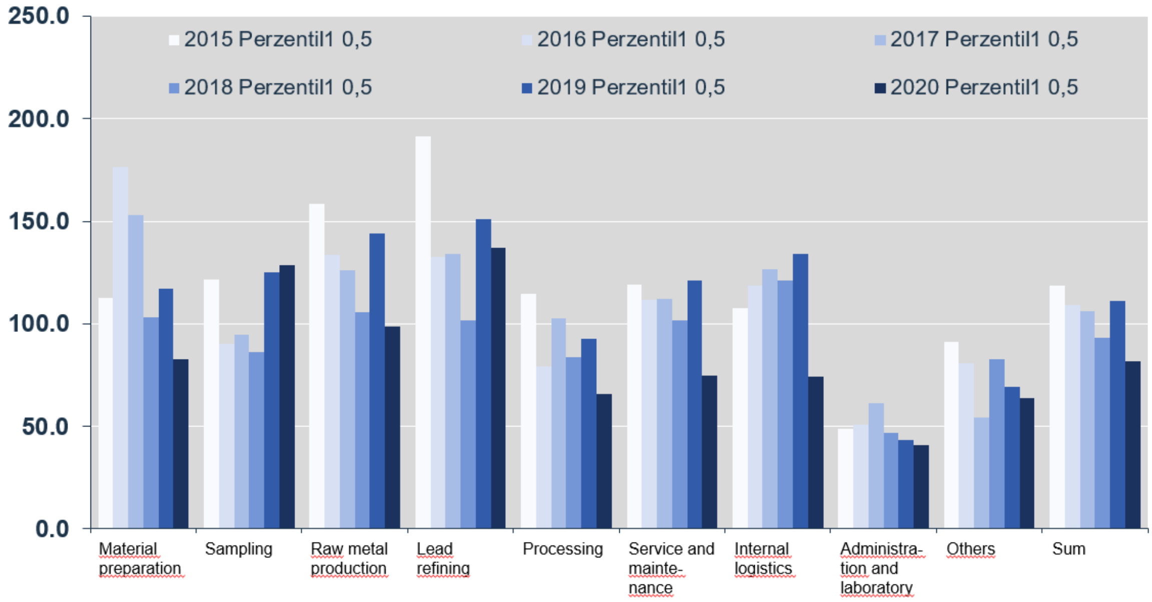


Figure 4-2 Median concentrations (P50) of blood lead levels (µg/L) in nine different working areas and sum of all working areas. Data from 1,849 employees were included in the analysis (figure modified from WVMetalle, 2021).

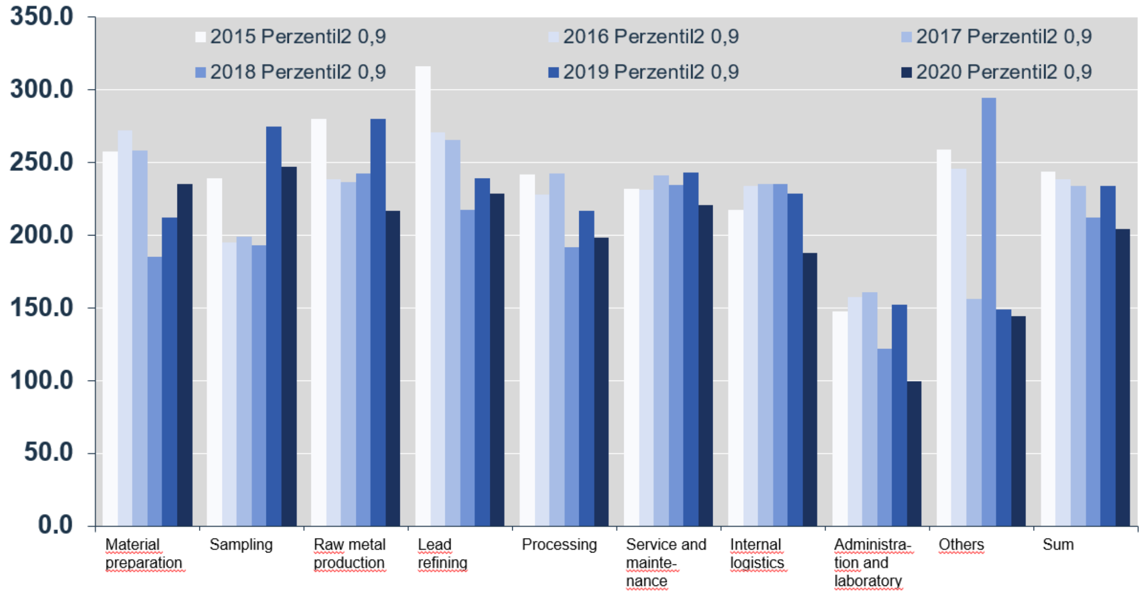


Figure 4-3 90th percentile concentrations (P90) of blood lead levels (µg/L) in nine different working areas and sum of all working areas. Data from 1,849 employees were included in the analysis (figure modified from WVMetalle, 2021).

4.6.5.3 Finland

Kauppinen et al. (2013) has assessed the prevalence (percent of employed) of exposure to chemical agents and exposure concentrations and its change in Finland during 1950–2020. The data includes all exposure situations of which many are historic.

The average exposure level for lead has decreased over the years from 1.2 µmol/L in 1950, 0.74 µmol/L in 1970 to 0.37 µmol/L in 2008. The authors predict that the average exposure level for lead in Finland will be 0.32 µmol/L in 2020, corresponding to 6.6 µg/100ml (Table 4-44). From 2008 to 2020, the reduction of exposure levels corresponds to an annual decrease of appr. 1%. Data on trend in workforce are presented in section 4.7.3.1.

Combining the trend in workforce and in exposure concentrations, Kauppinen et al. (2013) calculate the trend in so-called NOIE (national occupational inhalation exposure) values. The NOIE values are intended to be indicators of ‘national dose’, which may predict the agent-specific burden of work-related diseases in Finland (i.e. the future burden of the total exposure the year concerned). The NOIE value in 2008 was at 14% of the value in 1990 and the 2020 value was predicted to be at 4%. The data reflect strong reductions in historic exposures, but do not allow for any conclusions in development in the most recent years.

Table 4-44 Average exposure concentrations and its change in Finland during 1950–2020 including historic exposures (Kauppinen et al., 2013).

Exposure unit	Exposure concentration					Levels as compared to 1990 (%)				
	1950	1970	1990	2008	2020	1950	1970	1990	2008	2020
µmol/L	1.2	0.74	0.48	0.37	0.32	237%	153%	100%	78%	65%
µg/100 ml	24.9	15.3	9.9	7.7	6.6					

4.6.5.4 Romania

Average **blood-lead levels** in workers exposed whilst recovering lead from waste batteries (sector 2, **secondary lead production**) are shown in the figure below. Between 2012 to 2019, the average concentrations decreased from 47 to 32 µg/100 ml, but the AM is still significantly above the AM reported for secondary lead production from the Lead REACH Consortium survey of 16 µg/100 ml as shown in Table 4-14. Overall, the trend seems to be stagnating since 2015.

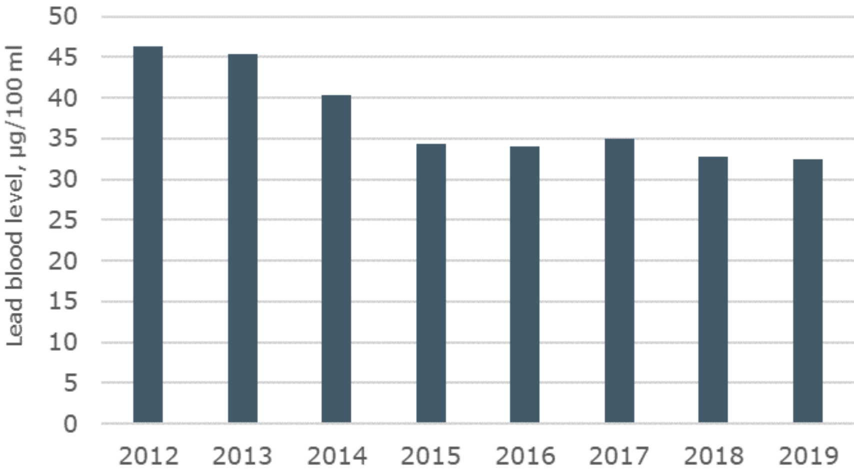


Figure 4-4 Trend in average (AM) blood-lead levels in workers exposed by recovery of lead from waste batteries in Romania (based on CNMRMC, 2019)

4.6.5.5 United Kingdom

PbB levels in the UK have been dropping steadily over the past decades. The PbB trend for male and female workers under medical surveillance in the UK from 2008/2009 to 2017/2018 is provided in the following figures. The figures for men only include data for workers with blood levels above 50 µg/100 ml, whereas the figures for female only include levels above 25 µg/100 ml. The figures for female workers are quite variable, ranging between 1 and 16 since 2012/13 (caused by the small number of lead exposed women), while the figures for male workers appear more stable between ~45 and 80 since 2012/13. Therefore, no trend can be read from the data of the recent years.

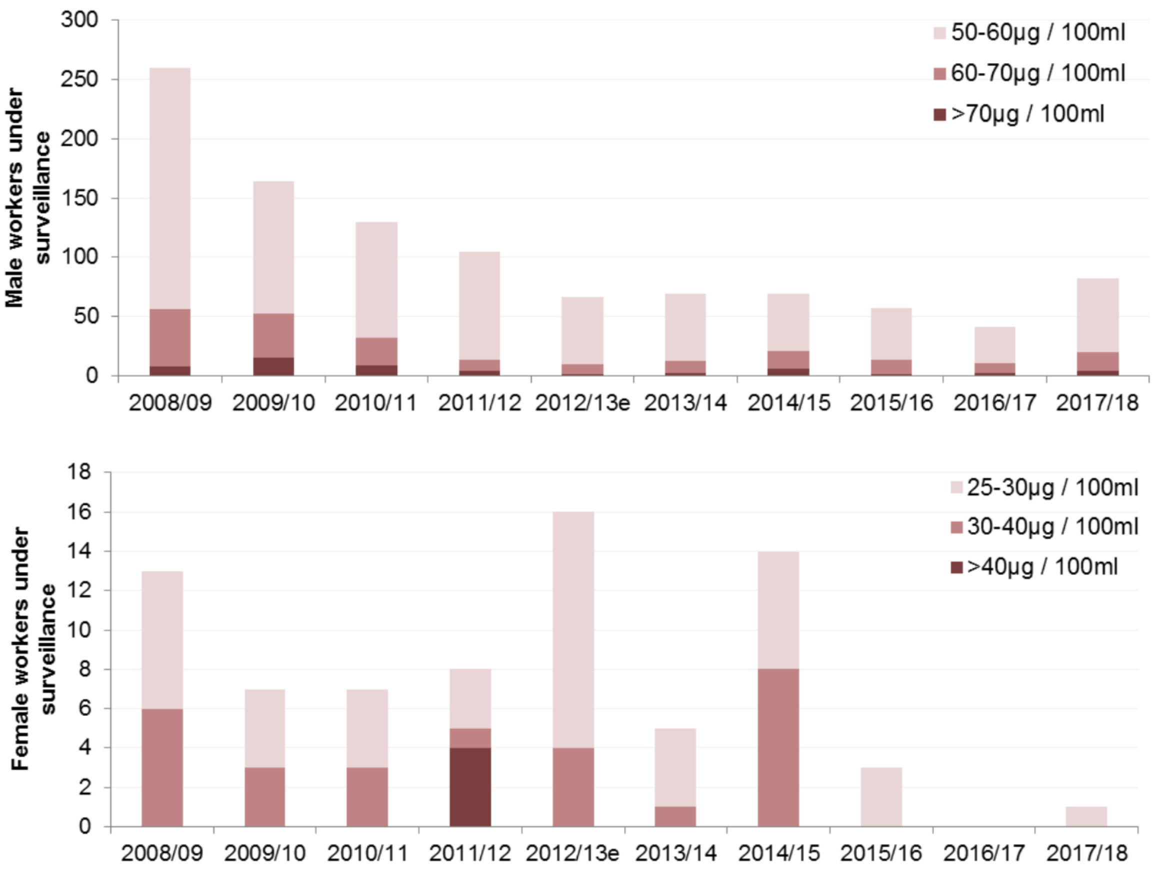


Figure 4-5 UK male and female workers with elevated blood levels (>25 µg/100 ml for female and >50 µg/100 ml for male) (HSE, 2019)

The figures below show the trend in the levels from 1992/93 to 2009/10. As demonstrated by the data from the two datasets, the number of men exposed at levels above 50 µg/100 ml decreased from approximately 1,350 in 1992/93 to 82 in 2017/18. For the women, the number of workers exposed at levels above 25 µg/100 ml decreased from approximately 110 in 1996/97 (1992/93 data are not available) to one in 2017/18. The number in 2017/18 corresponds to less than 1% of the number in 1992/93.

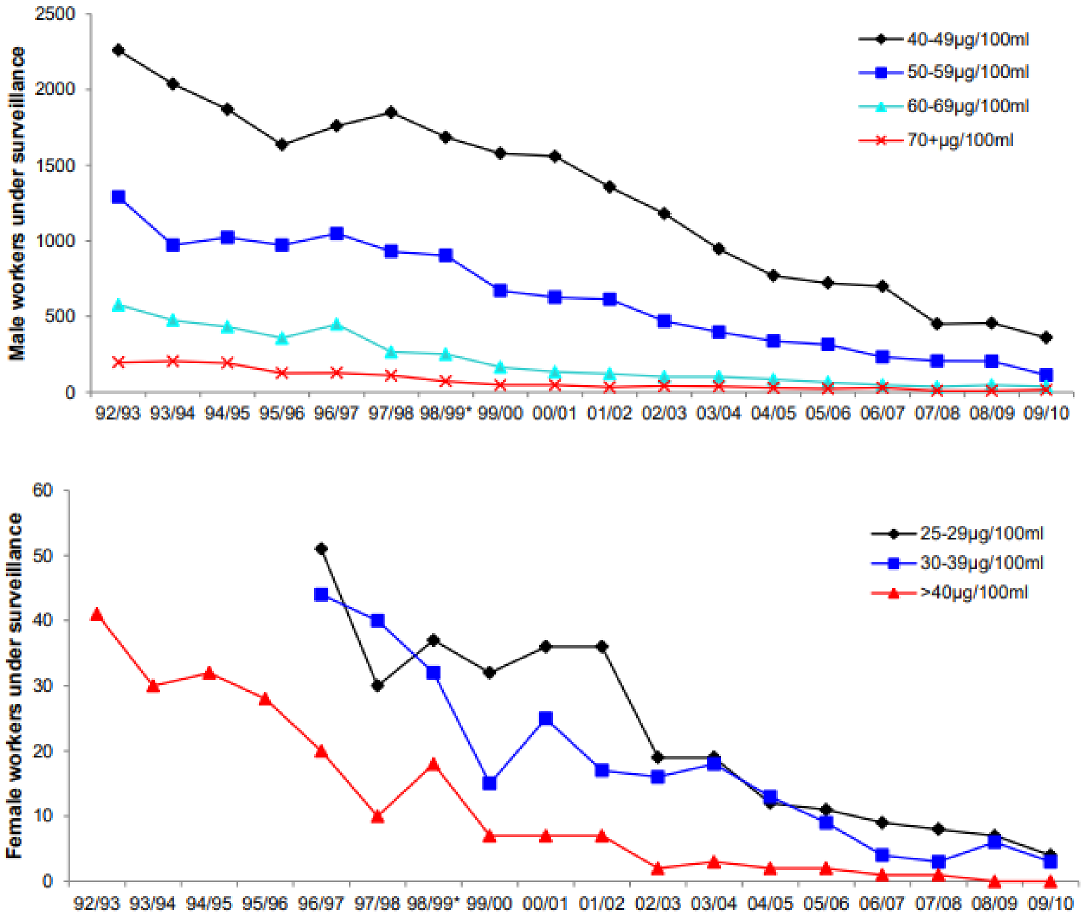


Figure 4-6 UK workers under surveillance with elevated blood levels (>40 µg/100 ml for men and >25 µg/100 ml for women). The x-axis indicates the years. (HSE, 2013)

Morton et al. (2010) analysed trends in blood-lead levels in UK workers between 1995 and 2007 by sector. Reductions in median blood-lead levels over the period 1995-2007 were seen in nearly all sectors and ranged from 1.6% per year for workers in the smelting industry to 12% per year for workers in pottery and glazing industries. Trends by sector are shown in Table 4-45. As shown in the table, for most sectors the trend was quite uncertain, and the 95% confidence interval ranged from positive to negative trends. An overall reduction of 3.1% per year across all industries was determined (95% confidence level is not provided for the total). The percentage of results above the UK suspension limit (at that time) of 60 µg/100 ml fell from 4.8% in 1995 to 0.6% in 2007.

*Table 4-45 Mixed effect analysis of blood-lead levels in UK workers between 1995 and 2007 showing sector medians and trends (Morton et al., 2010)**

Sector	Median for all years, µg/100 ml (95% confidence levels)	Trend, % change per year) (95% confidence levels)
Battery manufacturing	32 (24 to 41)	-3.8 (-7.9 to 1.2)
Chemical and pigment manufacture	15 (13 to 17)	-2.7 (-4.1 to -1.2)
Demolition	8.5 (7 to 10)	-4.4 (-6.5 to -2.3)
Glass making	20 (19 to 22)	2.7 (-3.3 to -2.0)

Sector	Median for all years, µg/100 ml (95% confidence levels)	Trend, % change per year) (95% confidence levels)
Occupational health provided samples	6.9 (6.3 to 7.7)	1.1 (0.047 to 2.1)
Other or unknown	12 (11 to 12)	-3.5 (-4.1 to -2.9)
Painting buildings and vehicles	18 (15 to 20)	-6.3 (-7.8 to -4.7)
Pottery and glazing	22 (20 to 25)	-12.0 (-13.0 to 10.0)
Scrap	21 (18 to 23)	-7.1 (-8.7 to 5.5)
Smelting, refining, alloys and casting	13 (12 to 14)	-1.6 (-2.0 to 1.0)
Smelting and alloys	19 (17 to 21)	-4.5 (-5.4 to 3.5)
Smelting and scrap	20 (18 to 22)	-6.3 (-7.4 to 5.1)
Working with lead alloys	14 (13 to 15)	-2 (-2.6 to 1.4)

4.6.5.6 USA

Koh et al. (2014) evaluated the trends over time from occupational lead exposure data reported in the published literature using meta-regression. The authors extracted various statistical parameters from journal articles reporting blood and personal air measurements from US worksites. The blood-lead measurement models predicted a statistically significant decline of 2-11% per year in 8 of the 13 industries (see table below). The air measurement models predicted a statistically significant decline of (3% per year) in only one of the seven industries; an increasing trend (7% per year) was also observed for one industry (bronze foundry). Of the five industries that met the inclusion criteria of the study for both air and blood sample data, the annual reduction in exposure to lead tended to be slightly greater for blood measurements than for air measurements (auto radiator repair, firing range, lead battery, secondary lead smelter, ship building/repair/demolition). The data show that there have been significant reductions in a wide range of sectors during the past decades in the USA. However, the data have limited validity for estimating current trends in Europe.

Table 4-46 Estimated trends from the mixed-effects meta-regression models, by industry and sample type (Koh et al., 2014)

Industry	Time span of measurement	No. of studies	Exposure change per year
Blood sample data			
Auto radiator repair	1979–1994	7	−2.4
Bridge construction/ maintenance /demolition	1980–2005	9	−11
Firing range	1974–1988	10	−10
Fuel additives	1977–1990	3	−4.6
General construction/renovation	1938–2005	4	−6.6

Industry	**Time span of measurement**	**No. of studies**	**Exposure change per year**
Lead battery	1953–1985	8	−2.6
Police protection	1956–1975	2	−0.5
Polyvinyl chloride (PVC)	1978–1997	3	0.4
Residential renovation	1962–1994	4	−4.4
Secondary lead smelter	1972–1991	8	−2.7
Ship building/repair/demolition	1984–2002	3	−2.1
Steel structure demolition/maintenance	1966–1989	3	−1.6
Transportation	1956–1986	3	−5.7
Air concentrations			
Auto radiator repair	1979–1994	5	−3.4
Bronze foundry	1993–2003	2	6.9
Firing range	1985–2001	6	−8.7
Lead battery	1953–2008	6	−0.1
Metal recycling	1994–2004	3	−24
Secondary lead smelter	1975–2004	3	−3.3
Ship building/ repair/demolition	1963–2002	3	−2.0

*Notes: * Further data on between-study variance and other statistical parameters available in Koh et al., 2014*

Locke et al. (2017) evaluated predictors of lead exposure for activities disturbing materials painted with or containing lead using historic published data from U.S. workplaces for the period 1960 to 2010. The blood-lead model estimated a significant 6.2% decline per year for three industries: autobody/radiator repair, steel structure construction and shipyards. A 2.8% decline per year was estimated for "general and residential construction" and a 2.2% decline per year for "miscellaneous" industries. The air model using workplace air concentrations estimated a 4.6% decline per year for all industries except shipyards, but the decline was not statistically significant.

4.6.5.7 Impact of European battery strategy and renovation wave on occupational lead exposure

The European Commission states "*Batteries are a key technology in the transition to climate neutrality, and to a more circular economy. They are essential for sustainable mobility and contribute to the zero pollution ambition*."[15] The sustainability of batteries throughout the lifecycle is a key for the goals of the European Green Deal and the battery sector is expected to grow significantly over the next decades to support this development. To ensure that the expected massive deployment of batteries does not hamper the efforts in the green transition, the Commission proposed a new Batteries Regulation in December 2020,

[15] Cited from: Questions and Answers on Sustainable Batteries Regulation (europa.eu)

setting out provisions ensuring the sustainability, circularity, performance and safety of batteries, by introducing legally binding measures affecting raw material supply, battery production, content of hazardous substances, energy efficiency, life time, collection and recycling schemes.

According to discussions with stakeholders from the battery sector, the new battery legislation will not affect the occupational exposure concentrations for lead significantly, because the recycling rate of lead acid batteries is already high in the EU (99% of end-of-life lead batteries are currently collected and recycled[16]) and the battery industry is proactively taking measures to limit the blood lead levels of its employees, independently of the battery legislation.

No quantitative information on expected trends in lead exposure concentrations in demolition and renovation related to expected increased activity of the sector due to the EU renovation wave strategy[17] has been obtained during stakeholder consultation. Lead-containing materials in buildings comprise leaded water pipes, roofing materials (flashings), window seals and leaded paints. The latter renders the most significant exposure source, as paint removal can cause considerable amounts of lead dust (depending on removal method). A few stakeholders suggested that the number of buildings with lead-containing materials is limited. At the same time, awareness about safe handling of hazardous materials is increasing in the sector. Therefore, the renovation wave is not expected to cause significant increases in exposure concentrations.

4.6.5.8 Conclusion

The available data show that blood lead levels in exposed have been reduced considerably during the past decades. This corresponds with the introduction of lower national limit values (see section 4.1) and efforts within the industry to meet voluntary targets (section 4.10). For the most recent years, the declining trend has been stagnating.

For the benefits assessment, the current exposure levels without anticipation about future changes are taken forward.

Possible future reductions in exposure concentrations related to continuous efforts within the main lead producing and processing sectors, as well as the impact of the recently introduced national BLV in Germany (15 µg/100 ml, May 2021) are reflected on in the sensitivity analysis.

4.6.6 Summary of exposure concentrations

The available information on blood lead concentrations for each sector have been summarised in the table below. For the sectors where large datasets were available, these data were used for describing the exposure concentration distributions at EU level, e.g. the datasets provided by the Lead REACH consortium. For other sectors, with smaller and/or more diverse information on exposure levels, the datasets were combined to obtain the parameters (arithmetic mean; median; P75, P90 and/or P95) for a descriptive distribution.

The datasets were combined by calculating weighted averages of a given parameter from different datasets. In case an important parameter was missing, this parameter was estimated by using the sector-specific relationship given by other datasets between different parameters (i.e. if the P95 was on average a factor 3.5 larger then median for a given sector, the median and the factor were used to estimate a missing P95 value).

In the "main" lead sectors 1 – 6 (Primary and secondary production, battery production, production of lead articles, foundries, production of lead compounds and frits) median values range from 12 - 15.4 µg/100ml, indicating that about half of the exposed workers in

[16] Eurobat, 2020: EUROBAT_Battery_Innovation_Roadmap_2030_White_Paper.pdf

[17] Renovation wave, 2021: https://ec.europa.eu/energy/topics/energy-efficiency/energy-efficient-buildings/renovation-wave_en (accessed 28. June 2021).

these sectors are exposed at or below the BLV that the RAC has proposed (15 µg/100ml). P90/P95 values range from 27 – 34.7 µg/100 ml and are thus well below the current EU BLV of 70 µg/100 ml. In copper production (sector 15) lead occurs as a by-product and processes are similar the sector 1. Exposure levels in copper production corresponds to the levels observed in the main lead sectors.

For most of the exposed workers in sector 7 – 14, lead exposure occurs more occasionally and/or at lower airborne concentration levels. Median levels range between 4.4 - 12 µg/100 ml and P95 between 10 – 24.1 µg/100 ml.

The summarised exposure data (Table 4-47) are taken forward in the disease burden calculations (sections 4.16 and 4.17) and the impact assessment.

Table 4-47 Blood lead levels per sector (µg/100 ml)

Sector	Mean (AM)	Median	P90	P95	Source
1. Primary lead production	14.2	12.0	27.0	-	Lead REACH Consortium, 2019
2. Secondary lead production (including lead battery recycling)	16.0	14.0	28.0	-	Lead REACH Consortium, 2019
3. Lead battery production	14	12	29	-	Lead REACH Consortium, 2019
4. Production of articles of lead metal	12.9	12.9	28.6	-	Estimated from Lead REACH Consortium, 2019; FIOH 2017
5. Foundries	17.3	15.4	-	34.7	Estimated from survey data, Julander et al. 2020; FIOH 2017
6. Production of lead compounds and lead frits	16	14	28	-	Lead REACH Consortium, 2019
7. Production of glass	11	12	24	-	Lead REACH Consortium, 2019
8. Ceramic ware production and enamelling	13	12	14	-	Lead REACH Consortium, 2019
9. Manufacture and use of plastics and paints	7.4	5.4	-	18.4	Estimated from HSE 2019; FIOH 2017
10. Work with lead metal	9.6	8.3	-	24.1	Estimated from Javelaud et al. (2004) as cited in LDAI, 2008; HSE 2019; FIOH 2017
11. Shooting	5.7	4.4	-	12.4	Estimated from FIOH 2017
12. Recycling of PVC and other plastics	4.4	3.7	8.8	10.0	Fruijtier-Pölloth, 2016
13. Demolition, repairing and scrap industry	9.8	7.2	-	23.6	Estimated from FIOH 2017; HSE 2019; Iarmarcovai, 2005; Guth et al. 2020
14. Other waste management	6.8	6.5	-	12.7	Estimated from FIOH, 2017; Mauriello et al.., 2017; HSE, 2019
15. Other – copper production	14.9	13.1	-	32.9	FIOH, 2017

4.7 Exposed workforce

4.7.1 Published sources

A number of sources provide data on occupational exposure to lead and lead compounds. In order to focus the study on sectors that continue to be relevant and have a potential for significant exposure, this report gives preference to more recent reports that also provide data on the extent of exposure.

4.7.1.1 CAREX Europe

The CAREX (CARcinogen EXposure) data for Europe show an exposed workforce of about 1.45 million workers distributed in 41 different sectors (CAREX, 1999). The table below shows the number of workers exposed to lead and inorganic lead compounds in 1991-1993 (EU15), supplemented with data from 1997 for four additional Member States (Estonia, Czech Republic, Latvia and Lithuania).

The industries with the largest number of exposed workers are: manufacturing fabricated metal products, manufacturing machinery except electrical equipment, construction, and personal and household services (Table 4-48). For some sectors, the data are difficult to interpret as it is unclear how workers within the sectors could be exposed to lead.

Table 4-48 CAREX estimate of workers in the EU exposed to lead and inorganic lead compounds 1993/1997. For countries where data from 1993 were unavailable, data from 1997 were used instead. (CAREX, 1999)

Industry	No. of workers
Personal and household services	328,538
Construction	180,012
Manufacture of machinery except electrical	117,397
Manufacture of fabricated metal products	113,660
Manufacture of transport equipment	84,315
Wholesale and retail trade and restaurants and hotels	73,448
Iron and steel basic industries	66,497
Communication	47,911
Manufacture of electrical machinery, apparatus, appliances	47,485
Manufacture of pottery, china and earthenware	45,274
Manufacture of plastic products not elsewhere classified	43,993
Non-ferrous metal basic industries	25,864
Manufacture of industrial chemicals	24,275
Sanitary and similar services	24,257
Electricity, gas and steam	21,522
Manufacture of glass and glass products	21,385

Industry	No. of workers
Manufacture of instruments, photographic and optical	20,029
Manufacture of other non-metallic mineral products	16,492
Water works and supply	15,855
Manufacture of other chemical products	14,719
Public Administration and Defence	13,573
Air transport	13,451
Land transport	10,779
Services allied to transport	10,763
Other manufacturing industries	9,970
Printing, publishing and allied industries	9,586
Water transport	9,291
Manufacture of rubber products	8,170
Crude Petroleum and Natural Gas Production	5,290
Manufacture of wood and wood and cork products	5,085
Manufacture of wearing apparel, except footwear	4,958
Metal Ore Mining	3,479
Food manufacturing	2,828
Manufacture of paper and paper products	2,562
Manufacture of miscellaneous products of petroleum and	1,852
Petroleum refineries	1,820
Manufacture of textiles	1,672
Medical, dental, other health and veterinary services	1,244
Beverage industries	423
Manufacture of leather and products of leather	327
Tobacco manufacture	90
Total	1,450,141

4.7.1.2 CAREX Canada

CAREX Canada (2019) (data last modified in 2019) estimates the number of exposed workers in Canada at 277,000 making up 1% of the Canadian population. About 90% of the exposed workers are male. The CAREX Canada data lists the 12 most significant sectors as shown below (Table 4-49). According to Carex Canada, the largest industrial group of lead-exposed workers is public administration, which includes police officers who are exposed to lead via use of ammunition. Other large occupational groups (especially for men) are car mechanics, plumbers and pipefitters. Additional occupations that are exposed include workers involved in mining, lead smelting and refining industries, battery production or recycling, steel welding or cutting operations, construction, rubber products and plastics industries, printing industries, and firing ranges. It is, however, difficult to make a clear fit between these occupations and the sectors shown in Table 4-49.

The table below shows the number of workers exposed by industry group and level of exposure to lead. These results highlight industries with the highest number of workers, as well as industries with the highest levels of exposure. Data for those industries with at least 4,000 workers exposed are shown. The exposure levels are indicated as low, moderate and high as described in the note to the table. Of the 218,900 workers in the main sectors, 25% are indicated with high exposure (20% or more samples have a value higher than 0.05 mg/m^3).

Based on a population of 448 million people in the EU, the corresponding figures of total exposed would be 3,3 million, if a similar per-capita ratio is assumed.

*Table 4-49 CAREX Canada estimates of number of workers exposed to lead in Canada (CAREX CANADA, 2019)**

Sector	Total numbers of exposed workers	Indicated exposure level		
		Low	Moderate	High
Public administration	41,000	16,000		25,000
Repair and maintenance	39,700	2,700	17,000	20,000
Specialty trade contractors	36,800	28,000	7,900	900
Fabricated metal product manufacturing	23,800	9,000	14,000	800
Transportation equipment manufacturing	19,200	4,100	12,000	3,100
Machinery manufacturing	11,300	11,000	200	100
Primary metal manufacturing	10,600	1,800	5,800	3,000
Educational services	9,500	1,100	5,800	2,600
Construction of buildings	9,300	5,400	3,900	
Motor vehicle parts dealers	8,300	1,500	6,800	
Heavy and civil engineering construction	5,300		5,300	

Sector	Total numbers of exposed workers	Indicated exposure level		
		Low	Moderate	High
Plastics and rubber products manufacturing	4,100	2,600	1,500	
Total, included sectors	**218,900**	**83,200**	**80,200**	**55,500**
Total all sectors	**277,000**			

** Indication of exposure levels (citation from CAREX Canada):*

***Low**: A group of workers (people in the same job category and industry) is put in this exposure category for one of two reasons: There are no valid measurements, but a hygienist identified this group as typically exposed during literature and other reviews; There are valid exposure measurements in the CWED (Canadian Workplace Exposure Database) and a hygienist review determined that exposure is plausible; AND EITHER: There are less than 10 samples available in the CWED, OR there are ≥10 measurements available but they do not meet the criteria for Moderate Exposure.*

***Moderate**: A group of workers is put in this exposure category if: There are at least 25 individual samples in the CWED, AND 20% or more samples have a value higher than 0.025 mg/m^3 (which is half the current occupational exposure limit for lead). OR there are at least 10, but less than 25, individual samples in the CWED, AND 20% or more samples have a value higher than 0.05 mg/m^3 (which is the current occupational exposure limit for lead).*

***High**: A group of workers is put in this exposure category if: There are at least 25 individual samples in the CWED, AND 20% or more samples have a value higher than 0.05 mg/m^3 (which is the current occupational exposure limit for lead).*

4.7.1.3 Finland

According to the Finnish Biological monitoring – annual statistics 2012, 4,500 workers are exposed to lead in Finland (Kiilunen, 2012). A breakdown by sector is not identified. The Finnish ASA register does not hold data on lead, as the ASA register includes only carcinogenic substances.

4.7.1.4 French SUMER database

The Medical Monitoring Survey of Professional Risks (Surveillance médicale des expositions aux risques professionnels, SUMER, provide extrapolations from a sample of workers who self-declare exposure in a survey administered by company medical officers during the workers' regular compulsory medical examination (Eurofound, 2013). For example, the data reported by an earlier SUMER survey for 2003 were extrapolated from a sample of 379 workers who declared that they may have been exposed to lead and its compounds (IVS, 2017).

The total estimate of exposed workers has nearly doubled (from ca. 115,000 to 202,000 workers) between the surveys in 2010 and 2016/17 (Table 4-50). This is partly due to the inclusion of new sector categories (Table 4-51) but does also reflect the uncertainty related to the estimate. Most notably, the sector category "Public administration" contributes with 70,700 exposed workers as the main contributing sector. In the listing of exposed by occupation "Army, police, firefighters" contribute with the largest group of exposed with 59,900 exposed (data not shown here).

A distinction between female and male workers is available for the total of exposed workers; 17,100 women, corresponding to 8.5% of the total workforce.

Table 4-50 Workers exposed to lead and its compounds in the SUMER survey, 2010 (Vinck and Emmi, 2015) and 2016/17 (Matinet et al., 2020)

	SUMER survey, 2010*	SUMER survey, 2016/17*
Total no. of workers (% of the workforce)	115,300 (0.5%)	202,300 (0,8%)
Duration of exposure (hours per week)	No indication: 5,600 (4.8%) <2h 65,700 (57%) 2-10h 22,000 (19.1%) 10-20h 7,300 (6.4%) >20h 14,700 (12.7%)	No indication: 71,200 (35%) <2h 71,200 (40%) 2-10h 29,400 (14.5%) 10-20h 4,600 (2.3%) >20h 16500 (8.2%)
Extent of exposure	Not declared: 17,300 (15%) Very low: 67,900 (58.9%) Low: 22,600 (19.6%) High: 5,300 (4.6%) Very high: N/A	Not declared: 95,300 (47.1%) Very low: 65,200 (32.2%) Low: 33,400 (16.5%) High: 5,200 (2.6%) Very high: 3,100 (1.5%)

* *Note: Low exposure: less than 50% of OEL, High exposure: >50% of OEL, Very high exposure: may exceed OEL.*

Table 4-51 Workers exposed to lead and its compounds by sector in the SUMER survey, 2010 (Vinck and Emmi, 2015) and 2016/17 (Matinet et al. 2020)

Sector	Number of exposed 2010	Percent of workforce exposed in sector 2016/17	Number of exposed 2016/17	Percent of workforce exposed in sector 2016/17
Manufacture of IT-equipment, electronics and optical products.	5,400	3.1	6,200	6.4
Manufacture of transport equipment	16,100	3.0	-	-
Production and distribution of water; sanitation, waste management and remediation.	4,300	2.6	3,800	2.6
Manufacture of rubber and plastic products and other non-metallic mineral products	7,200	2.1	-	-
Construction	27,200	1.8	32,500	2.4
Electrical equipment manufacturing	2,600	1.8	4 900	6.4
Metallurgy and manufacture of metal products except machinery and equipment	6,200	1.7	-	-
Scientific research and development	2,300	1.2	-	-

Sector	Number of exposed 2010	Percent of workforce exposed in sector 2016/17	Number of exposed 2016/17	Percent of work-force exposed in sector 2016/17
Other manufacturing industries; repair and installation of machinery and equipment	3,500	1.1	6,500	2.2
Public administration	-	-	70,700	2.5
Production and distribution of electricity, gas, steam and air conditioning	-	-	4,500	1.6
Woodworking, paper industries and printing	-	-	6,800	2.9
Education	-	-	13,100	1.0
Administrative and support service activities	-	-	11,000	0.5
Legal, accounting, management, architectural, engineering, control and technical analysis activities	-	-	11,000	0.9

It should be noted that the SUMER estimates are based on self-declaration and encompass a large number of workers that are exposed to low concentrations for short periods of time (in the 2010 dataset, the majority of workers are exposed to "very low" concentrations for less than two hours per week). As noted in the explanatory note for the SUMER 2003 survey, the respondents were considered exposed as soon as the agent was present at the workplace, regardless of the duration and intensity of exposure. As a result, workers in the SUMER dataset should be treated as "potentially exposed" rather than exposed to specific concentrations, in particular since the exposure levels are extrapolated from a limited set of self-estimated values.

In addition, the SUMER data consider all lead compounds and sectors that may have since reduced or eliminated exposure to lead.

4.7.1.5 Romania

A dataset on occupational exposure concentrations and numbers of exposed workers by sector and year in Romania was obtained as part of the stakeholder consultation (CNMRMC, 2019, 2021). The same dataset has recently been published by Negru et al. (2020.). The data on the number of exposed workers are shown in the table below. The data were collected along with airborne and blood lead concentrations from the regional public health authorities in Romania for this study. They are not routinely collected as part of the national surveillance programmes or scientific studies. Therefore, they may not capture the full picture of occupational lead exposure in Romania. For most sectors, data are available for only a few years and a total of 1,670 workers is estimated from the average by sector for those years where data are available. The main sectors in terms of number of workers are manufacturing batteries, producing electric and electronic components and metalworking. The data indicates a stable number of exposed workers in each sector. According to Negru (2020), the general trend in many sectors is to replace the lead alloys with others without or with low lead content.

Table 4-52 Number of workers exposed to lead in Romania (Negru et al., 2020)

Sector	2012	2013	2014	2015	2016	2017	2018	2019	Average *	Average extrapolated to EU-27
Production of lead	-	-	-	-	-	-	-	-	58	1,337
Manufacture of batteries	-	-	371	932	637	616	614	-	634	14,620
Recovery of lead from waste batteries	75	73	73	68	73	78	77	77	74	1,706
Production of electric and electronic components	565	564	551	549	571	564	533	529	553	12,752
Manufacture of thermal ceramic products (terracotta)	31	31	31	41	26	26	26	-	30	692
Production and sale of dyes and additives for plastics	38	-	18	96	-	-	-	-	51	1,176
Metalwork	-	-	-	-	-	150	-	-	150	3,459
Geochemical analysis laboratory	-	23	-	-	-	-	-	-	23	530
Manufacture of articles of metal wire	-	-	97	97	97	97	97	97	97	2,237
Total	709	691	1141	1783	1404	1531	1347	703	**1,670**	**38,509**

** Average for those years where data are available, calculated as part of this study.*

4.7.1.6 UK HSE data

Data on workers subject to medical surveillance of blood-lead levels are provided for the UK by the Health and Safety Executive (HSE). The data include workers with "significant" (HSE, 2019) lead exposures, where employers have decided that they should be under medical surveillance. The data provided by UK HSE for 2017/18 are reproduced in the following table.

Notably, when the HSE UK data are compared with the CAREX data from Canada (section 4.7.1.2), policemen, being estimated as the largest group of exposed workers in Canada, are not included in the UK dataset.

Table 4-53 Exposed workforce under medical surveillance in the UK in 2017/18 (HSE, 2019)

Sector	Sector No *	Men	Women	Fraction of women of total	All	Total EU-27 if extrapolated
Smelting, refining, alloy-ing and casting	1, 5	745	44	5.6%	789	5,289
Lead battery manufacture	3	803	20	2.4%	823	5,514
Lead battery recycling	2	394	5	1.3%	399	2,675
Badge and jewellery enamelling and other vit-reous enamelling	7	5	-	-	5	35
Glass making (including cutting and etching)	7	125	13	9.4%	138	929
Glass recycling (including TV and monitors)	14	167	1	0.6%	168	1,129
Manufacture of pigments and colours	6	19	-	-	19	130
Potteries, glazers and transfers	8	3	-	-	3	17
Manufacture of inorganic or organic lead com-pounds (including lead salts, fatty acids)	6	53	4	7.0%	57	382
Shipbuilding, repairing and breaking	4, 12	60	-	-	60	399
Demolition industry	12	246	-	-	246	1,650
Painting of buildings and vehicles	9	207	-	-	207	1,389
Paint removal	12	425	7	1.6%	432	2,900
Work with lead metal and lead containing alloys	10	663	39	5.6%	702	4,707
Scrap industry (including pipes, flashing, cables)	12	477	13	2.7%	490	3,283
Other processes	-	526	61	10.4%	587	3,934
Total		**4,918**	**207**	4.0%	**5,125**	**34,363**

** Sector numbering with reference to the numbers used in the current study*

*** Numbers extrapolated in this study to the entire EU on a per capita basis*

4.7.2 Data from stakeholder consultation and literature

4.7.2.1 Lead REACH Consortium

The exposed workforce as reported by the Lead REACH Consortium is summarised below. A survey of blood-lead levels is carried out by the Lead REACH Consortium every four years or thereabouts. If they produce or use lead, companies report data on individual blood-lead measurements per worker. Although these data are for individual measurements, they provide estimates of the numbers of workers under medical surveillance; it is estimated that, on average, each worker provides four samples for each survey.

The data indicate the number of workers represented by the survey and are not extrapolated to the entire EU. According to the Lead REACH Consortium (2019), the data for the lead battery, primary and secondary lead production probably covers almost all companies in the EU. For the other sectors, it is more uncertain what proportion of the total exposed workforce within the sectors are represented by the survey. Therefore, the total number of exposed workers within the sectors in the EU is an underestimate.

The Lead REACH Consortium does not hold any data on occupations like demolition, remediation, and construction.

Table 4-54 Exposed workforce under medical surveillance represented by Lead REACH Consortium 2015-18 survey (Lead REACH Consortium, 2019, 2021)

Sector	Total[b]	Male workers[b]		Female workers[b]		
		All male workers [d]	Fraction of male workers	All female workers	Female workers of reproductive age	Fraction of female workers of reproductive age of total
Primary lead production	2,165	2,095	96.8%	70	50	2.3%
Secondary lead production	2,620	2,500	95.4%	120	90	3.4%
Lead battery production[a]	11,000	10,580	96.2%	420	220	2.0%
Lead sheet production[a]	400	385	96.3%	15	<10	<2.5%
Lead oxide and stabiliser production[a]	300	285	95.0%	15	<10	<3.3%
Lead crystal glass production[a]	500	380	76.0%	120	60	12.0%
Ceramic ware production[a]	200	185	92.5%	15	<15	<7.5%
Ammunition production[ac]	750	no data	no data	no data	no data	
Total reported[b]	**17,935**	**16,410**	**90%**	**775**	**<455**	**<2.5%**

a: Specific data for the UK were not available, therefore UK companies contribute to the estimate.

b: Totals may not equal the sum due to rounding. Female workers of reproductive age are defined as being <46 years.

c: Estimate from the 2013-16 survey, as data from the 2015-18 survey were not available.

d: Figure calculated by subtracting no. of female workers from total no.

The total number of workers in the companies is not reported in the Lead REACH Consortium survey, but data are available for 1998-2001 from the Voluntary Risk Assessment Report (VRAR) for lead as shown in the table below. The percentage of workers under medical surveillance ranged from 25% in lead crystal glass production to 76% in lead battery production. The low percentage in lead crystal production probably reflects that in many companies only some production lines process leaded glass. The total for all sectors was approximately 16,000 under medical surveillance. The total number under surveillance corresponded to 80% of the total workers in the production. The total number in the 2013/16 survey is slightly higher than that for the 1998-2001 survey, but the difference may be due to higher coverage in the 2013/16 survey (exact coverage not reported).

Table 4-55 Exposed workforce under medical surveillance represented by Lead REACH Consortium 2013-16 survey and the VRAR for lead (LDAI, 2008)

Sector	2013/16 survey	Data for 1998-2001 from the VRAR (LDAI, 2008)				
		Total no. of empl.	Medical surv.	% under medical surv. of total	Workers in the produc-tion	Coverage of survey in VRAR
Primary lead production	2,500	2,971	879	30%	799	78%
Secondary lead production	3,000	5,644	2,571	46%	2,344	17 of 28 sites
Lead battery production	11,000	11,436	8,646	76%	8,435	21 of 50 sites
Lead sheet production	350	947	403	43%	625	7 of 13 sites
Lead oxide and stabiliser production	350	1,663	716	43%	810	Lead oxide and stabi-liser prod. only
Lead crystal glass produc-tion	250	10,813	2,741	25%	6,890	86% of pro-duction vol-ume
Ceramic ware production	350	no data	no data	-	no data	-
Ammunition production	750	no data	no data	-	no data	-
Total reported	18,550	33,474	15,956	48%	19,903	-

4.7.2.2 Other stakeholders and literature

4. Production of articles of lead metal. The total number of workers exposed in the production of lead sheets and ammunition is, according to the Lead REACH Consortium survey 350 and 750, respectively. According to the company websites, lead sheet producers also produce many other types of lead articles such as lead plates, strips, bars, wires and tubing through a combination of rolling, drawing and extruding. The data does not include manufacture of cables with lead sheathing. The industry association EuropaCable has summarised data on exposed workforce and exposure concentration by six cable producers using lead for production of cables with leaded sheaths. The number of workers in each company involved in the melting of lead for sheathing is reported to range from 3 to 9; i.e. a total of some 25-50 workers. More workers (up to 10% of workers in a facility) may be exposed to lead when using plastic polymers with leaded pigments in two of the facilities. These are considered to be included under production and use of pigments. In 2015, the total annual consumption of lead metal for production of cables was about a fifth of the consumption of lead for sheet production (Table 4-7). As the processes involved are similar, the number of workers exposed by the production of cables is roughly estimated at about 70. According to Europacable, the total number of employees in the cable production sector in the EU is 30,000, i.e. a small percentage of all workers are exposed to lead.

Historically, a number of smaller companies have been involved in the production of fishing sinkers, balance weight and other small lead articles. Based on information from industry, many small lead foundries have closed, and fishing sinkers and small lead articles are to a large extent imported from countries outside the EU.

Based on the available data, the number of exposed workers in the EU due to the production of lead metal articles is estimated to be in the range 1,200 - 2,000.

6. Production of lead compounds and lead frits*. The total number of workers employed by companies producing lead compounds and lead frits covered by the Lead Consortium survey is 350. This number primarily concerns the production of lead oxides and stabilisers. Lead oxides account for by far the major part of the total volume of lead used to produce lead compounds in the EU as shown in*

Table 4-8. If the total number of exposed workforce from the UK from manufacture of lead compounds including lead salts and fatty acids are extrapolated to the entire EU, the total would be around 440 while the total exposed in the manufacture of pigments and colours would be 150. The number of workers in the UK exposed by manufacture of lead compounds decreased from 659 in 2009/10, 325 in 2016/17 and to 53 in 2017/18 reflecting the phasing out of lead stabiliser in PVC. Similarly, the total number of workers in Romania exposed by “Production and sale of dyes and additives for plastics” was 96 in 2015 but zero for the period 2016-2019. On the basis of the available data, the exposed workforce in the EU is estimated to be in the range of 500 - 1,000.

5. Foundries. According to stakeholder response from the European Foundry Association (CAEF), lead is an essential constituent of several non-ferrous metal alloys like aluminium, copper or zinc alloys. In the foundry industry, it is used to produce a broad variety of castings mainly made of copper and aluminium alloys. In Europe (mainly in Germany, Italy, France, Portugal and Poland), a large number of non-ferrous-metal foundries process lead-containing copper and aluminium alloys for the following applications:

- taps and fittings for water, gas and sanitary installations
- sliding materials (bearing bushes and shells)
- structural material for certain purposes, e.g. ship propellers, water turbines and pumps
- electrical conductors, switches and power supply lines.

According to Eurostat’s Structural Business Statistics, the total number of workers employed in casting of other non-ferrous metals (NACE code C24.54) is 23,044 in 1,357 companies. The total number of workers employed in the casting of light metals (NACE code C24.53) is 96,182 in a total of 1,600 companies in the EU in 2018 (EU-27, 2020).

According to CAEF (2021), approx. 80% of copper foundries are processing lead containing alloys with > 0.1 % lead. Using this fraction with the number of persons employed with the Eurostat data for "Casting of other non-ferrous metals" (23,044), CAEF regards it reasonable to speak about approx. 18.000 employees.

Regarding "Casting of light metals", being the relevant code for aluminium casting, reliable figures are not available, but CAEF sees a clear tendency towards „lead-free“ alloys in this sector. Therefore, 5% share of affected employees (out of 96,182) can be assumed.

In total, this amounts to appr. 23,000 workers potentially exposed to lead within the foundry sector.

Questionnaire responses (of the previous OEL study) have been obtained from 7 non-ferrous foundries using lead alloys. The total number of exposed workers in these 7 foundries are 241 corresponding to on average 34 per company. The data reported does not enable an estimate of the percentage of the total workers in these foundries as most companies only reported the total number of exposed workers but not the total number of workers.

The estimate of appr. 23,000 exposed workers is being taken forward in the assessment.

7. Glass production. The total number of workers exposed by glass production in the Lead REACH Consortium survey is reported at 500. The VRAR for lead (LDAI, 2008) indicates the total number of workers in the glass industry under surveillance at about 3,000 (taking the coverage of the survey into account). According to the BAT (Best Available Technique) Reference Document for manufacture of glass (BREF, 2013), there are many smaller companies, which often specialise in higher value-added products (lead crystal). According to the Lead REACH Consortium, the lead crystal production in the EU has declined steeply as many factories have switched from producing leaded crystal to a lead-free crystalline glass. As mentioned elsewhere, France, Germany, Ireland, the Czech Republic and Slovakia have some lead glass production remaining. Extrapolated on the basis of data from the UK shown above, the total in the EU would be some 1,070 workers (although there are no indications that the UK has any remaining production of lead glass).

According to Eurostat, 296,668 workers are employed in 14,119 enterprises within the activity "C231 - Manufacture of glass and glass products", corresponding to 21 employed per company. Only a minor fraction of the companies is working with leaded glass and only a fraction of the employed in such companies may be exposed.

On basis of the available information, it is estimated that the number of workers exposed at reported exposure levels (i.e. workers under medical surveillance) is in the range of 900 - 1,500.

8. Ceramic ware production and enamelling. The total number of workers exposed by production of glazes and ceramic ware in the Lead REACH Consortium survey is 200. The VRAR for lead did not include estimates for number of workers exposed in this sector. According to Eurostat (Table 4-80), the total number of employed within production of ceramic tiles and flags (C2331) and porcelain (C234) in the EU is appr. 160,000 but only a minor fraction is likely to be using leaded glazing. In Austria, artisan craftwork within ceramics including glazing has historically been widespread and has been a working area with many women among in the workforce. However, the activity within is sector has been declining during the past decades and today approximately 100 workers are estimated to work with glazing of ceramics (AUVA, 2021). Extrapolated to the EU, this estimate would result to about 5,000 workers. The total number of workers in Romania under surveillance only in this sector is 30, which extrapolated to the EU would be about 700. There are no Romanian companies in the Lead REACH Consortium survey. On this basis, the number of exposed workers at the reported levels is estimated to be in the range of 1,000 - 5,000.

9. Manufacture and use of plastics and paints. The majority of the lead pigments historically used in paints and plastics are now restricted under REACH. However, some lead chromates and lead oxides are still used. Occupational exposure due to manufacturing and use of plastics and paints with lead pigments takes place in a number of processes as described in 4.6.2.9. The applications of the two main lead chromate pigments currently used are described in the applications for authorisation of the pigments. However, the public part of the authorisation documents does not include information on number of companies applying the pigments or the number of workers exposed due to the production of paints and plastics, and application of the paints.

According to CEPE (2021), lead pigments for use in paints are not manufactured in the EU but imported from Canada. All bigger coatings manufacturers have stopped using lead pigments before the sunset date in May. Some smaller companies continued to use the pigments, since there was an authorization. The number of companies still using the pigments in paints is expected to be low and the number of workers being exposed to such pigments is also low. The use of for restoration of historical building and vintage cars is estimated to be extremely low. By May 2022, all authorizations for the remaining uses will have expired and from then the use of lead containing paints is forbidden by REACH (CEPE, 2021). By reviewing available data from Eurostat and estimating proportions of exposed companies and worker, the figure of 150 workers exposed due to the manufacture of paint was regarded as not unrealistic.

The number of workers exposed by painting buildings and vehicles in the UK in 2017/18 was 207, which extrapolated to the EU-27 is approximately 1,400. In other datasets, painting of building may be included in aggregated groups such as “Construction” and “Manufacture of transport equipment”.

The extrapolation from the Romanian estimate on total exposed workers within "Production and sale of dyes and additives for plastics" (51) results in appr. 1,200 workers in EU-27.

CAREX Canada indicates the number exposed by “Plastics and rubber products manufacturing”, but all at low or moderate exposure levels. It is not clear if these numbers still include workers exposed by production of PVC with lead stabilisers. According to the VRAR for lead, in 1998-2006 163 workers out of a total of 2,853 workers involved in PVC converting were under medical surveillance (data represented about 80% of the EU total). At that time, large quantities of lead-based PVC stabilisers were used in the conversion of PVC articles. Only small quantities of lead pigments are now used in the manufacture of plastics and rubbers, and the number of workers exposed during the conversion of plastics (not PVC) is considered small. As a basis for estimating the number exposed at the reported concentrations, the data from Romania and the United Kingdom are considered the most applicable, because there is a direct link between the reported concentrations and the number of workers.

On this basis, it is estimated that 1,000 - 2,000 workers are exposed due to the production and use of paints and plastics.

10. Work with lead metal. Many workers may potentially be exposed by working with lead metal, for example, soldering or constructing buildings and industrial installations using lead sheets, profiles and tubes. Many of the workers may only be exposed occasionally: the exposure levels depend on the actual time the workers use lead. The total number extrapolated from United Kingdom to the entire EU for the category “Work with lead metal and lead containing alloys” is about 4,700. In Romania, on average 553 workers were exposed in recent years by “production of electric and electronic components” and for one year a total number involved in “metalwork” is reported at 150. Extrapolated to the entire EU, this would be approximately 13,000. In France, the SUMER database indicates the number of exposed workers by “manufacture of IT-equipment, electronics and optical products” at 5,400 in 2010 (corresponding to 37,000 in EU-27). With the changing of the scope of the RoHS Directive, the use of lead solders has decreased significantly in recent years. Given that lead solders have been phased out for the production of nearly all electric and electrical equipment in the EU, the French and the Romanian estimate cannot be used for the entire EU. As basis for estimating the number exposed at the reported concentrations, the data from the United Kingdom are considered the most applicable because there is a direct link between the reported concentrations and the number of workers. However, considering the high numbers reported from other Member States, it is estimated that the total based on the data from the United Kingdom would be in the low end of the range. On this basis, the total number of workers exposed by work with lead metal is estimated at 5,000 - 20,000.

11. Shooting. As discussed in section 4.5, data from CAREX Canada indicates that policemen are the largest group of exposed workers in Canada. The surveys from the UK and Romania do not include specific data on exposure of policemen or firearm instructors (they may be included in ”other” in the survey from the United Kingdom).

Exposure can occur at different types of shooting ranges; shooting ranges for leisure shooting, for military and police training, shooting ranges for testing of ammunition or weapons in connection to ammunition and/or weapon manufacturers and shops.

A Danish investigation from 2012 concluded that a large proportion of Danish recreational indoor shooters had potentially harmful blood lead concentrations (Grandahl et al., 2012). The concentrations were related to the number of shots and frequency of stays at the shooting range, amongst other factors. No data on the total number of workers occupationally exposed by shooting exist. A recent review of lead exposure at firing ranges states that an estimated 1 million law enforcement officers train at indoor firing ranges in the USA, while the number of citizens that practice target shooting as a leisure activity is much higher (Laidlaw et al., 2017). Leisure shooting occurs more often at outdoor shooting ranges. Data on distribution on indoor vs. outdoor shooting ranges could not be identified.

According to CAREX Europe, there are 13,573 exposed within Public Administration and Defence. According to Eurostat, there are 3,240 police officers per one million people in the EU in 2016/1[18] corresponding to 1.6 million officers in the EU.

Vandebroek et al. (2019) studied lead exposure in 35 exposed from seven shooting ranges in Belgium and demonstrated that mean values for blood-lead were markedly higher in instructors (11.7 µg/100 ml) compared to maintenance/cleaning staff (5.7 µg/100 ml), Special Forces (3.9 µg/100 ml), and police officers (1.4 µg/100 ml). It is assumed that police officers are usually not exposed at the reported levels. According to discussions with the Austrian Employers' insurance association (AUVA), the exposure of trainees at shooting ranges is not significant in contrast to instructors' exposure. The worst-case exposure at shooting ranges may exist for cleaners, as ventilation typically is turned off and dust may raise during cleaning (AUVA, 2021).

According to the available information from stakeholders and literature, instructors and cleaning personnel are considered to be the working groups at shooting ranges with relevant exposure levels and these groups will be taken forward in the assessment.

Consultation with the national experts in this study and public available literature resulted in the following figures on the number of shooting ranges in the EU; 80 shooting ranges in Belgium used by military and police; 74 military firing ranges in Sweden, 89 location shooting ranges for hand gun training of the German Federal Armed Forces (figures for other types of training could not be identified). Apart from military and police training ranges, a large number of (usually smaller) shooting ranges used by hunters and for leisure occurs. These shooting ranges are typically not operated by employed persons and have therefore been omitted from the assessment. Based on the available information, it is estimated that there are between 3,000 and 5,000 shooting ranges in the EU-27, resulting in 12,000 – 20,000 occupationally exposed (assuming 4 exposed employees per shooting range).

12. PVC recycling. Tauw (2013) reports that 130 companies are registered with the PVC recycling organisation Recovinyl. The total number of employees is not reported but on the basis of data from 7 major recycling companies, the number of employees per tonne of recycled PVC was estimated at 0.0022 employees per tonne. With recycling of post-consumer PVC amounting to 500,000 t/year (VinylPlus, 2017), the total number of employees would be 1,100. Data for virgin PVC production presented in the VRAR (LDAI, 2008) indicates that only 6% of the employees were under medical surveillance. This implies that less than hundred workers are exposed at a significant level by the recycling of PVC. However, the data presented from a survey of 12 recycling companies in section 4.4.2.12 include blood-lead level data for 127 employees or an average of 10 employees per company. The industry association VinylPlus (2017) indicated that the number of PVC recycling companies is about 100; slightly below the number indicated by Tauw. Based on the available information, it is estimated that the reported concentrations (i.e. workers under medical surveillance) represent 300 – 1,000 exposed workers.

13. Demolition, repairing and scrap industry. The total number of workers exposed to lead during demolition, repairing, scrap collecting, and similar processes is high. The number of workers exposed by construction in France is 27,200 (SUMER database) while in Canada 14,600 are reported as potentially exposed but not at high level. The total reported in the CAREX EU database in the 1990's was 180,000. Construction includes both constructing buildings and infrastructure, and renovation and demolition. Many workers will only

[18] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Police,_court_and_prison_personnel_statistics

occasionally be exposed and at variable concentrations, depending on the specific lead content of the materials handled.

The number of employed listed under the relevant economic activities in the Eurostat database amounts to ca. two million (Table 4-80). However, only a fraction of the workers within these activities will be exposed to lead and many will only be exposed occasionally. Both situations with known exposure (and adequate controls) and no awareness of exposure do occur. In discussions with stakeholders (from EFBWW, FIEC and affiliates, 2021) the Eurostat data was recognized to be difficult to interpret.

The total extrapolated from the United Kingdom to the EU is about 8,000 for the sectors: shipbuilding, repair, demolition industry, paint removal, and scrap industry. Besides these, some activities could be included under “other”. As basis for estimating the number exposed at the reported concentrations, the data from the United Kingdom are considered the most applicable because there is a direct link between the reported concentrations and the number of workers. However, not all activities are included and the number may consequently be higher.

On this basis, the total number of exposed workers at the exposure levels reported from the United Kingdom (i.e. workers under medical surveillance) is estimated at 10,000 - 25,000. Besides these, a large number of workers may be exposed occasionally and potentially at lower exposure levels.

14. Other waste management

Exposure to lead may occur in waste management, e.g. incineration of waste, and remediation of contaminated sites. Limited data are available on number of workers exposed in waste management activities. The BREF (Best available techniques reference document) document for waste incineration (2019) lists ca. 560 waste incineration plants in EU-27 (including municipal, hazardous and sewage sludge incineration plants). Many processes related to waste incineration are automated or closed processes. Exposure to lead may occur during manual sorting of larger items from bottom ash or handling/treatment of fly ashes, slags and or flue-gas cleaning residues.

Data are available for glass recycling in the United Kingdom. Extrapolated to the entire EU the total number would be about 1,100.

According to Eurostat data, about 230,000 persons are employed within treatment of waste and remediation activities (Table 4-80). Only a minor fraction is expected to be exposed and exposure may occur occasionally and at low levels.

As a rough estimate it is assumed that 3,000-20,000 workers in the EU may have lead blood levels as reported for other waste management.

15. Other - Mining activities. No data are available on the number of workers occupationally exposed by mining. Lead is typically mined together with zinc. An indication of the potential number can be obtained by comparing to other metals. For the CMD 3 study, it was estimated that <1,100 workers were exposed to cadmium by mining of zinc ores with cadmium and 200-600 workers were exposed to arsenic from mining copper ores with arsenic. It is estimated that the number of workers exposed to lead by mining would in the same order of magnitude and total number of exposed workers is roughly estimated at 200 - 2,000.

15. Other - Production of copper. Three copper producers (with copper as main production output) are included in the Lead REACH Consortium survey under primary lead producers as these companies produce lead from ores. Other copper producers are also likely to process copper ores with lead content although the lead concentrations in the ores processed and the exposure of workers may be lower. Blood-lead level data for copper production is reported in the Finnish survey, but the copper producer in Finland is not indicated as a primary lead producer among the copper producers. It is not clear whether the source of exposure is lead in the raw materials or due to some workers using lead metal for soldering, welding or other processes described elsewhere. The most critical exposure by copper production is exposure to sulfidic fumes and arsenic, which determine the level of RPE applied. The impact assessment of arsenic under the CMD 3 project estimated the total number of workers exposed to arsenic in seven sites at approximately 1,500 which were covered by monitoring of arsenic in the work-place air. This corresponds to about 25% of the approximately 6,000 people employed in primary smelters. Workers in three sites are included under primary lead productions. It is here roughly assumed that the number of workers potentially exposed for lead is similar to the number exposed to arsenic and that half of these are included under primary lead production. This corresponds to approximately 500 - 1,000 workers.

15. Other - Manufacture of explosives. The number of workers in the company applying for authorisation for use of lead chromate for this application and three companies answering the questionnaires (consultation surveys) is between ca. 50 and 500 workers. Between 4% and 87% of the workers in the companies are exposed to lead, with the smaller companies having larger fractions of exposed (presumably because the larger companies have more production lines without lead). The Federation of European Explosives Manufacturers (FEEM) has 18 members (12 individual and 6 groups)[19]. FEEM (2021) informs that there are currently six companies (all detonators manufacturers) with approximately 510 workers potentially exposed to lead in the EU. Women represent 55% of the employed in the sector, however, it is not known if this also applies to the working areas with exposure to lead.

15. Other - Laboratories. As discussed in section 4.6.2.15, the main exposure risk in laboratories is probably due to lead in the samples (ores, waste products, leaded paint). The exposed workforce in the test laboratories of primary and secondary lead production and other sectors covered by the Lead REACH Consortium is included in the estimated workforce for each sector. For laboratories in other sectors, the exposure levels are considered low and the number of workers not further assessed.

15. Other. Extrapolated to the entire EU, the group "other" in the survey from the United Kingdom would correspond to 3,930 workers. The group may include some workers included in other sectors in the current report. It is here roughly estimated that some 1,000-5,000 workers have not been included in any of the other groups.

4.7.3 Trends in exposed workforce

4.7.3.1 Data from Finland

Data from Finland show a decreasing trend in the prevalence of workers exposed to lead in the period of 1970 to 2020. The prevalence is given in percent of employed. The increase in the prevalence from 1950 to 1970 may be explained by demographic changes in the Finnish labour force. A rise (25-31%) in the percentage of industrial workers was reported from 1950 to 1970, followed by a consecutive decrease in the year of 1990 and 2008 corresponding to increased regulation of lead (Kauppinen et al. 2013).

[19] http://www.feem.info/fr/About-FEEM/FEEM-Membership/FEEM-Members-List/

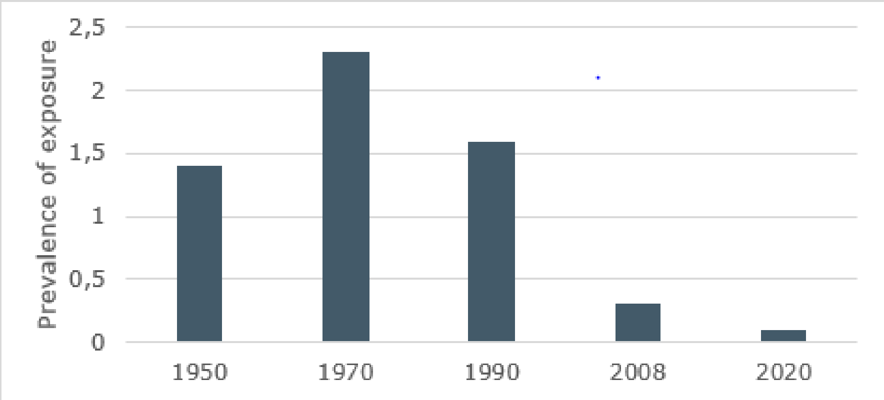


Figure 4-7 Trend in prevalence (percent of employed) of exposure to lead in Finland (data from Kauppinen et al. 2013).

4.7.3.2 Data from UK

Data from the UK show a decreasing trend of around 2.9% per annum over the past decade in the number of workers under medical surveillance, although this is a long-term trend with some years experiencing increases (HSE, 2017). This trend follows on from previous decreases dating back to the 1990s (as shown in the following figure).

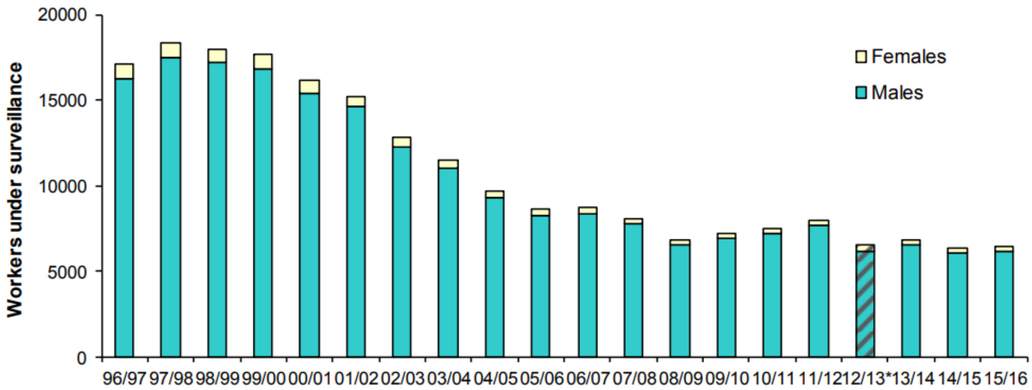


*Table 4-56 The total number of British lead workers under medical surveillance from 1996/97 to 2015/16 by sex. Note: * Data for 2012/13 include a correction for previous underestimation (HSE, 2013; HSE, 2019)*

The trend in number of male workers under medical surveillance by sector for the period 1992/93 to 2009/10 are shown in the figure below. A significant decreasing trend is seen for all sectors except the scrap industry and “shipbuilding, repairing and breaking”. For the female workers (not shown here), a similar decreasing trend is seen for the main sectors. For the other sectors, the number of female workers is low and no significant trend is seen.

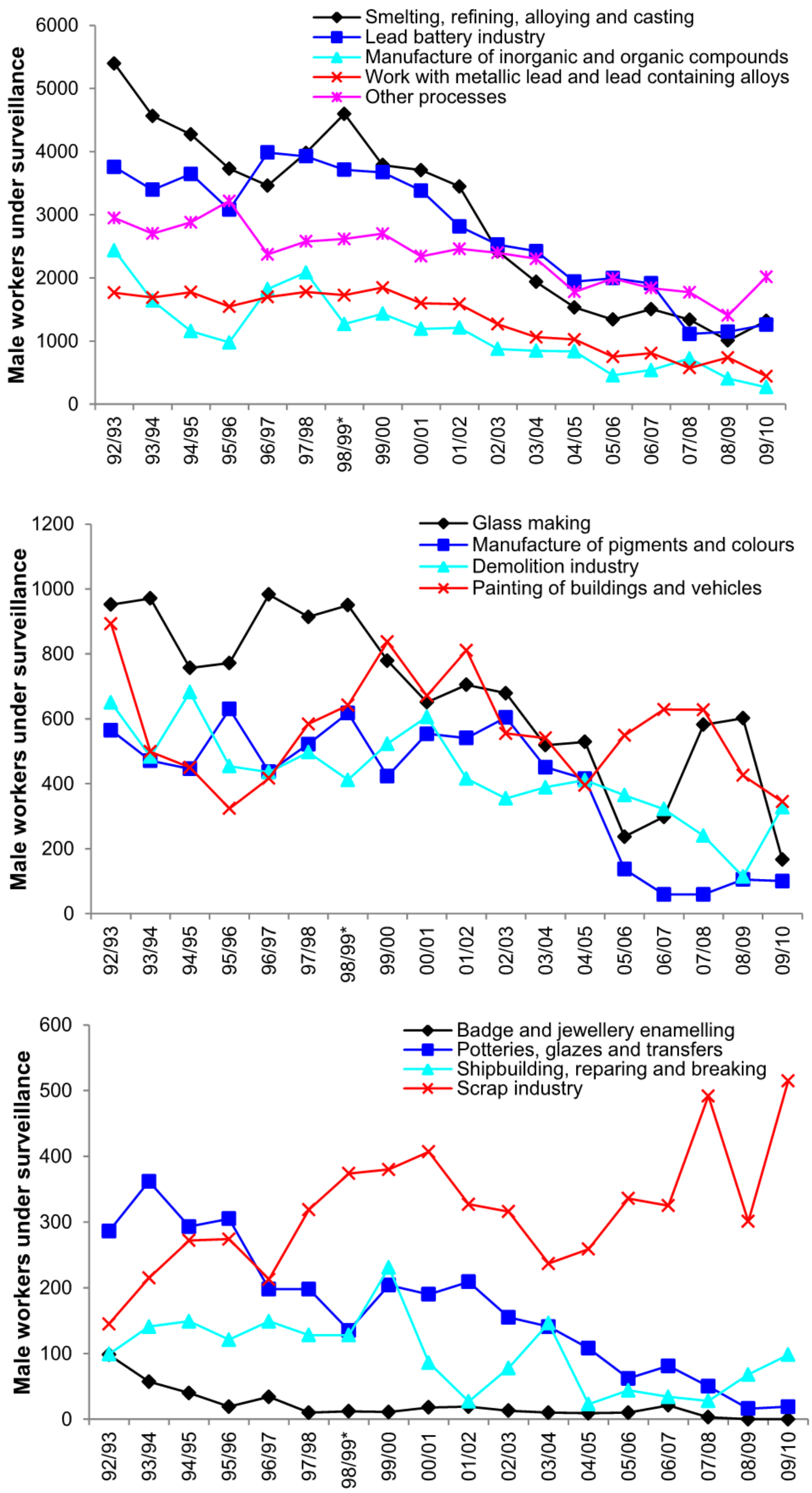


Figure 4-8 Trends in numbers of British male workers under medical surveillance from 1992/93 to 2009/10 by industrial sector (HSE, 2013)

The trend in number under medical surveillance may, however, primarily reflect the changes in blood-lead levels. With reduced blood-lead levels, some workers will no longer be under medical surveillance, but still be employed in the same industries. Consequently, the trend in exposed workforce would likely be lower than the trend in number of workers with blood-lead levels above the level where medical surveillance is required. The data shown in Table 4-55 indicate that for the main sectors covered by the Lead REACH consortium, the number of surveyed workers has in fact slightly increased. However, the trend is uncertain as the coverage of the 2013-16 survey is not reported.

4.7.3.3 Information on trends from other stakeholders

According to communication with stakeholders in Austria and Slovenia (AUVA, 2021; SI Chemicals Office, 2021) the use of lead for the production of crystal glass, glazes and enamel (e.g. for gas stoves, water heaters and cooking ware), tiles has been decreasing over the past two decades, either because lead has been substituted or because companies have been closing.

CNMRMC (2019) considers the available data for all sectors in Romania since 2012 as insufficient to conclude a trend in occupational concentrations.

The trend of decreasing numbers of workers under surveillance in the UK can be seen as an indication of reduced levels in blood but cannot be interpreted as a decrease of the exposed workforce.

Based on market projections for lead batteries, Eurobat (2021) expects the numbers of workers in the industry to be similar for the next 10 years. From 2030 and beyond, there will be significant changes to the automotive market in terms of electrification and replacement of the internal combustion engine, and it is not clear which role the lead battery will play in this transition. The same applies for industrial batteries where increased energy density will be required for many storage applications resulting in the need for a more diverse range of available battery technologies. Furthermore, the impact of other EU legislation such as the ELV (End-of-Life Vehicle) Directive, Battery Regulation and REACH on the battery market is uncertain. Therefore, in the view of Eurobat (2021), it is not possible to predict numbers of exposed workers in the EU lead battery sector beyond ten years even though it is likely that the lead battery workforce may decrease compared to the current level.

Increase of automatization plays a role in several sectors, however, according to communication with stakeholders from primary and secondary lead production, as well as the battery sector, even (semi-)automized solutions require manual interventions (i.e. service and maintenance), therefore a relationship between increased automatization and exposed workforce cannot be established.

In conclusion of the available information, it may be prudent to assume a stable number of exposed workers for the impact assessment.

4.7.4 Summary of exposed workforce

4.7.4.1 Total number of exposed workers

The total number of exposed workers extrapolated from various data sources are summarised below. The data from the Lead REACH Consortium and HSE in the UK only include workers included in surveillance programmes and thus represent the workers exposed at the highest levels. The data from the Lead REACH Consortium only cover some of the main sectors; whereas the dataset from the HSE includes a number of other sectors. In the UK, the sectors not covered by the Lead REACH Consortium accounts for about half of the exposed workers and consequently the totals, which may be extrapolated from the two datasets, are quite close. Data from Romania, extrapolated to the entire EU, reach nearly the same number as the extrapolation from the UK data.

Estimates based on extrapolations of other data sources such as the CAREX and the French SUMER databases, which include all potentially exposed workers, reach much higher numbers in the range of 373,000 - 1,450,000 workers. The CAREX EU data from the 1990’s could include a number of exposure sources which are not relevant today such as exposure to leaded petrol. These databases include all workers potentially exposed i.e. all workers which may come into contact with lead or lead compounds even the exposure level may be low or the exposure duration short. The total number is estimated to be significantly higher than the numbers of workers exposed at the reported exposure levels as discussed in next section.

Table 4-57 Summary of data on workers exposed to lead and its compounds

Source	Estimate	Extrapolated number of exposed workers in the EU-27
Lead REACH Consortium covering sector 1,2,3,4 (partly), 6 (partly), 7, 8 - workers included in surveillance programmes	18,000 (16,130 men; 775 women, of these 420 of childbearing capacity)	18,000
United Kingdom HSE data - workers included in surveillance programmes	5,875	39,400
Romania - workers exposed to lead	1,670	38,500
CAREX Europe estimate (1993/97) - all potentially exposed workers		1,450,000
CAREX Canada data estimate - all potentially exposed workers	277,000	3,299,000
Finnish Biological monitoring (2012) - all potentially exposed workers	4,500	373,000
French SUMER database estimate (2016/17) - all potentially exposed workers	202,300	1,350,000

4.7.4.2 Exposed workers by sector

Table 4-58 gives an overview of the number of exposed workers by sector. The numbers are estimated on the basis of data from both published sources and stakeholder consultation. A description of the data sources is provided in the previous sections of this chapter.

The estimated number of exposed workers are those represented by the reported blood-lead levels. From the main sectors reported by the Lead REACH Consortium, the data from the United Kingdom, and the data from Romania, there is a direct link between the number of exposed workers and the blood-lead levels: the number of exposed workers are those under medical surveillance and the monitoring data for these workers are used to estimate the statistical parameters on blood-lead levels.

A challenge in estimating the number of exposed workers is that a high number of workers particularly in demolition, waste management, and the use of articles of lead metal may only occasionally be exposed to lead, but sometimes at relatively high levels. This is illustrated by the large difference between the numbers of workers reported by the Lead REACH Consortium or extrapolated from surveillance data in Romania and the United Kingdom, and estimates based on the CAREX of SUMER database, which are ten times higher. Whereas the first sources are based on workers actually under medical surveillance (and thus expected to be exposed to lead at significant level), the latter data sources are based on information on uses of lead in the different sectors that potentially could lead to occupationally exposure. A large number of workers are probably exposed to lead, but at levels or durations that do not lead to elevated blood-lead levels.

In total, it is estimated that between 57,200 and 148,500 workers (mid-range 102,900) are exposed to lead at relevant levels in all sectors. Of these, 55,500 - 141,000 (mid-range 98,250) workers can be attributed to sectors that will be quantified in the impact assessment.

Table 4-58 Lead and its compounds, number of exposed workers at reported blood-lead levels

	Workers exposed at reported blood-lead levels			
	Lead REACH Consortium survey **	**Extrapolated from UK data (HSE 2019)**	**Other sources**	**Best estimate**
1. Primary lead production	2,165	5,300 (Smelting, refining, alloying and casting) 2,700 (lead battery recycling)		2,000 - 2,500
2. Secondary lead production (including lead battery recycling)	2,620			2,600 – 4,000
3. Lead battery production	11,000	5,500		11,000 - 13,000
4. Production of articles of lead metal	400 (lead sheet production)*** 750 (ammunition)	Included in above “Smelting....”	25-50 in lead cables manufacture, stakeholder cons. EuropeCable	1,200 - 2,000
5. Foundries		May be included in above “Smelting....”	Stakeholder consultation, Eurostat, CAEF (2021) 23,000 (all potentially exposed)	5,000 - 23,000
6. Production of lead compounds and lead frits	300	380 (lead compounds) 130 (pigments and colours)		500 - 1,000
7. Production of glass	500	930	Romania: 929	900 - 1,500
8. Ceramic ware production and enamelling	200	17	Romania: 692 Austria: 5000	500 – 5,000
9. Manufacture and use of plastics and paints		1,400 (Painting of buildings and vehicles)	Stakeholder consultation, CEPE Romania: 51	1,000 - 2,000
10. Work with lead metal		4,700	Romania: 553 in production of EEE; 150 metalwork	5,000 - 20,000
11. Shooting				12,000 - 20,000
12. Recycling of PVC and other plastics				300 - 1,000

	Workers exposed at reported blood-lead levels			
	**Lead REACH Consortium survey ** **	**Extrapolated from UK data (HSE 2019)**	**Other sources**	**Best estimate**
13. Demolition, repairing and scrap industry		Total: 8,250 400 shipbuilding, repair 1,650 (demolition industry) 2,900 (Paint removal) 3,300 (scrap industry)		10,000 - 25,000
14. Other waste management		1,100 (glass recyclers)		3,000 - 20,000
15. Production of copper		-	500-1,000	500 - 1,000
Total of above	**55,500 - 141,000 (mid-range 98,250)**			
Other		Total: 3,930 ****		1,210 – 3,510
- Mining activities			200 - 2,000.	200 – 2,000
- Manufacture of explosives			510	510
TOTAL (all sectors + other, rounded)	**57,200 - 148,500 (mid-range 102,900)**			

* *According to the Lead REACH Consortium the data for the lead battery, primary and secondary lead production probably covers almost all companies in the EU. For some sectors, it is more uncertain which percentage of the total exposed workforce within the sectors are represented by the survey. The total number of workers in the lead, zinc and tin production in the EU according to Eurostat's Structural Business statistics is 17,242 of which the primary and secondary lead production account for a part.*

** *The figures indicate the actual number of workers included in the survey i.e. the actual number in the EU will be higher, however, the coverage of the survey for some of the sectors is quite uncertain.*

*** *The companies typically produce also other articles of lead.*

**** *The group "other" in the UK summary may include sectors such as shooting and PVC recycling and the group is consequently not identical to the "other" group in this study.*

4.7.4.3 Exposed female workers and female workers of childbearing capacity by sector

The available sources, as presented in the previous sections of this chapter, as well as additional information from stakeholder consultation and Eurostat, have been used to derived estimates on the current number of workers of childbearing capacity. The figures on workers exposed per sector presented in Table 4-58 have been used for multiplication with the relevant fraction estimate for each sector (Table 4-59). For the sectors, where estimates were only available for women, the fractions have been recalculated under the assumption that 62% of the employment time, women may be of childbearing capacity. For the age limits, the current definition used by the UN (15-49 years; UN, 2019) has been used. The minor discrepancy to the upper age limit as reported by the REACH lead consortium (<46 years) has been neglected and the estimates from the Lead REACH Consortium have not been recalculated.

For the evaluation of the health endpoints related to females of childbearing capacity, the estimated numbers of 2,153 – 6,035 (mid-range 4,094) are taken forward.

Table 4-59 Lead and its compounds, fractions and number of workers of childbearing capacity.

Sector	Female workers		Workers of childbearing capacity	
	Fraction (%)*	Best estimate	Fraction (%) - comment	Best estimate
1. Primary lead production	**3.2**[a] 5.6[b]	64 - 80	2.3[a]	46 - 58
2. Secondary lead production (including lead battery recycling)	**4.6**[a] 1.3[b]	120 - 184	3.4[a]	88 - 136
3. Lead battery production	**3.8**[a] 2.4[b]	418 - 494	2.0[a]	220 - 260
4. Production of articles of lead metal	3.8[a]	46 - 76	<2.5[a]	30 - 50
5. Foundries	5.6[b]	280 – 1,288	3.5[g]	174 - 800
6. Production of lead compounds and lead frits	**15**[a] 7.0[b]	75 - 150	<3.3[a]	22 - 43
7. Production of glass	**24**[a] 9.4[b]	216 - 360	12.0[a]	108 - 180
8. Ceramic ware production and enamelling	7.5[a] **20**[e]	100 – 1,000	<7.5[a] **12** – Within artisanal ceramic works, the fraction of womens must be expected to be considerably higher. Artisanal ceramics is not included in the Lead REACH Consortium estimate.	60 - 600
9. Manufacture and use of plastics and paints	**7** (Manufacture of inorganic or organic lead compounds)[b]	70 - 140	5[g].	50 - 100
10. Work with lead metal	5.6[b]	280 – 1,120	3.5[g]	175 - 700
11. Shooting ranges	8.5[c] **10.6**[d]	170 - 1700	6.6[g]	789 - 1314
12. Recycling of PVC and other plastics	10.4[b] Due to lack of specific data, same estimate as for 14.	31 - 104	6.5	19 - 64

Sector	Female workers		Workers of childbearing capacity	
	Fraction (%)*	Best estimate	Fraction (%) - comment	Best estimate
13. Demolition, repairing and scrap industry	2.7 [b]	270 - 675	1.7	167 - 419
14. Other waste management	10.4 [b]	312 – 2,080	6.5 - Waste management is anticipated to be included under "Other" in the HSE (2019) data.	193 - 1290
15. Other - Copper production	**3.2[a]**	16 – 32	2.3[a]	12 - 23
Total		**3,317 – 9,483**		**2,153 – 6,035**

* *If more than one estimate is given, the bold estimate has been used. Sources for the estimates are as follows:*

a: Lead REACH Consortium, 2021

b: HSE (2019)

c: SUMER database France (Manitet et al, 2020)

d: Eurostat data for OC0 Armed forces, Employment by sex, age, professional status and occupation, 2019, EU-27.

e: Accounting for high fractions of women employed in artisanal crafts related activities within the sector, stakeholder consultation.

g: Study team estimate

e: FEEM (2021)

f: Study team estimate based on fraction for mining/primary production of lead.

4.7.4.4 Exposed male workers by sector

The available sources, as presented in the previous sections of this chapter, have been used to derive estimates on the current number of male workers in all sectors (Table 4-60). The figures on workers exposed per sector presented in Table 4-58 as well es the estimates in Table 4-59 have been used for the calculation. For the sectors, where estimates were only available for women, the fractions have been recalculated under the assumption that 62% of the employment time, women may be of childbearing capacity. For the age limits, the current definition used by the UN (15-49 years; UN, 2019) has been used. The minor discrepancy to the upper age limit as reported by the REACH lead consortium (<46 years) has been neglected and the estimates from the Lead REACH Consortium have not been recalculated.

For the evaluation of the health endpoints related to male workers only, the estimated numbers of 51,900 – 131,600 (mid-range 91,750) are taken forward.

Table 4-60 Fractions and number of male workers exposed to lead and its compounds.

Sector	Fraction (%) of male workers	Best estimate on male workers
1. Primary lead production	96.8[a]	1,936 – 2,420
2. Secondary lead production (including lead battery recycling)	95.4[a]	2,480 – 3,816
3. Lead battery production	96.2[a]	10,582 – 12,506

Sector	Fraction (%) of male workers	Best estimate on male workers
4. Production of articles of lead metal	96.3[a]	1,156 – 1,926
5. Foundries	94.4[b]	4,720 – 21,712
6. Production of lead compounds and lead frits	95.0[a]	475 - 950
7. Production of glass	76.0[a]	684 – 1,140
8. Ceramic ware production and enamelling	93.0[a]	465 – 4,650
9. Manufacture and use of plastics and paints	80.0[d]	800 – 1,600
10. Work with lead metal	94.4[b]	4,720 – 18,880
11. Shooting ranges	89.4[c]	1,788 – 17,880
12. Recycling of PVC and other plastics	89.6[b]	269 - 896
13. Demolition, repairing and scrap industry	97.3[b]	9,730 – 24,325
14. Other waste management	89.6[b]	2,688 – 17,920
15. Other – Copper production	96.8[a]	484 - 968
Total (rounded)		**51,900 – 131,600**

a: Calculated based on data from Lead REACH Consortium, 2021

b: Calculated based on data from HSE (2019)

c: Calculated based on Eurostat data for OC0 Armed forces, Employment by sex, age, professional status and occupation, 2019, EU-27.

d: Estimate derived based on information from stakeholder consultation, compare with estimate in previous table.

4.8 Current risk management measures

This section starts out with an overall description of risk management measures followed by sector specific descriptions.

4.8.1 Overall description of RMMs

The recommended risk management measures extracted from REACH CSRs (Chemical Safety Reports) and provided by the Lead REACH Consortium are as follows:

Engineering and ventilation controls: Basic aspects of equipment and facility design should be such that lead emissions that may contribute to occupational exposures are minimised. Such measures may include enclosure of process equipment such that sources of dust or aerosol emissions are minimised, negative draft exhaust systems to reduce emissions from enclosures and/or local exhaust ventilation installed at unavoidable sources of process emissions. The design characteristics of any local exhaust ventilation (e.g. exhaust hoods) will be specific to the emission source being controlled. Area ventilation should also be balanced such that air flow within a work area moves from areas of low to high exposure potential. Air captured by ventilation controls may require treatment to minimise toxic substances prior to discharge or recirculation.

Cleaning: Ensure general shop cleanliness is maintained by frequent washing/vacuuming. Clean every workplace at the end of every shift. Dry or wet sweeping of floors.

Personal protective equipment: Assess the need to wear respiratory protective equipment (RPE) in production areas. Consider using effective masks accompanied by a compliance policy (ensure proper shaving; ensure workers do not remove RPE in production areas in order to communicate).

Where masks are used, employ formal mask cleaning and filter changing strategies; for workers in areas of significant exposure, provide sufficient working clothes to enable daily change into clean clothes. In such cases, all work clothing should be cleaned by the employer on a daily basis and not permitted to leave the work site.

Personal hygiene: Ensure workers follow simple hygiene rules (e.g. do not bite nails and keep them cut short, avoid touching or scratching face with dirty hands or gloves); ensure workers do not wipe away sweat with hands or arms, e.g. by providing disposable perspiration towels; ensure workers use disposable tissues rather than a handkerchief; prohibit drinking, eating and smoking in production areas; prevent access to eating and non-production areas in working clothes; ensure workers as a minimum wash hands, arms, faces and mouths (but preferably shower) and change into personal clothing (or clean coveralls provided by the company) before entering eating areas; for high exposure workplaces, at the end of a shift, workers may need to pass through a room containing washbasins for the cleaning of hands, followed by a ‘dirty’ room for the removal of working clothes, then through showers into a ‘clean’ room for changing into personal clothing; ensure workers handle dirty working clothes with care; consider making showering obligatory at the end of a shift, and provide towels and soap; allow no personal belongings to be taken into production areas, and allow no items that have been used in production areas to be taken home.

Blood-lead monitoring: Set in place a monitoring regime which covers all site activities (for women and for men); use certified laboratories to measure blood-lead levels or have own laboratory certified; consider benchmarking with other companies/sectors; define a policy for submitting workers to blood-lead monitoring, including increased frequency for workers undertaking high-risk jobs and workers with elevated blood-lead levels; ensure all workers have a blood test prior to working on site. The blood-lead levels of workers will be monitored on a regular basis, often in reference to an “action level” that is typically 5 µg/100 ml below the exposure limit deemed to be safe. If the action level is exceeded, appropriate measures are to be taken, (e.g. ban overtime, provide counselling on proper work practice and hygiene, instigate an individual blood-lead management plan, increase blood-lead sampling frequency) in an effort to prevent further increases in blood-lead. If the safe threshold (40 µg/100 ml for men; 10 µg /100 ml for women of reproductive capacity) is exceeded, continue ban on overtime, ensure strict hygiene procedures are followed, undertake detailed inspections to ensure correct use of personal protective equipment, undertake detailed inspections to ensure recommended workplace procedures are followed, move employee to workplace where exposure is expected to be lower or remove from lead environment altogether, further increase blood-lead sampling frequency, and continue frequent sampling until results are below the first action level.

Creating a culture of safety: Define and communicate a clear policy for controlling occupational exposure to lead; ensure managers set the example in terms of personal protection and hygiene; where possible involve occupational physicians in making workers take control of their own blood-lead levels; consider making low blood-lead levels a condition of employment, with disciplinary action taken where protective equipment and hygiene procedures are not followed; involve managers when workers’ blood-lead levels exceed action levels; consider publicising company blood-lead performance to workers via notices and briefings to ensure the topic remains a key priority; provide detailed training for new personnel on the risks of lead exposure and the procedures for protection; provide instruction on specific lead exposure risks for workers undertaking new tasks; provide regular refresher courses for all employees on the risks of lead exposure and the procedures for protection; involve worker representatives.

The recently updated German Technical Rule, TRGS, 505 (AGS, 2021) for lead contains detailed information on RMM applying to all sectors in order to achieve compliance with the in May 2021 updated German BLV of 150 µg/L. In addition to the RMM described above, the TRGS also describes construction measures required to control exposures.

Construction measures: Production sites should be closed facilities with automated gates or locks/double door system. Floors are sloped towards collecting ditches. Workplaces with high exposures have to be separated from workplaces with lower exposures. In highly contaminated area, cleaning routes for exiting vehicles or separation of indoor and outdoor vehicles have to be provided.

4.8.2 Sector-specific RMMs

The following section includes information on RMMs applied for the specific workplaces for each of the main sectors. As regards the organisational RMMs, the tables do not list the general RMMs described above.

4.8.2.1 Primary lead production

The following table shows RMMs applied in primary lead production.

Table 4-61 RMMs applied in primary lead manufacture (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Raw material handling	Ore/concentrate delivery, loading/unloading, and furnace feed mixing		Local exhaust ventilation with efficiency of at least 78% Closed cabin with positive pressure	Half mask, FFP2 for manual operations; APF = 10	Leather gloves for manual operations
Sintering	Feeding/unloading, sinter plant operation	Worker in control room for the majority of the shift	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2, for control walks and maintenance works; APF = 10	Leather gloves for control walks and maintenance works
Smelting	Furnace operation	Worker in control room for the majority of the shift	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2, for control walks and maintenance works; APF = 10	Leather gloves for control walks and maintenance works
Refining and casting	Decopperisation, softening (As, Sb, Sn removal), silver separation, zinc distillation, casting of lead ingots/slabs or lead alloy ingots	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Leather gloves

Workplace name	Description	Organisa-tional RMMs	Technical RMMs	RPE*	Other PPE
Internal lo-gistics	Storage and ship-ment of finished goods, intra-facility transport	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Leather gloves
Others	Repair, cleaning, and maintenance, quality control, and engineering	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Leather gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

Further information on RMM, costs and challenges were provided by stakeholder during consultation:

Technical RMM

- Control of airborne lead concentrations is especially challenging in primary production due to the nature and volumes of raw material. The lead ores require more violent operations compared to secondary lead materials (e.g. lead scrap, batteries), causing considerable dust generation.
- The capacity of a typical lead smelter is at least 60,000 t/y, while a typical secondary smelter has a capacity of 30,000 t/y (larger secondary smelters exist), meaning the scale of operations is larger in primary compared to secondary smelters.
- The efficiency of existing ventilation equipment may be increased by improving the maintenance and operation scheme of the equipment.

Restructuring and/or rebuilding for reducing occupational exposures

- New smelter plant including material handling, furnace, etc., meeting the IPPC (Integrated Pollution Prevention and Control) BAT requirements, increasing production capacity and allowing for improved control of emissions would require an approximate investment cost of €90 million
- Enclosed storage areas for primary and secondary materials with dedicated dust generation suppressing equipment, approximate investment cost of €5 million
- New refinery meeting the BAT requirements and allowing for improved control of emissions would require an approximate investment cost of €50 million

4.8.2.2 Secondary lead production

The following table shows RMMs applied in secondary lead production. The processes include precious metals refining which is performed in the same process.

Table 4-62 RMMs applied in secondary lead production, sector 2 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Raw material handling	Storage, transport and handling of batteries and other lead scrap	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Protective gloves
Shredding and sorting	For batteries, separation of sulphuric acid, shredding (breaking), grid-separation, elution of PbO-paste, also sorting of other lead scrap	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Protective gloves
Desulphurisation	Sulphur removal from PbO-paste	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Protective gloves
Melting and smelting	Melting of grids, smelting and reduction of paste	Control room for the majority of the shift	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2, for control walks and maintenance works; APF = 10	Thermal protective gloves
Refining and casting	Refining of lead, casting of ingots	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Thermal protective gloves
Storage, shipment and transport	Storage and shipment of finished goods, intra-facility transport	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Protective gloves
Others	Repair, cleaning, and maintenance	None	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP2; APF = 10	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.2.3 Battery production

Table 4-63 RMMs applied in battery production, sector 3 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Plate manufacturing	Casting/production of grids, oxide production, mixing, pasting, and curing operations	Frequency and duration of exposure not restricted (full shift exposure (8 hrs) for all workplaces). A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	Local exhaust ventilation with efficiency of at least 78%	FFP1 mask for manual operations; APF = 4	Protective gloves (heat and mechanical protection)
Plate treatment	Jar/tank formation, plate washing, drying, cutting		Local exhaust ventilation with efficiency of at least 78%	FFP1 mask; APF = 4	Protective gloves
Assembly	Stacking, assembly, welding and joining operations		Local exhaust ventilation with efficiency of at least 78%	FFP1 mask; APF = 4	Protective gloves
Battery formation	Acid filling, formation (wet batteries), finishing		Local exhaust ventilation with efficiency of at least 78%	FFP1 mask; APF = 4	Protective gloves
Internal logistics	Storage of raw materials and finished goods, intra-facility transport, shipment		Local exhaust ventilation with efficiency of at least 78%	Not required	Not required
Others	Cleaning and maintenance		Local exhaust ventilation with efficiency of at least 78%	FFP1 mask; APF = 4	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.2.4 Production of articles of lead metal

Production of articles includes the production of lead sheets and tubes, cables, lead keels and ammunition. The RMMs applied may vary by process. The specific processes for the manufacture of lead sheets-, which include raw material handling, smelting and refining, milling, sawing and slitting, represent the main workplaces for production of articles of lead metal.

Table 4-64 RMMs applied in lead sheet production, part of sector 4 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Raw material handling	Delivery, sorting, furnace loading	Duration of exposure: 3 hours	Local exhaust ventilation with efficiency of at least 78%	half mask, FFP2; APF = 10	Protective gloves (mechanical protection)
Smelting and refining	Melting, drossing and refining	Duration of exposure: 3 hours	Local exhaust ventilation with efficiency of at least 78%	half mask, FFP2; APF = 10	Thermal-protective gloves
Milling	Milling operations	Separation of workers is generally not required in the processes, unless a specific process step is conducted less than full-shift	Local exhaust ventilation with efficiency of at least 78%	Not required	Protective gloves
Sawing and slitting	Sawing and slitting operations		Local exhaust ventilation with efficiency of at least 78%	half mask, FFP2; APF = 10	Protective gloves (mechanical protection)
Storage and shipment	Internal logistics, storage, shipment of finished goods		Local exhaust ventilation with efficiency of at least 78%	Not required	Protective gloves
Others	Repair, cleaning and maintenance		Local exhaust ventilation with efficiency of at least 78%	half mask, FFP2; APF = 10	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

RMMs used in the production of ammunition are shown in the table below.

Table 4-65 RMMs applied in production of ammunition, part of sector 4 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Tower or Bleimeister process for production of lead-shot	Operator, material handling, (cleaning and maintenance)	Frequency and duration of exposure not restricted (i.e. > 8h/day	Basic general ventilation (1-3 air changes per hour); local exhaust ventilation	No	Gloves, with employee training

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Wire production process	Operator wire extrusion, material handling, (cleaning and maintenance)		Basic general ventilation (1-3 air changes per hour); local exhaust ventilation	No	Gloves, with employee training
Shaping the wire for production of air pellets, lead cores, blank bullets or lead shot	Operator wire shaping, pressing, cutting, (cleaning and maintenance		Basic general ventilation (1-3 air changes per hour); local exhaust ventilation	No	Gloves, with employee training
Ammunition assembly	Stacking, assembly and joining operations, (cleaning and maintenance		Basic general ventilation (1-3 air changes per hour)	No	Gloves, with employee training
Shooting/testing range/lab for quality control	Shooting, (cleaning and maintenance)		Enhanced general ventilation; local exhaust ventilation	No, except for cleaning and maintenance	No, except for cleaning and maintenance
Internal logistics	Storage of raw materials and finished goods, intra-facility transport, shipment		Basic general ventilation (1-3 air changes per hour)	No	No
Others	cleaning and maintenance by other worker		Basic general ventilation (1-3 air changes per hour)	No	Gloves, with employee training

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.2.5 Foundries

Data on RMMs have been obtained from five foundries. The processes reported are slightly different between the companies.

Table 4-66 RMMs applied in foundries, sector 5 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE	Other PPE
Fettling	Preparation before casting	Training, cleaning, rotating of workers	Redesign of work processes Local exhaust ventilation	HEPA masks	Googles, gloves
Melting	Melting, drossing		Local exhaust ventilation	Various answers	Googles, gloves
Casting/pouring	Casting, pouring of dross		Local exhaust ventilation	Various answers	Googles, gloves
Grinding	Grinding		Local exhaust ventilation	Various answers	Googles, gloves

4.8.2.6 Production of lead compounds and lead frits

Two examples from this sector are shown in the tables below. The processes are considered representative of the sector.

Table 4-67 RMMs applied in lead oxide/stabiliser production, part of sector 6 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Lead oxide production	Production of “crude” oxide, further oxidation/calcination, grinding/milling, packaging		Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Lead stabiliser production (wet process)	Loading of lead oxide into reaction vessels, slurry formation by addition of water, catalysts and acid compounds, centrifuge operation, drying process, bagging/drumming operations		Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Lead stabiliser compound production (dry/melting process)	Loading of lead oxide into reaction vessels, feeding of molten acid compound to reaction vessels, process control, cooling and forming of tablets, flakes etc., drying process, bagging/drumming operations	Frequency and duration of exposure not restricted (full shift exposure (8 hrs) for all workplaces). A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Mixing/blending of formulated stabiliser products	Material loading (manual or automated handling), operation of mixing/blending equipment, packaging operations		Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Internal logistics	Storage (raw materials, finished goods) and shipment of finished goods		Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Others	Repair, cleaning, and maintenance, quality control, engineering		Local exhaust ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

Table 4-68 RMMs applied in manufacture of lead dichloride (from lead dinitrate), part of sector 6 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Raw material handling	Raw material handling		Vessel ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Lead dichloride production	Aqueous sodium chloride reacts in a closed vessel with aqueous lead (II) nitrate to yield a lead (II) chloride precipitate and aqueous sodium nitrate. Product is filtered.		Vessel ventilation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves

Workplace name	Description	Organisa-tional RMMs	Technical RMMs	RPE*	Other PPE
Lead di-chloride drying	Wet filtrate is stocked and then dried (dry-ing- temperature 105°C). Lead chlo-ride is produced in crystalline form.	Frequency and duration of ex-posure not re-stricted (full shift exposure (8 hrs) for all workplaces). A reduction of exposure dura-tion can be achieved, for example, by the installation of ventilated (positive pres-sure) control rooms or by re-moving the worker from workplaces in-volved with rel-evant expo-sure.	Local ex-haust venti-lation with efficiency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves
Others	packaging, shipping, cleaning and mainte-nance, quality control		Local ex-haust venti-lation with dry filter; LEV effi-ciency of at least 78%	FFP1or 2 mask; APF = 4	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.2.7 Production of glass

Table 4-69 RMMs applied in lead speciality and lead crystal glass production, sector 7 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisa-tional RMMs	Technical RMMs	RPE*	Other PPE
Raw mate-rial han-dling	Raw material de-livery, batch for-mulation, pot fill-ing, melting		Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP1 for manual op-erations; APF = 4	Thermal protec-tive gloves for manual opera-tions
Forming processes	Manual operation of multi-pot sys-tems or semi-auto-mated cold-top fur-nace, blowing op-erations		Local exhaust ventilation with efficiency of at least 78%	Half mask, ffp1 for manual op-erations; APF = 4	Thermal protec-tive gloves for manual opera-tions
Cutting processes	Finishing, manual and automated cutting operations		Local exhaust ventilation with efficiency of at least 78%	Not required	Not required
Polishing processes	Acid polishing		Local exhaust ventilation with efficiency of at least 78%	Not required	Protective gloves

Workplace name	Description	Organisa-tional RMMs	Technical RMMs	RPE*	Other PPE
Others	Storage and shipment of finished goods, repair, cleaning and maintenance, quality control, engineering etc.	Frequency and duration of exposure not restricted (full shift exposure (8 hrs) for all workplaces). A reduction of exposure duration can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	Local exhaust ventilation with efficiency of at least 78%	Half mask, FFP1; APF = 4	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.2.8 Ceramic ware production and enamelling

Table 4-70 RMMs applied in production of ceramic ware, part of sector 8 (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Production of frits	Raw material handling, smelting, quenching, wet milling/grinding		Local exhaust ventilation with efficiency of at least 78%	Not required	Not required
Production and handling of pigments	Weighing, ball milling, filling		Local exhaust ventilation with efficiency of at least 78%	Not required	Not required
Lithography	Manual transfer of lithographs		Not required	Not required	Not required
Decoration	Manual painting and artwork, printing		Not required	Not required	Not required

Workplace name	Description	Organisational RMMs	Technical RMMs	RPE*	Other PPE
Glazing of ceramic	Dipping, spraying	Frequency and duration of exposure is not restricted (full shift exposure (8 hrs) for all workplaces). A reduction of exposure can be achieved, for example, by the installation of ventilated (positive pressure) control rooms or by removing the worker from workplaces involved with relevant exposure.	Local exhaust ventilation with efficiency of at least 78%	Not required	Not required
Others	Firing, cleaning and maintenance, quality control		Not required	Not required	Not required

* Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.

4.8.2.9 Manufacture and use of plastics and paints

RMMS used in the manufacture and use of pigments are described in the authorisation applications for three lead pigments. One example of application of the pigments in road markings is shown below.

Table 4-71 RMMs applied in professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking (DCC Maastricht B.V (2013a). Example of sector 9. Authorisation application for C.I. Pigment Red 104 (EC number 235-759-9).)

WCS	Description	Organisational RMMs	Technical RMMs	RPE	Other PPE
WCS 2	Charging/discharging premix or pre-compound	Max. 3 h/week Part of monitoring program (bio/air) OSH: basic	Containment of source Ventilation (general): 3 ACH Effective housekeeping practices are in place	Not required	Gloves: conform EN374 Working clothes
WCS 3	Storage and mixing of plastic compounds in an open vessel before application	Max. 6 h/week Part of monitoring program (bio/air) OSH: basic	Effective housekeeping practices are in place	Not required	Gloves: conform EN374 Working clothes
WCS 4	Application of hotmelt road marking (plastic compound) to road pavement	Max. 18 h/week Part of monitoring program (bio/air) OSH: basic	Effective housekeeping practices are in place	Not required	Gloves: conform EN374 Working clothes

WCS	Description	Organisa-tional RMMs	Technical RMMs	RPE	Other PPE
WCS 5	Handling and manip-ulation of coloured road marking	Max. 3 h/week Part of monitor-ing program (bio/air) OSH: basic	Effective house-keeping practices are in place	Not required	Gloves: con-form EN374 Working clothes
WCS 6	High energy manipu-lation/removal of col-oured road marking using abrasive techniques like grind-ing, drilling or sand-ing	Max. 3 h/week Part of monitor-ing program (bio/air) OSH: basic	Effective house-keeping practices are in place	APF 100	Gloves: con-form EN374 Working clothes

4.8.2.10 Work with lead metal (plumbing, soldering, and similar)

The German Social Accident Insurance has published a recommendation which measures to use during soldering (DGUV, 2018). The following measures are recommended;

- Substitution of lead containing solders
- Technical measures; LEV
- Organisational measures;
  - maintenance and cleaning scheme of LEV system
  - regulations for pregnant and nursing women under the Maternity Protection Act
- Instruction of employees about workplace hygiene
- Preventive occupational health care

The authors also note that so-called solder fume absorbers (table-top devices) are commonly used but do not offer sufficient protection.

4.8.2.11 Shooting

According to stakeholders in Belgium and Austria (AUVA, 2021), the only technical risk management measure used at indoor shooting ranges are general ventilation systems. The effectiveness of the ventilation system depends on the age of the system/shooting range, correct design and maintenance. In optimal situations, supply air is discharged through the back wall (behind the shooter) and extracted in the bullet trap area, creating a horizontal flow through the room and removing dust and fumes from the shooters breathing zone.

Exposures can also be reduced by keeping the shooting range clean and using vacuum cleaners, wet cleaning instead of brushes. During cleaning, the ventilation system should be turned on. Information about how commonly these housekeeping measures are used, has not been obtained.

4.8.2.12 Recycling of PVC and other plastics

Fruijtier-Pölloth (2016) collected data on the lead exposure of workers during the recycling of PVC post-consumer waste and during converting of recycled PVC granulate at 12 PVC recycling and/or converting plants in Europe.

The author noted that shredding operations, having a high potential for lead exposure, were often carried out without RPE. Workers were usually using gloves. One company converted shredded soft PVC in automated, closed systems. Additional information on RMM in recycling of PVC and other plastics has not been available.

4.8.2.13 Demolition, renovation, repairing and scrap industry

Many national authorities and industry organisations have prepared guidelines on RMMs used by renovation, demolition, waste management, etc. Commonly, a risk screening for presence of lead containing building materials and/or paints has to be performed before the beginning of demolition/renovation works.

According to several stakeholders within the demolition and construction sector, techniques for reducing exposures to dust will often reduce exposure to dust-borne lead. Most commonly, water is used to prevent dust formation. For example, during demolition of buildings with an excavator, water may be sprayed on the demolition site. During renovation of bridges, where lead-containing paint is removed by wet-sanding, the resulting lead-containing slurry is collected and treated as hazardous waste.

Guth et al. (2020) reports that bridge painting workers in the USA were medically removed from work for a two weeks period. Furthermore, they identified that certain tasks, e.g. abrasive blasting and painting, can lead to increases in PbB exceeding national limit values over a two month period, even though recommended exposure controls were applied. Therefore, the study supports a more frequent biological monitoring, i.e. monthly, for activities including lead exposure.

According to the recently update German Technical Rule 505, lead-containing surface coats on e.g. bridges have to be removed before welding or flame cutting activites are carried out.

Depending on the exposure situation, mobile or stationary LEV have to be provided for abrasive removal of lead-containing coats or paints. Waste bins containing lead-containing waste should be covered. To prevent dust formation, the descent rate or height of fall of materials is to be minimised.

4.8.2.14 Other waste management

No specific data on use of RMMs during soil remediation works and waste incineration to prevent/reduce lead exposure have been obtained.

Both in soil remediation and waste incineration technical measures, hygiene measures and PPE are used to prevent exposure to dust and hazardous substances. Many Member State authorities and industrial association have prepared guidelines and directives, which RMM shall be used in occupational settings related to soil remediation works and waste management. For example, the Occupational Health and Safety Authority of Denmark sets out instructions for use of technical measures (e.g. spraying with water to prevent dust), PPE, personal hygiene, instruction and supervision of employees in soil remediation works (AT, 2019).

4.8.2.15 Other

RMMs applied in the use of lead and/or lead monoxide used as a laboratory agent in chemical analysis is shown in the table below.

Table 4-72 Lead and/or lead monoxide used as a laboratory agent in chemical analysis (fire assay) (Lead REACH Consortium, 2019, based on REACH registrations)

Workplace name	Description	Separation	Localised controls	RPE*	Other PPE
High temp fusion mix	Heating of test material and fluxes; pouring into mould and cooled	Frequency and duration of exposure not restricted	High velocity air flow fume hoods with efficiency of at least 78%	Respirator	Protective gloves
Cupellation	Heating of lead 'button' to oxidise off the lead; precious metal analysis		High velocity air flow fume hoods with efficiency of at least 78%	Respirator	Protective gloves

* *Recommended minimum RPE except in cases where adequate ventilation/emission control is in place.*

4.8.3 Types of RMM currently used by enterprises

The table below lists the current use of RMM by companies as reported in the consultation survey. If a certain RMM is mentioned in at least one activity by a facility in a given sector, it is listed in the table. The table gives a broad overview of the commonly used RMM, however, data should be interpreted with care. Many facilities use multiple RMM within the same activity and certain RMM may only be used for specific activities. For example, several stakeholders from the battery sector inform that FFP2 masks (APF = 10) are most commonly used. Only for certain dirty works (maintenance, cleaning of facilites), half face masks with two filters (APF = 40) are available. A few manufacturers also introduced the use of ventilated helmets in high exposure workplaces.

Basically all stakeholders emphasize the importance of training in order to improve hygiene behaviour.

Spraytests for testing dermal contamination with lead have been introduced in some companies for interested employees. The non-hazardous test liquids give a yellow colour on hands/arms, if lead contamination is present on the skin. The test should be repeated after washing of the concerned areas.

Table 4-73 Types of RMM used by enterprises (%) in the sectors for which survey responses were provided.

RMM	1. Primary lead production	2. Secondary lead production	3. Battery production	4. Production of articles of lead	5. Foundries and production of articles of alloys	6. Production of lead compounds and lead frits	9. Manufacture and use of plastics and paints	10. Work with lead metal	15. Other
Restructuring operations/processes									
Temporary relocation of workers with high blood lead levels	100%	70%	83%	44%	100%	100%	100%	0%	50%
Permanent relocation of workers with high blood lead levels	25%	30%	17%	11%	67%	0%	100%	0%	33%
Reduced amount of substance used	0%	15%	0%	0%	0%	0%	0%	0%	17%
Reduced no. of workers exposed	25%	25%	25%	33%	0%	0%	0%	0%	33%
Rotation of the workers exposed	100%	35%	58%	22%	100%	100%	100%	0%	17%
Redesign of work processes	75%	45%	58%	67%	0%	0%	0%	0%	33%
Ventilation and extraction									
Closed systems	25%	25%	50%	33%	67%	0%	0%	0%	17%
Partially closed systems	100%	80%	75%	56%	33%	50%	100%	0%	67%
Open hoods over equipment or local extraction ventilation	100%	100%	92%	67%	100%	100%	100%	100%	100%
General ventilation	100%	95%	58%	67%	67%	100%	100%	100%	83%

RMM	1. Primary lead production	2. Secondary lead production	3. Battery production	4. Production of articles of lead	5. Foundries and production of articles of alloys	6. Production of lead compounds and lead frits	9. Manufacture and use of plastics and paints	10. Work with lead metal	15. Other
Pressurised or sealed control cabs	50%	50%	8%	0%	0%	0%	0%	0%	33%
Simple enclosed control cabs	50%	50%	8%	22%	67%	0%	100%	0%	67%
Personal protective equipment (PPE)									
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	0%	30%	17%	0%	0%	0%	0%	0%	17%
Powered air-purifying respirators	75%	100%	50%	11%	33%	50%	0%	0%	50%
Half and full facemasks (negative pressure respirators)	100%	55%	67%	33%	67%	100%	0%	0%	50%
Disposable respirators (FFP masks)	25%	80%	67%	33%	67%	100%	100%	0%	67%
Face screens, faceshields, visors	100%	70%	58%	0%	67%	100%	100%	0%	83%
Safety spectacles, goggles	100%	90%	83%	78%	100%	100%	100%	0%	67%
Gloves	100%	100%	92%	89%	100%	100%	100%	0%	100%
Gloves with a cuff/gauntlets/sleeving covering part or all of the arm	75%	65%	75%	33%	67%	100%	100%	0%	50%
Safety boots and shoes	100%	100%	83%	100%	100%	100%	100%	0%	100%
Rubber boots	25%	35%	67%	11%	0%	0%	0%	0%	0%

RMM	1. Primary lead production	2. Secondary lead production	3. Battery production	4. Production of articles of lead	5. Foundries and production of articles of alloys	6. Production of lead compounds and lead frits	9. Manufacture and use of plastics and paints	10. Work with lead metal	15. Other
Conventional or disposable overalls, boiler suits, aprons	100%	75%	67%	67%	67%	100%	100%	0%	50%
Coveralls/hazardous materials suits	50%	70%	50%	22%	33%	50%	0%	0%	50%
Organisational and hygiene measures									
Training and education	100%	100%	100%	100%	100%	100%	100%	100%	100%
Cleaning	100%	100%	100%	100%	100%	100%	100%	0%	83%
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	100%	100%	100%	56%	67%	100%	100%	0%	83%
Provision of separate storage facilities for work clothes	100%	100%	100%	89%	67%	100%	100%	0%	100%
Formal/external RPE cleaning and filter changing regime	50%	100%	75%	44%	67%	100%	0%	0%	50%
Blood-lead monitoring	100%	100%	100%	89%	100%	100%	100%	100%	83%
Continuous measurement of air concentrations to detect unusual exposures	0%	20%	8%	0%	67%	0%	0%	0%	17%
Creating a culture of safety	100%	100%	100%	100%	100%	100%	100%	0%	83%
Substitution or discontinuation in the past									

RMM	1. Primary lead production	2. Secondary lead production	3. Battery production	4. Production of articles of lead	5. Foundries and production of articles of alloys	6. Production of lead compounds and lead frits	9. Manufacture and use of plastics and paints	10. Work with lead metal	15. Other
Partial substitution of lead and its compounds used in this activity in the past	0%	5%	0%	11%	33%	0%	0%	0%	33%
Discontinuation of part of the activity using lead and its compounds	0%	5%	17%	11%	0%	0%	0%	0%	17%
Substitution or discontinuation in the past	25%	5%	0%	11%	0%	0%	0%	0%	0%
Total number of responses*	**4**	**20**	**12**	**9**	**3**	**2**	**1**	**1**	**6**

* *Companies were asked to provide one response per facility. However, some companies provided one response covering several facilities.*

4.9 Alternatives

Substitution is a key risk management measure for companies having difficulty achieving an OEL. Therefore, it is important to know whether alternatives exist for lead and lead compounds in each sector. The possible alternatives are discussed below.

4.9.1 Batteries

Alternatives to lead in batteries for vehicles have been extensively assessed as part of the evaluation of the exemption for lead-acid batteries under the Directive 2000/53/EC (ELV Directive) (Gensch et al., 2016a). The alternative battery technologies assessed are Li-ion batteries (lithium-ion), supercapacitors coupled with Li-ion batteries and NiMH (nickel metalhydride) batteries.

The evaluation concludes that based on the information submitted, the use of lead in automotive batteries cannot be avoided at present in cases where starter functionality is needed. In cases, where a dual battery system is in use, the use of a lead acid battery as an auxiliary battery would also be required even where starter functionality is not needed. This is based on the understanding that there is a lack of experience with batteries other than lead-acid batteries for this function, though this could change over the next few years as Li-Ion batteries are understood to provide a suitable candidate for such cases. Furthermore, Gensch et al. (2016a) conclude that as replacement with Li-Ion batteries is not yet implemented in vehicles on the market, time would be needed to finalise testing and type approval processes. In contrast, in the primary battery of dual systems, where the battery is only needed for propulsion (electric vehicles), other chemistries are currently in use, making the use of lead in batteries avoidable. The authors recommend that the exemption for lead in batteries should be reformulated to exclude such primary batteries from its scope (Gensch et al., 2016a).

The European Commission launched the European Battery Alliance in October 2017 to address the industrial challenges of providing capable batteries for transport, power and industrial applications (European Commission, 2019). The report from the Commission on the implementation of the Strategic Action Plan on Batteries and building a Strategic Battery Value Chain in Europe describes several initiatives concerning research, innovation and demonstration in designing and deploying the next generation of battery technologies. According to the report, current state-of-the-art batteries are largely based on lithium-ion chemistry, but the demand for higher energy density and performance requires short- to medium-term improvements, together with more radical changes towards a new generation of post-Li-ion batteries based on new advanced materials.

4.9.2 Lead sheeting and tubes

4.9.2.1 Sheeting

Many types of alternatives to lead sheets used for flashing are marketed. The alternatives are designed to look like lead and are available in a range of thicknesses. The materials are typically made as layered materials e.g. layer of bitumen or silicone reinforced with an aluminium mesh/grid. Lead flashing used on buildings has for many years been banned in Denmark and has been substituted by alternatives. Lead flashing is in particular used in the UK. Many alternatives are marketed in the UK and the price is lower than the price of lead flashing (e.g.[20]).

[20] https://www.roofingsuperstore.co.uk/blog/everything-you-need-to-know-about-lead-alternatives-to-lead-flashing/#lead-alternative . Accessed March 2021.

4.9.2.2 Tubes

Lead tubes have been phased out for most applications and, for example, have been banned in Denmark for many years. The alternatives are typically tubes of PVC or other plastics.

4.9.3 Lead sheathing on cables

Cables with lead sheathing are particularly used for cables for the petrochemical industry. The main advantages of lead sheathed cables are protection against the entry of hydrocarbons and moisture ingress and high corrosion resistance. A number of alternatives to lead sheathed cables have been introduced by industry manufacturers. Some of the lead-free cable designs include an inner layer of longitudinal aluminium bound with a HDPE (High Density Polyethylene) sheath and PA (Polyamide) cover. The advantages of lead-free alternative designs are the lower cable weight and reduced diameters, which can be beneficial in the installation. According to manufacturers of alternatives, a sheath which is composed of aluminium, HDPE and PA has the same functionality as a sheath of lead [21]. As an example, the international cable manufacturer Nexans has developed its new Hypron® cable range to provide an environmentally-friendly alternative to lead-sheathed cables for onshore power, control and instrumentation applications in the chemical, oil and gas industry[22]. According to the manufacturer, the design offers exactly the same protection against aggressive petrochemicals as traditional lead-sheathed cables, with the added advantage of improved ease of handling and installation thanks to its lower weight and smaller cross-section.

Cables with lead sheath have been banned in Denmark since 1 December 2002 with an exemption until November 2007.

4.9.4 Lead glass and ceramics

4.9.4.1 Electrical and electronic equipment

Alternatives to lead in crystal glass for electrical and electronic equipment has been assessed as part of the evaluation of the exemption for lead-acid batteries under the RoHS Directive 2011/65/EU (RoHS Directive) (Gensch et al., 2016b). The review describes the status for different alternatives and reaches the conclusion that the substitution and elimination of lead in lead glass and ceramics generally is still scientifically and technically impracticable in the applications in the scope of the exemption under RoHS. The authors conclude that while substitution or elimination of lead are not foreseeable for lead in glass and glass or ceramic matrix compounds, the information does not preclude lead-free solutions for ceramics becoming available within five years. The exemption for lead bound in crystal glass and ceramics under the RoHS Directive has been exempted until 2021-2024 depending on application.

The BAT Reference Document for the ceramic industry (BREF, 2007) describes a lead-free glaze formulation based on alkali boron silicates that has been developed by a tableware producer and which is similar to systems containing lead in terms of quality and properties of application. The alternatives are described in the publication (BREF, 2007).

4.9.5 Ammunition

Alternatives to lead shot is described in the Annex XV report on a proposal of a restriction on the use of lead shot in wetlands (ECHA, 2017). The review concludes: *"Alternatives to*

[21] Advantages and disadvantages of lead sheathed cables. https://www.incore-cables.com/lead-sheathed-cables/

[22] HYPRON, a new environmentally friendly alternative to lead-sheathed cables for onshore oil and gas installation https://www.oilandgasproductnews.com/article/470/hypron-a-new-environmentally-friendly-alternative-to-lead-sheathed-cables-for-onshore-oil-and-gas-installation

lead gunshot cartridges exist and are technically and economically feasible. The prices of lead and steel gunshot cartridges are currently comparable, while bismuth and tungsten-based gunshot cartridges, which are currently produced, sold and used in far lower volumes, are likely to remain more expensive than lead (and steel) gunshot cartridges. Modern shotguns and the majority of existing shotguns can be used with a 'standard' steel shot cartridge (sometimes after some adaptation to 'choke'). However, the use of 'high performance' steel shot (typically required for hunting large waterfowl e.g. geese) requires a shotgun that has passed a specific 'steel shot' proof." (ECHA 2017)

4.9.6 Fishing sinkers

Alternatives to fishing sinkers and other fishing tackle have been investigated by ECHA in a review of available information about lead in shot used in terrestrial environments, in ammunition and in fishing tackle (ECHA, 2018a). Various alternatives to the use of lead fishing sinkers and jigs are marketed including tin, bismuth, antimony, steel, brass, tungsten, terpene resin putty and polypropylene. Older assessments of the alternative products are more expensive than lead and each differs slightly in the types of uses for which it is appropriate. For an estimation of costs, the review draws on a study for the European Commission from 2004 (COWI, 2004). The total estimated cost in the EU-25 for various phase-out options ranged from €0.6 million to €207 million per year, depending on the scope of phase out. Corresponding cost-effectiveness estimates for the different phase-out options ranged from €300 to €39,000 per tonne of emission avoided. ECHA (2018a) concludes that although now relatively old, this study incorporates most of the necessary information for preparing an Annex XV restriction on the use of lead in commercial and/or recreational fishing. Furthermore, ECHA (2018a) concludes that the risk from lead in fishing tackle could be significantly reduced through a restriction on their marketing and use.

The sale of lead-containing fishing sinkers and other tackle for angling in Denmark has been banned since 1 December 2002 and alternatives are available for all applications.

A Danish investigation of alternatives to lead in sinking-lines for commercial fishing net concluded that a large part of the Danish net fishing fleet will experience problems in one or more of the following ways in the transition from using nets with lead sinking lines to using alternative zinc sinking lines: 1. Poorer working environment as a result of less deck space and more difficult working conditions; 2. Problems with space on board the vessel as nets using alternative sinking lines take up more than a 1/3 more space than nets with lead sinking lines. 3. Reduced vessel stability as a result of the increased weight of nets, eventually leading to exceeding what is allowed according to rules by the Danish Maritime Authority.

The available data indicated that lead may be phased out for most applications in this application area.

4.9.7 Foundries and leaded alloys

According to the European Foundry Association (CAEF, 2019a), no feasible alternatives to substitute lead in alloys for casting purposes are available: *"In rare cases, bismuth or selenium are possible alternatives but implicating unfavourable changes in the casting properties. Development and examination of alternative alloying substances is very time consuming and requires high financial expenditure. Due to this, SMEs are hardly able to afford this. This was confirmed by the European research project CASCOP[23]: in extensive trials bronze as well as lead-free and lead-reduced alloys were processed under defined production".*

[23] CASCOP 2004, accessed at: https://cordis.europa.eu/project/id/G1ST-CT-2002-50233 on 10 of February 2021.

According to Negru et al. (2020), the general trend in many sectors in Romania is to replace the lead alloys with alloys without lead or with low lead content.

Alternatives to lead as an alloying element in steel, aluminium and copper alloys for electrical and electronic equipment (EEE) has been assessed as part of the evaluation of the exemption for lead-acid batteries under the RoHS Directive (Directive 2011/65/EU) (Gensch et al., 2016b). Although the applications of the alloys in EEE may not be representative for all applications of the alloy, the evaluation for the applications in EEE is summarised in the following sections as it is indicative for the general applications.

4.9.7.1 Steel alloys

Gensch et al. (2016b) concludes that for lead in steel for machining purposes substitution with bismuth containing steel might not be reliable and might cause negative environmental impacts. Substitution with steel that does not contain lead is scientifically or technically practicable at least for some applications as shown by examples with lead-free re-phosphorised and re-sulfurised steel used for the production of specialty fasteners and of re-sulfurised steel used for the production of printer rails and printer shafts. For find substitutes for the remaining applications, a comprehensive survey of the supply chain and the applications used is required to narrow the scope of the exemption to a comprehensive list of applications (Gensch et al., 2016b).

4.9.7.2 Aluminium alloys

Substitution of lead as alloying element with bismuth is technically feasible and alternatives exist. These have been used as alloys in the automotive sector. Gensch et al., 2016b conclude that substitutes are available on the market and their producers claim they are reliable, similar to lead in aluminium alloys for machining purposes. Gensch et al. (2016b) recommend that the exemption could be renewed for a short period, to allow EEE manufacturers a sufficient transition period to move to the lead-free alloys available on the market.

4.9.7.3 Copper alloys

Suggested alternatives are stainless steel and alloys with a lower lead content. According to Gensch et al. (2016b) there are substitutes available that could be used for at least some applications. However, the use of alternatives requires adaptations in the machining process. Consequently, substitution is currently understood to have restrictions limiting its applicability to certain applications and requiring machining adaptations in others. There are results from publicly funded research that suggest how to overcome machinability challenges. Therefore, it can be assumed that at least for some applications, the machining problems can be overcome in the future (Gensch et al.,2016b)

4.9.8 PVC stabilisers

According to the Annex XV report on lead in PVC (ECHA, 2016), a number of stabilisers for PVC have been traditionally used in the EU and worldwide in the various PVC applications, such as: cadmium compounds; tin compounds; liquid mixed metal stabilisers etc. According to comments submitted from associated EU industry to ECHA, calcium-based systems are the logical replacement for the lead stabilisers. According to industry, the most common rigid PVC applications (e.g. window frames) uses a typical composition contain mainly calcium-based stabiliser systems at a concentration of approximately 3.5% (w/w). No other alternative technologies have been reported to ECHA as appropriate for lead and, therefore, after considering the information on the various alternative systems, ECHA decided to focus its assessment for potential alternative to lead stabilisers exclusively on the calcium based-systems. Overall, from the available studies and literature it can be generally concluded that:

- calcium-based stabilisers (incorporating the proven range of co-stabilisers) have low health and environmental toxicity;

- calcium-based systems have a much lower hazard profile (non-classified) than the lead compounds used as PVC stabilisers (ECHA, 2016)

Furthermore, ECHA concludes that the cost/performance difference between a lead formulation and a calcium-based system is negligible overall.

4.9.9 Pigments

As described in section 4.5.4, authorisation has been granted for two lead chromate pigments which are the lead pigments used in largest quantities. According to CEPE, the trade association representing the European paints industry, alternatives are available and widely used in the market place. The trade association argues that several global paint producers, including AkzoNobel, BASF and Jotun, have banned lead pigments from all of their formulations worldwide.[24]

4.10 Voluntary industry initiatives

The European Stabiliser Producers Association (ESPA) substituted lead stabilisers in the EU by 2015 as part of the VinylPlus Voluntary Commitment[25].

The International Lead Association (ILA) has established a voluntary employee blood-lead reduction programme, known as the Lead Action 21 programme. The Lead Action 21 Plan specifies as part of its charter that operations are managed responsibly and safely to continually reduce the impact to human health and the adoption of best practice is encouraged (ILA, 2018a). Enrolment into the programme and demonstration of continuous improvement are a condition of membership of the ILA.

The Lead Action 21 (LA21) programme[26] provides a focus for members to share past, present and future initiatives designed to encourage and embed the principles of sustainable development throughout the lead producing world. It sets out to:

- **Inform** - share knowledge of the safe production, use and recycling of lead and its contribution to life in the 21st century; share best practice to ensure the highest levels of protection for human health and the environment and make the highest standards the norm – everywhere;

- **Support** - build on the work of the International Lead Management Center and use its expertise to provide practical help and guidance to countries, in the developing world and those in transition, that need it; and

- **Improve** - put measures in place for continuous improvement.

Sectoral targets are established, the latest being zero employees exceeding a blood-lead level of 20 µg/100 ml. At the beginning of the programme in 2013, nearly 2,000 workers (representing 25% of all workers across ILA member companies in 2013) had a blood lead values exceeding 20 µg/100 ml. By the end of 2019, approximately 800 workers (representing just over 10% of the membership workforce in 2019) had blood lead levels exceeding 20 µg/100 ml. ILA emphasizes that this improvement has been achieved without corresponding reductions in air lead concentrations and is testament to the fact that blood lead

[24] EU paint associations oppose lead pigments authorisation. https://chemicalwatch.com/23102/eu-paint-associations-oppose-lead-pigments-authorisation

[25] ESPA (2016): Stabilisers – What's new? Update January 2016, accessed at: https://www.stabilisers.eu/wp-content/uploads/2016/01/ESPA-stabilisers_update_January-20161.pdf on 21 November 2018.

[26] International Lead Association (2018): Lead Action 21 0 Environmental and social responsibility for the 21st century. Available at: http://15elbc.ila-lead.org/responsibility/lead-action-21. Accessed March 2021.

levels can be reduced without recourse to using prohibitively expensive engineering solutions (ILA, 2020).

The ILA voluntary programme also highlights the reproductive toxicity concerns with exposure of women to lead. Therefore, it recommends that blood-lead levels of females of reproductive capacity (defined as ≤45 years of age or as agreed by the company medical advisor) be maintained below 10 µg/100 ml.

The documentation that supports the programme highlights women of childbearing potential and breastfeeding women as a sensitive subpopulation and recommends that exposure of female workers of childbearing potential be kept as low as reasonably practicable and certainly below 10 µg/100 ml. A DNEL of 40 µg/100 ml has been included in lead metal and lead compounds REACH Chemical Safety Reports authored by the Lead REACH Consortium to protect women of reproductive capacity.

As part of the initiative, the ILA has produced a number of guidance notes[27] for reducing occupational exposure to lead, and has set ten golden rules for good practice. These are:

- Plant workers must wear designated clothes, that are provided by their employer in the workplace;
- Wear clean work wear every day or shift and change during the working day if necessary;
- Wear appropriate fit tested and properly maintained respiratory equipment, and/or apply the correct ventilation;
- Always shower after the end of every shift and whenever potential contamination risks have been high;
- Do not take work wear home for cleaning or washing;
- Adopt work practices that minimise or mitigate occupational exposure to lead;
- Segregate work areas from administrative offices and eating areas;
- Ensure that drinking and eating areas are always clean and lead free;
- Always wash hands and face and scrub nails prior to eating at the workplace; and
- Never smoke at work.

In addition, as lead is specifically referenced in the EU Pregnant Workers Directive[28], all companies are mandated to follow procedures established in national implementation.

Eurobat, the Association of European Automotive and Industrial Battery Manufacturers, adopted “The EUROBAT Blood Lead Mitigation Programme”[29] in 2000 and revised it in 2013 and in 2017. The programme corresponds to the programme set out by the ILA. The strategic objective is to minimise the lead exposure of employees in the EU to a level that is as low as reasonably practicable. This will be achieved by setting a target to reduce blood lead levels of all employees to below 25 µg/dl by the end of 2019 and below 20 µg/dl by end of 2025.

When participating in the programme, companies follow the following blood monitoring scheme for taking blood lead samples of their employees (stakeholder consultation):

- < 10 µg/100 ml — at least once per year
- ≥ 10 µg/100 ml and < 15 µg/100 ml — at least every 6 months

[27] International Lead Association (2019): Guidance Notes. Partly available at: Resources – ILA (ila-lead.org) (accessed March 2021)

[28] European Commission (1992): Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). Available at: http://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:31992L0085

[29] Eurobat Occupational Health & Safety (eurobat.org) (accessed July 2021)

- ≥ 15 µg/100 ml to < 20 µg/100 ml at least every 3 months
- ≥ 20 µg/100 ml at least every 2 months

Female employees in age of childbearing capacity follow a scheme with more frequent sampling at lower PbB:

- < 5 µg/100 ml at least once per year
- ≥ 5 µg/100 ml to < 8 µg/100 ml at least every 3 months
- ≥ 8 µg/100 ml at least every 2 months

4.11 Best practice

4.11.1 Guidance prepared by the International Lead Association (ILA)

The International Lead Association (ILA) has produced guidelines designed to support the ILA Voluntary Blood-lead Reduction Programme. The guidelines tend to provide more detail than the older guidance notes available on the website of the organisation, for example in regards regular health surveillance (biomonitoring) and practical advice/ideas regarding engineering controls. The guidelines have been provided for the previous OEL study (Lassen et al., 2019), but are not public available and cannot be wholly reproduced here.

ILA has produced a number of guidance notes[30] for reducing occupational exposure to lead. The guidance notes tend to describe good practice rather than best practice.

General risk management measures that are recommended are (partly direct citation):

- Engineering and ventilation controls: The enclosure of equipment, negative draft exhaust systems (extract dust back into enclosures), and/or the use of specific LEV, should be installed where there are unavoidable emission sources. Work area ventilation should be balanced and air captured by the ventilation system may require treatment before discharge or recirculation;

- Workplace cleaning: Frequent washing/HEPA vacuuming is essential and the workplace should be cleaned after every shift;

- Personal Protective Equipment: A compliance policy should be considered where an assessment has indicated that PPE is needed, clean work clothes should be provided daily to workers in areas of significant exposure with the work clothing cleaned on-site by the employer under controlled conditions. Respirator and mask fit testing, cleaning and filter change regimes should also be maintained and workers should ensure the safety equipment fits well, is in good condition and the instructions for use are followed;

- Personal hygiene: Employers should ensure that workers have knowledge of basic, essential hygiene rules and these should be enforced. This includes workers in high exposure areas at the end of their shift passing through a room with wash basins to wash hands, then a 'plant side' changing room for removing work clothing, then through showers on the 'clean' side for changing into personal clothes; and

- Blood-lead monitoring: A blood-lead monitoring program should be put in place.

[30] International Lead Association (2019): Guidance Notes. Partly available at: Resources – ILA (ila-lead.org) (March 2021)

Specific measures are recommended for emissions (ILA, Undated,1).[31] Releases of lead (which would thus result in exposure) can occur during crushing operations (dust); sintering; transportation; furnace charging, smelting and tapping (lead smelting plants); battery breaking; and refining in primary and secondary circuits. The following measures are recommended for reducing exposure:

- The use of LEV and clean air stations with positive filtered air;
- Vehicles with enclosed cabs that have positive-pressure HEPA filtered air;
- Respiratory protection for those workers involved in processing operations;
- Regularly wash down areas with water and also keep working surfaces damp;
- Never dry sweep process areas; and
- Contain the whole process in one enclosed building if possible and separate operations from each other.

The ILA has also issued guidance notes on the design of changing room and washing facilities and effluent control and monitoring (ILA, undated,2).[32]

Table 4-74 Control of emissions

Process	Risk Management Measures
Furnace operations	Enclose furnace operations
Reaction temperatures	Reduce, where possible kettle or crucible temperatures for decreasing the rate of dross formation and the generation of sulphur dust
Furnace metal	Tap into moulds/pots under a ventilated shroud or directly into a bath with covered and ventilated lead for minimising fugitive emissions
Layout of the plant	The plant layout can be modified to reduce the quantity of materials handled and transported from one process to the next process
Ingot casting	Reduce temperature to below 500 ºC for reducing emissions with a controlled flow rate to reduce dross formation
Mechanical operations	Where possible, for tasks with high exposure use mechanical means
Capturing emissions	Capture dust or fumes; isolate emission sources using LEV or an appropriate sized baghouse filter plant
Exhaust characteristics	The capture velocity of the exhaust hood needs to be great enough to prevent dust or fumes from escaping from the air flow; Face velocity required will be at a minimum, one metre per second
Process risk assessment	Perform a risk assessment of the process; establish safe procedures; establish monitoring, inspection and maintenance regimes where engineering controls are used

Source: International Lead Association (undated): Control and Monitoring of Atmospheric Emissions. Available at: ILA9149_GN_Atmospheric_V04b.pdf (ila-lead.org) (March 2021)

31 International Lead Association (undated): Control and Monitoring of Atmospheric Emissions. Available at: ILA9149_GN_Atmospheric_V04b.pdf (ila-lead.org) (March 2021)

32 (a) International Lead Association (undated): Design of Changing Rooms and Washing Facilities. Available at: ILA_GN_Changing_new–V05.pdf (ila-lead.org) and (b) International Lead Association (undated): Effluent Control and Monitoring. Available at: ILA_GN_Effluent_V04.pdf (ila-lead.org) (March 2021)

Airborne dust and vapours from molten lead is a significant route of exposure. If the dust or vapour source cannot be minimised (e.g. by wetting down floors to stop settled dust from becoming airborne), then use of engineering controls such as local exhaust ventilation will be necessary to limit exposure. The following are some examples of engineering and procedural controls for secondary lead smelters listed in the detailed best practice guidelines designed to support the ILA Voluntary Blood-lead Reduction Programmes:

- Provide vehicles with enclosed cabs that have positive-pressure, HEPA filtered air
- Maintain raw material storage and handling areas under a negative-pressure enclosure to prevent contamination of adjacent work areas
- Minimize the height of free fall of materials dumped into storage bins
- Wash vehicles to prevent spread of contamination when exiting storage areas
- Vacuum the inside of mobile equipment frequently
- Wet down materials and surfaces to suppress dust generation
- Provide properly designed exhaust hoods with local exhaust ventilation for saws, shears, shredders, and crushers (hammer mills) to control lead emissions
- Provide enclosure and local exhaust ventilation for the shredded battery conveyor and transfer points
- Provide curtains or shields on battery- breaking equipment to contain mists and liquid droplets containing lead particulate
- Vacuum surfaces using HEPA filtered portable or central vacuum systems
- Provide efficient local exhaust ventilation and if possible enclose lead and slag tapping operations
- Install dross pot hoods with effective local exhaust ventilation · Consider use of supplied air islands during dispensing, and other materials handling operations
- Provide local exhaust ventilation for ingot casting
- Enclose refining kettles.

4.11.2 Guidance prepared by Member State authorities

Malta. Many Member State authorities have prepared guidelines for safer work with lead. As an example, the Occupational Health and Safety Authority of Malta has prepared guidelines which describe best practice when working with lead (OHSA, 2016). The following is an extract from the guidelines (partly direct citation) which in particular describe RMMs used in artisanal and small-scale operations:

4.11.2.1 Elimination and substitution:

- The most practical way by which lead can be eliminated is by replacing lead-containing material with a less hazardous material such as applying a non-leaded paint rather than one which contains lead.

- Process equipment can be changed, such as using less dusty methods for example vacuum blast cleaning, wet abrasive blast cleaning, shrouded power and chemical stripping in order to substitute for open abrasive blast cleaning thus reducing exposure to respirable airborne particulates, which contains lead.

- Demolition work can be performed using hydraulic shears instead of a cutting torch in order to reduce exposure to lead fumes generated by heating lead compounds.

4.11.2.2 Engineering controls:

Some engineering controls, which can be used to reduce worker exposure to lead, include:

- Ventilation; local or dilution. Local exhaust ventilation includes portable ventilation system and shrouded tools, which are supplied with ventilation. Processes where lead being released is localised includes welding, brazing and casting operations.

- Exhaust Ventilation Power Tools – which can be used for the removal of lead-based paint and which is equipped with dust collection shroud exhausted through high efficiency particulate air (HEPA) vacuum system.

- Enclosure/encapsulation – lead-based paint can be made inaccessible by encapsulating with material bound to surface such as acrylic or epoxy coating or through flexible wall coverings or by enclosing it in gypsum wallboard, plywood panelling and aluminium, vinyl or wood exterior siding.

- Process modification – wet working methods can minimise the amount of lead dust produced. Lead or lead-containing materials are cut by hand sawing or mechanical shearing rather than using oxy-fuel torches or arc-air gouging.

4.11.2.3 Administrative Controls:

- Worker education and training. Workers require training and instruction on hazards of lead, correct operation and use of engineering controls.

- Good housekeeping. Workers must maintain work areas and surfaces clean. Surfaces cannot be wiped or swept as this will raise lead dust in the air.

- Proper use of washing facilities and clean eating and drink areas. Adequate washing, showering and change facilities have to be provided. A separate room isolated from work area must be provided for storing food, drinking and eating food.

- Safe work procedures. Employers must ensure safe work procedures where workers are exposed to lead.

- Maintenance of equipment.

- Scheduling of the work or the worker. The amount of time a worker is exposed to lead should be minimised through job rotation and different work assignments.

- Implementation of a health protection program. If the workers are being exposed to high levels of lead, a health protection program has to be in place whereby employers regularly monitor the blood-lead levels of workers.

4.11.2.4 Personal Protective Equipment:

In case of residual exposure, where the workers are still exposed to a particular chemical after all possible measures were taken, the use of personal protective equipment (PPE), must be enforced. This is always the last resort. In any processes which generate airborne lead levels, employers must ensure that employees are given the appropriate personal protective equipment which includes coveralls, shoe covers, head covers, gloves and respirators. Leather gloves or the equivalent must be used when unencapsulated lead bricks are used.

4.12 Standard monitoring methods/tools

4.12.1 Standard for monitoring compliance with OEL

Procedures for monitoring of contaminants in the workplace are typically established by national guidelines prepared by the national working environment authorities. These guidelines would typically refer to European standards to be used for the monitoring.

As concerns the monitoring of substances in the workplace, guidelines refer to two European standards:

- EN 482:2012+A1:2015: Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents.
- EN 689:2018: Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values

The strategy described in EN 689:2018 gives a procedure for the employer to overcome the problem of variability and to use a relatively small number of measurements to demonstrate with a high degree of confidence that workers are unlikely to be exposed to concentrations exceeding the OELs.

EN-689:2018 comprises three main steps concerning groups of workers having similar exposure (SEG, similar exposure group). During the first step, Basic Characterization, the appraiser collects available information to allow reliable estimates of the exposure of the workers and to take the decision whether to perform exposure measurements. The second step, Initial Assessment, consists of performing between three and five representative exposure measurements for the workers of each SEG, to demonstrate by using a statistical test whether less than 5% of exposures in the SEG exceed the OEL (compliance). In a third step and based on IA (impact assessment) results, a program of Periodic Reassessment determines time intervals ranging from one to three years for performing new measurements, depending of the levels of exposure. This assumes that no major changes (e.g. process, RMM, quantities and nature of chemicals) have occurred during this period.

The compliance with an OEL is determined by either a screening or a test of compliance.

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

- If all results are below:
  - 1) 0.1 * OEL for a set of three exposure measurements or,
  - 2) 0.15 * OEL for a set of four exposure measurements or,
  - 3) 0.2 * OEL for a set of five exposure measurements
  - then it is considered that the OEL is respected: **Compliance**.
- If one of the results is greater than the OEL, it is considered that the OEL is not respected: **Non-compliance.** In case that the first measurement result is above the OEL, it is not necessary to perform any additional measurements.
- If all the results are below the OEL and a result above 0.1 * OEL (set of three results) or 0.15 * OEL (set of four results) or 0.2 * OEL (set of five results) it is not possible to conclude on compliance with the OEL. **No-decision.** In this situation additional exposure measurements shall be carried out in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OEL, as specified below.

Test of compliance with the OEL

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

In order to undertake the screening tests, ideally an analytical method with a limit of quantification (LOQ) at 0.1 * OEL would be required; otherwise it will be necessary to undertake more tests and the costs of monitoring increases.

4.12.2 Available analytical standards for monitoring inorganic lead and its compounds in air

A list of relevant analytical standards is shown in Table 4-75 on the basis of lists provided by the 'GESTIS - Analytical methods' database. All methods use an inhalable sampler and consequently measure the inhalable fraction.

The GESTIS (International limits for chemical substances) 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 with a ranking of the methods. An 'A' ranking indicates that all or most of the requirements of EN 482 are met, while a 'B' ranking indicates incomplete validation data, but a potential to meet the requirements of EN 482. Methods ranked 'C' in the original evaluation are not considered to be able to meet the requirements of the norm and are often not included in the 'method sheets'. Full details on the ranking procedures are available on the website.

The GESTIS - Analytical methods' database contains 8 standards for analysis of inorganic lead. Only the 4 methods with the Category A rating "*the methods meet all or most of the requirements of the EN 482 (1999)*" are shown in Table 4-75 overleaf.

Table 4-75 Analytical methods for inorganic lead and its compounds (as Pb) in air[1]

No	Source and method name	Lan-guage	Year of pub-lication [3]	Principle of the method	Flow rate (Recommended air volume; time)	Limit of quantifica-tion (LOQ) /Vali-dated working range (WR) /Expanded uncertainty (U)	Indica-tive rating [2]	Remarks
1	ISO 8518 Workplace air — Determina-tion of particulate lead and lead compounds — Flame or electrothermal atomic ab-sorption spectrometry (FAAS or ETAAS) method	English	2001 (re-viewed in 2013)	Particulates trapped on a suitable fil-ter in an **inhalable** sampler. Hotplate dissolution with HNO3, H2O2 and if lead silicate is present HF. Microwave dissolution with HNO3 and if lead silicate is present HF. Ultrasonic dissolution with 1+9 HNO3. Analysis by FAAS or ETAAS.	Flow rate: Sampler–depend-ent Recommended sampling time: 15 min–8 h	LOQ: ETAAS: 0,00034 mg/m^3 30 l FAAS: 0,0018 mg/m^3 480 l	A	
2	ISO 15202 Workplace air — Determina-tion 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	Eng-lish, French	Part 1:2012 (revised 2020) Part 2:2012 (revised 2020) Part 3:2004 (reviewed in 2019)	Particulates trapped on a suitable fil-ter 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–depend-ent Recommended sampling time: 15 min–8 h	LOQ: 0,028 mg/m^3 30 l 0,0017 mg/m^3 480 l	A	
3	MDHS 6/3	English	1998	Particulates trapped on an MCE or other suitable filter mounted in an	2 l/min 30–960 l	LOQ: ETAAS:	A	Similar method described in

No	Source and method name	Language	Year of publication [3]	Principle of the method	Flow rate (Recommended air volume; time)	Limit of quantification (LOQ) /Validated working range (WR) /Expanded uncertainty (U)	Indicative rating [2]	Remarks
	Lead and inorganic compounds of lead in air — Laboratory method using flame or electrothermal atomic absorption spectrometry			**inhalable** sampler. Hotplate dissolution with HNO3 and H2O2. Analysis by FAAS or ETAAS.		0,00034 mg/m3 30 l FAAS: 0,0018 mg/m3 480 l		ISO 8518
4	MDHS 91 Metals and metalloids in workplace air by X-ray fluorescence spectrometry	English	1998 (latest version from 2014)	Particulates trapped on an MCE or other suitable filter mounted in an **inhalable** sampler. Analysis by XRF.	2 l/min 60–960 l	LOQ: 0,017 mg/m3 60 l	A	Filter only analysis

[1] *Listed in the Gestis database as methods for "lead and its inorganic compounds".*

[2] *Category A rating "the methods meets all or most of the requirements of the EN 482 (1999)"*

[3] *Checked in this study for newest versions of standards. Year of newest version and review data has been obtained from standard organisations*

Source: Gestis database at https://amcaw.ifa.dguv.de/substance/methoden/073-L-Lead.pdf (March 2021)

4.12.3 Methods for biomonitoring of lead in blood

Lead concentrations in blood, plasma, urine, faeces, liver, kidney, hair, and other biological media have been used as biological indicators of exposure to lead. The following focuses on blood-lead monitoring only. The lead concentration in blood (mainly erythrocyte lead) is a representative of soft tissue lead and reflects, mainly, the exposure history of the previous few months and does not necessarily reflect the total body burden including the much slower elimination kinetics of lead in bone (Tiesjema and Mengelers, 2016).

The World Health Organization, WHO (2011) has prepared a brief guide to analytical methods for measuring lead in blood. According to the review: *“a number of laboratory methods are available to determine blood-lead concentrations. The most common are atomic absorption spectrometry (AAS), anodic stripping voltammetry (ASV) and inductively coupled plasma mass spectrometry (ICP-MS). In addition, a simple to use, portable device using ASV technology is available for performing blood-lead measurements at point of care. These methods differ significantly in their analytical capacities (e.g. limits of detection, accuracy), costs (e.g. purchase and maintenance costs, laboratory infrastructure required, reagents and supplies) and technical requirements (e.g. sample preparation, calibration, skilled personnel). These factors, taken in conjunction with the setting and resources of the laboratory, will influence the decision about the choice of method. The required limit of detection is an important consideration. In many countries, there has been a successive reduction in the blood-lead concentration considered to be of clinical concern.”*

Public health measures in a number of countries have succeeded in reducing the mean blood concentration in populations and this has resulted in increased interest in measuring ever-lower blood-lead concentrations and created a need for analytical methods that can perform at low levels of detection.

Different analytical methods are summarized in Table 4-76.

Whereas it may be challenging to reach a sufficiently low limit of quantification when monitoring the general population, the detection limits of most methods are well below the lowest existing BLVs in Member States and voluntary industry targets.

According to Caldwell et al. (2017), blood-lead levels in US children 1 to 5 years old have declined to a point (95^{th} percentiles around 3 µg/100 ml) that challenges the limit of detection (LOD) of many laboratories. The authors conclude that to achieve precise and accurate blood-lead measurements with lower LODs, laboratories need to evaluate potential sources of external lead contamination, optimize their analytical methods for low-concentration measurements, and participate in external proficiency testing programs, considering how they would perform if tighter acceptability criteria were used. Manufacturers of devices used in blood-lead sample collection could identify potential sources of lead contamination and take actions to reduce these sources (Caldwell et al., 2017).

Table 4-76 Overview of analytical methods for blood-lead measurement (WHO, 2011)

Method	Strengths	Limitations
Flame atomic absorption spectrometry (FAAS)	• Requires only basic laboratory expertise • Rapid analysis • Small sample size using Delves cup (50–100 µl) • Low purchase and running costs • Relatively few interferences • Robust interface	• Relatively high detection limit (~10 µg/100 ml) • Time needed for sample digestion/preconcentration if not using Delves cup • Large sample size needed for nebulization methods • Should not be left to run • unattended
Graphite furnace atomic absorption spectrometry (GFAAS)	• Good detection limit (<1–2 µg/100 ml) • Small sample size • Moderate purchase and running costs • Some multi-element capacity • Relatively few interferences (although more than with FAAS) • Widely used, available from multiple vendors	• Longer analysis time • Requires some laboratory expertise (more than FAAS) • Greater potential spectral interference than with FAAS
Laboratory anodic stripping voltammetry (ASV)	• Good detection limit (2-3 µg/100 ml) • Low purchase and running costs • Rapid • Small sample size (~100 µl) • Relative simplicity of equipment	• Requires some laboratory expertise (similar to GFAAS) • Sample pretreatment needed • Some factors might affect • measurement (e.g. presence of copper) • Becoming less available
Portable ASV	• Portable; measurement at point of • care possible • Simple to use; does not require • skilled laboratory personnel • Very low purchase and running costs • Reasonably good detection limit for a portable device (3.3 µg/100 ml) • Rapid	• Not as accurate as other methods • Can determine levels only up to 65 µg/100ml • Levels above 8 µg/100ml should be confirmed by a laboratory method
Inductively coupled plasma mass spectrometry (ICP-MS)	• Excellent method detection limit (~0.1 µg/100 ml) • Rapid • Small sample size (50–100 µl) • Relatively few, well-understood, spectral interferences • Isotopic measurements possible • Economic if very large number of samples • Multi-element capability	• High purchase and running costs • Highly skilled laboratory operator required

4.13 Relevance of REACH Restrictions and Authorisation and other legislation

This section summarises recent legislation that has impacted on the use of lead and its compounds or has the potential to do so in the future. Only legislation other than the OSH (Occupational Safety and Health) directives, being the focus of this study, is considered.

4.13.1 Candidate list

As of February 2021, the Candidate List of Substances of Very High Concern for Authorisation contains lead metal and 31 lead compounds.

Lead metal was added to the Candidate List in June 2018[33] due to its reprotoxic properties. The 31 other lead compounds are included either because of reprotoxicity or reprotoxicity and carcinogenicity[34].

4.13.2 Restrictions under REACH

Restrictions in the use of lead under REACH are listed in the table below with indication of the REACH Annex XVII entry number.

Table 4-77 REACH restrictions on inorganic lead and its compounds

Entry	Restriction
16	**Lead carbonates** (neutral anhydrous carbonate and trilead-bis(carbonate)-dihydroxide) shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as **paint**. However, Member States may permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings.
17	**Lead sulphates** (lead sulphate and sulphuric acid, lead salt) shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as **paint**. However, Member States may permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings.
19	Restrictions on arsenic compounds; among these some **arsenic-lead compounds**.
30	Since lead and lead compounds are Repr. 1A, they are covered by entry 30 in Annex XVII of REACH and this means that they cannot not be **placed on the market, or used, as substances, as constituents of other substances, or in mixtures, for supply to the general public** when the individual concentration in the substance or mixture is equal to or greater than: — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. The restriction does not concern lead in articles.
63	Prohibits the placing on the market and use of lead and its compounds in metallic and non-metallic parts of **jewellery articles**, if the lead concentration is equal to or greater than 0.05% by weight of the individual part. (with some derogations) Prohibit the placing on the market used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05% by weight, and **those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children**. That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm² per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article. Prohibits the use of **gunshot** containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight in or within 100 metres of wetlands after 15 February 2023 (with a single derogation until February 2024).

[33] ECHA, 10 new substances added to the Candidate List, accessed at: https://echa.europa.eu/fi/-/ten-new-substances-added-to-the-candidate-list on 21 November 2018.

[34] ECHA, Candidate List of substances of very high concern for Authorisation, accessed at: https://echa.europa.eu/candidate-list-table on 08 February 2021.

A restriction on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds has been proposed and evaluated by RAC and SEAC (Committee for Socio-Economic Analysis) and it is currently awaiting a decision by the European Commission[35]. The proposed restriction includes an exemption for use of recycled PVC with <1% lead in a number of articles mainly for the building sector. The European Stabiliser Producers Association (ESPA) substituted lead stabilisers in the EU by 2015 as part of the VinylPlus Voluntary Commitment[36]. However, as noted earlier in this document, there is still some occupational exposure by the recycling of PVC with lead stabilisers.

A restriction on the use of lead shots over wetlands (containing lead in concentrations greater than 1% by weight), where spent gunshot would land within a wetland, including shooting ranges or shooting grounds in wetlands, has been evaluated by RAC and SEAC and recently been decided by the European Commission, leading to an update of entry 63. Furthermore, a restriction report for use of lead in projectiles (for firearms and airguns), in fishing sinkers and lures for outdoor activities has been submitted by ECHA in January 2021 and is awaiting opinions by RAC and SEAC[37].

A restriction proposal for articles that contain lead chromate, lead sulfochromate yellow and lead chromate molybdate sulphate red (substances under Authorisation) by ECHA has been submitted in April 2021 but withdrawn again in May 2021, as the Dossier Submitter is awaiting further information on how the Commission intends to progress the decision-making on the proposed restriction of lead in PVC, before being able to complete the Annex XV dossier.

4.13.3 Authorisation

Three lead substances are subject to authorisation under REACH (Table 4-78). Authorisation has been granted for certain applications of the three substances.

Table 4-78 Lead compounds subject to authorisation under REACH

Substance (REACH registration name)	EC number	Authorised use	Quantities	Date of expiry of review period
Lead sulfochromate yellow	215-693-7	Distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use.	According to the authorisation decision, the total amounts used should not exceed 2,100 t/year	21/05/2022
		Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.)		21/05/2022
		Professional, non-consumer application of paints on metal surfaces (such as		21/05/2019

[35] ECHA, Lead and its compounds. Accessed at: https://echa.europa.eu/da/registry-of-restriction-intentions/-/dislist/details/0b0236e180a40af7 on 09 February 2021

[36] ESPA (2016): Stabilisers – What's new? Update January 2016, accessed at: https://www.stabilisers.eu/wp-content/uploads/2016/01/ESPA-stabilisers_update_January-20161.pdf on 9 February 2021.

[37] Lead and its compounds - Registry of restriction intentions until outcome - ECHA (europa.eu)

Substance (REACH registration name)	EC number	Authorised use	Quantities	Date of expiry of review period
		machines, vehicles, structures, signs, road furniture, etc.) or as road marking.		
		Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use.		21/05/2022
		Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use.		21/05/2022
		Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking.		21/05/2019
Lead chromate	231-846-0	Industrial use of lead chromate in the production of pyrotechnical delay devices contained into ammunition for naval self-protection	Not registered (i.e. <1 t/year), no indication of authorised quantities	04/08/2024
Lead chromate molybdate sulfate red	235-759-9	Distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use.	According to the authorisation decision, the total amounts used should not exceed 900 t/year	21/05/2022
		Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.)		21/05/2022
		Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking.		21/05/2019
		Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use.		21/05/2022
		Industrial use of solid or liquid colour premixes and precompounds containing pigment to colour plastic or plasticised articles for non-consumer use.		21/05/2022
		Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking.		21/05/2019

** The public parts of authorisation applications do not contain information on actual quantities.*

4.13.4 Other legislation

Lead and lead compounds are also covered by other pieces of EU legislation, such as the Restriction of Hazardous Substances Directive 2002/95/EC (RoHS Directive), the End of Life Vehicle Directive, Cosmetic Regulation, Toy Safety Directive, Batteries Directive, and Pregnant Workers Directive.

Legislation that is relevant to the design, use and end of life lead batteries includes the Battery Directive, End of Life Vehicle Directive, the Waste Framework Directive and Waste Shipment Regulations. Three of the mentioned legislations with potential significance on workers exposure to lead are discussed below.

Pregnant and Breastfeeding Workers Directive 92/85/EEC

The objective of this Directive is to protect the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding. Under the Directive, a set of guidelines detail the assessment of the chemical, physical and biological agents and industrial processes considered dangerous for the health and safety of pregnant women or women who have just given birth and are breast feeding.

Lead and lead derivatives are listed in Annex II of this directive, meaning that neither pregnant worker, nor breastfeeding workers may be obliged to perform duties for which a risk of exposure to lead has been identified.

However, it is also noted that the Pregnant Workers Directive does not provide sufficient protection from developmental effects, as it only contains provisions for pregnant workers (from the moment they have notified their employer, typically three months within pregnancy) and workers who have recently given birth or are breastfeeding. Lead absorbed in skeletal tissue (bones, teeth) is mobilised during pregnancy. Therefore, exposures long before pregnancy may cause health effects in offspring.

Young Workers Directive 94/33/EC

The objective of this Directive is to lay down minimum requirements for the protection of young people at work. The Directive defines "young people" and "children" and sets out necessary measures to prohibit work by children. It also obliges Member States to prohibit the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. "Lead and compounds thereof, in as much as the agents in question are absorbable by the human organism" are recognised as such and listed in the Annex of this Directive.

The measures of the Directive thus protect any worker under 18 years of age from the risk of exposure to lead.

Batteries Regulation

The Commission proposed a new Batteries Regulation[38] on 10 December 2020. This Regulation aims to ensure that batteries placed in the EU market are sustainable and safe throughout their entire life cycle. The current regulatory framework covers only the end-of-life stage of batteries through the Batteries Directive. There are currently no legal provisions in the EU that cover other aspects of the production and use phases of batteries, such as electrochemical performance and durability, GHG emissions, or responsible sourcing. The proposed Batteries Regulation is intended to replace the current Batteries

[38] Proposal for batteries regulation https://ec.europa.eu/environment/pdf/waste/batteries/Proposal_for_a_Regulation_on_batteries_and_waste_batteries.pdf

Directive. The new battery regulation is not expected to have a significant impact on lead exposures in the battery manufacture and recycling sectors. The recycling rate of lead acid batteries is already high in the EU (99% of end-of-life lead batteries are currently collected and recycled[39]) and the battery industry is proactively taking measures to limit the blood lead levels of its employees, independently of the battery legislation. Whether the battery regulation may stipulate increased or decreased use of lead acid batteries for applications where substitutions with other types of batteries are possible, is not known yet (Eurobat, 2021).

4.14 Intermediate uses not covered by certain REACH procedures

Under REACH regulations, an intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (REACH Article 3(15)). Several lead compounds occur in intermediate use, as indicated in their REACH registration dossiers. Lead compounds used as intermediates include:

- Lead
- Lead monoxide
- Tetralead trioxide sulphate
- Pentalead tetraoxide sulphate
- Lead dichloride
- Reaction product of lead chloride or lead sulphate with alkaline solution
- Lead oxide sulfate
- Lead carbonate
- Trilead diarsenate
- Lead telluride
- Lead sulphide
- Lead selenide
- Lead sulphate
- Trilead bis(carbonate) dihydroxide
- Acetic acid, lead salt, basic
- Slags, copper refining
- Matte, copper
- Flue dust, zinc-refining
- Leach residues, zinc ore, lead-contg.
- Slags, lead smelting
- Lead, bullion
- Slags, lead reverbatory smelting
- Wastes, lead battery reprocessing
- Calcines, lead-zinc ore conc.
- Matte, lead
- Flue dust, lead-refining
- Lead, dross, copper-rich
- Slimes and sludges, copper electrolytic
- Lead alloy, base, Pb,Sn, dross
- Slimes and Sludges, precious metal refining
- Lead, dross
- Zinc, desilverizing skims

[39] Eurobat, 2020: EUROBAT_Battery_Innovation_Roadmap_2030_White_Paper.pdf

- Residues, zinc smelting
- Lead, dross, antimony-rich
- Speiss, lead
- Lead, dross, bismuth-rich
- Slimes and Sludges, battery scrap, antimony- and lead-rich
- Lead, antimonial, dross
- Matte, precious metal
- Slimes and Sludges, zinc sulfate electrolytic
- Leach residues, zinc ore-calcine, zinc cobalt
- Waste solids, lead silver anode
- Flue dust, precious metal refining
- Slags, tellurium
- Residues, precious metal refining
- cementation
- Residues, copper speiss acid
- leaching
- Leach residues, tellurium

4.15 Market analysis

4.15.1 Stakeholder consultation and public sources on number of enterprises

Data on companies were obtained from the Lead REACH Consortium and supplemented with data from the impact assessments for arsenic and cadmium (previous OEL studies), the homepages of industry associations and stakeholder consultation. An overview of number of companies and sites by sectors for the main sectors is shown in Table 4-79.

The Lead REACH Consortium includes 88 companies that manufacture or import lead or its compounds into the EU[40]. The Association of European Manufacturers of Sporting Ammunition (AFEMS) is an associate member.

Batteries. According to EUROBAT, there are 30 lead-based battery manufacturers in 14 EU Member States and 41 battery recyclers in 15 EU Member States of the EU. A few companies have manufacturing/recycling sites in several Member States, some companies have more than one sites within the same Member State and some companies have activities in both manufacturing and recycling[41].

Lead-based battery manufacturers employ approximately 20,000 workers. The sector's annual turnover is €5 billion and its Research and Development (R&D) expenditure over the past five years has been in excess of €845 million[42].

Manufacture and use of plastics and paints. After the use of lead compounds as stabilisers in virgin PVC has been phased out, the main use of lead compounds in plastics and

[40] Lead Reach Consortium, Members, accessed at: https://ila-reach.org/the-consortium/members/ on 23 February 2021.

[41] Map of European lead battery capacity, accessed at: CTF -Map of European lead battery capacity (chargethefuture.org) on 23 February 2021.

[42] EUROBAT, EUROBAT Position - Annex XV SVHC report published in the context of SVHC identification in accordance with REACH Article 57 – Lead, accessed at: http://www.eurobat.org/images/news/position-papers/23042018_EUROBAT_Position_Paper_on_Annex_XV_Report_on_Lead_Metal.pdf on 23 February 2021.

paints is as pigments. The supply chain consists of manufacturers of the lead pigments, manufacturers of paints and converters of plastics, as well as downstream users of paints. Lead chromate yellow and lead chromate molybdate sulfate red, both subject to authorisation, are the main lead pigments used. The socioeconomic assessments for the authorisation applications are mainly confidential and the public part does not include information on number of downstream users or exposed workforce. According to the background document for lead chromate molybdate sulfate red (ECHA, 2010), "*The supply chains seem to contain a medium number of EU manufacturers and importers. As the pigments are used in many industrial sectors in the application areas of coatings / paints and plastics, a high number of downstream users is envisaged, including formulators and industrial users. Furthermore, a medium number of professional users are anticipated to involve in the supply chains. The involved actors in EU are probably widespread all over EU. Based on the available information, it is assumed that the supply chains of this substance contain many levels and a high number of actors, with the types of industry branches involved producing a large number of different products.*"

Table 4-79 Inorganic lead and its compounds – number of companies/sites by sector

Sector	Uses and/ or activities	No of companies/ enterprises	Known companies (excl. confidential information) in EU-27
1. Primary lead production		6 (covered by the Lead REACH Consortium) Distribution by MS of refined lead productions (primary and secondary) as shown in Table 4.5	Aurubis (DE); Berzelius Stolberg (DE); Boliden Rönnskär (SE); KCM (BG); KGHM Polska Miedz SA (PL); Portovesme (IT)*
2. Secondary lead production (including lead battery recycling)		43 (covered by the Lead REACH Consortium) Distribution by MS of refined lead productions (primary and secondary) as shown in Table 4.5	Amekon SA (EL), Azor Ambiental (ES), APSM (FR), Baterpol (PL), BMG Metall & Recycling (AT), Boliden Bergsöe (SE), BSB Recycling GmbH (DE), Campine (BE), Clarios (formerly JCI, DE), Eco-Bat spa (IT), Ecological Scrap Industry SpA (IT), Ecometal (EE), Elbat JSC (BG), Evros Lead (EL), Exide (PT, ES), Fenix Metals Sp zoo (PL), Harz-Metall GmbH (DE), HOPPECKE Batterien GmbH & Co. KG (DE), Huta Cynka (PL), KCM (BG), Kovohute Pribram Nastupnicka a.s (CZ), Le Plomb Francais sarl (FR), Mach Trade (SO), Metalblanc (FR), Metallo Belgium (BE), Metalurgica de Medina (ES), Monbat Italy SRL (IT), Monbat Recycling (BG), Monbat Recycling SRL (RO), MPI Reciklaza d.o.o (SO), Muldenhutten Recycling und Umwelttechnik GmbH (DE), New Meca srl (IT), Orzel Bialy (PL), Piombifera Italiana S.p.a. (IT), Piomboleghe Srl (IT), RECOBAT (ES), ROMBAT (RO), Sunlight Recycling (EL), Umicore (BE), Weser-Metall (DE), ZAP Sznajder Batterien SA (PL)*, ***

Sector	Uses and/ or activities	No of companies/ enterprises	Known companies (excl. confidential information) in EU-27
3. Lead battery production		30 (covered by the Lead REACH Consortium)	Akkumulatorenfabrik MOLL GmbH + Co. Kg (DE); BAE Batterien (DE); Banner (AT); Centurion (NL); Clarios (formerly JCI; CZ, DE, ES); EnerSys (DE, FR, PL), Exide (DE, ES, IT, PL, PT); FIAMM Energy Technology spa (IT); Hoppecke Batterien GmbH & Co KG (DE); Jász-Plasztik (HU), Jenox (PL); Loxa (PL); PPUH Autopart (PL); SIA (IT); MIDAC (IT); Moll (DE); Monbat (BG); Rombat (RO); SIA Industria Accumulatori SpA (IT); Sunlight Systems (GR); TAB (SO); Vipiemme (IT); ZAP SZNAJDER BATTERIEN S.A. (PL) ***
4. Production of articles of lead metal	Lead sheets	6 (covered by the Lead REACH Consortium) Additional 5 identified through business register search May also produce other lead articles, e.g. for radiation	Anton Schneider (DE); Jamestown Metal (IE); Le Plomb Francais (FR); Metal Processors (IE); Röhr+Stolberg GmbH (DE); Uzimet (NL) * Lam lavorazione piombo (IT), JL Goslar (DE), CO.M.E.T.A. s.r.l. (IT), D'huart industrie (FR), KC Dierovna, spol. S R.O. (SK)
	Ammunition	9 (covered by the Lead REACH Consortium survey)	No data
	Cables	At least 6 (data for 6 companies provided by EuropaCable)	Confidential
	Other products	No data. May also be covered by foundries.	
5. Foundries		Based on the data from CAEF and questionnaires: 90-270	Confidential
6. Production of lead compounds and lead frits		10 manufacturers (covered by the Lead REACH Consortium) 1 manufacturer with authorisation (lead chromate compounds) A large number of downstream users	5N Plus (BE); ASUA Products (ES); Baerlocher (DE); Chemson Polymer-Additive AG (AT); Colorobbia (IT); Coplosa (ES); Flaurea (BE); IKA Innovative Kunstofoffaufbereitung GmbH (DE); Penox (DE, ES); ZM Sileia (PL) * DCC Maastricht B.V. (BE) (authorisation)

Sector	Uses and/ or activities	No of companies/ enterprises	Known companies (excl. confidential information) in EU-27
7. Production of glass		4 (covered by the Lead REACH Consortium) According to BREF (2013), there are many smaller companies, which often specialise in higher value-added products (lead crystal, etc.). Additional 42 lead crystal manufacturers in EU-27 according to https://www.glassglobal.com	BACCARAT (FR); Fiskars (IE); Lalique (FR); St Louis (FR) * Rückl (CZ), Crystal BOHEMIA, a.s (CZ), Anita Crystal Factory (PL), Meissener Bleikristall GmbH (DE)
8. Ceramic ware production and enamelling		8 (covered by the Lead REACH Consortium) These companies mainly produce glazing. The number of users of the glazes is not reported According to Eurostat, the total number of producers of ceramics in the EU is 1,084. Only a minor fraction is assumed to use lead frits in glazing. Estimated additional number: 10-25	Colores Ceramicos SA (ES); CRISTALLERIE DE SAINT PAUL (FR); Esmalglass sau (ES); Ferro GmbH (DE); Ferro Spain (ES); Fritta SLU (ES); Smalticeram Unicer SpA (IT); SPC srl (IT) *
9. Manufacture and use of plastics and paints		Manufacture of paints 24 Manufacture of plastics 60 Estimates derived from Eurostat data and CEPE (2021)	No data obtained
10. Work with lead metal		1,250 – 5,000 Based on the assumption of 4 exposed workers/enterprise and an exposed workforce of 5,000 -20,000 (see section 4.7.2.2.)	E.g. roofing companies working with lead sheet (mainly in Ireland) and car mechanics, when exposed at relevant levels using older lead weights (instead of zinc weights) for balancing tires.
11. Shooting		3,000 – 5,000 shooting ranges used by military and police (see section 4.7.2)	Shooting ranges operated by national armed forces in the Member States. Shooting ranges for hunting and leisure excluded

Sector	Uses and/ or activities	No of companies/ enterprises	Known companies (excl. confidential information) in EU-27
12. Recycling of PVC and other plastics		The total number of recyclers of PVC in the EU is about 100 (VinylPlus, 2017). As most recycle PVC building materials, likely most of the companies handle PVC waste	No data obtained
13. Demolition, repairing and scrap industry	Demolition and renovation	No data - likely a large number across the entire EU	No data
	Scrap industry	No data - likely a large number across the entire EU	No data
	Recycling of glass	30-50 companies **	No data
	WEEE recycling	20 companies (consultation response for cadmium study under CMD 3 (RPA, 2018) extrapolated over EU28 on the basis of WEEE collection data)	
14. Other waste handling and remediation		700 (based on estimates on risk score and Eurostat data)	
15. Other	Copper production	7 primary copper smelters (3 of these included under primary lead production)	Atlantic Copper (ES); New Boliden Harjavalta/Pori (Fi), New Boliden Rönnskär (SE), Aurubis Hamburg (DE), Aurubis Pirdop (BG), GHM Głogów (PO), KGHM Legnica (PO) (3 of these included under primary lead production)
	Manufacture of explosives	6 according to FEEM	Confidential

Sector	Uses and/ or activities	No of companies/ enterprises	Known companies (excl. confidential information) in EU-27
	Laboratories	5 undertaking fire assay according to Lead Reach Consortium No data available for other laboratories; potentially a high number	Boliden Rönnskär (SE); Boliden Harjavalta Oy (FI); C Hafner GmbH + Co KG (DE); Umicore (BE) *

* *Data provided by Lead REACH Consortium 2019. Names of consortia members are available at from https://ila-reach.org/the-consortium/members/*

** *Data collected as part of the CMD 3 assessment of arsenic (RPA, 2018)*

*** *Data updated based on EUROBAT, accessed at: https://chargethefuture.org/ on 23 February 2021.*

4.15.2 Business statistics on number of companies and employees

The following table provides the number of companies and employees within industry and the building/construction sector by NACE code. For most of the sectors, the fraction of companies with potential exposure to lead is small and the data are difficult to interpret. The data provide part of the background for the discussion on number of workers potentially exposed in section 4.7. A score is assigned distinguishing between:

- A - Majority: The majority of the companies is likely to be involved in the work with lead.
- B - Some: A significant part of the companies may be involved in some work involving lead.
- C - Few: Only a few companies within the sector are likely to be involved with work with lead. The data from Eurostat's Structural Business Statistics has limited application for analysing the companies involved in work with lead and the possible occupational exposure.

Table 4-80 Number of companies and employees in 2018 according to Eurostat's Structural Business Statistics database (for EU27_2020).

Sector in this study	Eurostat economic activities (NACE rev. 2 code and label)	No. of enterprises	No. of employed	Exposure score*
1. Primary lead production and mining	B0729 - Mining of other non-ferrous metal ores	325	n.a.	B
	C2443 - Lead, zinc and tin production	173	15,875	A
2. Secondary lead production (including lead battery recycling)	C2443 - Lead, zinc and tin production	173	15,875	A
	E3832 - Recovery of sorted materials	16,126	188,037	B
3. Lead battery production	C272 - Manufacture of batteries and accumulators	460	32,473	A
4. Production of articles of metallic lead	C2593 - Manufacture of wire products, chain and springs	4,261	104,079	C
	C2599 - Manufacture of other fabricated metal products n.e.c.	43,831	361,534	C
	C273 - Manufacture of wiring and wiring devices	3,770	221,804	C
	C2732 - Manufacture of other electronic and electric wires and cables	1,754	102,815	C
	C301 - Building of ships and boats	7,840	155,324	C
	C2454 - Casting of other non-ferrous metals	1,357	23,044	A
5. Foundries and production of articles of leaded alloys	C2433 - Cold forming or folding	n.a.	30,829	C
	C2453 - Casting of light metals	1,600	96,182	B
	C2454 - Casting of other non-ferrous metals	1,357	23,044	A
	C2562 - Machining	120,435	792,400	C
6. Production of lead compounds and lead frits	C2012 - Manufacture of dyes and pigments	473	24,206	C
	C2013 - Manufacture of other inorganic basic chemicals	912	63,508	C
	C2014 - Manufacture of other organic basic chemicals	1,885	224,137	C
7. Production of glass	C231 - Manufacture of glass and glass products	14,119	296,668	C

Sector in this study	Eurostat economic activities (NACE rev. 2 code and label)	No. of enterprises	No. of employed	Exposure score*
	C2319 - Manufacture and processing of other glass, including technical glassware	3,510	38,145	B
8. Ceramic ware production and enamelling	C2331 - Manufacture of ceramic tiles and flags	1,084	61,078	C
	C234 - Manufacture of other porcelain and ceramic products	13,515	98,524	C
	C3212 - Manufacture of jewellery and related articles	27,569	84,009	C
9. Manufacture and use of plastics and paints	C203 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,356	150,384	C
	C222 - Manufacture of plastics products	48,353	1,315,281	C
	C2221 - Manufacture of plastic plates, sheets, tubes and profiles	6,000	272,416	C
	C2223 - Manufacture of builders' ware of plastic	10,416	226,558	C
10. Work with metallic lead	C2512 - Manufacture of doors and windows of metal	54,847	302,627	C
	C26 - Manufacture of computer, electronic and optical products	36,417	1,000,000	C
	C261 - Manufacture of electronic components and boards	10,000	289,395	C
	C27 - Manufacture of electrical equipment	42,350	1,474,720	C
11. Shooting	O84.2.2 - Defence activities		Data not available	B
	O84.2.4 - Public order and safety activities		Data not available	B
12. Recycling of PVC and other plastics	C2221 - Manufacture of plastic plates, sheets, tubes and profiles	6,000	272,416	C
	C2223 - Manufacture of builders' ware of plastic	10,416	226,558	C
	C33 - Repair and installation of machinery and equipment	200,000	1,173,079	C

Sector in this study	Eurostat economic activities (NACE rev. 2 code and label)	No. of enterprises	No. of employed	Exposure score*
13. Demolition, repairing and scrap industry	C3315 - Repair and maintenance of ships and boats	16,408	91,165	B
	E383 - Materials recovery	19,224	205,726	B
	E3831 - Dismantling of wrecks	3,097	17,689	B
	E3832 - Recovery of sorted materials	16,126	188,037	B
	E39 - Remediation activities and other waste management services	4,080	35,000	B
	F4311 - Demolition	24,004	94,062	B
	F4333 - Floor and wall covering	170,130	427,167	B
14. Other waste handling and remediation	C231 - Manufacture of glass and glass products	14,119	296,668	C
	C2319 - Manufacture and processing of other glass, including technical glassware	3,510	38,145	B
	E3821 - Treatment and disposal of non-hazardous waste	6,000	183,842	C
	E3822 - Treatment and disposal of hazardous waste	1,000	29,156	B
	E39 - Remediation activities and other waste management services	4,080	35,000	B
15. Other	C241 - Manufacture of basic iron and steel and of ferro-alloys	2,616	331,670	C
	C2444 - Copper production	239	38,504	A

** Exposure scores - A: The majority of the companies is likely to be involved in the work with lead. B: A significant part of the companies may be involved in some work involving lead. C: Only a few companies within the sector are likely to be involved with work with lead. The data from Eurostat's Structural Business Statistics has limited application for analysing the companies involved in work with lead and the possible occupational exposure.*

4.15.3 Example of Eurostat size class distribution data

Table 4-81 below presents an extract of the available data from Eurostat on size class distribution of enterprises for activities relating to sector 1 (Primary production of lead) and 13 (Demolition, repairing and scrap). Sector 1 and 13 have been chosen here as examples to illustrate the applicability of the data.

In contrast to the business statistics, size class distribution data is only available on a 3-digit-level, making the data less useful for specific activities. As can be seen from the table below, there is a huge fraction of enterprises within the lowest size class 0-9 persons. For sector 1 (primary production of lead), the number and size of lead mines in the EU-27 is well known (6 sites, all >250 employees), and the Eurostat data is of limited value.

For sector 13 (Demolition, repairing and scrap) detailed data on number and size of companies could not be identified. However, in discussions with stakeholders it was recognized that the Eurostat figures apparently comprise a large fraction of one-man-companies (not comprised by the scope of the study), inactive companies and that only a fraction of the companies would experience exposure to lead. Therefore, it was concluded to omit the smallest size class (0-9 persons) from the assessment for sector 13.

In conclusion, for the sectors, where reliable information is available from literature and stakeholder consultation, the number and size class distribution data available from Eurostat has been dismissed for the assessment. For other sectors, e.g. sector 13, where robust estimates on number and size distribution have not been available from literature and stakeholder consultation, Eurostat data are used with modification based on assumptions that have been discussed with stakeholders (mostly industry associations).

The summary of data to be taken forward on the cost assessment is presented in the next section.

Table 4-81 Example of Eurostat data on size class distribution of enterprises for sector 1 (Primary production of lead) and 13 (Demolition, repairing and scrap)

NACE_R2/SIZE_EMP	**Total**	From 0 to 9 persons employed	From 10 to 19 persons employed	From 20 to 49 persons employed	From 50 to 249 persons employed	250 persons employed or more
B072 - Mining of non-ferrous metal ores	**328**	251	conf	18	conf	conf
E383 - Materials recovery	**19,224**	15,824	1,701	1,145	493	-
E390 - Remediation activities and other waste management services	**4,080**	3,433	303	221	108	-

4.15.4 Summary on number and size distribution of enterprises with exposed workers

Table 4-82 shows the size distribution of enterprises in small, medium or large sized enterprises. The data is based upon information obtained during stakeholder consultation of the current and previous OEL study, public sources and Eurostat as explained in sections 4.15.1 - 4.15.3. When specific data on enterprise size could not be obtained from stakeholder consultation or public sources, the proportions for small, medium and large enterprises were taken from Eurostat.

Table 4-82 Distribution of EU enterprises with exposed workers by size of enterprise by sector

Sector	Number of enterprises			
	Small <50 employees	Medium 50-249 employees	Large >249 employees	Total no. of enterprises
1. Primary lead production	0%	0%	100%	6
2. Secondary lead production (including lead battery recycling)	15%	63%	22%	43
3. Lead battery production	0%	20%	80%	30
4. Production of articles of lead metal	47%	32%	21%	26
5. Foundries	59%	31%	10%	180 (90-270)
6. Production of lead compounds and lead frits	10%	50%	40%	11
7. Production of glass	76%	13%	11%	46
8. Ceramic ware production and enamelling	96%	3%	1%	26
9. Manufacture and use of plastics and paints	80%	10%	10%	84
10. Work with lead metal	90%	10%	0%	3,125 (1,250 – 5,000)
11. Shooting ranges	100%	0%	0%	4,000 (3,000 – 5,000)
12. Recycling of PVC and other plastics	75%	25%	0%	100
13. Demolition, repairing and scrap industry	91%	8%	1%	14,179
14. Other waste handling and remediation	75%	25%	0%	700
15. Other (Copper production)	0%	80%	20%	7

Source: Eurostat (2018), consultation

4.16 Current disease burden (CDB)

The current disease burden has been calculated using the ERR and DRRs as described in section 2.3, the exposure concentrations and trends for each sector (section 4.6.6) and the number of exposed workers for each sector (section 4.7.3). For further variables used in the model, please refer to the methodological report.

The relationships between exposure to lead and health effects (the ERR and DRRs derived in section 2.3) have been developed on the basis of blood lead levels, and not from airborne lead exposure, as the blood lead levels are broadly recognised as the more reliable parameter for describing actual exposure. As documented in section 2.3.4, a method for conversion between air and blood lead levels has been evaluated as acceptable for the range from 50 to 650 µg Pb/L blood (close to the range of BLV options 45 to 700 µg Pb/L). This range of blood lead levels corresponds to a range of 0.5 to 34 µg Pb/m³ air (below the range of OEL options 4 to 150 µg Pb/m³ air).

In order to calculate the CDB based on airborne exposures, available airborne exposure data have to be converted into blood lead levels using Equation 2-10 in section 2.3.4. For illustration, the converted blood data are shown for some parameters from the battery sector and compared with available measured data (Table 4-83). The example data show that the converted blood lead levels exceed the measured levels with a factor of ca. 4, which would cause a gross overestimation of ill-health cases. Furthermore, P90 and P95 air lead concentrations cannot be converted as they lie outside the validated range of the method. Any extrapolation would introduce significantly increased uncertainty. Due to these issues, the steering group of the study agreed that the study team should evaluate the disease burden based on blood lead level data only.

Table 4-83 Example of exposure data from the battery sector, comparison between measured and converted blood lead levels.

Parameter	Air lead concentration (Measured data, inside RPE) µg/m³	Blood lead levels, µg Pb/L	
		Measured	Converted
Median	<10 (anticipated 10)	120	478
Mean	30	140	608
P90	70	290	Out of validated range (> 650)

The table below presents the current burden of disease calculated from blood lead levels.

For lead and its compounds, the regulatory developments (i.e. the REACH Annex XVII Entries restriction, the lower national limit values, and the voluntary industries targets) have resulted in a significant reduction of exposure concentrations during the past decades. Exposure of most workers is considerably below the current BLV of 700 µg/L. Therefore, the number of new disease cases per year is relatively limited.

Table 4-84 Current burden of disease due to past exposure based on blood lead levels

Endpoint	New cases per year (incidence) in 2021
Central nervous system cancer	0.2
Neuropathy	7
Anaemia	50
Chronic kidney disease stage 1	155
Elevated blood pressure	73
Male fertility	12
Pre-eclampsia	1
Developmental toxicity	36

4.17 Future disease burden (FDB)

The future burden of disease is estimated using the data in the preceding sections for exposed workers (section 4.7.4) and exposure levels (section 4.6.6). The future burden of disease predicts the number of cases over the next 40 years.

The number of cases for the future burden of disease is shown in Table 4-85, together with the present value of the healthcare costs over 40 years for both a static discount rate and a declining discount rate in Table 4-86 and Table 4-87. The estimates are based on the assumption that the number of workers exposed to lead and its compounds is the same as for the current burden of disease and that the workforce has a turnover of 5% per year. This means that the entire workforce can be considered to have changed over a period of 20 years.

The predicted number of cases is 6 for CNS/brain cancer and 11,859 for other adverse health effects (without developmental endpoint of loss of IQ-points) over a 40-year period for a workforce of 98,850.

Most companies do already comply with significantly lower limit values than the current EU limit values for lead and its compounds. Therefore, the lowering of the current BLV of 700 µg/L to the next lower option (300 µg/L) must be expected to result in limited additional benefit.

Table 4-85 Baseline future burden of disease (cases), 5% turnover of workforce a year

Sector	Number of cases over 40 years								
	Central nervous system (CNS) Cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity (Lost IQ points)	Total (excl. dev tox)
1. Primary lead production	0.2	11	70	216	103	19	1	25	420
2. Secondary lead production	0.3	17	106	328	157	28	2	60	639
3. Lead battery production	1.4	65	402	1,240	595	111	4	120	2,420
4. Production of articles of lead metal	0.2	9	53	164	79	15	1	20	320
5. Foundries and production of articles of alloys	1.7	80	676	2,093	951	140	9	275	3,951
6. Production of lead compounds and lead frits	0.1	4	24	75	36	7	1	17	147
7. Production of glass	0.1	4	23	71	35	5	2	74	140
8. Ceramic ware production and enamelling	0.3	14	86	265	126	22	5	161	517
9. Manufacture and use of plastics and paints	0.0	2	11	35	17	3	0	18	69
10. Work with lead metal	0.6	29	193	595	282	49	4	171	1,153
11. Shooting	0.2	8	51	156	74	13	3	155	305

Sector	Number of cases over 40 years								
	Central nervous system (CNS) Cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity (Lost IQ points)	Total (excl. dev tox)
12. Recycling of PVC and other plastics	0.0	0	2	5	2	0	0	5	9
13. Demolition, repairing and scrap industry	0.9	42	266	822	390	70	3	101	1,593
14. Other waste management and soil remediation	0.0	2	24	76	34	4	3	218	144
15. Copper production	0.1	3	21	66	31	5	0	9	127
Total	**6**	**290**	**2,009**	**6,208**	**2,912**	**491**	**39**	**1,430**	**11,954**

Table 4-86 Baseline future burden of disease (PV40), 5% turnover of workforce a year, static discount rate

Sector	PV40 over 40 years, static discount rate (€) Range of Method 1 – Method 2								
	Central nervous system cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity	Total
1. Primary lead production	116,000 - 61,000	435,000 - 795,000	464,000 - 507,000	5 million - 5 million	5 million - 9 million	137,000 - 131,000	51,000 - 57,000	163,000 - 345,000	11 million - 15 million

Sector	PV40 over 40 years, static discount rate (€) Range of Method 1 – Method 2								
	Central nervous system cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity	Total
2. Secondary lead production	172,000 - 89,000	662,000 - 1 million	705,000 - 770,000	7 million - 7 million	8 million - 14 million	210,000 - 201,000	121,000 - 136,000	387,000 - 819,000	17 million - 24 million
3. Lead battery production	690,000 - 360,000	3 million - 5 million	3 million - 3 million	27 million - 27 million	29 million - 51 million	818,000 - 785,000	246,000 - 276,000	773,000 - 2 million	63 million - 89 million
4. Production of articles of lead metal	88,000 - 46,000	339,000 - 620,000	353,000 - 385,000	4 million - 4 million	4 million - 7 million	108,000 - 104,000	42,000 - 47,000	132,000 - 280,000	8 million - 12 million
5. Foundries and production of articles of alloys	821,000 - 428,000	3 million - 6 million	4 million - 5 million	45 million - 45 million	46 million - 82 million	1 million - 988,000	569,000 - 637,000	2 million - 4 million	103 million - 144 million
6. Production of lead compounds and lead frits	40,000 - 21,000	153,000 - 280,000	162,000 - 177,000	2 million - 2 million	2 million - 3 million	48,000 - 46,000	35,000 - 40,000	113,000 - 238,000	4 million - 6 million
7. Production of glass	42,000 - 22,000	161,000 - 294,000	152,000 - 166,000	2 million - 2 million	2 million - 3 million	40,000 - 38,000	126,000 - 142,000	481,000 - 1 million	4 million - 6 million
8. Ceramic ware production and enamelling	142,000 - 74,000	532,000 - 972,000	567,000 - 620,000	6 million - 6 million	6 million - 11 million	161,000 - 154,000	326,000 - 365,000	1 million - 2 million	15 million - 21 million
9. Manufacture and use of plastics and paints	21,000 - 11,000	79,000 - 144,000	75,000 - 82,000	756,000 - 756,000	816,000 - 1 million	21,000 - 20,000	24,000 - 27,000	113,000 - 240,000	2 million - 3 million

Sector	PV40 over 40 years, static discount rate (€) Range of Method 1 – Method 2								
	Central nervous system cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity	Total
10. Work with lead metal	298,000 - 155,000	1 million - 2 million	1 million - 1 million	13 million - 13 million	14 million - 24 million	364,000 - 349,000	264,000 - 296,000	1 million - 2 million	31 million - 44 million
11. Shooting	80,000 - 42,000	310,000 - 566,000	335,000 - 366,000	3 million - 3 million	4 million - 6 million	92,000 - 89,000	166,000 - 186,000	1 million - 2 million	9 million - 13 million
12. Recycling of PVC and other plastics	2,000 - 1,000	7,000 - 14,000	11,000 - 12,000	107,000 - 107,000	108,000 - 195,000	2,000 - 2,000	5,000 - 5,000	31,000 - 65,000	273,000 - 401,000
13. Demolition, repairing and scrap industry	440,000 - 229,000	2 million - 3 million	2 million - 2 million	18 million - 18 million	19 million - 34 million	515,000 - 494,000	158,000 - 177,000	654,000 - 1 million	42 million - 59 million
14. Other waste management and soil remediation	21,000 - 11,000	88,000 - 161,000	162,000 - 177,000	2 million - 2 million	2 million - 3 million	30,000 - 29,000	195,000 - 218,000	1 million - 3 million	5 million - 8 million
15. Copper production	31,000 - 16,000	119,000 - 216,000	141,000 - 155,000	1 million - 1 million	1 million - 3 million	39,000 - 37,000	17,000 - 19,000	60,000 - 128,000	3 million - 5 million
Total	**3 million - 2 million**	**11 million - 21 million**	**13 million - 15 million**	**134 million - 134 million**	**139 million - 251 million**	**4 million - 3 million**	**2 million - 3 million**	**9 million - 20 million**	**317 million - 448 million**

Notes: Static discount rate: 4% per year. Range: For a description of methods 1 and 2, see section 3.5 of Methodological Note.

Table 4-87 Baseline future burden of disease (PV40), 5% turnover of workforce a year, declining discount rate

Sector	PV40 over 40 years, declining discount rate (€ million) Range of Method 1 – Method 2								
	Central nervous system cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity	Total
1. Primary lead production	157,000 - 81,000	476,000 - 834,000	472,000 - 516,000	5 million - 5 million	5 million - 9 million	139,000 - 133,000	51,000 - 58,000	164,000 - 347,000	12 million - 16 million
2. Secondary lead production	232,000 - 120,000	723,000 - 1 million	717,000 - 783,000	8 million - 8 million	8 million - 14 million	213,000 - 203,000	122,000 - 136,000	390,000 - 824,000	18 million - 25 million
3. Lead battery production	931,000 - 483,000	3 million - 5 million	3 million - 3 million	28 million - 28 million	32 million - 54 million	832,000 - 792,000	248,000 - 278,000	778,000 - 2 million	68 million - 94 million
4. Production of articles of lead metal	119,000 - 62,000	371,000 - 650,000	359,000 - 392,000	4 million - 4 million	4 million - 7 million	110,000 - 105,000	42,000 - 48,000	133,000 - 282,000	9 million - 12 million
5. Foundries and production of articles of alloys	1 million - 575,000	3 million - 6 million	5 million - 5 million	48 million - 48 million	51 million - 87 million	1 million - 998,000	572,000 - 641,000	2 million - 4 million	111 million - 152 million
6. Production of lead compounds and lead frits	54,000 - 28,000	168,000 - 294,000	165,000 - 180,000	2 million - 2 million	2 million - 3 million	49,000 - 47,000	36,000 - 40,000	113,000 - 239,000	4 million - 6 million
7. Production of glass	57,000 - 30,000	176,000 - 309,000	155,000 - 169,000	2 million - 2 million	2 million - 3 million	40,000 - 38,000	127,000 - 142,000	484,000 - 1 million	5 million - 6 million
8. Ceramic ware production and enamelling	192,000 - 100,000	581,000 - 1 million	577,000 - 630,000	6 million - 6 million	7 million - 11 million	163,000 - 156,000	327,000 - 367,000	1 million - 2 million	16 million - 22 million

Sector	PV40 over 40 years, declining discount rate (€ million) Range of Method 1 – Method 2								
	Central nervous system cancer	Neuropathy	Anaemia	Chronic kidney disease stage 1	Elevated blood pressure	Male fertility	Pre-eclampsia	Developmental toxicity	Total
9. Manufacture and use of plastics and paints	28,000 - 15,000	86,000 - 152,000	76,000 - 83,000	803,000 - 803,000	905,000 - 2 million	21,000 - 20,000	24,000 - 27,000	114,000 - 241,000	2 million - 3 million
10. Work with lead metal	402,000 - 208,000	1 million - 2 million	1 million - 1 million	14 million - 14 million	15 million - 26 million	370,000 - 353,000	265,000 - 298,000	1 million - 2 million	33 million - 46 million
11. Shooting	108,000 - 56,000	339,000 - 594,000	341,000 - 372,000	4 million - 4 million	4 million - 7 million	94,000 - 89,000	167,000 - 187,000	1 million - 2 million	10 million - 14 million
12. Recycling of PVC and other plastics	2,000 - 1,000	8,000 - 14,000	11,000 - 12,000	114,000 - 114,000	120,000 - 206,000	2,000 - 2,000	5,000 - 5,000	31,000 - 65,000	294,000 - 421,000
13. Demolition, repairing and scrap industry	593,000 - 308,000	2 million - 3 million	2 million - 2 million	19 million - 19 million	21 million - 35 million	523,000 - 498,000	159,000 - 178,000	658,000 - 1 million	45 million - 62 million
14. Other waste management and soil remediation	28,000 - 14,000	96,000 - 169,000	165,000 - 180,000	2 million - 2 million	2 million - 3 million	31,000 - 29,000	196,000 - 219,000	1 million - 3 million	5 million - 8 million
15. Copper production	42,000 - 22,000	130,000 - 227,000	144,000 - 157,000	2 million - 2 million	2 million - 3 million	40,000 - 38,000	17,000 - 19,000	61,000 - 129,000	4 million - 5 million
Total	**4 million - 2 million**	**12 million - 22 million**	**14 million - 15 million**	**143 million - 143 million**	**155 million - 265 million**	**4 million - 4 million**	**2 million - 3 million**	**9 million - 20 million**	**343 million - 472 million**

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

Range: For a description of methods 1 and 2, see section 3.5 of Methodological Note.

4.18 Summary of the baseline scenario

Table 4-88 below provides a summary of the baseline scenario for this impact assessment.

Table 4-88 Lead compounds – summary of the baseline scenario

Item	Detail
Chemical agent	Lead and its compounds
Classification	Repr. 1A (H360-Df, Repr. 2; H361f: C ≥ 2.5%) Acute Tox. 4* (H332) Acute Tox. 4* (H302) STOT RE 2* (H373**, STOT RE 2; H373: C ≥ 0,5 %) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
Key sectors	1. Primary lead production 2. Secondary lead production 3. Lead battery production 4. Production of articles of lead metal 5. Foundries and production of articles of alloys 6. Production of lead compounds and lead frits 7. Production of glass 8. Ceramic ware production and enamelling 9. Manufacture and use of plastics and paints 10. Work with lead metal 11. Shooting 12. Recycling of PVC and other plastics 13. Demolition, repairing and scrap industry 14. Other waste management and soil remediation 15. Other
Types of cancer caused	brain/ Central nervous system cancer
No. of exp. workers	98,850
Change exp. level	Modelled: 0% (past, future)
Change no. of exp. work-ers	Modelled: 0% (past, future)
Period for estimation	40 years
Current disease burden (CDB) - no. of cancer cases	Incidence cancer: 0.2 per year

Item	Detail
Future disease burden (FDB) - no. of cancer cases	40-year period: 6 cases of central nervous system cancer
CDB no. of other adverse health effects, no. of cases	Neuropathy 7 Anaemia 50 Chronic kidney disease stage 1 154 Elevated blood pressure 72 Male fertility 12 Pre-eclampsia 1 Developmental toxicity (effects on the foetus; total IQ loss) 35
FDB no. of other adverse health effects, no. of cases	Neuropathy 290 Anaemia 2,009 Chronic kidney disease stage 1 6,208 Elevated blood pressure 2,912 Male fertility 491 Pre-eclampsia 39 Developmental toxicity (effects on the foetus; total IQ loss) 1,430
Exp. no. of deaths FDB cancer	4.8 deaths over 40 years
Exp. no. of deaths FDB other adverse health effects	0.6 deaths over 40 years (Women, fatal outcome of eclampsia)
Monetary value FDB cancer	€ 3 million - € 2 million
Monetary value FDB other adverse health effects over 40 years	Neuropathy € 11 million - 21 million PV Anaemia € 13 million – 15 million PV Chronic Kidney Disease Stage 1 € 134 million – 134 million PV Elevated blood pressure € 139 million - 251 million PV Male fertility € 4 million - 3 million PV Pre-eclampsia € 2 million - 3 million PV Developmental toxicity € 9 million – 20 million PV Total € 612.7 million - € 317 million - 448 million PV

5. Benefits assessment

The benefits assessment consists of the following sub-sections:

- Ch. 5.1: Summary of the key features of the model
- Ch. 5.2: Direct benefits – health - avoided cases of ill health
- Ch. 5.3: Direct benefits – workers & families
- Ch. 5.4: Direct benefits – public sector
- Ch. 5.5: Direct benefits – companies
- Ch. 5.6: Direct benefits – environmental
- Ch. 5.7: Direct benefits - market efficiency
- Ch. 5.8: Indirect benefits
- Ch. 5.9: Aggregated benefits

5.1 Summary of the key features of the model

The model developed to estimate the benefits in terms of reduced costs takes into account the cost categories set out in Table 5-1 below. More details are presented in the methodology report.

Table 5-1 The benefits framework

Category	Cost (to be reduced)	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[43]	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[44]: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	

- [43] 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.
- [44] Willingness to Pay: The maximum sum an individual is willing to pay for a service/goods in order to avoid loss, in this case, in terms of health treatment.

Cate-gory	Cost (to be reduced)	Notes
	Approach 2 DALY[45]: Mortality	
	Approach 2 DALY: Morbidity	

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

- Method 1 (intangible costs estimated based on WTP to avoid a case): *Ctotal= Ch+Ci+Ce+Cp+Cvsl+Cvsm*
- Method 2 (intangible costs estimated based on monetised DALYs): *Ctotal= Ch+Ci+Ce+Cp+Cl+Cdaly*

The abbreviations are explained in Table 5-2 below. *Cl* is not considered under Method 1 since *Cvsl* may already include these costs.

Table 5-2 Overview of cost categories

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

The benefit model provides the following two outputs:

- The number of new cases for each health endpoint assigned to a specific year in the 40-year assessment period; and
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

The model assumes an annual staff turnover of 5%. Even though this rate is lower than the turnover ratios in the published literature and Eurostat which are typically derived at the level of individual companies rather than sectors, it is deemed that a ratio of 5% is suitable to account for the fact that some workers may continue to work in the same sector and continue to be exposed. Hence, the whole workforce is replaced every 20 years, and within the time period of 40 years, two cohorts of workers are being exposed two lead. The

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

turnover caused by treatment or early retirement due to the conditions considered in this report is not modelled.

A detailed overview of the key features of the model for the estimation of the benefits using Method 1 and 2, and the assumptions underpinning it are set out in the methodology report.

5.1.1 Relevant health endpoints for lead

The substance assessment for lead entails eight endpoints, of which seven are non-carcinogenic:

- Central nervous system (CNS) Cancer
- Neuropathy (Neurotoxicity)
- Anaemia (Haematoxicity)
- Chronic Kidney Disease, Stage 1 (CKD 1, Nephrotoxicity)
- Elevated systolic blood pressure (Elevated blood pressure, Cardiovascular effects)
- Reduced fecundability (Male fertility)
- Pre-eclampsia (Female fertility)
- Reduced IQ of newborns (Developmental toxicity)

Three of the endpoints (i.e. neuropathy, chronic kidney disease stage 1, and elevated blood pressure) are set as endpoints with a chronic character, where the treatment period amounts to 20 years in the model.

5.1.2 Summary of the key assumptions for lead

5.1.2.1 Onset of disease

The time required for the endpoints to develop over an average working considers the minimum and maximum time required to develop the condition (MinEx and MaxEx) and the distribution of new cases between these two points in time, combined with the latency period with which the effects are diagnosed. These parameters are presented in the table below. None of the endpoints has minimum exposure time and most endpoints have their maximum exposure time at 10 years or less. Only Central nervous system cancer has a maximum exposure time of 40 years. The same endpoint is further the only endpoint with a latency.

Table 5-3 Onset of the disease as measured by MinEx, MaxEx, and latency in years

Endpoint	MinEx	MaxEx	Latency
Central nervous system cancer	0	40	30
Neuropathy	0	7	0
Anaemia	0	10	0
Chronic kidney disease stage 1	0	5	0
Elevated blood pressure	0	10	0
Male fertility	0	3	0
Pre-eclampsia	0	1	0

Endpoint	MinEx	MaxEx	Latency
Developmental toxicity	0	1	0

5.1.2.2 Effects of disease

The key assumptions on the effects of the disease entering the model are summarised below:

- Treatment period,
- Years lived with disability of the disease (YLD),
- Fatality rate,
- Additional life expectancy at death, and
- Disability weights during treatment and after treatment.

The table below presents the treatment period, YLD, fatality rate, and additional life expectancy at death for the eight endpoints. Only two endpoints have a potentially fatal outcome.

Table 5-4 Treatment period, YLD, Fatality rate, and Additional life expectancy at death in years

Endpoint	Treatment period	YLD	Fatality rate	Additional life expectancy at death
Central nervous system cancer	5	5	80%	22
Neuropathy	20	20	0%	-
Anaemia	1	1	0%	-
Chronic kidney disease stage 1	20	20	0%	-
Elevated blood pressure	20	20	0%	-
Male fertility	5	5	0%	-
Pre-eclampsia	1	1	1.5%	54
Developmental toxicity	1	1	0%	-

The table below summarises the disability weights during and after treatment. For the endpoint Central nervous system cancer, the same weights are used as for other cancers in this study.

Table 5-5 Assigned disability weights during and after treatment

Endpoint	During Treatment	After Treatment
Central nervous system cancer	0.265	0.515
Neuropathy	0.030	0.030
Anaemia	0.045	0.004
Chronic kidney disease stage 1	0.000	0.000
Elevated blood pressure	0.041	0.041
Male fertility	0.008	0.000
Pre-eclampsia	0.049	0.000
Developmental toxicity	0.000	0.000

5.2 Direct benefits – health - avoided cases of ill health

The table below presents the cases of ill health associated with all endpoints and BLV options over the study period of 40 years. For the endpoint developmental toxicity, the effects are in the form of IQ loss of newborns, which is also the format this endpoint is presented as. The number of cases is further plotted in a continuous form in the figure below.

Table 5-6 Cases by endpoint for each BLV option, as well as the total IQ loss associated with developmental toxicity

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L (baseline)
Central nervous system cancer	0	0	0	2	5	6
Neuropathy	0	0	0	110	225	290
Anaemia	0	206	365	628	1,450	2,009
Chronic kidney disease stage 1	0	640	1,123	1,935	4,474	6,208
Elevated blood pressure	0	0	547	943	2,127	2,912
Male fertility	0	0	104	181	377	491
Pre-eclampsia	1	7	16	23	34	39
Developmental toxicity (total IQ loss)	289	642	890	1,059	1,330	1,430

Source: study team's calculation

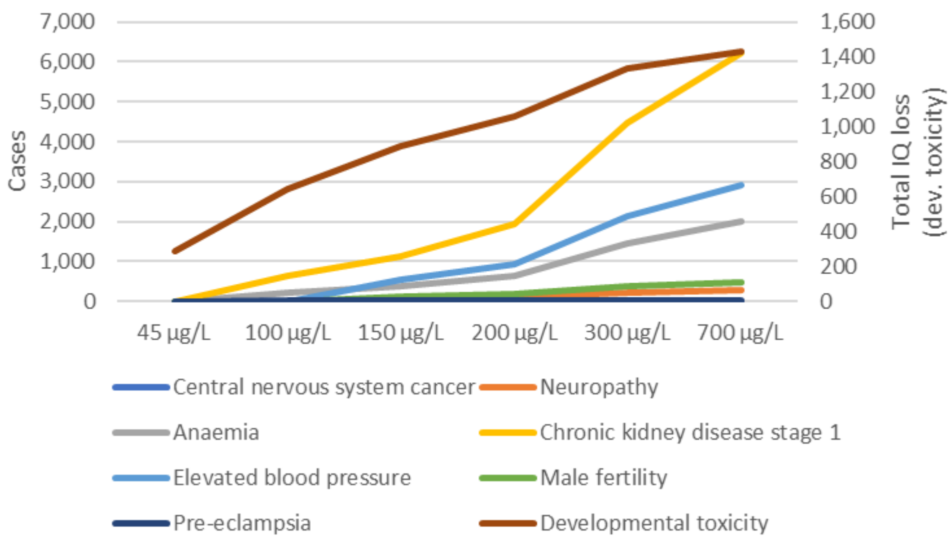


Figure 5-1 Cases of Central nervous system cancer, Neuropathy, Anaemia, Chronic kidney disease Stage 1 (CKD1), Elevated blood pressure (BP), Reduced Fecundability, and Pre-eclampsia (on the left axis), as well as total IQ loss for developmental toxicity (on the right axis) for each BLV option. Source: study team's calculation

5.3 Direct benefits – workers & families

The avoided costs of ill health relative to the baseline for workers and their families are calculated with the benefit approaches described in the table below. The benefits of the avoided cost of ill health is defined as cost of ill health in the baseline scenario, less the cost of ill health following the introduction of a BLV.

Table 5-7 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

In the following, the results are presented for respectively method 1 and 2. The table and figure below present the benefits according to method 1. In line with the number of cases above, the effect of cancer is limited. This can be traced back to the low number of cases that can be attributed to lead exposure. Rather, the two chronic endpoints, Chronic kidney disease stage 1 and Elevated blood pressure, dominate the benefits for both method 1 and 2.

For both endpoints (i.e. Chronic kidney disease stage 1 and Elevated blood pressure), two main factors explain the comparably high size of the benefits. Both endpoints have a high number of cases. Both endpoints have moreover a chronic character, with a treatment period of 20 years. The annual benefits therefore accumulate over a long period, when for example compared against cancer. For Chronic kidney disease stage 1, the number of cases is the primary benefit driver, while the cost per case is the lowest among the in total three chronic endpoints (with neuropathy as the third chronic endpoint, which has a comparably small number of cases). In the case of elevated blood pressure, the cost per case is the primary benefit driver with a lower number of cases than chronic kidney disease stage 1. When compared to the other substance reports, the cost per case of the chronic endpoints is somewhat similar. More details on the monetisation of effects are provided in the methodological note.

It should finally be noted that there is a degree of uncertainty behind the monetisation of effects, as the severity of the endpoints can be highly variable for patients. This introduces uncertainty for monetisation of the effects, especially for milder effects like chronic kidney disease stage 1 and elevated blood pressure.

Table 5-8 METHOD 1: Benefits to WORKERS & FAMILIES (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	3	3	3	2	1	-
Neuropathy	9	9	9	5	2	-
Anaemia	6	5	5	4	2	-
Chronic kidney disease stage 1	55	49	45	38	15	-
Elevated blood pressure	117	117	95	79	31	-
Male fertility	1	1	1	1	0	-
Pre-eclampsia	2	2	1	1	0	-
Developmental toxicity	7	5	3	2	1	-
Total	**200**	**191**	**162**	**132**	**52**	**-**

Source: study team's calculation

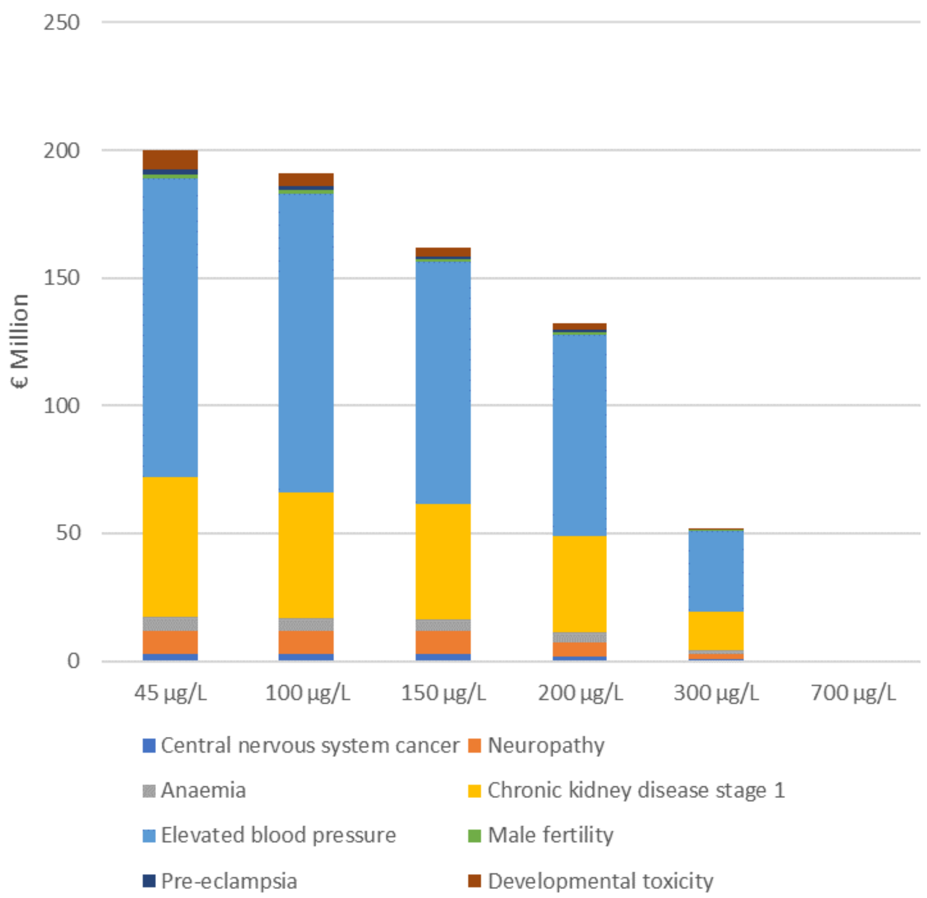


Figure 5-2 METHOD 1: Benefits to WORKERS & FAMILIES (relative to the baseline), € million. Source: study team's calculation

The following table and figure present the benefits according to method 2. It can be seen that the benefits are particularly higher for neuropathy and elevated blood pressure, which can be explained by some limited differences in the unit values of Cvsm in method 1 and CI and Cdaly in method 2.

Table 5-9 METHOD 2: Benefits to WORKERS & FAMILIES (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	2	2	2	1	0	-
Neuropathy	18	18	18	11	4	-
Anaemia	7	6	5	5	2	-
Chronic kidney disease stage 1	44	39	36	30	12	-
Elevated blood pressure	224	224	182	152	60	-

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Male fertility	1	1	1	1	0	-
Pre-eclampsia	2	2	1	1	0	-
Developmental toxicity	12	9	6	4	1	-
Total	**310**	**300**	**251**	**204**	**80**	**-**

Source: study team's calculation

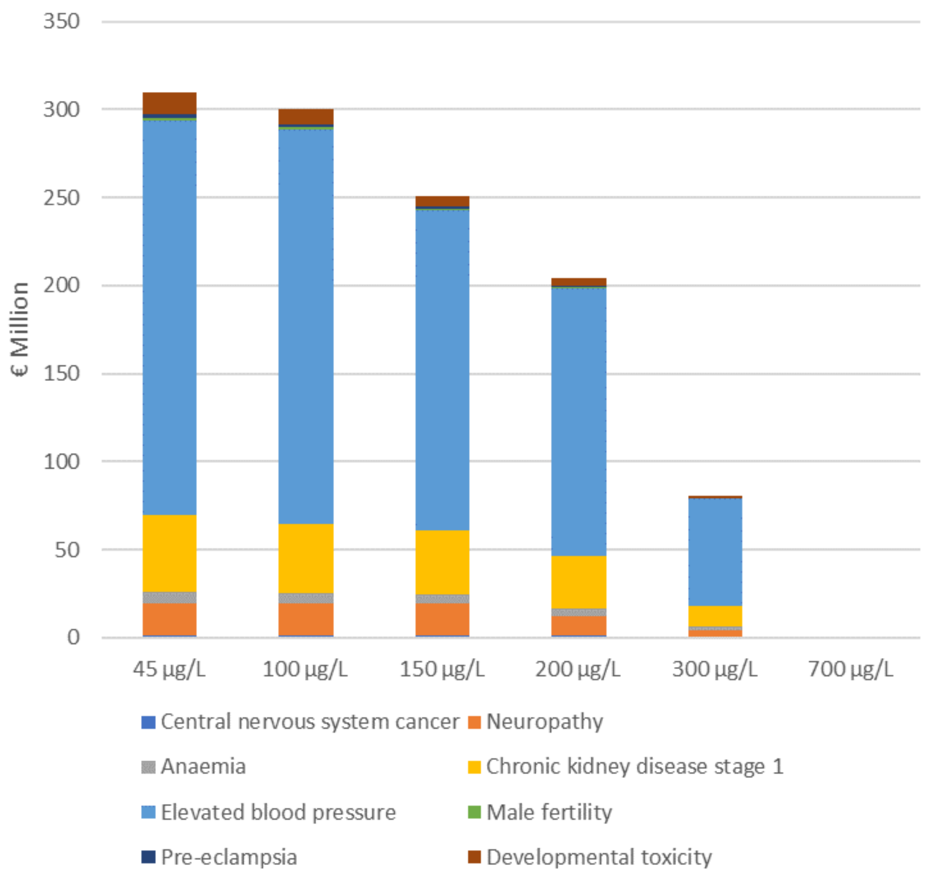


Figure 5-3 METHOD 2: Benefits to WORKERS & FAMILIES (relative to the baseline), € million. Source: study team's calculation

5.4 Direct benefits – public sector

The benefits of the avoided costs of ill health relative to the baseline to the public sector are compose of cost of treatment and tax revenue, as summarised in the table below.

Table 5-10 Benefits to the public sector

Stakeholder group	Costs	Method of summation
Public sector	Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue)	CtotalGov=Ch+0.2(Cp+Cl)

Note: 20% tax rate assumed

The following table and figure present the benefit for the public sector.

Table 5-11 Benefits to PUBLIC SECTOR (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	0	0	0	0	0	-
Neuropathy	3	3	3	2	1	-
Anaemia	5	4	4	3	1	-
Chronic kidney disease stage 1	91	81	74	62	25	-
Elevated blood pressure	24	24	20	16	7	-
Male fertility	2	2	2	1	0	-
Pre-eclampsia	0	0	0	0	0	-
Developmental toxicity	3	2	1	1	0	-
Total	**128**	**117**	**104**	**86**	**35**	**-**

Source: study team's calculation

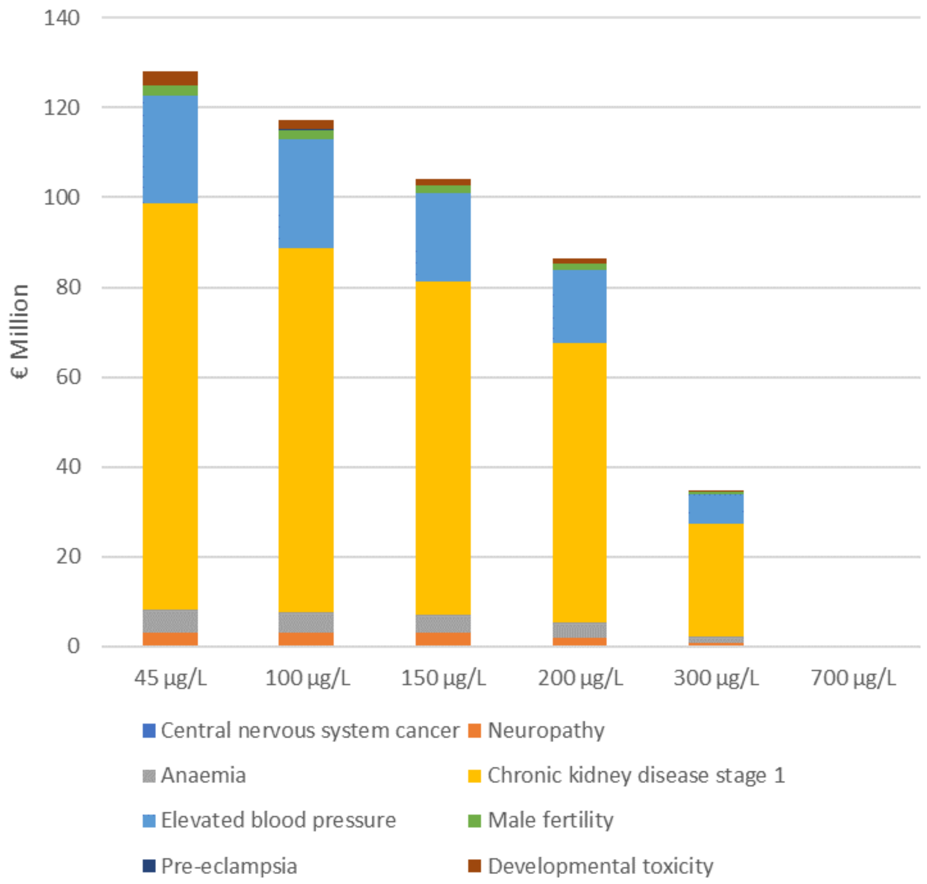


Figure 5-4 Benefits to PUBLIC SECTOR (relative to the baseline), € million. Source: study team's calculation

5.5 Direct benefits – companies

The benefits of employers are composed of the cost savings for employers (of avoided sick leave, reduced labour productivity, and reduced administrative and legal costs like replacing employees) as well as the loss in labour productivity for a fatality. The table below summarises these benefits. For the endpoints for neuropathy, Chronic kidney disease stage 1, male fertility, and developmental toxicity, no costs for employers are associated.

Table 5-12 Benefits to employers

Stakeholder group	Costs	Method of summation
Employers	Ce, Cp	CtotalEmployer=Ce+0.8*Cp[46]

The resulting benefits for employers are presented in following table and figure.

[46] Ce for cancer is taken from published literature rather than estimated as an output of the benefits model.

Table 5-13 Benefits to EMPLOYERS (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	0.0	0.0	0.0	0.0	0.0	-
Neuropathy	-	-	-	-	-	-
Anaemia	2.8	2.6	2.3	2.0	0.8	-
Chronic kidney disease stage 1	-	-	-	-	-	-
Elevated blood pressure	3.1	3.1	2.5	2.1	0.8	-
Male fertility	-	-	-	-	-	-
Pre-eclampsia	0.1	0.1	0.1	0.1	0.0	-
Developmental toxicity	-	-	-	-	-	-
Total	**6.1**	**5.8**	**5.0**	**4.1**	**1.6**	**-**

Source: study team's calculation

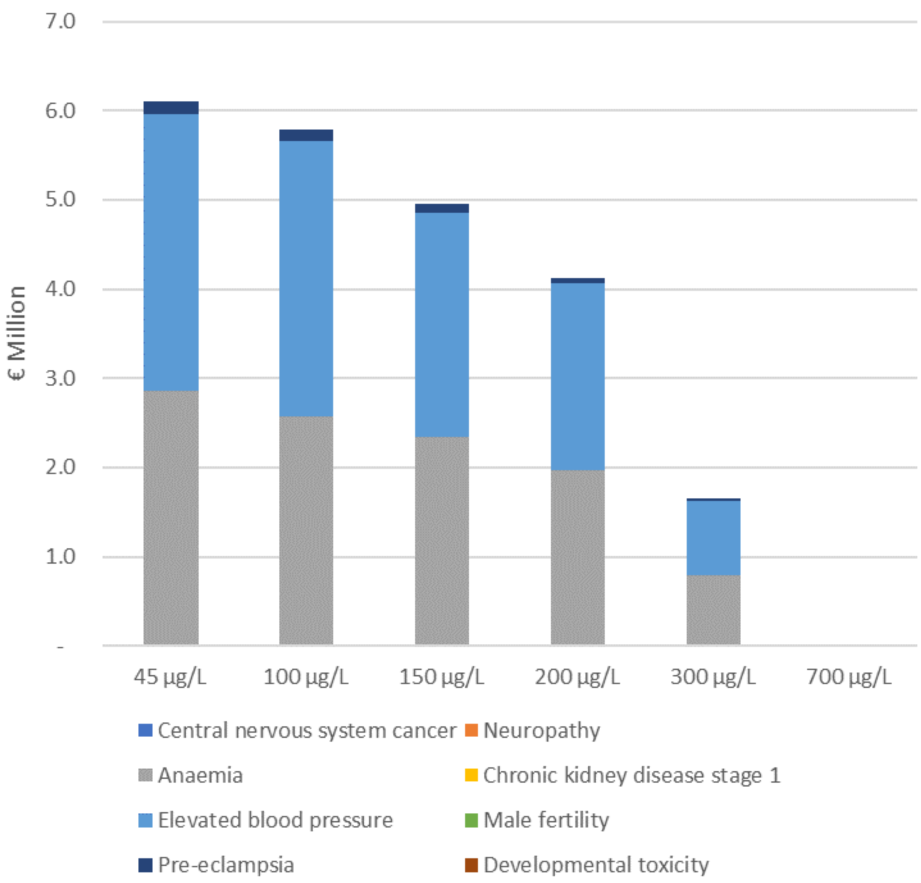


Figure 5-5 Benefits to EMPLOYERS (relative to the baseline), € million. Source: study team's calculation

5.6 Direct benefits – environmental

Section 9 on the environmental impacts provides a detailed assessment of the environmental impacts.

5.7 Direct benefits - market efficiency

A reduction of the EU-wide BLV will lead to an increased harmonisation of limit values across Europe. The increased harmonisation will in turn improve the level playing field for enterprises across the internal market, as the gap between the lowest and highest BLV in the EU will decrease. The level playing field will therefore improve with more stringent BLVs. As section 8.6.1 below shows, only a BLV of 150 for men and 45 for women (at a child-bearing age) will introduce a fully levelled playing field (i.e. all Member States having the same limit value). The BLVs of 300 µg/L would provide the greatest marginal gains in terms of the number of Member States with the same limit value. The BLV of 150 would introduce a nearly completely level playing field, in which only few Member States have a lower limit value for women.

Medium and large companies with facilities across the EU can further benefit from a simplification of the applicable limit values, potentially providing savings for research- and design cost, as common solutions can be adopted across facilities, as opposed to designing site-specific solutions to meet different BLV requirements.

5.8 Indirect benefits

The harmonisation of BLVs can make it easier for companies working in more than one EU Member State as only one set of limit value has to be followed, as also elaborated in the paragraph above. Next to savings in research- and design cost, an administrative simplification can be expected for companies. This indirect benefit is however limited to those cases, where related companies have no enterprises subject to a national BLV that is lower than the one of the CAD. The scope for diverging national BLVs decreases however with the stringency of the BLV of the CAD. A lower BLV option will hence increase the benefit of administrative simplification. As also elaborated in section 7.3.3 below, the sectors are mostly composed of large and, to a lesser extent, medium enterprises, and are likely to benefit most of administrative simplifications (e.g. sectors 1, 2, 3, 6 and 15).

The introduction of RMMs in response to a revised BLV will provide synergies in terms of exposure reduction for other chemical substances used in production sectors. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.

Finally, the benefits of healthier staff could have indirect effects on the reputation of the sectors and associated companies, as work with lead may be less perceived as a risky line of work associated with health issues. As a result of such an improvement in the public image, companies may have it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.

5.9 Aggregated benefits

The composition of the aggregated benefits (cost savings) is summarised in the table below. As for the benefits for workers & families, two benefit methods are applied.

Table 5-14 Aggregated benefits

Costs	Method of summation
Aggregated	Method 1: Ctotal= Ch+Ci+Ce+Cp+Cvsl+Cvsm Method 2: Ctotal= Ch+Ci+Ce+Cp+Cl+Cdaly

In the following table, the aggregated benefits are presented for respectively method 1 and 2. The table and figure below present the benefits according to method 1. It should be noted that the aggregate benefits under method 1 do not entirely equal the sum of the benefits for workers & families, public sector, and companies. The indirect benefit of lost working days (Cl) enters partially into the benefits for the public sector. That benefit does however not enter into the aggregate benefits of method 1, as it may already be included in the value of statistical morbidity (Cvsm), as also described in the methodological note.

Table 5-15 METHOD 1: Benefits from avoided ill health (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	3	3	3	2	1	-
Neuropathy	11	11	11	7	3	-
Anaemia	13	12	11	9	4	-
Chronic kidney disease stage 1	134	120	110	92	38	-
Elevated blood pressure	139	139	113	94	38	-
Male fertility	4	4	3	2	1	-
Pre-eclampsia	2	2	1	1	0	-
Developmental toxicity	7	5	3	2	1	-
Total	**315**	**297**	**256**	**210**	**84**	**-**

Source: study team's calculation

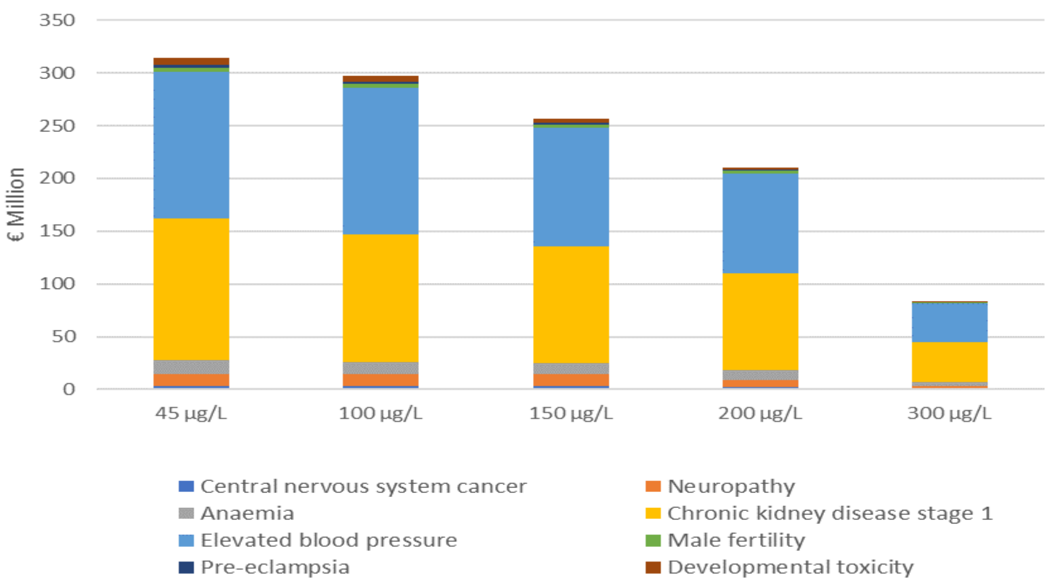


Figure 5-6 METHOD 1: Benefits from avoided ill health (relative to the baseline), € million. Source: study team's calculation

To provide more sector details, the aggregated benefits under method 1 are once more presented for each sector and BLV in the table below.

Table 5-16 METHOD 1: Benefits avoided ill health by sector and BLV, € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	11.0	10.6	9.5	8.1	3.6	-
2. Secondary lead production	16.8	16.3	15.0	12.9	3.3	-
3. Lead battery production	63.0	60.8	55.1	47.2	24.0	-
4. Production of articles of lead metal	8.4	8.1	7.4	6.4	3.2	-
5. Foundries and production of articles of alloys	102.4	100.4	95.0	86.4	43.4	-
6. Production of lead compounds and lead frits	3.9	3.8	3.5	3.0	1.4	-
7. Production of glass	4.1	3.8	3.3	2.5	-	-
8. Ceramic ware production and enamelling	14.4	13.7	12.3	10.4	4.6	-
9. Manufacture and use of plastics and paints	1.9	1.5	0.7	-	-	-
10. Work with lead metal	30.6	28.2	22.2	14.0	-	-
11. Shooting	8.6	5.5	0.4	-	-	-
12. Recycling of PVC and other plastics	0.3	0.1	0.0	-	-	-
13. Demolition, repairing and scrap industry	41.5	38.0	28.9	17.1	-	-
14. Other waste management and soil remediation	4.6	2.8	0.1	-	-	-
15. Copper production	3.3	3.2	2.9	2.4	0.2	-
Total	**315**	**297**	**256**	**210**	**84**	-

Source: study team's calculation

In the following table, the results are presented according to method 2. The table and figure below show the aggregated benefits per endpoint and BLV.

Table 5-17 METHOD 2: Benefits from avoided ill health (relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system cancer	2	2	2	1	0	-
Neuropathy	21	21	21	13	5	-
Anaemia	15	13	12	10	4	-
Chronic kidney disease stage 1	134	120	110	92	38	-
Elevated blood pressure	251	251	204	170	68	-
Male fertility	3	3	3	2	1	-
Pre-eclampsia	3	2	2	1	0	-
Developmental toxicity	16	11	7	5	1	-
Total	**444**	**424**	**360**	**295**	**117**	-

Source: study team's calculation

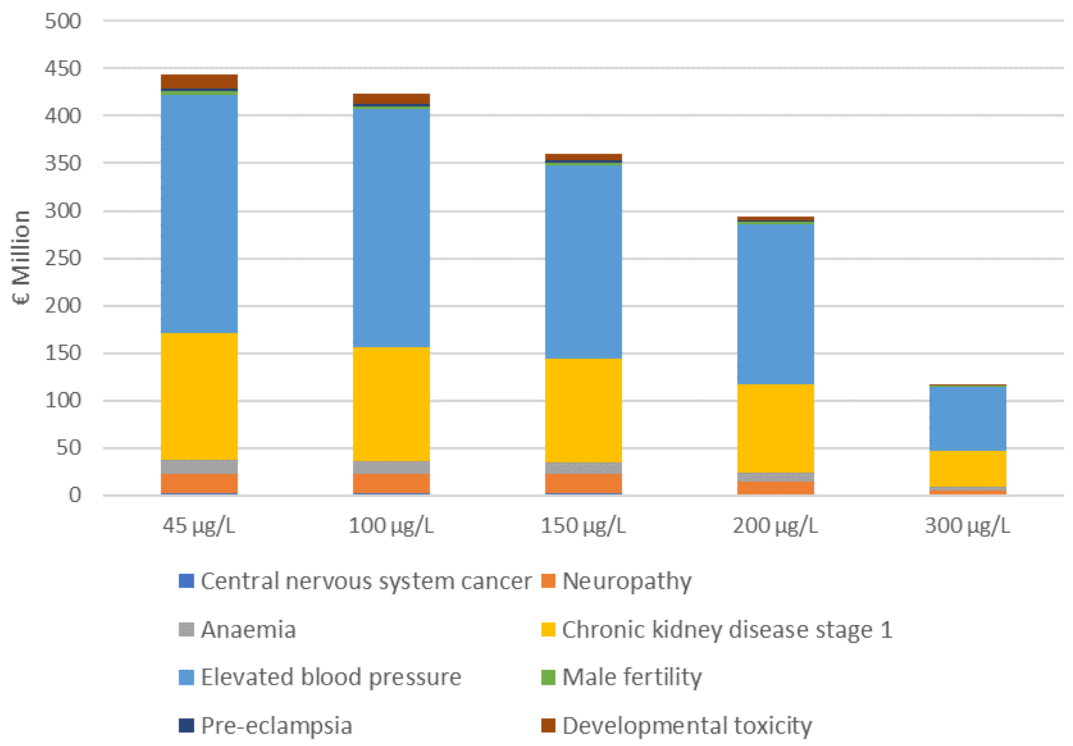


Figure 5-7 METHOD 2: Benefits from avoided ill health (relative to the baseline), € million. Source: study team's calculation

To provide more sector details, the aggregated benefits under method 2 are once more presented for each sector and BLV in the table below.

Table 5-18 METHOD 2: Benefits avoided ill health by sector and BLV, € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	15.4	15.0	13.4	11.3	5.1	-
2. Secondary lead production	23.8	23.2	21.1	18.2	4.7	-
3. Lead battery production	88.7	86.3	77.4	66.3	33.5	-
4. Production of articles of lead metal	11.8	11.5	10.4	9.0	4.5	-
5. Foundries and production of articles of alloys	143.4	141.0	132.7	120.5	60.2	-
6. Production of lead compounds and lead frits	5.5	5.4	4.9	4.2	2.0	-
7. Production of glass	6.0	5.7	4.8	3.5	-	-
8. Ceramic ware production and enamelling	20.7	19.8	17.6	14.8	6.5	-
9. Manufacture and use of plastics and paints	2.7	2.3	1.1	-	-	-
10. Work with lead metal	43.4	40.7	31.4	19.6	-	-

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
11. Shooting	12.4	8.8	0.6	-	-	-
12. Recycling of PVC and other plastics	0.4	0.2	0.0	-	-	-
13. Demolition, repairing and scrap industry	58.4	54.6	40.5	23.8	-	-
14. Other waste management and soil remedia-tion	7.0	4.5	0.2	-	-	-
15. Copper production	4.7	4.5	4.1	3.4	0.3	-
Total	**444**	**424**	**360**	**295**	**117**	**-**

Source: study team's calculation

6. Costs assessment

6.1 Introduction

This section comprises the following subsections:

- Section 6.2: Impact of costs on different stakeholders
- Section 6.3: The cost framework
- Section 6.4: Direct costs - compliance costs for companies
- Section 6.5: Direct costs – administrative burdens and charges
- Section 6.6: Direct costs – enforcement - for public authorities
- Section 6.7: Indirect costs

Section **6.8**: **Aggregated costs**

6.2 Impact of costs on different stakeholders

The introduction of reduced BLV options leads to different types of costs that are differently distributed across stakeholder. The costs assessed in this section, together with an indication of which stakeholders are likely to be affected, are presented in Table 6-1 below.

Table 6-1 Impact of costs on different stakeholders

Type of cost		Consumers	Workers	Companies	Public authorities
Direct	Compliance costs Monitoring costs Administrative burden			✓	✓
Indirect	Product choice/price	✓	✓	✓	✓
Enforcement	Transposition cost Enforcement, monitoring and adjudication				✓
Employment	Lost wages		✓		

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

A continuous cost function estimates the costs for the BLV options, subsequently integrating these to estimate the costs for the intervening BLV values.

6.3 The cost framework

6.3.1 Introduction

Compliance costs refer to the additional costs of complying with a revised limit value. Or alternatively, the costs incurred by companies to reduce their exposure concentrations below the limit value. The compliance costs are primarily determined by the number of companies above the limit value and the costs for individual companies to reduce the exposure concentration to a level below the limit value. The costs for each company depend on the size of the relevant activities like the number of machines and number of workers. Further cost factors are the gap between the actual exposure and the limit value, as well as the type of RMMs required to close the gap.

For the previous OELs studies, a cost model was developed to estimate the costs of complying with the different limit value options. This cost model has been further refined for this study. In summary, the characteristics of the relevant sectors, the RMMs in place, and the sizes of the companies, and the required reduction in exposure, are used to recommend suitable RMMs for each company. The model subsequently selects the cheapest of the suitable options. The results are summed up across all companies and sectors. A detailed description of the model is provided in the methodology report.

6.3.2 Summary of the key features of the cost model

The cost model is described in the methodology report accompanying this substance report. The model uses several inputs to calculate the predicted costs incurred for a range of BLV options. There are ten types of inputs:

- Limit value options, see chapter 3
- Number of small, medium and large enterprises at each of the current exposure concentrations for each sector,
- Estimated breakdown of primary risk management measures (RMM) used by enterprises for each sector,
- Suitability of RMMs,
- Effectiveness of RMMs,
- Cost of RMMs, see methodology report,
- Discount rates,
- Level of compliance with the target BLV option,
- Estimated average number of workers affected by lead, and
- Estimated average number of workstations with lead exposure in small, medium and large enterprises.

The output is the cost of implementing the BLV, split by:

- Sector,
- Company size: small, medium and large, and

Capital expenditure (one-off) and operating expenditure (recurrent).

6.3.3 Number of enterprises at current exposure levels

The key input parameters for both the cost and benefit estimation models developed for this study are the distribution of exposure levels across enterprises or workers, respectively. Whilst the distribution function for the benefit model focuses on the distribution of the work-force over different exposure concentrations, the key parameter for the cost function is the distribution of companies across different exposure levels. This is a simplification, as there is a there can be large variation between workers within one company, also, there can be considerable differences between the workplaces within one company. However, such granular data have not been applicable/ sufficiently available, and the number of companies together with their distribution across the different size bands and exposure concentrations is taken as a proxy in the cost model. The exposure data was analysed to provide estimated percentile values (50th or median, 75th, 90th, 95th and 100th).

Member States have already implemented BLVs at different levels. The implementation of these various BLVs (as well as efforts in meeting voluntary industry targets) are reflected using the most recently available and relatively low exposure concentration data, e.g. P95 concentrations are close to or well below 300 µg/L and thus well below the current EU BLV of 700 µg/L.

The cost model is based on three sizes of enterprise named small, medium and large. Small companies are those with less than 50 employees.

To obtain a cost estimate for each sector, the numbers of small, medium and large companies with lead exposure at the relevant exposure concentrations are entered into the model for each BLV option. These numbers are based upon the analysis described in section 4.6.6, 4.7.4 and 4.15.4.

Table 6-2 Number of enterprises with lead exposure across exposure contribution ranges by size of enterprise by sector

Sector exposure levels µg/L	Small	Medium	Large
1. Primary lead production	**0**	**0**	**6**
120	0	0	3
153	0	0	2
229	0	0	1
309	0	0	0
670	0	0	0
2. Secondary lead production	**6**	**27**	**9**
140	3	14	5
171	2	7	2
241	1	4	1
311	0	1	0
599	0	1	0
3. Lead battery production	**0**	**5**	**25**
122	0	3	12
158	0	1	6
243	0	1	4
334	0	0	1
700	0	0	1
4. Production of articles of lead metal	**12**	**8**	**5**
129	6	4	3

Sector exposure levels µg/L	Small	Medium	Large
163	3	2	1
241	2	1	1
322	1	0	0
681	1	0	0
5. Foundries and production of articles of alloys	**106**	**56**	**18**
154	53	28	9
185	27	14	5
254	16	8	3
321	5	3	1
589	5	3	1
6. Production of lead compounds and lead frits	**1**	**6**	**4**
140	1	3	2
171	0	1	1
242	0	1	1
313	0	0	0
608	0	0	0
7. Production of glass	**35**	**6**	**5**
120	17	3	3
146	9	1	1
206	5	1	1
266	2	0	0
513	2	0	0
8. Ceramic ware production and enamelling	**41**	**1**	**0**
120	21	1	0
153	10	0	0
229	6	0	0
309	2	0	0
670	2	0	0
9. Manufacture and use of plastics and paints	**67**	**8**	**8**
54	34	4	4
72	17	2	2
114	10	1	1
161	3	0	0
394	3	0	0
10. Work with lead metal	**2,813**	**313**	**0**
83	1,406	156	0
107	703	78	0
163	422	47	0
222	141	16	0
496	141	16	0
11. Shooting	**4,000**	**0**	**0**
44	2,000	0	0
56	1,000	0	0

Sector exposure levels µg/L	Small	Medium	Large
84	600	0	0
113	200	0	0
245	200	0	0
12 Recycling of PVC and other plastics	**75**	**25**	**0**
37	38	13	0
47	19	6	0
71	11	4	0
96	4	1	0
209	4	1	0
13 Demolition, repairing and scrap industry	**12,903**	**1,134**	**142**
72	6,451	567	71
95	3,226	284	35
152	1,935	170	21
215	645	57	7
525	645	57	7
14. Other waste management and soil remediation	**525**	**175**	**0**
65	263	88	0
75	131	44	0
97	79	26	0
118	26	9	0
192	26	9	0
15. Copper production	**0**	**6**	**1**
81	0	3	1
103	0	2	0
154	0	1	0
208	0	0	0
452	0	0	0
Total	**20,585**	**1,770**	**225**

Note: Totals may not be the sum of all sectors due to rounding
Source: study team's calculation

6.3.4 Estimated breakdown of RMMs used by enterprises

The model requires a profile of the primary risk management measure used by enterprises in each sector. This is based upon the information in section 4.8, together with detailed examination of the survey data, interview data and information from the site visits. Most companies use many measures simultaneously for exposure control and the translation of the data into model input data is a challenging approximation. The obtained data on use of measures are transformed into percentages adding up to 100% for each sector as the model input data, as this is required by the model mechanistics. Effectively, the percentages on use of RMM in the table below are used in the model as fractions of RMM currently contributing to exposure reductions within a sector.

Special consideration has been given to the definition of organisational measures in the cost model, as the significance of this item is important for lead exposure management. Based on information primarily obtained from companies performing in the upper range of exposure management, the following cost aspects have been included in the definition of organisational measures:

- Additional time per worker for personal hygiene
- Supervision and review workers personal habits
- Additional time and resources for clean work clothing
- Training and awareness raising of workers
- Additional cleaning of workplaces

For more information on the cost model, please see the methodological note.

Table 6-3 Percentage breakdown of primary RMMs by sector. For further explanation, see text.

Type of RMM	Full enclosure LEV	Partial enclosure LEV	Open hood LEV	Pressurised/ sealed cabin	Simple enclosed cab	Breathing apparatus	Mask with a HEPA filter	Simple mask	Organisational measures	General dilution ventilation	No ventilation
1. Primary lead production	0%	10%	25%	0%	10%	5%	25%	0%	20%	5%	0%
2. Secondary lead production	0%	5%	20%	0%	5%	5%	25%	10%	25%	5%	0%
3. Lead battery production	5%	10%	20%	0%	5%	5%	5%	20%	25%	5%	0%
4. Production of articles of lead metal	0%	5%	20%	0%	5%	0%	25%	10%	25%	5%	5%
5. Foundries and production of articles of alloys	0%	5%	20%	0%	5%	0%	10%	25%	20%	5%	10%
6. Production of lead compounds and lead frits	0%	5%	20%	0%	5%	0%	10%	25%	20%	5%	10%
7. Production of glass	0%	0%	20%	0%	0%	0%	0%	20%	0%	20%	40%
8. Ceramic ware production and enamelling	0%	0%	10%	0%	0%	0%	0%	10%	0%	20%	60%
9. Manufacture and use of plastics and paints	0%	5%	20%	0%	5%	0%	0%	10%	0%	20%	40%
10. Work with lead metal	0%	0%	5%	0%	0%	0%	0%	10%	0%	5%	80%
11. Shooting	0%	0%	0%	0%	0%	0%	0%	10%	0%	20%	70%
12. Recycling of PVC and other plastics	15%	0%	10%	0%	0%	0%	0%	30%	0%	20%	25%
13. Demolition, repairing and scrap industry	0%	0%	20%	0%	0%	0%	0%	40%	0%	0%	40%
14. Other waste management and soil remediation	0%	0%	0%	0%	0%	0%	0%	30%	0%	0%	60%
15. Copper production	0%	5%	20%	0%	5%	0%	20%	20%	5%	5%	0%

6.3.5 Turnover of enterprises per sector and size

The average annual turnover of small, medium and large companies in the key sectors is shown in Table 6-4. As outlined in sections 4.5.5 and 4.15.2, the Eurostat activity categories do only partly correspond to the relevant sectors where lead exposure occurs. Therefore, turnover data has been compared with data obtained in the stakeholder consultation and by internet search. The turnover data presented below has been used in the cost model to calculate the cost of discontinuations.

Table 6-4 Average annual turnover by size of enterprise by sector, €

Sector	Average, annual turnover in €			Source (Eurostat NACE codes)
	Small	Medium	Large	
1. Primary lead production	-	-	€ 500,000,000	Stakeholder consultation
2. Secondary lead production (including lead battery recycling)	€ 10,000,000	€ 56,000,000	€ 298,000,000	Eurostat (C244, E383)
3. Lead battery production	€ 35,000,000	€ 120,000,000	€ 180,000,000	Stakeholder consultation Eurostat (C272)
4. Production of articles of lead metal	€ 2,700,000	€ 18,000,000	€ 207,000,000	Eurostat (C251, C254)
5. Foundries	€ 5,900,000	€ 41,000,000	€ 471,000,000	Eurostat (C241, C243, C245)
6. Production of lead compounds and lead frits	€ 5,700,000	€ 36,000,000	€ 479,000,000	Eurostat (C201, C256)
7. Production of glass	€ 1,300,000	€ 15,000,000	€ 169,000,000	Eurostat (C231)
8. Ceramic ware production and enamelling	€ 1,400,000	€ 11,000,000	€ 71,000,000	Eurostat (C233, C234, C321)
9. Manufacture and use of plastics and paints	€ 1,900,000	€ 19,000,000	€ 200,000,000	Stakeholder consultation Eurostat (C222)
10. Work with lead metal	€ 2,300,000	€ 18,000,000	€ 165,000,000	Eurostat (C261, C273, F439)
11. Shooting ranges	€ 1,000,000	-	-	Arbitrary estimate
12. Recycling of PVC and other plastics	€ 1,000,000	€ 19,000,000	-	Internet search on market data of PVC recyclers on Vinylplus homepage, Eurostat Eurostat (C222)
13. Demolition, repairing and scrap industry	€ 2,170,000	€ 14,420,000	€ 144,000,000	Eurostat (F431)

Sector	Average, annual turnover in €			Source (Eurostat NACE codes)
	Small	Medium	Large	
14. Other waste handling and remediation	€ 2,800,000	€ 23,000,000	€ 188,000,000	Eurostat (E382, E390)
15. Other (Copper production)	€ 15,200,000	€ 75,000,000	€ 546,000,000	Eurostat Eurostat (C244)

Source: study team's calculation

6.4 Direct costs - compliance costs for companies

The following sections summarise information on compliance cost for companies that was obtained in the survey, during stakeholder consultation and from literature. These information, alongside with the results of the baseline analysis on exposure concentrations, current risk management measures and market analysis, form the input data for the cost model used in the current study to estimate the total compliance cost for companies (see sections 6.4.2, 6.4.3 and 6.4.4).

6.4.1 Survey and stakeholder consultation data on compliance costs

6.4.1.1 Consultation survey - Summary of RMM needed to achieve compliance

The following tables list the RMM which would be needed by companies in order to achieve compliance for the most significant activity in a facility in a given sector based on responses in the survey. The survey results on additional RMM are only displayed for sector 2 and 3 here, as many respondents ticked off the same RMM for both achieving compliance with lowered limit values as well as those that they are already currently using (section 4.8.3), even though they were ask to tick-off only additional RMM for achieving compliance. A common reason for ticking the same RMMs as in the previous section on current RMM was that the same RMM would be needed, and its use/effectiveness should be enhanced when complying with lower limit values. For example, "temporary relocation of workers with high blood lead levels" is currently a commonly used RMM. When a lower BLV should be introduced, relocation would still be an important measure, but the blood lead level (PbB) triggering relocation would be lowered.

Some respondents found it difficult to foresee, which RMM would be required to achieve compliance with the lower BLV options, the response rate is therefore lower for the lower BLV options.

The tables thus give a broad overview of the RMM needed to achieve compliance and gives an indication, which RMM should be included in the total compliance costs estimates (section 6.4.2) provided by the company respondents. Furthermore, the data is used for selection of RMM to be quantified in the compliance cost model.

Table 6-5 displays the additional risk management measures to be implemented in sector 2 **Secondary lead production,** while Table 6-6 shows the additional RMMs for sector 3 **Battery production**. Comparing the results with the currently used measures (Table 4-73), it appears that most of the additionally required measures already are in place. However, the use of existing measures in is likely to be extended to more activities.

An **increased use of ventilation and extraction** measures appear to become more relevant at 150 µg/L blood, and 7 out of 8 respondents (sector 2) indicate that the use of closed systems (for specific activities where this is possible) would become relevant.

Even though 100% of the respondents from sector 2 indicate that they are currently using **powered air-purifying respirators**, all respondents also ticked of this option as an additionally required RMM at a BLV of 150 µg/L blood. This indicates that the use of this RPE would be extended to several activities.

Organisational and hygiene measures, hereunder especially training and education, cleaning, measures for workers' personal hygiene, provision of separate storage facilities for work clothes, external RPE cleaning and maintenance and "Creating a culture of safety" appear to be the most important measures to ensure compliance with lower limit values.

Table 6-5. Risk Management Measures included in compliance cost estimates for companies performing secondary lead production (sector 2).

RMM	300 µg/L blood	150 µg/L blood	45 µg/L blood
Restructuring operations/processes			
Temporary relocation of workers with high blood lead levels	5	4	2
Permanent relocation of workers with high blood lead levels	1	3	3
Reduced amount of substance used		1	
Reduced no. of workers exposed	1	2	1
Rotation of the workers exposed	2	4	1
Redesign of work processes	2	6	4
Ventilation and extraction			
Closed systems	2	7	4
Partially closed systems	2	4	2
Open hoods over equipment or local extraction ventilation	4	4	2
General ventilation	3	5	3
Pressurised or sealed control cabs	2	5	4
Simple enclosed control cabs	3		
Personal protective equipment (PPE)			
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	1	4	2
Powered air-purifying respirators	8	8	5
Half and full facemasks (negative pressure respirators)	5	4	1
Disposable respirators (FFP masks)	4	3	2
Face screens, face-shields, visors	4	4	2

RMM	300 µg/L blood	150 µg/L blood	45 µg/L blood
Safety spectacles, goggles	3	3	1
Gloves	6	6	2
Gloves with a cuff/gauntlets/sleeving covering part or all of the arm	2	4	2
Safety boots and shoes	4	4	2
Rubber boots	2	3	2
Conventional or disposable overalls, boiler suits, aprons	4	4	2
Coveralls/hazardous materials suits	3	4	2
Organisational and hygiene measures			
Training and education	8	8	5
Cleaning	8	8	5
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	8	8	5
Provision of separate storage facilities for work clothes	8	8	5
Formal/external RPE cleaning and filter changing regime	8	7	5
Blood-lead monitoring	8	8	5
Continuous measurement of air concentrations to detect unusual exposures	3	6	4
Creating a culture of safety	7	7	5
Substitution or discontinuation in the past			
Partial substitution of lead and its compounds used in this activity in the past		1	1
Discontinuation of part of the activity using lead and its compounds	1	2	3
Substitution or discontinuation in the past			
Total number of company responses	9	8	7

Table 6-6. Risk Management Measures included in compliance cost estimates for companies producing lead batteries (sector 3).

RMM	300 µg/L blood	150 µg/L blood	45 µg/L blood
Restructuring operations/processes			
Temporary relocation of workers with high blood lead levels	5	4	2
Permanent relocation of workers with high blood lead levels		3	3
Reduced amount of substance used		1	2
Reduced no. of workers exposed	1		2
Rotation of the workers exposed	1	3	3
Redesign of work processes		4	3
Ventilation and extraction			
Closed systems		3	2
Partially closed systems	1	3	2
Open hoods over equipment or local extraction ventilation	3	3	3
General ventilation	2	2	2
Pressurised or sealed control cabs	1	2	2
Simple enclosed control cabs		2	2
Personal protective equipment (PPE)			
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)		1	2
Powered air-purifying respirators	3	3	3
Half and full facemasks (negative pressure respirators)	3	3	3
Disposable respirators (FFP masks)	3	3	3
Face screens, faceshields, visors	1		2
Safety spectacles, goggles	3	3	2
Gloves	3	3	2
Gloves with a cuff/gauntlets/sleeving covering part or all of the arm	1		2

RMM	300 µg/L blood	150 µg/L blood	45 µg/L blood
Safety boots and shoes	1	1	2
Rubber boots	1		1
Conventional or disposable overalls, boiler suits, aprons	3	3	2
Coveralls/hazardous materials suits	1	1	2
Organisational and hygiene measures			
Training and education	5	4	3
Cleaning	5	4	3
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	5	4	3
Provision of separate storage facilities for work clothes	5	3	2
Formal/external RPE cleaning and filter changing regime	3	4	3
Blood-lead monitoring	5	4	3
Continuous measurement of air concentrations to detect unusual exposures	3	3	2
Creating a culture of safety	5	5	3
Substitution or discontinuation in the past			
Partial substitution of lead and its compounds used in this activity in the past		1	
Discontinuation of part of the activity using lead and its compounds			
Substitution or discontinuation in the past		1	
Total number of company responses	6	5	3

6.4.1.2 Consultation survey - Cost estimates for achieving compliance

In the survey, respondents were asked to indicate the magnitude of both investment and annual recurrent cost imposed by introduction of lowered limit values. Most companies choose to answer this question for the BLV options rather than the OEL options. The results are displayed in Table 6-7 below.

Many companies found it difficult to estimate these costs, the response rate to these questions is therefore rather low. Roughly speaking, the estimated investment cost increases with one order of magnitude with each lowering step of the BLV option. In some answers, the investment costs exceed the annual turnover by 1-2 orders of magnitude, which in the case of respondents from sector 2 would mean discontinuation of the activities using lead.

In some cases, OPEX costs have been provided alongside with the investment costs presented in the above sections. In such cases, annual recurrent OPEX costs made up 5 – 10% of the investment cost.

Table 6-7. Estimated total initial investment costs by companies needed to achieve compliance with BLV option levels of 300, 150 and 45 µg/L blood, as responded in the consultation survey.

Sector	Annual turnover	300 µg/L blood	150 µg/L blood	45 µg/L blood	No. of responses
1	> €100 million	-	-	-	0
2	> €100 million	€10,000 - €100 million	€1 million - €1 billion	€10,000 - €100 million	4
2	€50 – 100 million	< €10,000	€10,000 - €1 billion	€100 million - €1 billion	3
2	€10 – 50 million	€100,000 - €1 million	€10 million - €100 million	€100 million - €1 billion	1
2	€2 – 10 million	-	-	-	0
3	> €100 million	€100,000 - €100 million	€1 million - €1 billion	€1 million - €10 million	5
3	€50 – 100 million	-	-	-	0
3	€10 – 50 million	€10,000 - €100,000	€1 million - €10 million	-	1
4	> €100 million	-	-	-	0
4	€50 – 100 million	-	-	-	0
4	€10 – 50 million	-	-	-	0
4	€2 – 10 million	€10,000 - €100,000	€100,000 - €1 million	€1 million - €10 million	1
5	> €100 million	-	< €10,000	€1 million - €10 million	1
5	€50 – 100 million	-	-	-	0
5	€10 – 50 million	€100,000 - €1 million	-	-	1
6	€10 – 50 million	< €10,000	€10,000 - €100,000	-	1
6	€2 – 10 million	-	€10,000 - €100,000	-	1
9	€10 – 50 million	-	-	-	0

Sector	Annual turnover	300 µg/L blood	150 µg/L blood	45 µg/L blood	No. of responses
10	-	-	-	-	0
15	> €100 million	€10,000 - €100,000	€10,000 - €10 million	€100 million - €1 billion	2
15	€50 – 100 million	-	-	-	0

6.4.1.3 Consultation survey – Lowest feasible 8 hour TWA concentrations

Many industry stakeholders observe/experience that there is no direct correlation between PbA and PbB but rely primarily on PbB monitoring as the most reliable metric of exposure. Therefore, achieving a BLV of < 150 µg/L, is often regarded as *feasible* when investments in both RPE and other technical RMM are combined.

Reliance on technical RMMs alone in order to achieve compliance of the lowest OEL options are not regarded as economically viable. According to follow-up discussions with a few stakeholders from the battery sector, compliance to OEL values < 75 or < 50 µg/m³ would require entirely new processes that have not been established at all.

Data provided by a large secondary lead producer (belonging to the top performers with respect to exposure controls within Europe) indicate that the total investment of different RMM needed for compliance with the OEL option of 50 µg/m³ would be around €50 million. Assuming an investment of between 10% and 20% of the profits, a minimum period of 15-20 years is anticipated to make it economically feasible to achieve 0.05 mg/m³. Investment would have to be made on a priority basis annually.

Responses on lowest technically and economically feasible levels are summarised in the Figures below. Figure 6-1 and Figure 6-2 show responses for the sectors secondary lead production and battery manufacture, respectively, for these sectors ≥ 8 responses have been available.

In sector 2, **50 µg/m³** is regarded as the lowest technically feasible option, while the majority of respondents regards the current OEL of **150 µg/m³** as the lowest economically feasible option.

In sector 3, the few answers favour **75 µg/m³** as the lowest technically and economically feasible option.

Figure 6-3 shows the responses across all sectors. The responses are dominated by the responses from sector 2 and do not allow for additional conclusions.

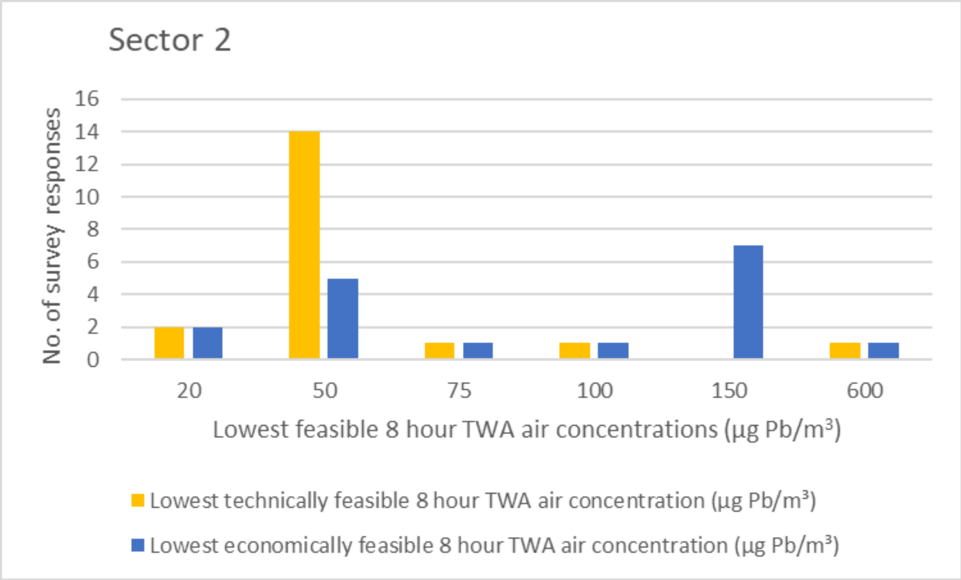


Figure 6-1 Lowest feasible 8 hour TWA air concentrations (µg/m³) for sector 2.

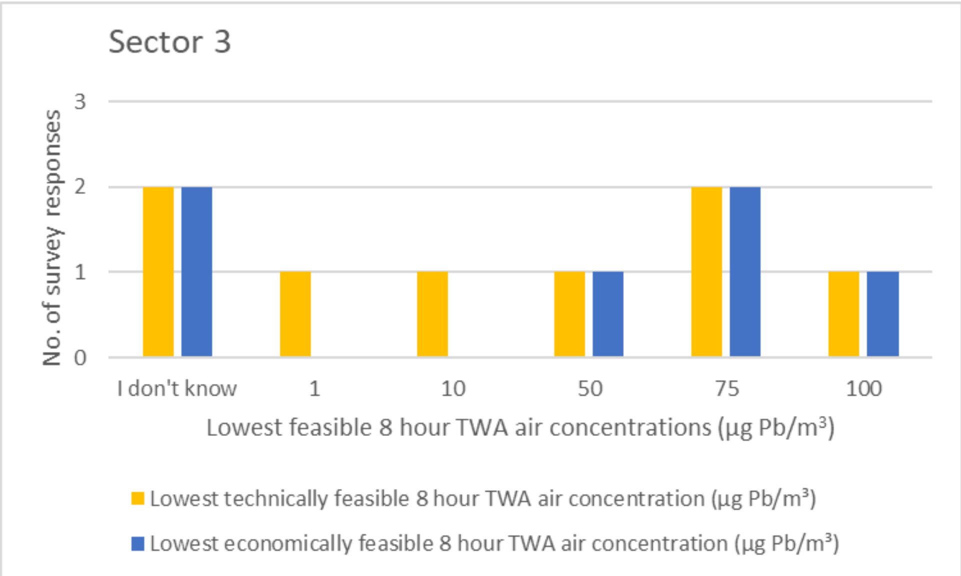


Figure 6-2 Lowest feasible 8 hour TWA air concentrations (µg/m³) for sector 3.

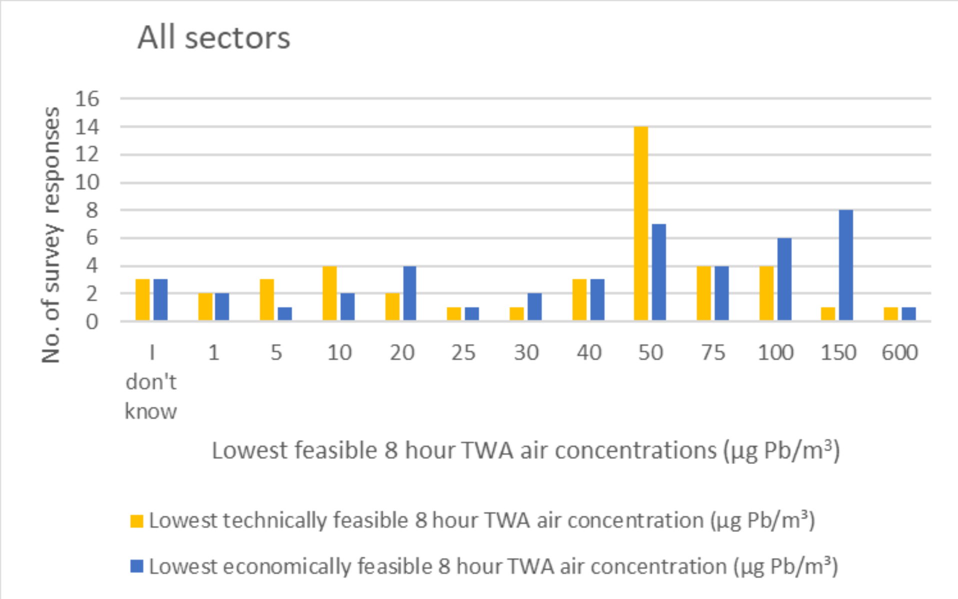


Figure 6-3 Lowest feasible 8 hour TWA air concentrations (µg/m³) for all sectors.

6.4.1.4 Consultation interviews - Additional information on compliance costs

During stakeholder communication, several interviews with companies, HSE professionals, industry associations and Member State officials were conducted (see Annex 1 for summary of consultation). Qualitative information on RMM needed to reach compliance as well as some cost estimates on specific RMM obtained during these interviews are provided in the following sections.

Many stakeholders found it difficult to provide specific information on which RMMs would be the most appropriate to use upon introduction of lowered limit values because exact knowledge about the effectiveness of single RMM is lacking. Especially the varying contributions of inhalation and oral exposure, as well as the large significance of individual behaviour complicates the definition of effectiveness of single RMM. Most companies work with a multi-facetted approach in reducing exposure and exposure reductions cannot be attributed to single RMMs.

The following section present main trends, considerations and cost estimates regarding different types of RMM from mainly company stakeholders.

Restructuring and/or rebuilding for reducing occupational exposures

Several stakeholders (representatives from sector 1 – Primary production, sector 2 – Secondary production, sector 3 – Lead battery production, sector 4 – Production of lead articles) indicate that redesign and/or rebuilding of production and handling facilities would be required to reduce **airborne exposure** significantly, meaning to the **BLV option of 50 µg/m³** for most stakeholders. Design, topography and space limitations of current facilities may not allow for further installations for reduction of lead emissions, making rebuilding necessary. Replacement of existing facilities has most often been mentioned as necessary for older facilities (> 20 years old), in a few cases also for "new" facilities (built 10-20 years ago). The costs related to redesigning/rebuilding heavily depend on type and size of facility. Examples of costs for rebuilding facilities are:

- Sector 1: New smelter plant including material handling, furnace, etc., meeting the IPPC BAT requirements, increasing production capacity and allowing for improved control of emissions, approximate investment cost of €90 million;

- Sector 1: New refinery, approximate investment cost of €50 million
- Sector 2: New battery breaking facility, approximate investment cost of €16 million
- Sector 2: Updating equipment of rotary furnaces (new charging conveying systems, semi-automating claying and tapping, new feed system for handling refinery drosses and slags), approximate investment cost of €10 million
- Sector 2: Updating equipment at the furnace (charging conveying systems, semi-automating claying and tapping, appr. investment of €3,5 million.
- Sector 2: Sprinkling system in shaft furnace area (also applicable for other sectors), approximate investment cost of €50,000
- Sector 1 and 2: Fume pelletising system (also applicable for other sectors), appr. investment of €1,2 million
- Sector 1 and 2: Enclosed storage areas for primary and secondary materials with dedicated dust generation suppressing equipment, approximate investment cost of €5 million

The cost estimates above represent large companies. Additionally, some cost estimates have been obtained for medium-sized companies, but these are not displayed here due to confidentiality reasons.

According to stakeholder communications, control of airborne lead concentrations is especially challenging in primary production due to the nature and volumes of raw material. The lead ores require more violent operations compared to secondary lead materials (e.g. lead scrap, batteries), causing considerable dust generation. The capacity of a typical lead smelter is at least 60,000 t/y, while a typical secondary smelter has a capacity of 30,000 t/y (larger secondary smelters exist), meaning the scale of operations is larger in primary compared to secondary smelters.

Ventilation and extraction

Improvement of ventilation and extraction systems are commonly mentioned with regard to reducing primarily airborne, but also blood lead exposure levels. All companies participating in the survey-follow up interviews already have different kinds of ventilation and extraction systems installed. Compliance to lowered limit values would require improvement of existing extraction systems and/or installation of extraction system at emission sources that currently lack extraction. However, in some cases the effectiveness of existing ventilation equipment may be increased by improving the maintenance and operation scheme of the equipment.

Several stakeholders note that installation of extraction systems at certain point emission sources is not possible due to space limitations and material handling installations (e.g. overhead cranes).

- Sector 2: Replacement of furnace extraction system, appr. investment of €1.2 million
- Sector 2: Replacement of extraction plant for material processing, appr. investment of €3.5-5 million
- Sector 2: Bag filter replacement at reverb furnace, appr. investment of €3 million
- Sector 1, 2, 3, 4: Increasing capacity of extraction system at source (furnace roof, lead well, launders, refinery, battery breaker), appr. investment of €0.1-2.5 million depending on location

- Applicable to several sectors: Noise abatement for LEV fans, appr. investment of €0.6 million

RPE and PPE

Respiratory protection equipment is used to commonly used within the lead industry. Irrespective of the type of RPE, an important function (or even the most important function according to a few stakeholders) of any RPE is to provide a barrier function to prevent hand-mouth contact and thus reducing oral exposure. On the other hand, the handling of the RPE may also lead to oral exposure.

RPE with an assigned protection factor (APF) of 10 is commonly used within the main lead industries. Some companies also use powered respirators with an APF of 40, either as a standard or for certain 'dirty' activities, and a few stakeholders regard the upgrade of RPE (i.e. use of ventilated helmets) as a key measure for reaching lower PbB.

It has to be noted the APF is an indication of protection level. The actual protection factor depends on the maintenance and cleanliness of the RPE, the fitting and the wearers level of proficiency in correct handling of the RPE. These parameters are highly important for reducing PbB.

Some stakeholders note that upgrading RPE to equipment with higher APF (e.g. air-fed systems) are regarded as ergonomically impracticable as they restrict the employees' movement during smelting and refining operations.

- Several sectors: Introducing additional RPE or upgrading RPE, approximate investment €1,000/employee/year for headpiece, breathing apparatus, power unit and materials
- Additional investment for infrastructure/facility for cleaning, storage and maintenance, appr. investment €100,000
- Recurrent cost cleaning and maintenance

Hygiene measures

Various hygiene measure are already in place in all companies participating in the survey and the follow-up interviews. However, several stakeholders recognise that the use of hygiene measure would have to be improved or extended to more activities if lower blood lead limit values are introduced, i.e.:

- Building of new welfare building, approximate investment €500,000
- More frequent change of uniform (daily, or even twice a day), €350 /employee/year
- Air shower prior to access to control rooms
- Additional shower for canteen break or obligatory shower also for activities with expected low lead exposures (e.g. within glass sector), €4,000 /employee/year
- Introducing external laundry regime for work clothing
- Introducing external RPE cleaning regime or building of dedicated mask wash facility
- Providing tissues and towels for wiping the face and hands
- Providing test kits for detecting lead dust on the skin
- Providing drinks facilities in production area

There is broad agreement across the industry stakeholders, that PbBs are highly dependent on personal hygiene and behaviour. Therefore, the presence of hygiene facilities cannot stand alone but has to be accompanied by awareness raising and education.

Organisational and management measures

According to several HSE managers at companies and other stakeholders, a large number of organisational and hygiene measures are already in place in order to control PbB. However, most of these RMMs could be enhanced and would need to be improved upon introduction of the lowest limit value options.

- Education, training and awareness raising of production employees
- Education, training and awareness raising of production managers
- Supervision of employees to ensure that PPE is used correctly, and hygiene rules are followed.
- Prohibition of smoking, drinking, and eating in production areas
- Additional cleaning of production areas, annual €30,000 – 60,000 (medium-sized companies)

A few stakeholders indicated that national regulations of workers' rights and/or "industrial culture" may interfere with the desired occupational safety standards of a company. For example, in some Member States, employees may be granted the right to smoke during (a break in) work, whilst in other Member States, smoking "inside the fence" is prohibited for any company under the IED (Industrial Emissions Directive).

Furthermore, reduction of PbB can be achieved by a successful cooperation and coordinated efforts between employers, employees, work councils and medical staff. A few international stakeholders mention the German organisation of blood lead management as a role model.

6.4.1.5 Time needed to achieve reductions in lead levels

In the follow-up interviews, stakeholders from companies were asked about their experiences and estimates regarding time needed to achieve lower exposure levels. The information is summarised in the table below. All estimates regarding future reductions are obtained through the qualified views of companies' HSE responsibles or similar staff. Still, the figures are estimates and actual periods for achievable reductions in exposure concentrations may deviate.

Periods for reductions from 400 to 300 µg/L range between 3 months and 5 years.

Periods for reductions from 300 to 200 µg/L range between 8 years and 10 years.

Periods for reductions from 200 to 150 µg/L range between 3 years and 18 years.

Furthermore, one stakeholder from the battery sector stated that the BLV option of 45 µg/L is unachievable.

The information supports the notion that the lower BLV options are aspired, the more time is needed to achieve compliance.

Table 6-8 Estimates on time periods needed in order to achieve lower exposure levels.

Sector	Period	Level at beginning of period (µg/L)*	Level at the end of the period (µg/L)*	Comment	Source
1. Primary production	3-4 years	Ca. 400	Ca. 300	Commonly achieved reduction during temporary relocation from workplace with lead exposure to workplace without/low lead exposure	Stakeholder consultation
2. Secondary lead production	3-4 months	Ca. 400	Ca. 250-300	Commonly achieved reduction during temporary relocation from workplace with lead exposure to workplace without lead exposure	Stakeholder consultation
3. Battery manufacture	4-5 years	Most workers at 300-400	Only 1.5% of workers > 300	Achieved reduction due to more frequent use of RPE and improvement of organisational measures	Stakeholder consultation
	3-5 years	200	150	Estimated achievable reduction upon implementation of further RMM	Stakeholder consultation
3. Battery manufacture	8-10 years	Current levels	200 or lower	Estimated achievable reductions. Estimates apply for enterprises across the industry.	Stakeholder consultation
	Ca. 18 years	Current levels	150		
4. Production of lead articles	5-10 years	PbA 150 µg/m³	PbA 100 µg/m³	Estimated achievable reduction. Significant investment needed.	Stakeholder consultation
	Ca. 5 years	200	150	Estimated achievable reduction.	
5. Foundry	3 months	300	280	Arithmetic means. Blood lead levels were investigated in a total of 17 workers of a bronze (lead-tin, 0-20% Pb) foundry. Repeated measurements were made after a blood-lead reduction programme was initiated.	Schirmberg, 2004 in LDAI, 2008
	6 months	300	250		
	1 year	300	240		
6. Production of lead compounds and lead frits	10 years	300	200	Achieved reduction due to improvement in organisational and hygiene measures. No significant change in PbA over the same period.	Stakeholder consultation

** Blood lead levels, if not stated otherwise. PbA – lead concentration in workplace air.*

6.4.1.6 Industry report on cost estimates for OEL compliance for in secondary lead production

The International Lead Association (ILA) has in 2020 commissioned Engitec Technologies SpA, (Engineering and contracting company providing equipment and plants for the recovery of non-ferrous materials) to describe the technical solutions and the economic impact on primary and secondary lead smelters operating in EU to comply with 6 possible OEL reference values (150, 100, 50, 10 and 4 µg/m³). In 2021, in support of the present limit value study, the report has been updated with an additional reference value (20 µg/m³).

The report focusses on the impact on secondary smelters, however, many solutions may also apply to primary smelters. Cost estimates for a single plant and explanations regarding the required RMM are included in the table below.

The authors of the Engitec report (Engitec, 2021) believe that a limit of 50 µg/m³ associated with the correct use of technological advanced respirators and PPE, efficient housekeeping and well managed auxiliary systems like laundry, change rooms, canteens and job rotation, continuous monitoring of the “lead blood” of the operators, appears feasible.

In discussion with ILA and a secondary smelter representative, it was considered that the estimates presented in the table below could actually be underestimated.

Table 6-9. Estimated costs for an average secondary smelter plant producing 50 kt lead metal per year, annual turnover of 100 million € and required risk management measures for obtaining reference OELs in air (summarised from Engitec, 2021).

Reference OEL (µg/m³)	Estimated cost Factor compared to the baseline scenario of 150 µg/m³	Risk Management Measures required
Current OEL of 150	CAPEX 2.5 – 3 million € [1,2]	Most smelters do comply with the current OEL and BLV. The smelters that don’t meet the existing limit of 150 µg/m³ possibly causing part of the workers with lead in blood above the current BLV of 700 µg/L are in need to introduce the following improvements: 1. Increase the sanitary **ventilation** at least to 70t of air per one t of lead produced 2. Improve the quality of **respirators and PPE** and their maintenance 3. Introduce partition walls (**physical separation**) between areas at high dust concentration (i.e. W1, W3, W4) and other operative areas and concentrate there the sanitary air ventilation 4. Improve the **housekeeping and handling logistic** If measures are taken, blood levels are expected to be reduced by 15-20%
100	CAPEX 4.8 million €	The smelters that currently meet the existing limit of 150 µg/m³, but not less, are in need to introduce the following improvements: 1. Increase the sanitary **ventilation** at least to 80t of air per one t of lead produced 2. Improve the **enclosures of the furnaces and kettles** 3. Introduce partition walls (**physical separation**) between areas at high dust concentration (i.e. W1, W3, W4) and other operative areas and concentrate there the sanitary air ventilation

Reference OEL (µg/m³)	Estimated cost Factor compared to the baseline scenario of 150 µg/m³	Risk Management Measures required
		4. Improve the quality of **respirators and PPE** and their maintenance 5. Improve the **housekeeping and handling logistic** Also, in this case, different designs of smelters may require different costs of investment to obtain the same results.
50	CAPEX 6.9 million € Capital expenditure and increased operative costs apply	The introduction of the limit of 50 µg/m³ implies significant modifications to the production line and Advanced process control's (APC) systems: 1. Increase the sanitary **ventilation** at least to 90t of air per one t of lead produced. The ventilation should be concentrated on areas where workers are mostly present, and it should be possible to adjust ventilation in different areas dependent of greater or smaller need. Dust collected should be prevented from being dispersed in the surrounding environment by wetting or pelletizing material immediately after collection. 2. Improve the **enclosures of the furnaces and kettles** **Foundry**: Furnace charge preparation should be fully automatic, and metals should be added separately with individual ventilation hoods. This will avoid dispersion of dust during transport and addition of metal to the furnace. Further, the furnaces should be placed in an enclosed environment with negative pressure. **Refinery**: Refining kettles should also be placed under sealed hoods so that no gas nor dust can exit. 3. Introduce partition walls (**physical separation**) between areas at high dust concentration (i.e. W1, W3, W4) and other operative areas and concentrate there the sanitary air ventilation. All operations involving batteries (shredding, smelting and refining) must be performed in a **wet type unit** placed an area completely separated from other working areas and be kept under ventilation. Lead-Acid mist generated must be fully captured and washed in a scrubber. 4. Improve the quality of **respirators and PPE** and their maintenance 5. Improve the **housekeeping and handling logistic.** Regardless of the limit value set on air concentrations, good housekeeping is essential for keeping blood levels of lead low. "Good housekeeping" implies keeping floors clean of shredding remains, spillage etc. using vacuum cleaners. Further, equipment must be cleaned from dust routinely. Also, in this case, different designs of smelters may require different costs of investment to obtain the same results.
20	CAPEX 16.5 million €	The introduction of the limit of 20 µg/m³ implies significant modifications to the production line and APC's systems as previously listed: 1. Increase the sanitary **ventilation** up to 200t of air per one t of lead produced. The ventilation should be concentrated on all areas of the workspace, including areas where workers are not intensively present. Dust collected should be prevented from being dispersed in the surrounding environment by wetting or pelletizing material immediately after collection. 2. **Redesign and replace the hood systems** in shredding and sorting, foundry and refinery in order to keep fully enclosed the furnaces and kettles. Limit to the minimum the access of personnel, thus in some parts the introduction of operational devices like anthropomorphic robots or similar equipment to replace the personnel, may be required.

Reference OEL (µg/m³)	Estimated cost Factor compared to the baseline scenario of 150 µg/m³	Risk Management Measures required
		3. **Introduce fully automatic and enclosed systems** for furnaces feed and metal and slag transfer and handling, that shall be divided in two specific tunnels. **Foundry**: Furnace charge preparation should be fully automatic, and metals should be added separately with individual ventilation hoods. Further, metals must never touch the floor. This will avoid dispersion of dust during transport and addition of metal to the furnace. Further, the furnaces should be placed in an enclosed environment with negative pressure. **Refinery**: Refining kettles should also be placed under sealed hoods so that no gas nor dust can exit. Dust should be wetted or handled in sealed, ventilated enclosures upon collection. Ingot casting machine must be kept under negative pressure and casting shall be done from the bottom of the kettles. 4. Place, where not present, partition walls (**physical separation**) between areas at high dust concentration (i.e. W1, W3, W4) and other operative areas and concentrate there the sanitary air ventilation. All operations involving batteries (shredding, smelting and refining) must be performed in a **wet type unit** placed an area completely separated from other working areas and be kept under ventilation. Lead-Acid mist generated must be fully captured and washed in a scrubber. 5. Improve the **quality of respirators and PPE** and their maintenance 6. Improve the **housekeeping and handling logistic:** **Buildings**: Exposed parts of buildings, where escaped dust may settle, should be designed to minimize the area exposed and maximize the access of vacuum cleaners. **Housekeeping**: Regardless of the limit value set on air concentrations, good housekeeping is essential for keeping blood levels of lead low. "Good housekeeping" implies keeping floors clean of shredding remains, spillage etc. using vacuum cleaners. Further, equipment must be cleaned from dust routinely. Probably only few or none smelters in EU reaches such limit, thus the cost of investment should be quiet similar for all the smelters. This limit is very hard to reach, and probably economically impossible for some companies.
10	CAPEX 19.5 million € It is estimated that capital expenditure and new operative costs will exceed the profits. Energy costs for ventilation will increase by a factor 5.	The introduction of the limit of ¨10 µg/m³ implies significant modifications to the production line and APC’s systems. Lead is mainly produced via pyrometallurgical processes, however these processes appear unrealistic from an economical and technological point of view at 10 µg/m³. 1. Increase the sanitary **ventilation** up to 350t of air per one t of lead produced 2. **Redesign and replace the hood systems** in shredding and sorting, foundry and refinery in order to keep fully enclosed the furnaces and kettles. Limit the access of personnel to a minimum, thus in some parts the introduction of operational devices like anthropomorphic robots or similar equipment to replace the personnel, may be required. 3. Introduce fully automatic and enclosed systems for furnaces feed and metal and slag transfer and handling

Reference OEL (µg/m³)	Estimated cost Factor compared to the baseline scenario of 150 µg/m³	Risk Management Measures required
		4. Place, where not present, partition walls (physical separation) between areas at high dust concentration (i.e. W1, W3, W4) and other operative areas and concentrate there the sanitary air ventilation 5. Improve the quality of respirators and PPE and their maintenance 6. Improve the **housekeeping and handling logistic**. Operational methods and careful housekeeping will reduce productivity. Improvements of equipment may require replacement of them. The activity will not be economically sustainable. Probably no secondary smelters in EU reaches such limit, thus the cost of investment should be quite similar for all the smelters.
4	CAPEX 37.5 – 45 million € [3]	The introduction of the limit of 4 µg/m³ requires the use of a different technology based on hydrometallurgy rather than pyrometallurgy. The new technology shall be based on direct leaching, being also the battery dismantling and components separation of the full wet type. The only pyrometallurgical operations shall be limited to lead cathodes melting and alloying in kettles, plus the smelting of dross and not leachable components. The configuration of the facility may be summarized as follows: 1. Battery receiving and storing (only in boxes or pallets) 2. Battery dismantling and components separation (full wet system) 3. Pb bearing materials direct leaching 4. Pb electrolytic deposition (tank house) 5. Cathodes melting, alloying and casting in ingots or hogs 6. Smelting of dross and posts and relevant fumes processing system 7. Sanitary ventilation system (min. 70t of air per 1 t of Pb produced) 8. Auxiliary services such as change house, respirators and PPE maintenance, and laundry Given the magnitude of the investment and the broad range of modification necessary for the installation of the new units, the Capex has been calculated on the basis of a green field plant. Clearly a general conversion of the process for all the EU smelters appears impossible for economic reasons and probably may be realized only on very long terms basis.

[1] *The cost estimate assumes a plant producing 50 kt lead metal per year and yielding an annual turnover of 100 million €.*

[2] *Cost estimates include the additional costs for installing new RMMs needed to lower the lead air concentration. Regular operating costs are not included.*

[3] *The cost estimate for reaching a limit value of 4 µg/m³ is not comparable with cost estimates for other scenarios, since these are all based on the assumption that the existing facilities only need to be renovated or changed. Contrarily, the limit of 4 µg/m³ requires the construction of a new plant, which obviously requires a higher expenditure.*

The Engitec report also includes considerations about recurrent operating expenses comprising personnel cost (additional working time spent due to the maintenance of equipment and ventilation system, cleaning, the slower actions due to the increased personal protection devices) and energy costs (mainly due to the increased ventilation rate). The estimated OPEX cost are shown in the figure below.

The reference OEL of 4 µg/m³ results in a saving of OPEX due to the implement of a new production process. The saving is then given by less maintenance, reduced amount of produced dust due to limited dry materials handling, quicker action due to the light PPE required by the workplace conditions, and energy savings for ventilation.

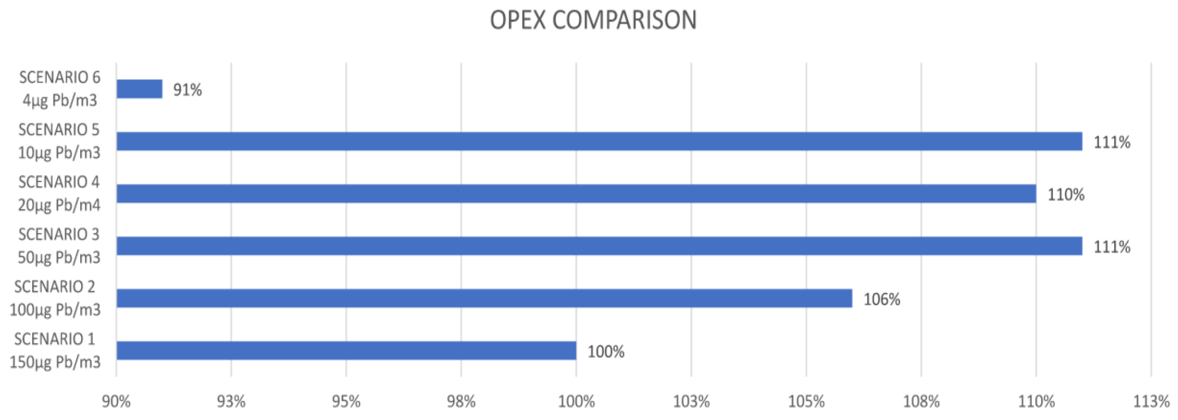


Figure 6-4. Estimates of operating expenses occurring at the different reference OEL relative to the baseline scenario of 150 µg/m³.

6.4.2 Compliance costs for companies

The Present Value (PV) of the estimated compliance cost (that accrue on top of the baseline costs associated with the BLV of 700) for a time period of 40 years are presented in the tables below. Table 6-10 presents the total compliance over 40 years, Table 6-11 presents the one-off investment costs over 40 years, and Table 6-12 presents the recurring operational costs over 40 years.

As described above, the cost model chooses the economically most advantageous option to achieve compliance with a given BLV option. The model calculates both one-off and recurring costs, based on the expected lifetime of each type of RMM. The model considers RMMs that already exist in the baseline and calculates their costs over the 40 years. These costs are deducted from the cost of the new RMMs, as companies would have incurred these costs already in the baseline.

The present value of the compliance costs range between € 6.3 billion for a BLV of 45 µg/L and € 0.1 billion for a BLV of 300 µg/L. There is a substantial increase in the compliance cost for all sectors, going from a BLV of 100 to 45. In sectors 2 – 5, 8, 10, and 13, the cost of calculated discontinuations (see section 6.4.4) contribute significantly to the compliance costs at the BLV of 45 µg/L. In the case of sector 12, the sector will incur an overall cost savings, as it saves recurring costs by switching to different RMMs.

Table 6-10 Compliance costs PV (€ million) over 40 years for BLV options by sector

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	555	183	71	37	16	0
2. Secondary lead production	734	249	86	37	15	0
3. Lead battery production	1,424	463	203	111	40	0

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
4. Production of articles of lead metal	265	85	30	16	6	0
5. Foundries	1,613	491	177	64	21	0
6. Production of lead com-pounds and lead frits	246	63	15	6	2	0
7. Production of glass	24	8	3	1	0	0
8. Ceramic ware production and enamelling	15	4	1	1	0	0
9. Manufacture and use of plastics and paints	17	4	2	1	0	0
10. Work with lead metal	362	100	49	23	9	0
11. Shooting	130	23	8	3	-	0
12. Recycling of PVC and other plastics	6	1	0	-0	-	0
13. Demolition, repairing and scrap industry	783	123	91	45	22	0
14. Other waste management	50	7	1	1	-	0
15. Other - Copper production	69	16	8	4	1	0
TOTAL	**6,293**	**1,819**	**745**	**348**	**134**	**0**

Source: study team's calculation

Most of the compliance costs can be attributed to one-off compliance cost. Table 6-11, which presents the one-off compliance costs, shows that about 80% of the total compliance costs entail one-off costs.

Table 6-11 One-off compliance cost (CAPEX, in € million) over 40 years for BLV options by sector

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	449	122	40	19	7	0
2. Secondary lead production	586	170	45	22	8	0
3. Lead battery production	1,078	439	179	91	37	0
4. Production of articles of lead metal	214	59	17	8	3	0

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
5. Foundries	1,198	408	141	42	15	0
6. Production of lead compounds and lead frits	212	56	11	5	2	0
7. Production of glass	19	7	3	1	0	0
8. Ceramic ware production and enamelling	12	3	1	0	0	0
9. Manufacture and use of plastics and paints	16	3	1	1	0	0
10. Work with lead metal	298	84	42	20	7	0
11. Shooting	91	15	4	2	-	0
12. Recycling of PVC and other plastics	8	1	0	0	-	0
13. Demolition, repairing and scrap industry	657	103	71	36	18	0
14. Other waste management	37	6	0	0	-	0
15. Other - Copper production	57	16	8	3	1	0
TOTAL	**4,933**	**1,491**	**565**	**253**	**101**	**0**

Source: study team's calculation

The recurring costs are thus small in comparison to the one-off costs above, as Table 6-12 below shows. In five sectors, some enterprises incur a cost saving in the recurring cost by changing to more cost-efficient RMMs for different BLVs, allowing these to save costs while still maintaining compliance. For example, if exposures can be sufficiently reduced by introducing organisational measures and/or enclosures instead of ventilation, operational expenses for local exhaust ventilation or general workroom ventilation can be saved, and the overall recurring cost may be negative.

Table 6-12 Recurring compliance cost (OPEX, in € million) over 40 years for BLV options by sector

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	106	61	32	18	9	0
2. Secondary lead production	147	79	41	15	7	0
3. Lead battery production	346	24	24	19	3	0
4. Production of articles of lead metal	50	26	13	8	3	0

Sector	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
5. Foundries	414	83	36	21	6	0
6. Production of lead compounds and lead frits	35	7	4	1	0	0
7. Production of glass	5	1	0	-0	0	0
8. Ceramic ware production and enamelling	3	1	1	0	0	0
9. Manufacture and use of plastics and paints	1	0	0	0	-0	0
10. Work with lead metal	65	16	7	2	1	0
11. Shooting	39	9	4	1	-	0
12. Recycling of PVC and other plastics	-2	-0	-0	-0	-	0
13. Demolition, repairing and scrap industry	125	20	20	9	4	0
14. Other waste management	13	1	0	0	-	0
15. Other - Copper production	12	0	-1	0	-0	0
TOTAL	**1,360**	**328**	**180**	**95**	**34**	**0**

Source: study team's calculation

6.4.3 Sector/use-specific cost curves

The following figures present the estimated compliance cost in the form of figures. Figure 6-5 presents the total compliance cost, Figure 6-6 presents the one-off CAPEX cost, and Figure 6-7 presents the recurring OPEX cost. Please note that the x-axes of the graphs are not in scale.

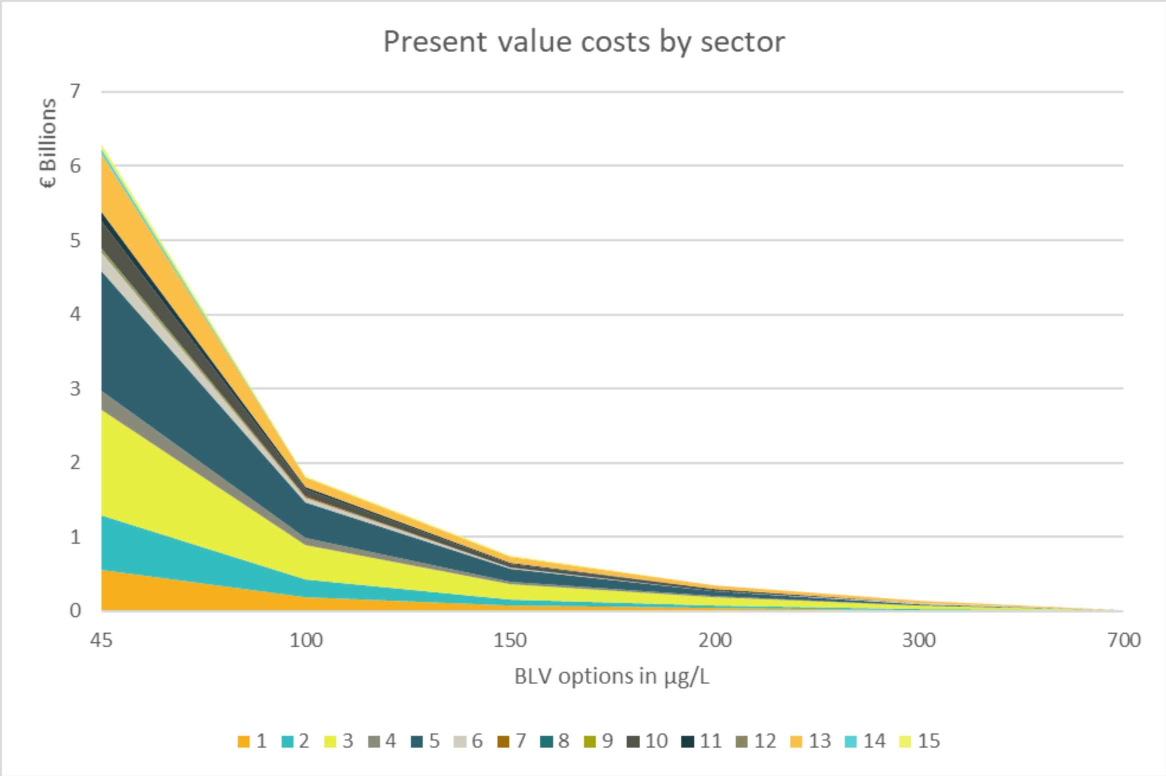


Figure 6-5 Compliance costs PV (€ million) over 40 years for BLV options by sector. Source: study team's calculation

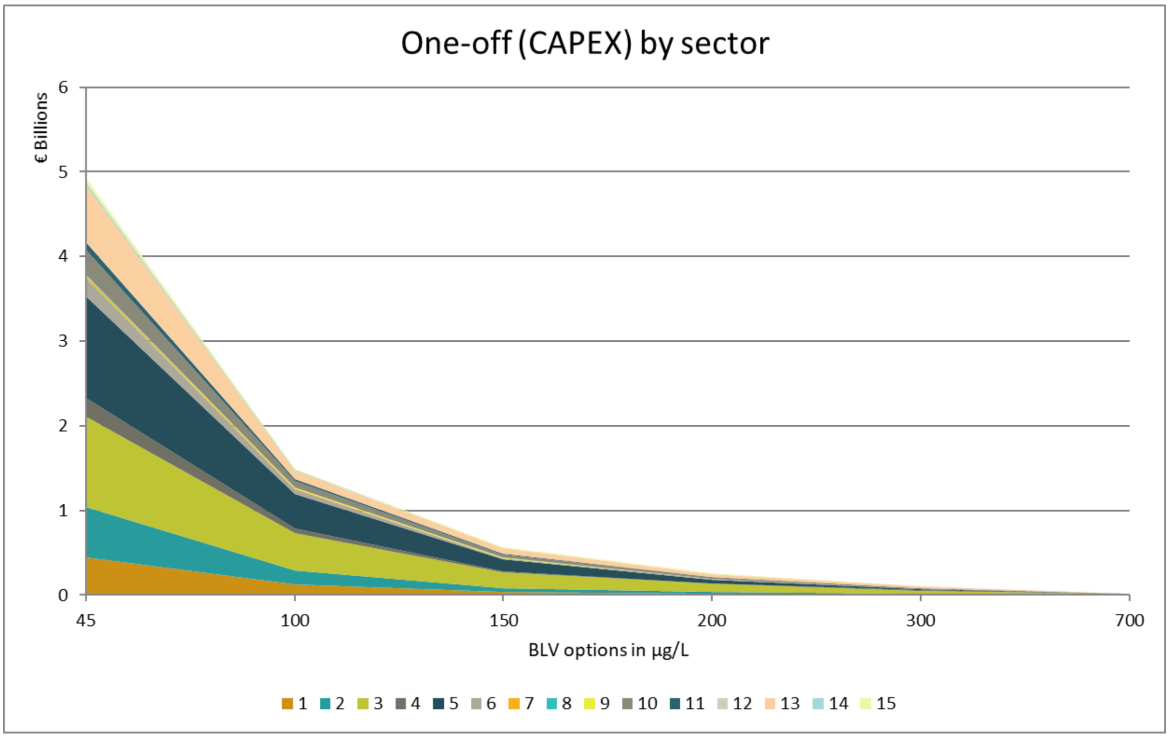


Figure 6-6 One-off compliance cost (CAPEX, in € million) over 40 years for BLV options by sector. Source: study team's calculation

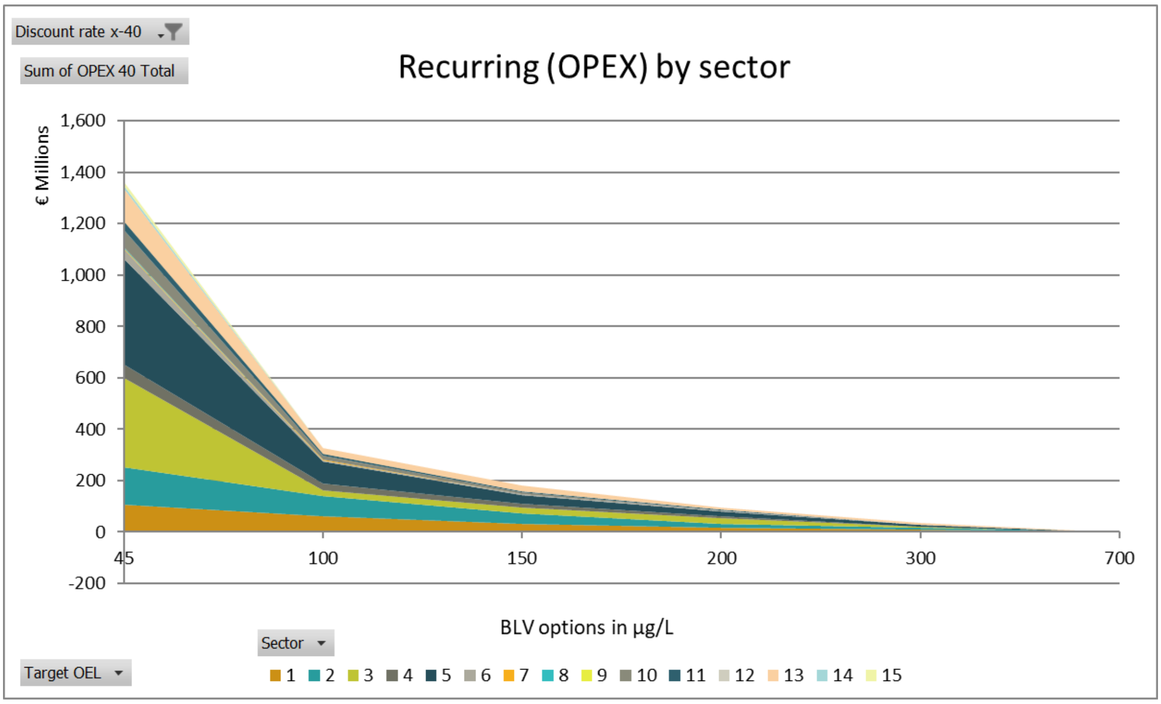


Figure 6-7 Recurring compliance cost (OPEX, in € million) over 40 years for BLV options by sector. Source: study team's calculation

6.4.4 Discontinuation costs by sector

A significant part of the cost of compliance is the cost of a company discontinuing if either the model can find no risk management measures that can comply with the target limit value or the costs of the risk management measures is higher than the cost of discontinuing. The discontinuation cost is taken as the loss of profit taken over 20 years and the average profit is assumed to be 10% of the turnover of an average company in sector[47]. The average turnover of small, medium and large companies in the sectors is shown in Table 6-4.

It is assumed that if the company had to discontinue activities leading to lead exposure, this would mean the closure of this company. The lost profit is assumed to be 10% of annual turnover for 20 years discounted, irrespective of company size. The business of the companies in the main sectors (primary and secondary lead producers, lead acid battery manufacturers, lead article manufacture) is entirely based on lead, meaning that in case RMM compliance costs exceed discontinuation, discontinuation cost for the whole company would become the output option. This is different from assumptions in other impact assessment studies, where discontinuations often only concern a part of the activities (i.e. those with exposure) within large companies.

For some companies, discontinuation would only apply for certain activities or divisions of the company. This applies primarily to the sectors 5, 7-9 and 12-13. For example, a glass manufacturer may discontinue to produce lead crystal glass tableware but continue to produce tableware of lead-free glass. In such case, only the lost profit of the division or activity including lead exposure should be accounted for in the calculation of discontinuation costs. However, such granular data have not been available, and the discontinuation of certain

[47] In RAC/SEAC 2017, on page 30, SEAC states that the "welfare impacts should be measured in terms of the expected profit losses as those correspond to the loss in producer surplus." The study team makes the assumptions of profits being an average of 10% of turnover and that the losses are taken over 20 years.

divisions or activities is therefore not accounted for. This leads to an overestimation of the discontinuation costs.

For companies with lead exposure, some discontinuations occur for the BLV targets of 45 and 100 µg/L, based on the assumptions underlying the cost model calculations.

The adjusted values representing lost profit over 20 years of discontinued enterprises by sector are shown in Table 6-13 and

Table 6-14 for the BLV options of 45 and 100 µg/L, respectively.

Comparing the cost of discontinuations with the total compliance costs (Table 6-10), it can be seen that the discontinuations costs comprise a significant part of the compliance cost for sector 2, sector 3 , sector 5, sector 8 and sector 13 at the BLV option of 45 µg/L.

The data should be interpreted with care, as companies would usually always try to find other means for reaching compliance than closing. Such other possibilities cannot be reflected in sufficient detail in the cost model. As an example, lead glazes in the ceramics sector can be substituted relatively easy (section 4.9) and would presumably be the preferred option by companies before discontinuing. In some sectors, e.g. lead acid battery manufacture or demolition of lead-painted buildings, substitution is not possible, but companies may still find other ways of complying, e.g. restructuring the unit where the main lead exposure occurs or discontinuing only the activities with lead exposure without closing the whole company.

Further detail on discontinuation cost is provided in section 7.3.

Table 6-13 Average lost profit (discounted) by size of discontinued enterprises by size and sector (Discounted loss over 20 years) for the BLV option of 45 µg/L, € millions

Sector	Average lost profit (discounted) in € millions		
	Small	Medium	Large
1. Primary lead production	-	-	€ 0
2. Secondary lead production	€ 0.0	€ 158	€ 421
3. Lead battery production	€ 0.0	€ 0	€ 509
4. Production of articles of lead metal	€ 3.8	€ 25	€ 0
5. Foundries	€ 42	€ 174	€ 666
6. Production of lead compounds and lead frits	€ 0.0	€ 0.0	€ 0
7. Production of glass	€ 0.0	€ 0.0	€ 0.0
8. Ceramic ware production and enamelling	€ 5.9	€ 0.0	€ 0.0
9. Manufacture and use of plastics and paints	€ 0.0	€ 0.0	€ 0.0
10. Work with lead metal	€ 0	€ 25	€ 0.0

Sector	Average lost profit (discounted) in € millions		
	Small	Medium	Large
11. Shooting	€ 0.0	-	-
12. Recycling of PVC and other plastics	€ 0.0	€ 0.0	-
13. Demolition, repairing and scrap industry	€ 0	€ 183	€ 0
14. Other waste management	€ 0.0	€ 0.0	€ 0.0
15. Other - Copper production	€ 0.0	€ 0.0	€ 0.0
Total	€ 51	€ 567	€ 1,596

Source: study team's calculation

Table 6-14 Average lost profit (discounted) by size of discontinued enterprises by size and sector (Discounted loss over 20 years) for the BLV option of 100 µg/L, € millions

Sector	Average lost profit (discounted) in € millions		
	Small	Medium	Large
1. Primary lead production	-	-	€ 0
2. Secondary lead production	€ 0.0	€ 0.0	€ 0
3. Lead battery production	€ 0.0	€ 0	€ 0
4. Production of articles of lead metal	€ 0.0	€ 0	€ 0
5. Foundries	€ 8	€ 58	€ 0
6. Production of lead compounds and lead frits	€ 0.0	€ 0.0	€ 0
7. Production of glass	€ 0.0	€ 0.0	€ 0.0
8. Ceramic ware production and enamelling	€ 2.0	€ 0.0	€ 0.0
9. Manufacture and use of plastics and paints	€ 0.0	€ 0.0	€ 0.0
10. Work with lead metal	€ 0	€ 0	€ 0.0
11. Shooting	€ 0.0	-	-
12. Recycling of PVC and other plastics	€ 0.0	€ 0.0	-
13. Demolition, repairing and scrap industry	€ 0	€ 0	€ 0

Sector	Average lost profit (discounted) in € millions		
	Small	Medium	Large
14. Other waste management	€ 0.0	€ 0.0	€ 0.0
15. Other - Copper production	€ 0.0	€ 0.0	€ 0.0
Total	€ 10.3	€ 57.9	€ 0.0

Source: study team's calculation

6.4.5 Monitoring costs

Companies must currently demonstrate compliance with existing OEL and BLVs and perform health surveillance according to the requirements in the CAD.

Regarding the compliance to OELs, implementation and enforcement practices differ between Member States. While some companies are measuring PbA levels on a regular basis (every 1 – 5th year), others rely mainly or solely on blood lead monitoring. It is assumed that the introduction of a lowered OEL would not change this practice. The competent Member States authorities may prepare specific guidelines on which measures to implement in a given occupational environment upon introduction of a lowered OEL. By applying these measures, it is assumed that OEL compliance is achieved without additional measurements.

PbB levels are recognized as the main exposure metric in occupational settings.

Regarding the compliance to BLVs, the CAD does currently require medical surveillance if:

- exposure to a concentration of lead in air is greater than 0.075 mg/m³ (75 µg/m³), calculated as a time-weighted average over 40 hours per week , or
- a blood-lead level greater than 40 µg/dL (400 µg/L) blood is measured in individual workers.

The main part of the companies in the lead-producing and lead-processing sectors follow the voluntary industry program on health surveillance (section 4.10). The ILA/Eurobat program requires blood lead levels measured at least once a year in every worker. At PbB > 100 µg/L, measurement frequencies are increasing (section 4.10). Female employees in age of childbearing capacity are likewise tested at least once a year, and testing frequency is increased to every 3 months or more frequent when PbB exceed 50 µg/L. Some of the companies consulted during the study stated that they routinely monitored all exposed every 3 months and it was also indicated that personal medical conditions contribute to determining the monitoring frequency. Cost estimates ranged from €78 - €179 per sample, depending on whether internal staff are used for the sampling (mostly at large companies) or external medical personal is engaged for the sampling, and which cost attributes were included in the estimate. One of the stakeholders provided a split up of the monitoring cost per sample into sampling by medical staff (35%), shipment and laboratory analysis (32%), loss of working time following hygiene procedure (22%) and data processing and reporting (11%). The latter is an administrative cost related to the monitoring.

Total currently occurring monitoring costs range from € 10,000/year for a small company (ca. 14 employees in the monitoring program) to € 65,000/year for a large company (ca. 800 employees in the monitoring program). Available data indicate that the cost of monitoring per employee is higher for smaller companies.

The currently used trigger values for medical surveillance correspond to the lowest BLV options considered in this study. Possibly, the introduction of the lowest BLV options considered in this study, may cause a reduction of the currently used trigger values for medical surveillance and thus lead to an increase in sampling frequency for the workers, exceeding these trigger values. Also, a certain administrative burden cannot be excluded as a given company's monitoring program may need reassessment if lowered limit values are introduced. The administrative cost of updating an existing monitoring program are expected to be small, and are not considered further here.

Monitoring of exposures is commonly implemented throughout the industry as a mean of exposure management and for limit value compliance. Common practice appears to exceed current legal requirements as stated in the CAD. It is therefore anticipated that the lowering of limit values will not have a significant effect on the cost of monitoring and the monitoring cost is not further estimated here.

6.4.6 Compliance cost of a differentiated BLV for groups at extra risk

As outlined in section 4.2 "Groups at Extra Risk", the need for and implications of differentiated limit values for certain groups within the workforce has been discussed by the steering group of this study. It is not within the scope of this study to provide a conclusion on how to account for differences in susceptibility towards lead exposure between different groups within the workforce when setting limit values.

The compliance cost assessment performed in this study includes the introduction of necessary RMM for compliance with all BLV options. This means, also the lowest BLV option of 45 µg/L (originally included for female workers of reproductive capacity) has been included for all workers. It is currently unclear, whether the introduction of a BLV of 45 µg/L for female workers of childbearing age would be justifiable seen from a gender equality perspective.

The following sections provide qualitative information on possible options for allowing reduced exposures for female workers in case the introduction of a new BLV above the biological guidance value as proposed for women by RAC (45 µg/L) should become relevant.

6.4.6.1 Current exposure and RMM for women of childbearing age

Exposure concentration data for women and women of childbearing age are provided in section 4.6.3. Women and women of childbearing age do generally have lower blood lead levels compared to male employees within the same sectors. For several sectors, average blood lead levels in women of childbearing age do not exceed 45 µg/L (ranging from 33 to 130), however, P90 blood lead levels always exceed 45 µg/L for in all sectors (for which data has been available).

In the consultation survey and interviews, stakeholders were asked about

1. the number of female employees;
2. voluntary targets for female employees;
3. RMMs for female employees;
4. whether there are any activities reserved for male employees only; and
5. whether the company has any issues with reserving certain activities for male workers only.

58 stakeholders responded to the survey sections about voluntary targets and RMM for female employees.

Number of female employees

Approximately 25% of the survey respondents had no women employed in areas with exposure, 25% of the respondents had less than >0 - 5% of women among the exposed employees and 50% had >5% of female workers. Follow-up interviews indicated that the survey responses on number of employees and number of exposed male and female employees have to be interpreted with care as some respondents distinguished between exposed and non-exposed employees, while others did not. In some cases, women would mainly be working within administration and only be exposed during visits in the production (which may occur a few times a year). All in all, the data provided in the consultation survey is in line with data provided by the Lead REACH Consortium and other sources (section 4.7.4.3).

Voluntary targets for female employees

About half of the respondents indicate that they work with voluntary industry targets for female employees, most of these refer to the ILA/EUROBAT target of <100 µg/L for female employees, others indicate company internal targets ranging from 50 - 350 µg/L.

RMMs for female employees

The following risk management measures are mentioned by respondents to implement the existing voluntary targets for female employees:

- Removal from workplaces with lead exposure (> 5 answers)
- Training, education and information (> 5 answers)
- Increased frequency of blood lead monitoring (> 5 answers)
- Improved RPE (1- 5 answers)
- Reduction of number of women working in areas with exposure (1- 5 answers)
- Temporary relocation (1- 5 answers)
- Permanent removal from workplace once the target has been reached (1- 5 answers)
- Prohibition of female workers in areas with lead exposure (1- 5 answers)
- Prohibition of pregnant workers in areas with lead exposure (1- 5 answers)
- Changing clothing every day Improved RPE (1- 5 answers)
- Individual risk assessment by medicals/OH responsible Improved RPE (1- 5 answers)

Activities reserved for male employees and related issues

A little more than half of the respondents indicate that certain activities are reserved for male workers only. All these respondents specify that this concerns activities in workplaces with lead exposure, e.g. smelting, refining, casting, production. These respondents do not have any issues with reserving certain activities for male workers only, even though two thirds of them have women employed.

A little less than half of the respondents indicate that there are no activities reserved for male workers only. Five respondents indicate that activities cannot be reserved for male workers only due to reasons related to gender discrimination, gender equality and/or internal company goals on diversity among employees/better balance between genders.

During the follow-up interviews, several stakeholders indicate that a lower BLV for women would not cause any impact on their business.

The responding companies are spread throughout the EU and no Member State dependency can be read from the survey results.

6.4.6.2 Measures for reaching compliance with a BLV 45 µg/L for women of childbearing age

Cost estimates for compliance costs of combinations for differentiated target limit values have not been developed because of the large uncertainty and limited data availability related to the potentially occurring compliance costs for a BLV option of 45 µg/L for women/female workers of reproductive age only. These limitations refer to the large variation in the fractions of women employed between the single companies within a sector, a large variation in PbB data for female workers in between companies, the uncertainty as to whether it is legal to have different (i.e. lower) limit values for female workers and whether implementation at a national or company level would be relevant at all.

Instead, the available measures allowing for a reduction of PbB levels in female employees are described and evaluated qualitatively. The most important measures and their impact on compliance costs for the employer are displayed in Table 6-15 below.

Several companies, which have participated in the stakeholder consultation, did not expect a significant impact of a 45 µg/L for women only. The low number of women working in workplaces with lead exposure was explained with historical and cultural reasons. Two stakeholders stated that women do not pass the medical test (physical constraints), which is mandatory at engagement of new employees at certain physically demanding workplaces.

In conclusion, the magnitude of additional compliance cost of a BLV of 45 µg/L for women largely depends on the compliance strategy, a company would choose and would be allowed to choose. Permanent relocation and exclusion of women from workplaces will in many cases be the cheapest option and therefor the preferred option. In cases where women are (to be) employed and gender equality considerations prohibit exclusion of women from workplace with lead exposure, additional compliance cost can be expected due to additional training, additional monitoring and use of more advanced RPE.

Table 6-15 Additional RMM required for the BLV option of 45 µg/L for women of reproductive capacity

Possible additional RMM required	**Estimated economic impact per female employee**
Training, education, and information	Medium. Depending on the intensity of training, number of employees participating in the training. A minimum annual cost of €1,000 per employee covering instructor costs, working hours used for training and administrative costs can be anticipated. Information about health risks may cause women to drop engagement in workplaces with lead exposure.
Increased blood level monitoring	Low - medium. Depending on PbB levels, number of employees, and individual medical condition. The laboratory cost per sample may range between €15 and 25, moreover administrative cost and cost for sampling through nurse or medical doctor. Depending on monitoring scheme, six – 12 samples may be necessary €25/sample
Advanced RPE	Medium – high.

Possible additional RMM required	Estimated economic impact per female employee
	Depending on the type of RPE, whether the same type of RPE is already used within the enterprise and the number of RPE users. The acquisition cost of a ventilated helmet with powered breathing apparatus is appr. €1,000. Moreover, the infrastructure for storage, cleaning and maintenance of the RPE is needed. Responsibility for equipment maintenance may be given to the employee (typically less efficient) or transferred to a dedicated service inside/outside the company (best practice).
Permanent relocation from workplaces with lead exposure	Low.
Increased frequency of relocation	Low. Relocation becomes relevant when a trigger value is exceeded. Relocation causes primarily an administrative burden (an estimate of €200 per case has been mentioned by a single stakeholder).
Exclusion of women from workplaces with lead exposure	Low.

Source: Stakeholder consultation

6.4.7 Relationship between BLV and OEL

The relationship between BLV and OEL options to be investigated in this study have been subject to discussion in the steering group. On the one hand, stakeholders found it difficult to provide descriptive and/or quantitative information on airborne lead concentration management relating to the lowest OEL option, on the other hand, there is an interdependency between airborne (PbA) and blood lead levels (PbB). This means that some of the RMMs used to reduce PbB will reduce the PbA. It was agreed that the study should estimate the achievable range of OEL options based on a given BLV option. The following paragraphs summarise the relationship between PbA and PbB, both from earlier assessments and current occupational settings, to support such an estimation.

Relationships between airborne concentrations and blood lead concentrations have been subject to numerous studies. The figure below illustrates the large scatter of the correlation between blood lead and air lead concentration (AGS, 2017). It should be noted that the data are based on an older study (Kentner and Fischer, 1994, cited in AGS, 2017) and that measured values for airborne concentration in the lower range (< ca. 30 µg/m³) are not available. Further details about PbB – PbA relationship are provided in section 2.3.4.

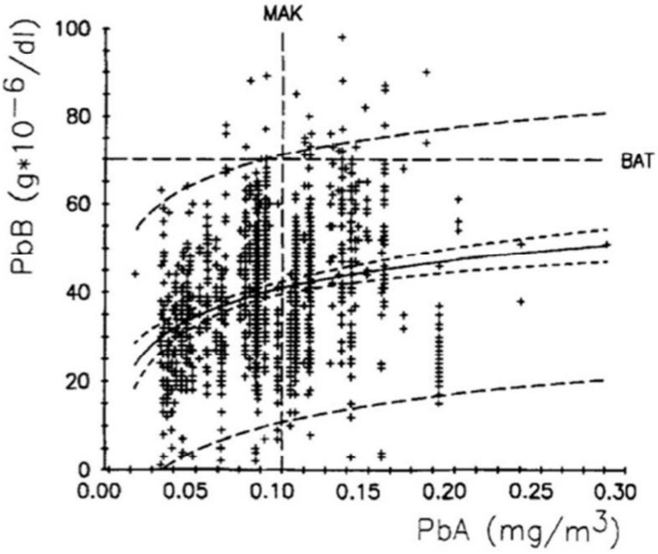


Figure 6-8 Air lead concentrations (PbA) correlated to blood lead concentrations (PbB). Source: Kentner and Fischer, 1994, (cited in AGS, 2017).

RAC states that the correlation between air concentration and blood concentration is influenced by various factors and is therefore not constant over various occupational settings. Therefore, the correlation between airborne and blood concentrations over a range of settings is always flawed with uncertainties.

6.4.7.1 Summary of approaches in derivation of OELs from BLVs

In the annex to the RAC opinion (RAC, 2020), the authors emphasize the special situation with lead, where PbB is more important as an exposure metric than airborne concentrations and where blood lead limits values are used to derive occupational exposure limit value for the workplace air:

"The international and national bodies proposing occupational limit values since the latest EU recommendation (SCOEL 2002) have used various argumentations but have all ended up basing their overall recommendation mostly on human data on adult neurotoxicity with some variation… . All these recommendations use a biological limit value (BLV), more specifically PbB, as the relevant exposure metric. Those that also recommend an occupational exposure limit value (OEL) for workplace air to support achieving the desired BLV targets, have derived an OEL that best corresponds to the established BLV. Lead is unique in this regard, since for most substances with a national or international BLV, the BLV is derived from the OEL instead.

RAC recognizes that "*proposing an OEL value for air is more complicated than for other compounds as the derivation of the OEL is based on a correlation to the established BLV*" (RAC, 2020).

Several correlations (between BLV and OEL levels) that have been developed and/or used by other authorities have been reviewed by RAC. Three of most recent correlation results as well as the relationship of the current limit values in the CAD are shown in the table below.

Table 6-16 Different correlation approaches summarised from the RAC (2020) annex. The bold printed figures were finally chosen by RAC as the more appropriate approach for correlating the limit values.

Source	Correlation BLV ~ OEL, 8-hour TWA	Comment
AGS (2017)	150 µg/L ~ 11.5 µg/m³ (50th percentile) 150 µg/L ~ 3.9 µg/m³ (95th percentile)	Assessment of the PBPK model by OEHHA (2013). AGS noted the high uncertainty for a correlation between PbB levels and Pb concentrations in air and that data were missing in the lower exposure range. Due to this uncertainty, AGS did not use the model to derive an OEL for lead in air.
Safe Work Australia (2014)	200-300 µg/L ~ 50 µg/m³	Based on measured historical correlations between PbB and air concentrations observed in a number of industrial settings (not representative of current workplace conditions)
ANSES (2017a)	180 µg/L ~ 30 µg/m³	Based on measured historical correlations between PbB and air concentrations observed in a number of industrial settings (not representative of current workplace conditions)
CAD	700 µg/L ~ 150 µg/m³ 150 µg/L ~ 32 µg/m³	Proportional relationship of the current limit values in the CAD used to derive an OEL based on BLV 150 µg/L

Compliance with a BLV is recognized as the primary tool for protecting workers from lead toxicity by many national and international authorities including the RAC.

RAC considers that, if an air limit value is required to maintain continuity with current limits values under the CAD, the BLV should not be exceeded in the majority of workers, i.e. at least at the 95th percentile level. Despite considerable uncertainties in all of the available correlation data, the Physiologically-based Pharmacokinetic (PBPK) modelling approach by OEHHA (2013) was seen as the most appropriate approach, rendering an predicted air concentration of 3.9 µg/m³ as corresponding to a PbB concentration of 150 µg/L (95th percentile). Thus, an OEL (8 h TWA) of 4 µg/m³ has been recommended by RAC.

6.4.7.2 Stakeholder consultation data on relationship between PbB and PbA

For the purpose of illustration, the summarised measured data received from the Lead REACH Consortium (shown in Table A3-1 and see Table A3-4 in Annex 3 to this report) and the modelled relationships between PbB and PbA from the OEHHA data are depicted in Figure 6-9 below. For the Lead REACH Consortium survey data, average, median and P90 values from the workplaces for each sector for PbB and PbA, respectively, have been correlated. For PbA, more than 2,000 personal samples counts were included in the analysis, for PbB appr. 70,000 samples. The data points do neither represent relationships of exposure concentrations of a single worker, nor direct temporal relationships, but are statistical parameters (AM, median and P90) summarised for each workplace. Please note that PbA data at higher concentrations are available in the data set, but the PbA axis has been cut at 300 µg/m³ to make the graph more readable.

While the OEHHA modelled data relate a PbB range of about 50-650 µg/L to a range of about 0.5-34 µg/m³ PbA, the measured data show that PbB ranging from about 75-350 µg/L correspond to a PbA range of about 0.5-300 µg/m³ in the graph below. Effectively this means, low PbB levels appear to be achievable despite associated high PbA concentrations.

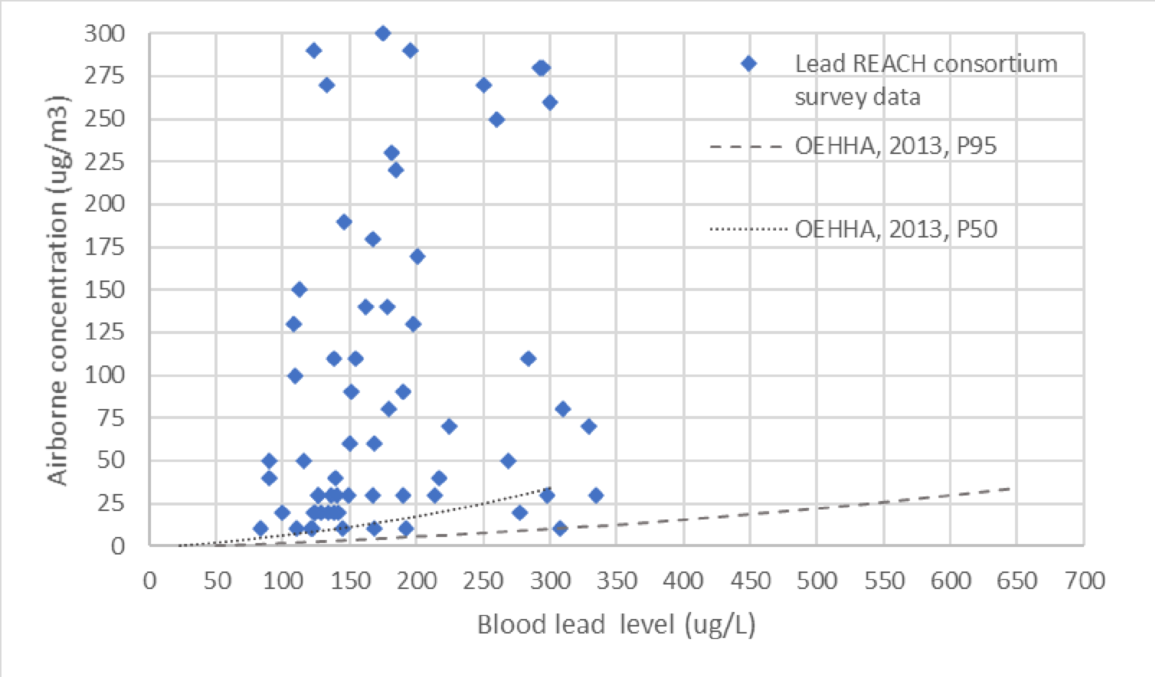


Figure 6-9 Illustration of Lead REACH Consortium data and OEHHA modelled correlation between blood lead levels and airborne concentrations.

The large scattering and apparently weak correlation between airborne and blood lead concentration data is exemplified in an illustration provided by a European battery producer below (Figure 6-10). While the factory design is fictitious, the PbA and PbB concentration data are measured data from 2012. The figure shows that the PbB concentrations can diverge considerably even within the same workplace and thus emphasizes the significance of personal behaviour in preventing elevated PbB levels.

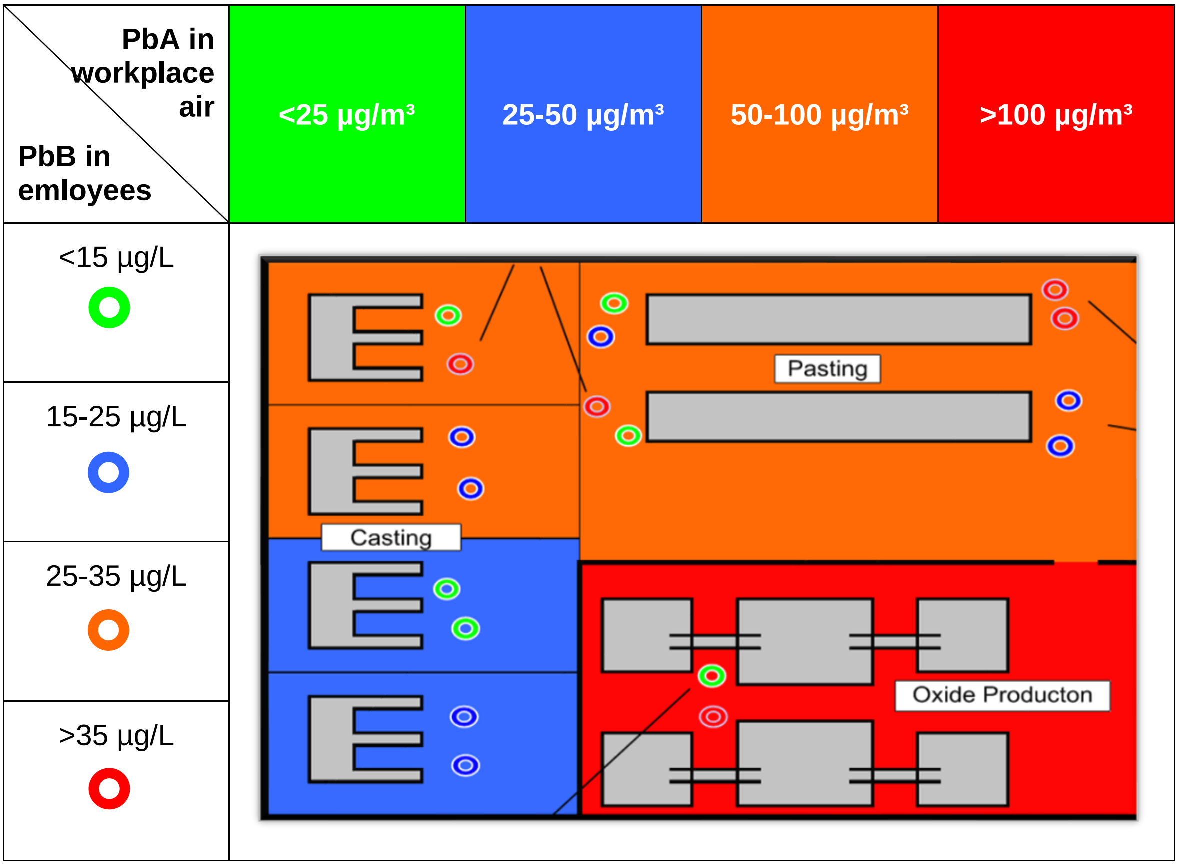


Figure 6-10 Measured PbB concentration in employees (coloured circles) and lead concentration in the workplace air (background colours). Illustration modified from a presentation obtained from Kurz, 2021.

In the consultation survey, respondents have been asked, which OEL levels (airborne concentration without PPE) they regard as achievable, when implementing a given level of BLV. The results on this question are summarised in Table 6-17 below. About one third of the respondents answered to this question, however, most choose the answer option "I don't know", demonstrating that respondents found it difficult to relate PbB and PbA levels. Based on the limited responses, the limit value combinations **BLV 300 / OEL 150** as well as **BLV 150 / OEL 50** (units µg/L / µg/m³) are regarded as realistically achievable.

In the follow-up interviews with stakeholders, interviewees emphasize the key role of RPE for achieving low blood lead levels. Therefore, RPE use is encouraged or even mandatory (depending on national legislation) even when the PbA levels are below the current OEL (national or company internal target). In workplaces current OELs may be exceeded, RPE use is mandatory and used on a regular basis.

A few stakeholders note that setting very low OELs (e.g. 4 µg/m³) would be regarded as unachievable within some workplaces. This would discourage efforts in reducing PbA levels and encourage more widespread use of RPE and/or upgrading of RPE instead.

Table 6-17 Number of responses for achievable OELs upon achievement of a BLV option.

	BLV option		
Achievable OEL when implementing a given BLV level	**300 µg/L**	**150 µg/L**	**45 µg/L (for female employees)**
4 µg/m³	0	0	2
20 µg/m³	0	3	1
50 µg/m³	1	7	2
100 µg/m³	4	1	0
150 µg/m³	6	1	1
"I don’t know"	7	8	12
Response rate %	30%	33%	30%

Source: Consultation survey

6.4.7.3 Conclusion on achievable OELs within BLV compliance

Neither available historic data (section 6.4.7.1), nor the comparison of the most comprehensive data set from current occupational settings (section 6.4.7.2) allows for unambiguous conclusions on correspondence of BLV and OEL options. The stakeholder consultation data (consultation survey and interviews) favour an OEL of 50 µg/m³ as achievable through implementation of RMM for PbB control as well as additional PbA RMM, depending on workplace characteristics.

6.5 Direct costs – administrative burdens and charges

Member State authorities incur administrative costs in documenting the implementation of the CAD. Whereas the CAD entails no provisions that require regular reporting by the Member States to the EU, the national transpositions may entail some form of regular reporting. Such administrative costs would however arise from national implementation, and not from EU provisions. To the extent that the CAD induces administrative costs owing to EU provisions, these would be attributable to the baseline.

The six investigated options only entail a change of the limit value, and therefore do not introduce new administrative requirements as such. Accordingly, no administrative costs are associated with the options.

6.6 Direct costs – enforcement - for public authorities

Public authorities incur costs for the transposition of a reduced BLV as well as costs for enforcement, monitoring and adjudication. These aspects are discussed in discussed in the following two sections.

6.6.1 Transposition

Member States incur costs for the transposition of relevant changes into national legislation. The exact costs depend on the specific changes agreed in EU legislation, and the level of national autonomy in the transposition (which influences e.g. the number of departments involved in transposition or implementing the Directive). Some Member State may further require regulatory impact assessments. Sweden is for example obliged to carry out an impact assessment on new EU legislation. The transposition costs are therefore likely to vary significantly between Member States.

Specific data on the costs of transposition of EU legislation by specific Member States are not readily available. For one UK impact assessment for example, *"the costs of amending current regulations to implement a Directive are thought to be around £700,000"* (around €950,000 in €2021, RPA (2012)). Whereas no details are provided for that calculation, it is expected that these costs correspond to a substantial legislative change, which would include the costs of making (e.g. preparing an impact assessment, drafting and discussing a legislative proposal), printing and publishing the legislation. A second estimate by the UK Department for Transport (2011) provides a substantially lower value, stating that *"a combination of legal and technical resources as well as policy advisors are usually required to implement such a change, costing approximately £15,687 per amendment"* (approximately €20,000 in 2021).

Almost all Member States have transposed the CAD and its limit value for lead. The cost of revising one or two existing BLVs would therefore be closer to the low-end estimate. It appears, however, that there has been a general trend towards more comprehensive and thus more expensive impact assessment in the Member States (e.g. RPA, 2015), which suggests that the costs are likely to exceed €20,000.

This study thus assumes €50,000 per Member State as an approximation of the general order of magnitude of the transposition costs in Member States that have not transposed the CAD and the current BLV. For those Member States that have transposed the current CAD with respect to lead, the change to a different value (in case the current BLV were to be higher than the revised BLV) is assumed to entail a lower cost of €20,000. It is further assumed that the cost of revising one or two BLVs are not significantly different.

Section 4.1 above shows that almost all Member States have either an OEL or a BLV in place – or as in most cases both. Estonia, as the only Member State, has not transposed the BLV of 700 µg/L, and will therefore incur a transposition cost of €50,000. [48] These transposition costs are however only attributed to the baseline, as the six options introduce the revision of an existing limit value, as opposed to introducing a completely new limit value.

Table 6-18 below presents for each BLV option, which Member States have to revise at least one BLV value. Based on the unit costs established above, the table calculates the transposition cost, which is about € 500,000 (+/- €20,000) for all six options. The reason for the symmetry of the transposition cost is that nearly all Member States currently have at least one BLV above 300 µg/l (which is simultaneously the least ambitious option).

[48] https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:31998L0024. There is also no evidence that Estonia has transposed the CAD in the transposition registry of the CAD. While there also is no transposition entry for Malta and Sweden, both of these have introduced a BLV.

Table 6-18 Estimated cost of transposition, relative to the baseline

BLV	MS required to revise at least one BLV	Number of MS	Transposition cost (relative to baseline)
300 µg/l	All Member States except EE[1], DE, DK, FI	23	€ 460,000
200 µg/l	All Member States except EE[1], DE, DK	24	€ 480,000
150 µg/L	All Member States except EE[1], DE	25	€ 500,000
100 µg/L	All Member States except EE[1]	26	€ 520,000
45 µg/L	All Member States except EE[1]	26	€ 520,000
1: Estonia has not transposed the current CAD's limit values, and therefore incurs a transposition cost that is only attributable to the baseline (700 µg/l)			

Source: study team's calculation

6.6.2 Enforcement, monitoring and adjudication costs

Member States that have transposed the CAD and the corresponding OEL and BLV for lead, are principally already required to inspect associated companies. The introduction of a reduced limit value on its own should therefore not lead to additional cost of enforcement or monitoring.

There could be an additional cost due to the need to ensure compliance with the new rules or the need for a higher monitoring frequency. Such enforcement costs depend on the inspection regime in each country, and they are not estimated in this study.

Estonia will incur an increase in enforcement and monitoring costs, as it still needs to transpose the CAD's current limit values. These costs are however attributed to the baseline, as the costs are not introduced by the six options, but rather the initial CAD.

6.7 Indirect costs

Indirect costs could arise in terms of the availability of products, the choice and quality of products, as well as possible ripple effects through the value chain; these types of costs are also discussed in more detail in chapter 6.8 on Market effects

6.8 Aggregated costs

The aggregated costs entail nearly exclusively compliance cost, of which particularly one-off investment costs. The cost elements of monitoring, administration, and enforcement cannot be attributed to the reduced BLVs, as these already occur as part of the baseline.

The lowest BLV of 45 µg/L leads to the highest compliance cost, and these are significantly higher than the other BLV options. The BLV of 100 µg/L will introduce significant compliance costs, while the costs associated with the BLVs of 150, 200, and 300 µg/L are limited.

Table 6-19 Aggregated costs by cost category and BLV, in € million

Stakeholder	Cost	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Companies	Compliance cost, PV-CAPEX	4,933	1,491	565	253	101	0
	Compliance cost, PV-OPEX	1,360	328	180	95	34	0
	Monitoring cost	0	0	0	0	0	0
Public administration	Administrative burden, recurring	0	0	0	0	0	0
	Transposition cost, PV	0.5	0.5	0.5	0.5	0.5	0
	Enforcement cost	0	0	0	0	0	0
	Total cost	**6,293**	**1,820**	**745**	**348**	**135**	**0**

Source: study team's calculation

7. Market effects

Market effects relate in this context to impacts of reduced BLVs on the lead market. Reduced BLVs can namely impact research & innovation, the functioning of the Single Market, the competitiveness of EU lead businesses, as well as changes in employment.

Accordingly, this section is composed of the following sub-sections:

- Section 7.1 Overall impact
- Section 7.2 Innovation and growth
- Section 7.3 Single market
- Section 7.4 Cost competitiveness, and
- Section 7.5 Employment

7.1 Overall impact

There are two primary drivers behind the market impacts: i) the compliance cost incurred to achieve a new BLV, and ii) the feasibility of meeting these new requirements. Some enterprises may, in extreme cases, choose to discontinue their activities as they are unable to meet a reduced BLV at a cost that secures continued profitability.

Table 7-1 below presents the average 40-year PV of the compliance cost per business per sector and BLV, which is calculated as the total compliance cost divided by the number of businesses per sector.

Table 7-2 presents the same figures as annual compliance costs, which is calculated as the average 40-year PV of the compliance cost per business by 40 years. Based in the assumptions used in the cost model, the recycling of PVC and other plastics sector (sector 12) even incurs a small cost saving, as a limited set of enterprises can incur cost savings and still achieve compliance.

Significant costs per business occur for companies in sector 1 (Primary production) and 3 (Battery production), especially at the lower BLV options. In sector 1, all primary producers are large companies with 50 – 2,300 exposed employees (consultation survey). In sector 3, 80% of the 30 companies are large companies with 300 – 1,800 exposed employees each (consultation survey). As the calculated compliance cost depends on company size, number of employees and annual turnover, the compliance cost per business is generally higher in the sectors with larger proportions of large companies and high numbers of employees.

Additionally to the increased use of organisational measures and more advances RPE, the cost model calculates with investment in reworking production facilities, which contributes significantly to the cost but could also make the companies more competitive in the long run.

Both in primary lead production and battery manufacture, companies face special challenges. According to communication with stakeholders, control of exposure levels (especially PbA) in primary production is more challenging compared to e.g. secondary production, because of the large volumes of materials processed and the "violence" of the operations required to process materials in primary production. Additionally, non-occupational background PbB levels are often quite high in areas with lead mining, making it more difficult to reach the lowest OEL and BLV options.

As shown in section 4.6.4, a larger proportion of respirable particles, potentially increasing the uptake of lead via the lungs, occurs in the battery sector. The relatively good solubility of several lead compounds used in battery manufacture (e.g. pentalead tetraoxide sulphate, tetralead trioxide sulphate, orange lead) also contributes to the increased uptake of lead into the human body.

Table 7-1 Compliance cost over 40 years per business per BLV, in €

Sector	Compliance cost, average cost per business (€) BLV,					
	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	92,500,000	30,500,000	11,900,000	6,200,000	2,700,000	0
2. Secondary lead production	17,100,000	5,800,000	2,000,000	863,000	360,000	0
3. Lead battery production	47,500,000	15,400,000	6,800,000	3,700,000	1,300,000	0
4. Production of articles of lead metal	10,200,000	3,300,000	1,200,000	601,000	216,000	0
5. Foundries	9,000,000	2,700,000	984,000	353,000	118,000	0
6. Production of lead compounds and lead frits	22,400,000	5,700,000	1,400,000	560,000	218,000	0
7. Production of glass	532,000	173,000	65,000	31,000	8,000	0
8. Ceramic ware production and enamelling	574,000	145,000	45,000	23,000	11,000	0
9. Manufacture and use of plastics and paints	205,000	42,000	19,000	12,000	5,000	0
10. Work with lead metal	116,000	32,000	16,000	7,000	3,000	0
11. Shooting	32,000	6,000	2,000	700	-	0
12. Recycling of PVC and other plastics	64,000	6,000	2,000	-300	-	0
13. Demolition, repairing and scrap industry	55,000	9,000	6,000	3,000	2,000	0
14. Other waste management	71,000	10,000	700	700	-	0
15. Other - Copper production	9,800,000	2,300,000	1,100,000	503,000	156,000	0

Source: study team's calculation

Table 7-2 Total PV divided by 40 as "annual cost" per business per BLV, in €

Sector	Annual compliance cost, average cost per business (€) BLV,					
	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
1. Primary lead production	2,300,000	763,000	298,000	155,000	68,000	0
2. Secondary lead production	428,000	145,000	50,000	22,000	9,000	0
3. Lead battery production	1,200,000	385,000	170,000	93,000	33,000	0
4. Production of articles of lead metal	255,000	83,000	30,000	15,000	5,000	0
5. Foundries	225,000	68,000	25,000	9,000	3,000	0
6. Production of lead compounds and lead frits	560,000	143,000	35,000	14,000	5,000	0
7. Production of glass	13,000	4,000	2,000	800	200	0
8. Ceramic ware production and enamelling	14,000	4,000	1,000	600	300	0
9. Manufacture and use of plastics and paints	5,000	1,000	500	300	100	0
10. Work with lead metal	3,000	800	400	200	80	0
11. Shooting	800	200	50	20	-	0
12. Recycling of PVC and other plastics	2,000	200	50	-10	-	0
13. Demolition, repairing and scrap industry	1,000	200	200	80	50	0
14. Other waste management	2,000	300	20	20	-	0
15. Other - Copper production	245,000	58,000	28,000	13,000	4,000	0

Source: study team's calculation

7.2 Innovation and growth

Research and development (R&D) are important activities in the sectors' capacity to develop new products and produce existing ones more efficiently and sustainably, in a way that protects the safety of workers. European businesses invested € 204 billion into research and innovation in 2019 – and equivalent of 1.9% of the gross domestic product (GDP).

The composition of the investigated sectors does not match the classifications of other statistical systems like Eurostat's NACE codes. As the market analysis in section 4.15 above shows the sectors are composed of subsets of multiple NACE sectors. It is therefore challenging and imprecise to determine the R&D expenditure in the sectors through sector statistics, as the bulk of these expenditures would be attributed to enterprises without lead exposure.

It can however be said that the compliance costs will redirect resources away from other purposes, including research and innovation.[49] Particularly for the lower BLVs, these compliance costs can be regarded to have a significant impact on the availability of financing for research and innovation.

7.3 Single market

7.3.1 Competition

Table 7-3 presents an initial screening of competition impacts, to identify the most significant competition impacts. The most significant competition impacts are discussed in further detail below.

Table 7-3 Screening of competition impacts

Impacts	Key questions	Yes/No
Existing firms	Additional costs?	Yes
	Scale of costs significant?	Yes, only for the lower BLVs
	Old firms affected more than new?	Possibly
	Location influences?	No
	Some firms will exit the market?	Yes
	Are competitors limited in growth potential?	No
	Increased collusion likely?	No
New entrants	Restrict entry?	Possibly
Prices	Increased prices for consumers	Few sectors and BLVs
Non-price impacts	Product quality/variety affected?	Possibly
	Impact on innovation	Yes
Upstream and downstream market	Will BLVs affect vertically integrated companies more or less than non-integrated ones?	Unknown
	Will BLVs encourage greater integration and market barriers?	Unknown
	Will BLVs affect bargaining power of buyers or suppliers?	Unknown

- [49] Tool # 21 of the Better Regulation toolbox on

7.3.1.1 Additional costs and their significance

Section 6 above assesses the overall compliance associated with the different BLVs, and calculates a 40-year of the compliance costs of up to € 6.3 billion for the lowest BLV of 45 µg/L and ranging down to € 0.1 billion for a BLV of 300 µg/L. It should be noted that there is a strong increase in the compliance cost going from a BLV of 100 µg/L to 45 µg/L. A BLV of 100 µg/L corresponds to a PV of € 1.8 billion.

Based on the market analysis in section 4.15, Table 7-4 below presents the number of companies per company size and sector. It is evident that small companies compose of the largest number of impacted enterprises. A particularly high number of companies is found in the work with lead metal and demolition sectors and shooting ranges (sectors 10, 11, 13). A reduction of BLVs will thus impact about 22,500 companies, of which about half is found in one sector.

A comparison with the average compliance cost per company in Table 7-1 above shows further that those sectors with a high compliance cost per company, tend be composed of a small number of enterprises, such as e.g. sectors 1, 3, and 6.

Table 7-4 Number of companies with exposed workers per sector and size

Sector	Small	Medium	Large
1. Primary lead production	-	-	6
2. Secondary lead production (including lead battery recycling)	6	27	9
3. Lead battery production	-	5	25
4. Production of articles of lead metal	12	8	5
5. Foundries	106	56	18
6. Production of lead compounds and lead frits	1	6	4
7. Production of glass	35	6	5
8. Ceramic ware production and enamelling	25	1	-
9. Manufacture and use of plastics and paints	67	8	8
10. Work with lead metal	2,813	313	-
11. Shooting ranges	4,000	-	-
12. Recycling of PVC and other plastics	75	25	-
13. Demolition, repairing and scrap industry	12,903	1,134	142
14. Other waste handling and remediation	525	175	-
15. Other (Copper production)	-	6	1
Total	**20,572**	**1,773**	**226**

Source: Eurostat (2018), consultation, reproduced from chapter 4.15.4

Table 7-5 presents the compliance as a percentage of the average turnover per business. The compliance costs are generally of limited significance for most sector and BLV combinations, staying well below 0.5%. However, for production of articles of lead metal (sector 4), the compliance costs are well above 1% for medium sized enterprises for a BLV of 100 µg/L. In that sector, medium enterprises compose about 30% of all enterprises.

For the lowest BLV of 45 µg/L, seven sectors face compliance costs above 1% of the turnover (i.e. sectors 2 - 6, and 8). Particularly for sector 4, the compliance cost increase significantly.

In some cases, compliance to the BLV and OEL options may be more difficult to reach for older facilities, as space is often more limited in older factory designs, making it more challenging or even impossible to install space-consuming RMM such as larger welfare facilities and/or ventilation systems needed for compliance.

Table 7-6 further provides the annual compliance cost per business and size.

Table 7-5 Compliance cost per business as percentage of annual turnover, by size, sector, and BLV. Colour gradient, ranging from 0% (white) to 10% and beyond (red), to highlight the significance of the cost.

BLV	45 µg/L			100 µg/L			150 µg/L			200 µg/L			300 µg/L		
Sector	Small	Medium	Large	Small	Medium	Large	Small	Medium	Large	Small	Medium	Large	Small	Medium	Large
1	-	-	0.9%	-	-	0.3%	-	-	0.1%	-	-	0.1%	-	-	0.0%
2	1.5%	0.9%	0.8%	0.5%	0.3%	0.3%	0.2%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%
3	-	0.9%	1.5%	-	0.2%	0.5%	-	0.1%	0.2%	-	0.0%	0.1%	-	0.0%	0.0%
4	2.4%	2.7%	0.8%	0.8%	1.3%	0.2%	0.3%	0.6%	0.0%	0.2%	0.3%	0.0%	0.1%	0.1%	0.0%
5	1.3%	1.5%	0.5%	0.5%	0.6%	0.1%	0.1%	0.3%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%
6	1.3%	1.5%	0.4%	0.3%	0.5%	0.1%	0.1%	0.2%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%
7	0.8%	0.3%	0.1%	0.2%	0.1%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
8	1.7%	0.7%	-	0.4%	0.2%	-	0.1%	0.1%	-	0.1%	0.0%	-	0.0%	0.0%	-
9	0.2%	0.1%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
10	0.2%	0.1%	-	0.1%	0.0%	-	0.0%	0.0%	-	0.0%	0.0%	-	0.0%	0.0%	-
11	n/r	-	-	n/r	-	-	n/r	-	-	n/r	-	-	n/r	-	-
12	0.2%	0.0%	-	0.0%	0.0%	-	0.0%	-0.0%	-	0.0%	-0.0%	-	-	-	-
13	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
14	0.1%	0.0%	-	0.0%	0.0%	-	0.0%	0.0%	-	0.0%	0.0%	-	-	-	-
15	-	0.5%	0.2%	-	0.1%	0.0%	-	0.1%	0.0%	-	0.0%	0.0%	-	0.0%	0.0%

Note: A white-red gradient is applied to reflect the significance of the compliance cost. The gradient ranges from 0% of turnover to 10% of turnover, which equals the profit margin, and above.
'n/r': For sector 11 (shooting ranges), the assessment is not relevant as these are dominantly publicly owned facilities where turnover is an irrelevant factor (e.g. national armed forces)
Source: study team's calculation and sections 4.15 and 6.3.5.

Table 7-6 Total PV of compliance cost divided by 40 as "annual cost" per business, by size, sector, and BLV, in EUR

BLV	45 µg/L			100 µg/L			150 µg/L			200 µg/L			300 µg/L		
Sector	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**
1	-	-	2,312,000	-	-	762,000	-	-	298,000	-	-	156,000	-	-	68,000
2	76,000	240,000	1,199,000	25,000	79,000	415,000	9,000	27,000	142,000	4,000	11,000	63,000	2,000	5,000	26,000
3	-	515,000	1,321,000	-	130,000	437,000	-	46,000	194,000	-	24,000	106,000	-	9,000	38,000
4	33,000	241,000	772,000	11,000	115,000	190,000	4,000	53,000	48,000	2,000	27,000	25,000	800	10,000	9,000
5	38,000	301,000	1,083,000	13,000	112,000	255,000	3,000	60,000	38,000	1,000	20,000	16,000	500	7,000	5,000
6	36,000	263,000	1,063,000	9,000	95,000	237,000	3,000	41,000	34,000	1,000	17,000	13,000	500	7,000	5,000
7	5,000	24,000	59,000	1,000	8,000	21,000	500	3,000	8,000	200	1,000	4,000	70	400	900
8	12,000	41,000	-	3,000	12,000	-	800	5,000	-	400	2,000	-	200	1,000	-
9	2,000	11,000	22,000	500	2,000	5,000	200	800	2,000	100	600	1,000	40	300	700
10	2,000	11,000	-	600	3,000	-	300	1,000	-	100	600	-	40	300	-
11	800	-	-	100	-	-	50	-	-	20	-	-	-	-	-
12	800	4,000	-	200	80	-	60	-1	-	30	-107	-	-	-	-
13	900	6,000	5,000	200	400	900	100	300	600	70	100	300	40	70	200
14	900	4,000	-	100	600	-	3	70	-	3	70	-	-	-	-
15	-	199,000	432,000	-	50,000	87,000	-	24,000	41,000	-	11,000	19,000	-	3,000	6,000

Source: Study team's calculation

7.3.1.2 Number of firms exiting the market

Discontinuations are only associated with the two most stringent BLVs of 45 and 100 µg/L, whereas no discontinuations are associated for the BLVs of 150, 200, and 300 µg/L. For the BLV of 100 µg/L, the number of firms exiting the market is limited to a few single enterprises. The impact on competition is therefore negligible.

The BLV of 45 µg/L leads to the exit of a limited number of enterprises in eight sectors (i.e. sectors 2-5, 8, 10, and 13). Overall, 29 firms would exit the market because of a BLV of 45 µg/L.

Table 7-7 Number of firms exiting the market by sector, BLV, and size

	45 µg/L			100 µg/L		
	S	M	L	S	M	L
1. Primary lead production	-	-	-	-	-	-
2. Secondary lead production (including lead battery recycling)	-	2	1	-	-	-
3. Lead battery production	-	-	2	-	-	-
4. Production of articles of lead metal	1	1	-	-	-	-
5. Foundries	5	3	1	1	1	-
6. Production of lead compounds and lead frits	-	-	-	-	-	-
7. Production of glass	-	-	-	-	-	-
8. Ceramic ware production and enamelling	3	-	-	1	-	-
9. Manufacture and use of plastics and paints	-	-	-	-	-	-
10. Work with lead metal	-	1	-	-	-	-
11. Shooting ranges	n/r	-	-	n/r	-	-
12. Recycling of PVC and other plastics	-	-	-	-	-	-
13. Demolition, repairing and scrap industry	-	9	-	-	-	-
14. Other waste handling and remediation	-	-	-	-	-	-
15. Other (Copper production)	-	-	-	-	-	-
Total	**9**	**16**	**4**	**2**	**1**	**-**
Grand total			**29**			**3**

'n/r': For sector 11 (shooting ranges), the assessment is not relevant as these are dominantly publicly owned facilities where competitiveness is an irrelevant factor (e.g. national armed forces)
Source: study team's calculation

Whereas the number of firms exiting the market is small, when compared to the number of enterprises in the associated sectors, that number is more significant when compared to the number of enterprises with exposed workers (Table 7-8). However only for the BLV of 45 µg/L and sector 8, notable changes in the market structure are to be expected, as 12% of the existing enterprises with exposed workers exit the market, leading to a consolidation of the sector. Furthermore, the number of firms existing in sectors 2-5 are significant (>5%), but without ramifications on the market structure. Although enterprises may choose to discontinue activities that entail lead exposure, the discontinuations do not necessarily imply that associated enterprises exit the sector. In the case of e.g. sector 8, enterprises may choose substituting to non-lead glazing.

For the BLV of 100 µg/L, the number of exits is negligible in comparison to the number of existing enterprises.

Table 7-8 Share of enterprises exiting the market in response to a BLV of 45 and 100 µg/L

Sector	Enterprises in sector (a)	Enterprises with exposed workers (b)	BLV of 45 µg/L			BLV of 100 µg/L		
			Discontinuations	As % of (a)	As % of (b)	Discontinuations	As % of (a)	As % of (b)
1	498	6	-	-	-	-	-	-
2	16,299	43	3	0.0%	7.0%	-	-	-
3	460	30	2	0.4%	6.7%	-	-	-
4	62,813	26	2	0.0%	7.7%	-	-	-
5	123,392	180	9	0.0%	5.0%	2	0.0%	1.1%
6	3,270	11	-	-	-	-	-	-
7	17,629	46	-	-	-	-	-	-
8	42,168	26	3	0.0%	11.6%	1	0.0%	3.9%
9	68,125	84	-	-	-	-	-	-
10	143,614	3,125	1	0.0%	0.0%	-	-	-
11	n/a	4,000	n/r	-	-	n/r	-	-
12	16,416	100	-	-	-	-	-	-
13	236,661	14,179	9	0.0%	0.1%	-	-	-
14	28,709	700	-	-	-	-	-	-
15	2,855	7	-	-	-	-	-	-
Total	**762,909**	**22,556**	**29**	**0.0%**	**0.1%**	**3**	**0.0%**	**0.0%**

Source: study team's calculation based on section 4.15
Note: n/a entries occur when the number of companies operating in the sector is unknown; 'n/r': For sector 11 (shooting ranges), the assessment is not relevant as these are dominantly publicly owned facilities where competitiveness is an irrelevant factor (e.g. national armed forces)

7.3.1.3 Market entry barriers

The BLVs of 150, 200, and 300 µg/L introduce limited compliance costs for most sectors (see Table 7-5), and no discontinuations are associated for any BLV and sector combinations. The highest cost associated with these BLVs are seen in production of articles of lead metal sector (sector 4). Capital costs account for about three-quarters of the compliance cost, which adds to any potential deterrence due to increased investments that are required to enter the market. These costs are however limited on the overall level. The three BLVs will therefore not introduce market entry barriers.

For the BLV of 100 µg/L, the market entry barrier will increase for sector 4, when compared to the BLVs above, as the compliance cost further increase for small and medium enterprises. As already mentioned, the majority of these costs are upfront investment costs. The increased investment requirement will increase the hurdle for new market entrants, which may even face higher costs than incumbent sectors, as the cost calculation already deducts costs that can be attributed to the baseline.

The BLV of 45 µg/L introduces significant compliance costs in sectors 2 - 6 and 8, where the compliance cost comprises more than 1% of the turnover, which also gives rise to the exit of up to 12% of the enterprises with exposed workers in sector 8. Capital expenditures compose at least 75% of the compliance cost in the related sectors (see section 6.4.2 above). The BLV of 45 µg/L increases thus the market entry barrier for sectors 2 – 6 and 8. Particularly in the case of sector 4, a high increase in the capital costs can be expected to deter entry.

7.3.2 Consumers

The Herfindahl-Hirschman Index (HHI) is a common indicator of market concentration, that is used to measure the market power that companies have in a specific sector.[50] The index assesses the degree of competition in a sector, based on the market share of enterprises. The index ranges from a value of 0 (a sector with perfect competition) to a value of 1 (a sector with monopoly). A value of 0 describe a sector with many enterprises with little market power, and a value of 1 describes a sector with one enterprise with all the market power. In a highly competitive sector, enterprises are in strong competition and are therefore generally not able to pass on price increases to consumers. In a monopolistic market, enterprises tend in turn to be able to pass-on price increases.

A further factor determining the ability to pass on prices to consumers, is the exposure of European sectors towards international competition. If international competition is significant, then European companies will also not be able to pass on prices to consumers, as non-EU producers facing lower requirements will be provide more competitively priced products. Due to the artificial aggregation of sectors of lead uses, which is not consistent with available statistical classifications, it is not possible to properly identify the level of international competition. The type of products in some sectors, render international competition however unlikely. This applies to the sectors shooting ranges (sector 11) and demolition, repairing and scrapping (sector 13).

For sector 11, competitiveness is further an irrelevant factor as most of the entailed shooting ranges are publicly owned facilities (e.g. national armed forces). The analysis is therefore not deemed relevant for shooting ranges.

Table 7-9 presents the HHI for each sector in the baseline and the two BLVs in which discontinuations are projected to occur. The HHI for the baseline can also be regarded as relevant for the BLVs of 150, 200, and 300 µg/L, as the market structure will not change because of discontinuations. The compliance cost for these BLVs are further limited to negligible when

- [50] Brezina et al. (2016), Herfindahl–Hirschman index level of concentration values modification and analysis of their change. Cent Eur J Oper Res 24, 49–72. https://doi.org/10.1007/s10100-014-0350-y compared to the turnover, that there may not be much of a price increase to pass on to consumers at all.

For the baseline, and the BLVs of 150, 200, and 300 µg/L, three sectors (10, 13, 14) are characterised by a high degree of competition. As described above, the latter two sectors are unlikely to be characterised by international competition, making it likely that companies will pass on prices to consumers. It is therefore assessed as unlikely that consumers will face higher prices because of the compliance costs in sector 10. Similarly, eight further sectors are considered an unconcentrated market (2, 3, 4, 5, 7, 8, 9, 12), in which consumers are likely to experience a limited price increase. For the sectors of primary lead production (sector 1), production of lead compounds (sector 6), and copper production (sector 15) however, the price increases will likely be passed on to consumers, owing to a moderate to high market concentration.

The market concentration does not significantly change due to the discontinuations associated with a BLV of 100 µg/L. The sectors' ability to pass the compliance costs on to consumers is therefore as above.

The BLV of 45 µg/L only leads to a limited increase in the market concentration the lead battery production (sector 3) and ceramic ware production and enamelling sector (sector 8), where enterprises will gain a slightly higher market power. Both sectors are however also likely to be exposed to a high degree of competition. Therefore, despite a high market power, companies in these sectors are unlikely to be able to properly pass on the compliance cost to consumers

Table 7-9 Market concentration, based on the number of enterprises in the market for three scenarios, as measured by the Herfindahl-Hirschman Index (HHI)

Sector	Baseline	BLV of 45 µg/L	BLV of 100 µg/L
1. Primary lead production	0.17	0.17	0.17
2. Secondary lead production (incl. lead battery recycling)	0.05	0.05	0.05
3. Lead battery production	0.03	0.04	0.03
4. Production of articles of lead metal	0.14	0.14	0.14
5. Foundries	0.03	0.03	0.03
6. Production of lead compounds and lead frits	0.19	0.19	0.19
7. Production of glass	0.15	0.15	0.15
8. Ceramic ware production and enamelling	0.08	0.11	0.09
9. Manufacture and use of plastics and paints	0.09	0.09	0.09
10. Work with lead metal	0.00	0.00	0.00
11. Shooting ranges	n/r	n/r	n/r
12. Recycling of PVC and other plastics	0.03	0.03	0.03
13. Demolition, repairing and scrap industry	0.00	0.00	0.00
14. Other waste handling and remediation	0.00	0.00	0.00
15. Other (Copper production)	0.32	0.32	0.32

Source: study team's calculation based on sections 4.15 and 6.4.4
Note: (1) The HHI is a common measure of market concentration based on the market share of all enterprises, which can be deducted from the number of enterprises and average turnover per sector and size.
(2) The index has a range of 0 to 1, where 0 is a perfectly competitive sector (i.e. many enterprises with little market power) and 1 is a monopoly (i.e. one enterprise with all market power).The following categorisations apply: HHI < 0.01: high competition; HHI < 0.15: an unconcentrated sector; HHI < 0.25: moderate concentration; HHI > 0.25: high concentration.
(3) A green background colour reflects a highly competitive sector (HHI < 0.01); A yellow colour reflects an unconcentrated sector (HHI < 0.15); A red colour indicates a highly concentrated sector (HHI > 0.25).
(4) An increased HHI is associated with an increase in market concentration, providing more power to individual enterprises - and vice versa. An increased HHI leads thus to an increased ability to pass on price increases to consumers - and vice versa. See more information in Brezina et al. (2016)
(5) 'n/r': For sector 11 (shooting ranges), the assessment is not relevant as these are dominantly publicly owned facilities where competitiveness is an irrelevant factor (e.g. national armed forces)

Enterprises which cannot pass on price increases to consumers may pursue compensating the compliance cost by reducing the product quality or reducing the product variety. At the same time, such efforts can be risky, as a high degree of competition can provide a lot of market power to consumers. It is not possible to assess in specific detail which sectors are likely to pursue such efforts, as it would require primary data collection on consumer preference and their specific market power across sectors, which lies beyond the scope of this assessment.

7.3.3 Internal market

As also elaborated in 5.7 above, a reduction of the EU-wide BLV will lead to an increased harmonisation of limit values across Europe, which will improve the level playing field for enterprises across the internal market, as the gap between the lowest and highest BLV in the EU will decrease. The level playing field will thus improve with more stringent BLVs. Section 8.6.1 below shows that only a BLV of 150 µg/L for men and 45 µg/L for women (at a childbearing age) introduces a fully levelled playing field (i.e. all Member States having the same limit value). The BLVs of 300 µg/L would provide the greatest marginal gains in terms of the number of Member States with the same limit value. The BLV of 150 µg/L would introduce a nearly completely level playing field, in which only few Member States have a lower limit value for women.

Differences in national transposition of the CAD and other legislation impacting workers' exposure to lead (e.g. labour law provisions regarding workers' rights regarding smoking or refusal of RPE use when PbA levels do not exceed the OEL) may potentially compromise the level playing field conditions created by harmonised limit values.

Parallel to the improvement of the playing field, medium and large enterprises with facilities across the EU facilities may benefit from a simplification of the applicable limit values. This could provide savings in terms of research- and design cost, as common solutions can be adopted across facilities, as opposed to designing site-specific solutions to meet different BLV requirements.

The sectors that mostly are composed of large and, to a lesser extent, medium enterprises, are likely to benefit most of the above simplifications (e.g. sectors 1, 2, 3, 6 and 15). The lead battery production sector is for example dominantly composed of large enterprise, of which at least three are confirmed to have multiple locations across the EU (i.e. Clarios, EnerSys, and Exide; see section 4.15).

7.4 Competitiveness of EU businesses

7.4.1 Cost competitiveness

The compliance costs associated with a reduced BLV will be more significant the stricter the BLV. The burden of the compliance cost will make enterprises less cost competitive, of which particularly the BLV of 45 µg/L. Those enterprises competing with lead free products or enterprises that are already compliant with a reduced BLV, will be less cost competitive.

For those sectors where no lead-free alternative products are available all companies will remain cost competitive, to the extent that international competitors are no competitive threat.

7.4.2 Capacity to innovate

The compliance costs, particularly for the lower BLVs of 45 and 100 µg/L, will impact enterprises' capacity to innovate, as research and innovations likely will be diverted.

7.4.3 International competitiveness

The compliance cost associated with a further reduction of the EU BLV can impact the international competitiveness of the EU sectors. Table 7-10 below shows that the EU27 and three non-EU countries have a binding BLV in place. The EU has moreover the highest value among these.

A BLV option of 300 µg/l would already put the EU27 at par with the lowest, binding, non-EU BLV found for men (and women at a non-reproductive age). Such a BLV would lead to reduced limit value in 89% of the EU Member States.[51] A limit value of 100 µg/l would also put the EU on par with the lowest, binding, BLV found for women at a reproductive age among non-EU countries.

In the case of shooting ranges (sector 11) and the demolition, repair and scrap industry (sector 13), a stricter BLV setting than non-EU countries has little relevance for these sectors. Neither sector is exposed to international competition, given that the nature of their activities on the

- [51] 89% of Member States currently have a BLV between 300 and 700 µg/l, as shown in section 8.6.1

EU market are virtually exclusively executed on EU territory, requiring adherence to EU rules. To the extent the respective activities are executed on non-EU territory, compliance with EU rules is not necessarily required. As further indicated above, international competitiveness is irrelevant for most shooting ranges, as these are publicly owned (e.g. national armed forces).

Section 4.10 on Voluntary industry initiatives shows that a substantial number of EU sectors and enterprises pursue a voluntary limit value of 200 µg/l. A BLV option of 300 or 200 µg/l would therefore only limitedly affect the international competitiveness of EU lead sectors – as these are already pursuing a 200 µg/l target. The assessment of the compliance cost burden above (section 6.4.2) further shows that a BLV of 150 will lead to significant compliance cost in few sectors, whilst a BLV of 45 and 100 µg/L introduce a high burden across the sectors.

Although there are only few non-EU countries with a BLV, almost all investigated countries (except for India) have an OEL lower than the EU's 0.15 mg/m³. Based on the correlation established between blood and air concentrations in section 2.3.4 above however, all of these OELs correspond to a BLV above 300 µg/l.[52] All alternative BLV options would thus impose stricter compliance requirements than most non-EU countries.

Table 7-10 BLVs and OELs in non-EU countries, compared against EU's baseline value

Country	Lead (as Pb) in blood	Specification of BLV	OEL [mg/m³, (ppm)]	Specification of OEL
Australia	30 µg/100 ml 10 µg/100 ml	-men and women not of reproductive capacity -women of repro-ductive capacity	0.05	-dusts and fumes
Brazil	-		0.1	
Canada, Ontario	-		0.05	-elemental, inor-ganic and organic compounds of lead, except tetraethyl lead
Canada, Québec	-		0.05	-K
China	-		0.05 (I) 0.03 (R)	
India	-		0.15	-dusts and fumes
Japan	-		0.05	
Japan – JSOH (non-binding)	15 µg/100 ml	-except alkyl com-pounds	0.03	-for lead com-pounds except alkyl lead compounds; K; R1

[52] The lowest OEL identified, is 0.03 mg/m3, with a corresponding blood concentration of about 600 µg/l

Country	Lead (as Pb) in blood	Specification of BLV	OEL [mg/m³, (ppm)]	Specification of OEL
Norway	0.5 µmol/l 1.5 µmol/l	-women of childbearing age other workers	0.05†	-dusts and fumes; except lead acetate, lead phosphate, lead chromate and lead subacetate; R
Russia	-		0.05	-aerosol
South Korea	-		0.05	-K, R1
Switzerland	400 µg/l 100 µg/l	-men, women >45 years -women <45 years	0.1 (I)	-except alkyl lead compounds; K2, R1,
Turkey	70 µg/100 ml		0.15	
USA, ACGIH (non-binding)	200 µg/l		0.05	-K
USA, NIOSH (non-binding)	60 µg/ 100 g		0.05 (T)	
USA, OSHA	50 µg/ 100 g		0.05 (T)	
European Union	70 µg/100 ml	-mandatory health surveillance for workers at > 40 µg/100 ml	0.15	
(I) = inhalable fraction/aerosol (R) = respirable fraction/aerosol (T) = total dust K = carcinogenicity notation assigned K2 = assigned as Carc. Category 2 R1 = assigned as Repr. Category 1A or 1B R2 = assigned as Repr. Category 2 - no value available				

Source: section 4.1

7.5 Employment

The impacts associated with the potentially temporary loss of employment can be monetised based on the approach set out in ECHA (2016a) and adapted from Haveman and Weimer (2015) and Dubourg (2016). The impacts include the following components:

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

- The value of leisure time during the period of unemployment.

Table 7-11 Social cost (in € million) due to unemployment resulting from discontinuances

Sector	BLV of 45 µg/L			BLV of 100 µg/L		
	Discontinuances	Number of workers	Total social cost	Discontinuances	Number of workers	Total social cost
1. Primary lead production	-	-	-	-	-	-
2. Secondary lead production	3	300	€ 24 million	-	-	-
3. Lead battery production	2	840	€ 69 million	-	-	-
4. Production of articles of lead metal	2	92	€ 8 million	-	-	-
5. Foundries and production of articles of alloys	9	400	€ 33 million	2	92	€ 8 million
6. Production of lead compounds and lead frits	-	-	-	-	-	-
7. Production of glass	-	-	-	-	-	-
8. Ceramic ware production and enamelling	3	105	€ 9 million	1	35	€ 3 million
9. Manufacture and use of plastics and paints	-	-	-	-	-	-
10. Work with lead metal	1	13	€ 1 million	-	-	-
11. Shooting	n/r	-	-	n/r	-	-
12. Recycling of PVC and other plastics	-	-	-	-	-	-
13. Demolition, repairing and scrap industry	9	27	€ 2 million	-	-	-
14. Other waste management and soil remediation	-	-	-	-	-	-
15. Other (Copper production)	-	-	-	-	-	-
Total	**29**	**1,777**	€ **145** million	**3**	**127**	€ **10** million

Source: study team's calculation based on section 4.15 and Duborg (2016)
Note: Social cost are calculated as follows: €30,000 x no. of job losses x Ratio of social cost per job loss over annual pre-displacement wage (2.72 as per Duborg 2016, Table A7)
'n/r': For sector 11 (shooting ranges), the assessment is not relevant as these are dominantly publicly owned facilities where competitiveness is an irrelevant factor (e.g. national armed forces)

8. Distributional effects

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

This section comprises the following subsections:

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

8.1 Businesses

The costs and benefits for businesses (relative to the baseline) are summarised in Table 8-1 for the different BLV options (the benefits are shows as negative costs). Businesses will clearly face a net cost, where the compliance costs strongly outweigh the benefits for employers.

Table 8-1 Costs and benefits to EMPLOYERS (PV over 40 years, BLV options relative to the baseline), in € million

BLV option	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Benefits (avoided costs of ill health accrued by employers)	6	6	5	4	2	-
Compliance costs	-6,293	-1,819	-745	-348	-134	-
Net benefit (benefits - costs)	**-6,287**	**-1,813**	**-740**	**-344**	**-132**	**-**

Source: sections 5.5 and 6.4

8.2 SMEs

SMEs can be proportionately higher impacted by regulatory changes that introduce substantial adjustment or administrative costs. Their limited size often makes it more difficult to access capital, and most often at a higher cost of capital than large enterprises.[53] SMEs can therefore be exposed to proportionally higher costs, as compared to the large enterprises.

The table below presents the estimated share of small and medium enterprises as well as the total share of SMEs out of all EU enterprises with exposed workers. Most of the covered sectors are dominantly composed of SMEs. Many of the sectors entail however less than 100 enterprises across Europe. Sectors with a high share of SMEs as well as a high number of enterprises (i.e. above 1,000) are sectors working with lead metal (sector 10), shooting ranges (sector 11), and the demolition, repairing, and scrapping industry (sector 13); of which the latter is likely to pass on costs to consumers. These sectors moreover consist of nearly

- [53] Tool # 22 of the Better Regulation toolbox on SMEs exclusively small enterprises. Looking across all sectors, small enterprises comprise the dominating share in eight (out of 15) sectors.

When measured by the number of enterprises thus, the majority of enterprises that would need to comply with a stricter BLV would primarily consist of SMEs.

Table 8-2 Distribution of EU enterprises with exposed workers by small and medium size, as well as total share of SMEs out of EU enterprises with exposed workers by sector

Sector	Share of no. of enterprises by size			Total no. of enterprises
	Small <50 employees	Medium 50-249 employees	Total SMEs	
1. Primary lead production	0%	0%	0%	6
2. Secondary lead production (including lead battery recycling)	15%	63%	78%	43
3. Lead battery production	0%	22%	22%	32
4. Production of articles of lead metal	47%	32%	79%	26
5. Foundries	59%	31%	90%	180 (90-270)
6. Production of lead compounds and lead frits	10%	50%	60%	11
7. Production of glass	76%	13%	89%	46
8. Ceramic ware production and enamelling	96%	3%	99%	26
9. Manufacture and use of plastics and paints	80%	10%	90%	84
10. Work with lead metal	90%	10%	100%	3,125 (1,250 – 5,000)
11. Shooting ranges	100%	0%	100%	4,000 (3,000 – 5,000)
12. Recycling of PVC and other plastics	75%	25%	100%	100
13. Demolition, repairing and scrap industry	91%	8%	99%	14,179
14. Other waste handling and remediation	75%	25%	100%	700
15. Other (Copper production)	0%	80%	80%	7

Source: Eurostat (2018), consultation, reproduced from chapter 4.15.4

8.3 Workers

As the assessment of the benefits in section 5 above shows, workers benefit increasingly from decreasing BLVs. The table below shows, how many cases are avoided under each endpoint for each BLV option. It is evident that a substantial number of cases of non-fatal endpoints can be avoided, increasing the well-being of potentially thousands of workers. Accordingly, workers and families can incur substantial benefits.

Table 8-3 Number of avoided cases by endpoint over 40 years for each BLV option

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Central nervous system Cancer	6	6	6	4	1	0
Neuropathy	290	290	290	179	64	0
Anaemia	2,009	1,803	1,645	1,381	559	0
Chronic kidney disease stage 1	6,208	5,568	5,085	4,273	1,734	0
Elevated blood pressure	2,912	2,912	2,365	1,969	785	0
Male fertility	491	491	387	310	114	0
Pre-eclampsia	38	32	23	16	4	0
Developmental toxicity (total IQ loss)	1,141	788	540	370	100	0

Source: study team's calculation, reproduced from section 5.2

Workers can, however, also face the risk of incurring cost because of the BLVs. In the limited number of situations where companies are projected to discontinue their activities according to the cost model, workers risk becoming unemployed. These costs would comprise a loss of income during the search for new employment and the more intangible welfare loss of being unemployed. Whereas the latter is not quantified in this study, the former is one of several components in the social cost of unemployment referred to in section 7.5, which is estimated at € 145 million and € 10 million for the BLVs of respectively 45 and 100 µg/L.

According to the assessment of employment impacts above (section 7.5), a discontinuation of activities and therewith an increased risk of unemployment can be considered as likely for the BLVs of 45 and 100 µg/L, leading to the potential lay off of respectively 1,777 and 127 workers.

8.4 Consumers

As already concluded in section 7.3.2 above, consumers may face increased prices in sectors with concentrated markets, in which enterprises enjoy sufficient market power to pass on price increases and where these are not strongly exposed to a high degree of international competition. Furthermore, consumers may face a decrease in product quality or variety in generally unconcentrated sectors where enterprises only have limited market power and are not strongly exposed to a high degree of international competition.

This picture can be expected to be consistent across the BLVs, as the market structure will only change in two sectors for the BLV of 45 µg/L – and only by a marginal extent.

8.5 Taxpayers/public authorities

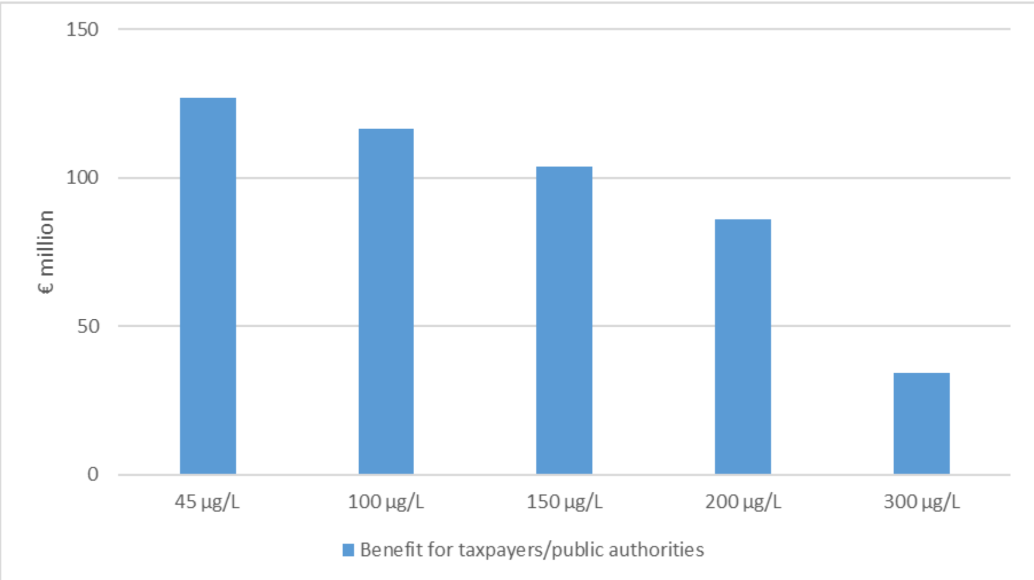
The cost to taxpayers and public authorities are summarised in Table 8-4 below, demonstrating that the transposition costs are marginal when compared to the avoided costs of healthcare and avoided loss of tax revenue.

Table 8-4 Costs and benefits to the public sector (PV over 40 years, relative to the baseline), € million

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Avoided costs of healthcare and avoided loss of tax revenue (benefit)	128.2	117.4	104.2	86.4	34.7	0
Transposition costs	-0.5	-0.5	-0.5	-0.5	-0.5	0
Net benefit (benefit – cost)	**126.8**	**116.5**	**103.8**	**86.0**	**34.2**	**0**

Source: study team's calculation, reproduced from sections 5.4 and 6.6.1

Figure 8-1 Net benefits to the public sector (relative to the baseline), € million. Source: Study team's calculation



8.6 Specific Member States/regions

8.6.1 Member State national limit values

The table below shows how many Member State national limit values go above the proposed BLV options. The table further categorises limit values for men and women above 45 and women below 45. Only one Member State, Estonia, has not identified a limit value and is thus effectively above the CAD's limit value.

23 Member States have a limit value for men and women above 45 that is between 300 and the CAD's value of 700 µg/l. Eleven of these Member States have a limit value of exact 700 µg/l. A limit value of 300 µg/l would therefore lead to a reduced BLV in 89% of the Member States. The limit values of 200 and 150 µg/l would lead to further reductions in respectively 26 (adding Finland and Hungary) and 27 Member States (adding Denmark).

With respect to limit values for women below 45, only 16 Member States have a limit value between 300 and 700 µg/l. A BLV of 300 µg/l would thus lead to a reduced limit value in 63% of the Member States. A BLV of 200 µg/l would further improve the national limit value in an additional five Member States, summing up to a share of 85%. Only a BLV of 45 µg/l would lead to a reduced limit value in all Member States.

Table 8-5 Member States with national BLVs for men and women that are higher than the proposed BLV options, as well as the share (and number) of Member States above the BLV

BLV option (µg/l)	Men & Women (>45 years)		Women (<45 years)	
	MS where current BLVs are higher or not identified	**% (and number) of MSs above BLV option**	**MS where current BLVs are higher or not identified**	**% (and number) of MSs above BLV option**
700	EE[2]	4% (1)	EE[2]	4% (1)
300	AT[1], BE, BG, CY, CZ, DE, EE[2], EL, ES, FR[3], HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	89% (24)	AT[1], BE, CY, CZ, EE[2], EL, ES, IE, IT[5], LT, LU, LV, MT, NL, PL, PT, RO	63% (17)
200	AT[1], BE, BG, CY, CZ, DE, EE[2], EL, ES, FI, FR[3], HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	96% (26)	AT[1], BE, BG, CY, CZ, DE, EE[2], EL, ES, FI, FR[4], HR, IE, IT[5], LT, LU, LV, MT, NL, PL, PT, RO, SI	85% (23)
150	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[3], HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	100% (27)	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[4], HR, HU, IE, IT[5], LT, LU, LV, MT, NL, PL, PT, RO, SI	93% (25)
100	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[3], HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	100% (27)	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[4], HR, HU, IE, IT[5], LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI	96% (26)
45	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[3], HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	100% (27)	AT[1], BE, BG, CY, CZ, DE, DK, EE[2], EL, ES, FI, FR[4], HR, HU, IE, IT[5], LT, LU, LV, MT, NL, PL, PT, RO, SE[1], SI, SK	100% (27)
1: respectively women >50 & <50; 2: No BLV is defined; 3: men only; 4: all women: 5: women at childbearing age				

Source: study team's calculation based on section 4.1.3

8.6.2 Number of affected enterprises across Member States

Based on the assessment in chapter 4, the distribution of enterprises is established per sector. Based on the data, a wide variety of sectors can be particularly found in France, Germany, Italy, Poland, and Spain.

No information could be gathered for sectors 5 (Foundries), 9 (Manufacture and use of plastics and paints), 10 (Work with lead metal), 11 (Shooting ranges), 12 (Recycling of PVC and other plastics), 13 (Demolition, repairing and scrap industry), 14 (Other waste handling and remediation). The distribution of the population was used to approximate the distribution.

Table 8-6 Percentage distribution of the number of enterprises with lead exposure across Member States, per sector.

	1. Primary lead production	2. Secondary lead production	3. Lead battery production	4. Production of articles of lead metal	6. Production of lead compounds and lead frits	7. Production of glass	8. Ceramic ware production and enamelling	15. Other	Remaining sectors (5, 9-14)
Austria	-	3%	3%	-	8%	-	-	-	2%
Belgium	-	8%	-	-	25%	-	-	9%	3%
Bulgaria	17%	8%	3%	-	-	-	-	9%	2%
Croatia	-	-	-	-	-	-	-	-	0%
Cyprus	-	-	-	-	-	-	-	-	1%
Czechia	-	3%	3%	-	-	25%	-	-	2%
Denmark	-	-	-	-	-	-	-	-	1%
Estonia	-	3%	-	-	-	-	-	-	0%
Finland	-	-	-	-	-	-	-	18%	1%
France	-	8%	3%	18%	-	38%	13%	-	15%
Germany	33%	15%	23%	27%	25%	13%	13%	18%	19%
Greece	-	8%	3%	-	-	-	-	-	2%
Hungary	-	-	3%	-	-	-	-	-	2%
Ireland	-	-	-	18%	-	13%	-	-	1%
Italy	17%	15%	20%	18%	8%	-	25%	-	14%
Latvia	-	-	-	-	-	-	-	-	0%

	1. Primary lead production	2. Secondary lead production	3. Lead battery production	4. Production of articles of lead metal	6. Production of lead compounds and lead frits	7. Production of glass	8. Ceramic ware production and enamelling	15. Other	Remaining sectors (5, 9-14)
Lithuania	-	-	-	-	-	-	-	-	1%
Luxembourg	-	-	-	-	-	-	-	-	0%
Malta	-	-	-	-	-	-	-	-	0%
Netherlands	-	-	3%	9%	-	-	-	-	4%
Poland	17%	13%	20%	-	8%	13%	-	18%	8%
Portugal	-	3%	3%	-	-	-	-	-	2%
Romania	-	5%	3%	-	-	-	-	-	4%
Slovakia	-	-	-	-	-	-	-	-	1%
Slovenia	-	-	-	9%	-	-	-	-	0%
Spain	-	10%	7%	-	25%	-	50%	9%	10%
Sweden	17%	3%	-	-	-	-	-	18%	2%

Source: study team's calculation based on section 4.15.1 and Eurostat (Distribution of population)

9. Environmental impacts

9.1 PBT screening

PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) criteria as laid out in Annex XIII to the REACH regulation do not apply to lead metal and its inorganic compounds as they only apply to organic substances.

Lead is an element and can therefore not undergo degradation. Its mobility and bioavailability in the environment depend on speciation. As it cannot be degraded, it may be regarded as persistent.

Bioaccumulation is of potential concern both because of the possibility of chronic toxicity to the organisms accumulating lead in their tissues and because of the possibility of toxicity to predators eating those organisms. Bioaccumulation and bioconcentration of metals depend on speciation and especially homeostatic regulation in organisms. As the 'bioaccumulative' criterion is not applicable to lead, bioaccumulating properties cannot be concluded.

Lead and lead compounds have a harmonised classification (see section 2.2.1) the CLP Regulation (1272/2008) as Repr. 1A and furthermore meets the criterion for environmental toxicity with NOEC, HC_{5-50} and PNEC (Predicted No Effect Concentrations) values below 10µg/L (REACH registration dossier[54]). Based on this, lead fulfils the toxicity criteria (T).

In conclusion, lead is not assessed as being vPvB or PBT, however, a minority of data submitters (0.72% of REACH registrations) indicate that they consider lead a PBT substance[55].

9.2 Current environmental exposure

9.2.1 Sources

In soil, lead can naturally originate from the mineral bedrock that formed the soil. Natural background concentration are difficult to determine, since lead pollution has been going on for a long time. Anthropogenic sources of lead in soil includes the formerly used lead-containing petrol, mining operations, metal processing as well as production, use and disposal of lead-containing products like lead-acid batteries, lead sheets etc. Also, lead-containing ammunition have been deposited at or near shooting ranges. Thus, soils in urban and industrial areas have increased concentrations of lead.

Emissions from point sources to air, soil and water as reported in the European Pollutant and Transfer Register are shown in Table 9-1 below. About 500 facilities have been reporting lead emissions in 2017, emitting an estimated total of 260 tons, with main contributions from the energy sector (mainly thermal power stations and other combustion installations) and metal production and processing (lead mining, smelting and refining). The main emission is to the air (ca. 200 tons). Lead containing particles emitted to air will, depending on wind and climatic conditions, deposit on soil and water surfaces in vicinity of their emission source. The E-PRTR over the years data did not allow for any conclusion on time trends. All in all, it appears that significant amounts of lead are emitted to the environment annually.

[54] REACH registration dossier https://echa.europa.eu/da/registration-dossier/-/registered-dossier/16063/2/3, accessed 05.07.2021.

[55] Lead Brief Profile https://echa.europa.eu/da/brief-profile/-/briefprofile/100.028.273, accessed 05.07.2021.

Table 9-1 Emission of lead and lead compounds from point sources in EU27 in 2017 as reported in the European Pollutant and Transfer Register (E-PRTR, 2021)

Sector (as organised in E-PRTR)	No. of facilities	Reported emission, t/year		
		Air	Land	Water
Chemical industry	12	0.6	0.0	0.8
Energy industries	15	1.8	0.0	1.1
Energy sector	25	39.4	0.0	0.2
Mineral industry	17	2.4	0.0	4.9
Paper and wood production processing	32	2.5	0.0	1.9
Production and processing of metals	71	96.7	0.0	3.5
Waste and waste water management	79	1.9	0.4	12.2
Other activities	245	47.9	0.0	42.7
Total (as summarised in the E-PRTR)	**496**	**193.2**	**0.4**	**67.4**

Note: At the time of writing this chapter (July 2021), the E-PRTR data for 2018 and 2019 have been incomplete for several Member States, including Germany, Portugal and Italy, therefore 2017 data has been chosen for reporting here.

9.2.2 Environmental levels in relation to hazard data

A large amount of environmental concentration data from relevant exposure scenarios are available in the VRAR (LDAI, 2008b) for lead. Key data are summarised here and reported together with environmental hazard data (PNEC, EQS, limit values). The data are summarised in Table 9-2 below.

Predicted environmental concentrations (PEC) and measured concentrations in the water in same cases exceed the predicted-no-effect-concentrations (PNEC) for water by a factor 1.5 – 2. Also, for the ambient air, maximum PEC exceed the human health limit value with a up to 5times. Measured concentrations in soil in vicinity of metal processing plants may exceed the terrestrial PNEC by one order of magnitude. The data indicate that lead emissions from lead metal processing plants potentially can harm aquatic and terrestrial organisms and the general population via ambient air, and that emissions need to be efficiently controlled to limit the hazard to the environment.

Table 9-2 Examples of measured or predicted environmental concentrations (PEC) and environmental hazard values for lead

Compartment	PEC or measured concentrations, reported in the VRAR (LDAI, 2008b)	Environmental hazard values	
		Value	Source
Water	0.05 µg/l and 4.09 µg/l 2.40 to 4.72 µg/l (lead metal producers) 0.80 and 1.02 µg/l (lead stabiliser producers) Measured concentrations range <0.4 – 5.9 µg/l	Environmental quality criteria 7.2 µg/l PNEC 2.4 µg/l for freshwater PNEC 3.3 µg/l for marine water	Directive 2008/105/EC on EQS ECHA, 2021
Soil	PEC 28 and 32 mg/kg dw Measured 400-1500 mg/kg dw (0-30 cm depth) at a distance of 0-500 from plant Measured 7-120 mg/kg dw (430-470 m from the site) Measured 2,000-5,000 mg/kg dw (1 km downwind from plant)	PNEC of 212 mg/kg dw soil	ECHA, 2021
Air	PEC 0.055 and 2.32 µg/m³ PEC 0.72 – 1.63 µg/m³ (lead metal producers) PEC 0.45 - 0.80 µg/m³ (lead oxide producers) PEC 0.028 – 0.037 µg/m³ (lead stabiliser producers) Measured 1.7 µg/m³ (30 m downwind from plant edge, 2002) 1.4 µg/m³ (at 200 m downwind from plant edge, 2002). 0.74 µg/m³ (500 m from plant edge under prevailing wind, 2002) Measured range 0.03 – 2.5 µg/m³ (several plants, 50 – 500 m, data from 2000)	0.5 µg/m³ (limit value in ambient air for protection of human health)	Directive 2008/50/EC on ambient air quality and cleaner air for Europe

9.3 Waste management and disposal

Lead emissions from waste management and disposal are described in high detail the VRAR (LDAI, 2008c). Some key points on waste management of lead processing industrial sites have been summarised here.

Waste management

Battery producers

For most sites, wastewater undergoes physico-chemical treatment at on-site waste water treatment plants (WWTP) before discharge to the receiving surface water and/or municipal sewage treatment plants (STP) (29/31). The sludge is either recycled or disposed to a landfill. Lead waste is recycled.

Lead oxide production

For lead oxide producers, wastewater either undergoes physico-chemical treatment before discharge to the receiving surface water and the sludge is recycled, or wastewater is discharge to SPT. The lead waste is mainly landfilled and recycled.

Lead sheet production

Information for on-site WWTP reveals that for most of the lead sheet producing companies no on-site treatment of wastewater takes place since in most cases no process wastewater arises from the lead sheet production process. In some cases, the wastewater is treated off-site or is recycled into the process. Lead waste is mainly recycled or disposed to a landfill. In some cases, incineration takes place.

Lead crystal glass production

Information for on-site WWTP reveals that for most of the sites the wastewater undergoes physico-chemical treatment (on site) before discharge to the receiving surface water and/or municipal STP. The sludge is either recycled or disposed to a landfill. Lead waste is mainly recycled and disposed to a landfill, in one case reused in brick production.

Disposal

Lead entering into standard municipal solid waste (MSW) incineration will be distributed among various output fractions such as stack emissions (flue gas), wastewater, fly ash, bottom ash and slag. The distribution pattern of lead over these incineration residues depends on the physico-chemical properties, the gas cleaning technology and the operation and maintenance conditions. While the flue gas and wastewater emissions are immediate, emissions of the incineration residues (via disposal and/or re-use) are delayed.

Discharge of wastewater results only from incineration plants equipped with wet flue gas cleaning systems. Dry and semi-dry systems have no water emissions.

Most of the fly ash generated by incinerators is landfilled with or without prior treatment. Fly ash is commonly placed in hazardous waste landfills or used for reclamation of old mine shafts or quarries. Furthermore, processed bottom ash is used in engineering applications as a bulk fill (for example, to construct embankments) as a substitute aggregate or for bound uses through incorporation into road paving or construction blocks. Lead concentrations in leachate from landfills depend on land fill management.

Sludge from municipal STP is either applied to agricultural soil, incinerated, or landfilled, depending on concentrations of hazardous substances and national regulations.

9.4 Impact of introduction of additional occupational RMM on environmental exposure

Through the analysis of consultation results, literature review and cost-benefit modelling, the study team have identified four primary RMM's currently used for controlling occupational exposure to lead and its compounds. These are:

- Organisational measures, including training, supervision, reviewing of working habits, measures for personal hygiene, cleaning
- Open hoods over equipment or local extraction ventilation
- RPE, simple respirators as well as half and full facemasks (negative pressure respirators)
- Partially closed systems

The listed measures are primarily important for reducing blood lead levels but (apart from organisational measure) are also important for compliance to the OEL options.

Table 9-3 below outlines how alternative RMM processes are likely to change for the BLV options, together with the broad environmental impact of each change. The environmental impact of all RMMs are outlined in the Methodological Note.
The use of alternative RMMs to meet new BLVs are not anticipated to contribute to environmental impacts and should generally lead to no change or possibly even lower environmental exposures. It is unlikely that the alternative RMMs will result in rogue emissions or increased waste by-products as they arrive at the same endpoint. For example, where partially closed system may be replaced by a full enclosure system, the same endpoint (filters) will occur. Slight reductions of environmental exposure may occur due to the limited potential of diffuse emissions when more of the lead dust is captured by more efficient extraction systems.

Table 9-3 Primary and alternative RMMs for BLV options, together with the broad environmental impact

Primary RMM	Alternative RMM for BLV options[1]		Broad environmental impacts
	300, 200, 150 µg/L	100, 45 µg/L	
Organisational measures, hereunder - Training and education - Supervision and working habits reviews - Personal hygiene - Cleaning	Current organisational measures may stay unchanged or may be intensified. Increased cleaning of work places and increased personal hygiene (showering, air showering, increased change of working clothing) would cause increased local management of lead dust with discharge water (either on-site WWTP or discharge to municipal STP).	Current organisational measures will be intensified. Increased cleaning of work places and increased personal hygiene (showering, air showering, increased change of working clothing) would cause increased local management of lead dust with discharge water (either on-site WWTP or discharge to municipal STP).	No impact or slight reduction
Open hoods over equipment or local extraction ventilation	Open hoods or Partially closed systems, resulting in larger amounts of lead dust captured in the filters of the ventilation system	Partially closed systems, resulting in larger amounts of lead dust captured in the filters of the ventilation system	No impact or slight reduction
RPE, simple respirators as well as half and full facemasks (negative pressure respirators)	Unchanged or increased use of half and full facemasks and ventilated helmets.	Increased use of half and full facemasks and ventilated helmets. Increased use of RPE may discourage further reduction of airborne lead concentrations in the workplace air.	No impact or slight reduction
Partially closed systems	Partially closed systems	Partially closed systems, full enclosures and/or redesign and rebuilding of facilities,	No impact or slight reduction

[1] WWTP – waste water treatment plant, STP – sewage treatment plant

9.5 Conclusion

Lead in the environment occurs naturally as well as from anthropogenic sources. Environmental levels of lead can be high and can potentially to exceed environmental hazard limit values in vicinity of point sources. Control of any environmental emissions is therefore important.

The environmental impact of additional risk management for occupational exposure control caused by lowered limit values for lead is expected to have no or a slightly reducing effect on environmental exposures.

10. Limitations and sensitivity analysis

This section presents the limitations and uncertainties of this study, and it contains the following sections:

- Section 10.1 Overview of limitations and uncertainties
- Section 10.2 Key limitations and uncertainties

10.1 Overview of limitations and uncertainties

This section presents an overview of the limitations and uncertainties of this study and considers their potential impact on the conclusions. The table below provides a summarised overview of each element and assesses their significance for the results of this study. A more detailed assessment of some of these limitations and uncertainties is provided in the next sections.

Table 10-1 Overview of limitations and uncertainties and their effect on the costs and benefits

Limitation or uncertainty	**Explanation**	**Estimates in this study are likely U (underestimates) or O (overestimates)**	
		Costs	**Benefits**
Included in the sensitivity analysis			
Exposure concentrations & future trends	Exposure concentrations are assumed to be stable for the future years based on the stagnating trend during the recent years. However, voluntary industry programs as well as the recently updated German Biological Limit Value (BLV) of 150 µg/L may stipulate further reductions. The current assumption may lead to an overestimation of the benefits estimate but also in an overestimation of compliance cost. Inaccuracies in the exposure concentrations impact the costs and benefits.	O	O
Number of workers / companies	The number of exposed workers ranges widely and plausibly from 55,500 to 141,000 workers, which corresponds approximately to a threefold difference. The number of workers is the primary determinant of the costs and benefits. Accordingly, the costs and benefits have a wide plausible range. The costs and benefits modelled under the core scenario may therefore be equally under- or overestimated, meaning the cost benefit ratios do not change.	U or O	U or O
Workforce turnover	The workforce turnover rate has a significant impact on the estimated benefits. A higher workforce turnover leads to an increased number of non-cancer cases, owing to a short MaxEx[56] and zero latency of these endpoints. The true turnover rate will vary across sectors, but the model enables only a uniform turnover rate. Assessing the sensitivity towards the turnover provides a probable range for the benefits, which is assessed below.	-	U or O

[56] The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase)

Limitation or uncertainty	Explanation	Estimates in this study are likely U (underestimates) or O (overestimates)	
		Costs	**Benefits**
Discount rate	The estimates in this report have all been modelled using a static discount rate of 4%. A declining discount rate allocates more weight to costs and benefits that occur after 20 years. The assessment below shows that although the costs and benefits increase (owing to lower discounting effect), the cost-benefit ratios do not change. This further shows that the costs and benefits are generally equally distributed over time.	-	-
Not included in the sensitivity analysis			
Additional health endpoints	Lead has various non-cancer endpoints, comprising neurotoxic, haematological, nephrotoxic, cardiovascular, developmental, and reproductive effects. These endpoints have been included in the benefits assessment as they are currently viewed as the most sensitive. Lead may have additional health endpoints at current exposure levels or may contribute to other adverse health effects but these cannot be quantified.	Not relevant	U
Slope of Exposure Risk Relationships and Dose Response Relationships (ERRs,DRRs)	There are uncertainties in the evidence available to develop the ERRs[57] and DRRs[58]. The uncertainty could go in both directions. Compared to other substances, lead toxicity is relatively well investigated and literature on health effects of lead is considerable. The uncertainties are not expected to cause significant changes of the benefits estimate.	Not relevant	O or U
Treatment period for non-cancer endpoints	The benefits increase with the treatment period of the endpoints. For the endpoints Neuropathy, Elevated blood pressure and chronic kidney disease stage 1, the treatment period is set at 20 years due to the chronic character of the endpoints. This gives these endpoints a relatively high weight in the total benefit calculation. The true treatment period is however likely to diverge from the assumed 20 years. Accordingly, the benefits of these endpoints may be under- or overestimated	Not relevant	O or U
Share of discontinuations	The decision for an enterprise to discontinue activities depends on the cost of the RMMs[59] in relation the turnover and profit margin for that individual enterprise. There are hence several variables that determine the share of discontinuations, which may lead to an over- or underestimation of discontinuations. Given the limited number of discontinuations across the BLVs, the significance of this uncertainty is regarded as limited.	O or U	Not relevant

[57] Exposure Risk Relationships
[58] Dose Response Relationships
[59] Risk Management Measures

Limitation or uncertainty	Explanation	Estimates in this study are likely U (underestimates) or O (overestimates)	
		Costs	Benefits
'Positive biases in reported data	It is possible that there is some self-selection among companies that participated in the consultation for this study or provided data for the surveys of the industry associations. Worse-performing companies are less likely to report their exposure concentrations and are probably less likely to be member of an industry association. This may underestimate both costs and benefits and has not been further assessed.	U	U
Risk management measures (RMMs) in place	The assumptions about RMMs in place impact on the costs since it is costlier for a company that already has RMMs in place to make improvements. To mitigate a potential positive bias in the reported data, the model inputs assume lower proportions of companies with RMMs than the data reported through consultation.	U	Not relevant
Effectiveness of RMMs	Depends on size distribution of lead dust particles and solubility of the specific lead compounds. Both parameters vary across the sectors and workplaces. Different particle sizes and different solubilities determine the uptake of lead, and thus influence the effectiveness of RMMs. As such detailed information was not available for all sectors and it was not possible to include this variability into the cost model, one value of effectiveness has been assigned to each type of RMM.	O or U	Not relevant
Transposition cost	The true transposition cost may diverge from this study's assessment. However, even if the true transposition were five-fold of what has been assessed, the change in costs would be insignificant when measured against the overall compliance costs of all BLVs.	U	Not relevant
Impact of other Occupational Exposure Limits (OELs)	In the copper smelting sector, the introduction of an OEL for arsenic can be expected to have a certain impact on lead exposure, as there is an overlap of risk management measures for reducing arsenic and lead exposure in copper production. To a lesser extent, the implementation of an OEL for chromium VI may reduce lead exposures during welding, at least for limited fraction of welding processes, where both lead and chromium VI exposures occur. The introduction of a lowered limit value for asbestos is expected to have no or a limited impact on the cost and benefit assessment for lead and its compounds.	O	O

** The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase)*

10.2 Key limitations and uncertainties

The number as well as the turnover of workers are key determinants of the scale of the costs and benefits. At the same time, these are subject to some uncertainty, as the number of workers has a wide plausible range and the turnover of employees has not been possible to determine accurately.

10.2.1 Concentration levels and future trends

A change in the concentration level influences the excess risk for exposed workers, which impacts the benefits. To assess the sensitivity of the results towards small changes in the concentration levels, two sensitivity scenarios have been established. These correspond respectively to a 5% increase and decrease of the exposure concentrations in each concentration band.

The table below presents the impact on the costs and benefits if the derived exposure concentrations were 5% higher or lower than calculated. As can be expected, the costs and benefits respectively increase and decrease. The scenario of an increased concentration does not lead to significant changes in the cost-benefit ratio. However, the scenario of a decreased concentration does increase the cost-benefit ratio. For the BLV of 300 µg/L, the cost-benefit ratio changes by a factor of two.

The reason for the change in the cost-benefit ratio is that the benefits decrease more strongly than the compliance costs. In the decreased exposure concentration scenario, the concentration of several thousands of workers, particularly in sectors 3 and 5, falls below the minimum threshold of the DRRs. As a result, a high number of workers change from having an excess risk in the standard estimate to no risk in the decreased exposure concentration scenario. This effect is in comparison almost negligible in the increased concentration scenario.

Table 10-2 Sensitivity of changes to exposure concentrations on benefits and costs for two sensitivity scenarios. Presented as the benefits, costs, and cost-benefit ratios for each BLV and sensitivity scenario.

	45 µg/L	**100 µg/L**	**150 µg/L**	**200 µg/L**	**300 µg/L**
Increased exposure concentration by 5%					
Benefits M1	€ 340 million	€ 320 million	€ 280 million	€ 220 million	€ 90 million
Benefits M2	€ 480 million	€ 460 million	€ 390 million	€ 310 million	€ 130 million
Compliance cost	€ 6,900 million	€ 2,100 million	€ 880 million	€ 400 million	€ 140 million
Cost-benefit ratio M1	20	7	3	1.8	1.6
Cost-benefit ratio M2	14	5	2	1.3	1.08
Standard estimate					
Benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million
Benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million
Compliance cost	€ 6,300 million	€ 1,800 million	€ 750 million	€ 350 million	€ 130 million
Cost-benefit ratio M1	20	6	3	1.7	1.6
Cost-benefit ratio M2	14	4	2	1.2	1.08
Decreased exposure concentration by 5%					

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L
Benefits M1	€ 250 million	€ 230 million	€ 190 million	€ 150 million	€ 44 million
Benefits M2	€ 350 million	€ 330 million	€ 270 million	€ 210 million	€ 62 million
Compliance cost	€ 6,100 million	€ 1,700 million	€ 700 million	€ 320 million	€ 130 million
Cost-benefit ratio M1	24	7	4	2	3
Cost-benefit ratio M2	17	5	3	1.5	2

Source: study team's calculation

The decreased exposure concentration scenario also provides a view of the likely effect of future concentration trends on the benefits. The decreased concentration scenario shows that the benefits strongly decrease in response to small changes of the exposure concentrations (-5%). This is because the exposure concentration for a couple of thousand workers (especially in sectors 3 and 5) falls below the minimum threshold of all but exclusively female-related endpoints (i.e. pre-eclampsia and developmental toxicity). Therefore, based on this threshold, future reductions in exposure concentration would cause a strong reduction in the benefits.

In terms of the effect of a future exposure concentration on the compliance cost, enterprises would adjust their choice of RMMs (at the end of their lifetime, when reinvestments are required) to the reduced exposure concentration. This would also reduce the compliance cost. These effects can however not be quantified, as the cost model is not able to capture changing investment behaviours over time.

10.2.2 Number of workers

The assessment of the number of exposed workers in section 4.7.4 above estimates a wide range of potentially exposed workers, ranging from 57,200 to 148,500 exposed workers – corresponding to a three-fold difference. To assess the sensitivity of the results towards the number of exposed workers, two scenarios were established that approximately correspond to the above range: A 50% increase of workers to about 147,000, and a 50% decrease of workers to about 49,000. For the cost model, the change in workers is translated to a proportionate change in the number enterprises.

Table 10-3 below presents the effect of these scenarios on the benefits, costs, and the cost-benefit ratios, and compares them against the results of the standard estimate of workers. When compared to the standard estimate, the costs and benefits change in proportion to the number of workers, which can be traced back to the fact that the benefits are directly determined by the number of exposed workers, and that the costs are determined by the number of enterprises, which in turn are determined by the number of workers. Therefore, the cost-benefit ratios do not change. It is thus only the total costs and benefits that change.

Table 10-3 Sensitivity of number of exposed workers on the costs and benefits for two sensitivity scenarios. Presented as the benefits, costs, and cost-benefit ratios for each BLV and sensitivity scenario.

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L
50% increase of workers – 147,000 workers					
Benefits M1	€ 470 million	€ 450 million	€ 380 million	€ 320 million	€ 130 million
Benefits M2	€ 670 million	€ 640 million	€ 540 million	€ 440 million	€ 180 million
Cost	€ 9,400 million	€ 2,700 million	€ 1,100 million	€ 520 million	€ 200 million
Cost-Benefit ratio M1	20	6	3	1.6	1.5
Cost-Benefit ratio M2	14	4	2	1.2	1.1
Standard estimate of workers – 98,000					
Benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million
Benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million
Cost	€ 6,300 million	€ 1,800 million	€ 750 million	€ 350 million	€ 130 million
Cost-Benefit ratio M1	20	6	3	1.7	1.6
Cost-Benefit ratio M2	14	4	2	1.2	1.08
50% decrease of workers – 49,000 workers					
Benefits M1	€ 160 million	€ 150 million	€ 130 million	€ 110 million	€ 40 million
Benefits M2	€ 220 million	€ 210 million	€ 180 million	€ 150 million	€ 60 million
Cost	€ 3,100 million	€ 910 million	€ 370 million	€ 170 million	€ 70 million
Cost-Benefit ratio M1	19	6	3	1.5	1.8
Cost-Benefit ratio M2	14	4	2	1.1	1.2

Source: study team's calculation

10.2.3 Turnover of workers

The sensitivity towards workers' turnover is assessed with two sensitivity scenarios, respectively composed of an increase and decrease of the annual workers' turnover. The increased turnover corresponds to a doubling of the annual rate from 5% to 10%, which results in a 100% turnover of workers within 10 years, leading to four cohorts of workers for in the 40-year study period. The decreased turnover corresponds in turn to a halving of the annual rate from 5% to 2.5%, resulting in a 100% turnover of workers within 40 years. Table 10-4 below presents the benefits of both methods and for each BLV, for the two sensitivity scenarios and the standard scenario.

Table 10-4 Sensitivity of workers' turnover on the benefits, presented for an increased, standard, and decreased turnover, for each BLV & benefit method (€ million)

	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L
Increased workers' turnover of 10% annually – 100% turnover of workers in 10 years					
Benefits M1	€ 530 million	€ 500 million	€ 430 million	€ 350 million	€ 140 million
Benefits M2	€ 740 million	€ 710 million	€ 600 million	€ 490 million	€ 200 million
Standard workers' turnover of 5% annually – 100% turnover of workers in 20 years					
Benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million
Benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million
Decreased workers' turnover of 2.5% annually – 100% turnover of workers in 40 years					
Benefits M1	€ 220 million	€ 210 million	€ 180 million	€ 150 million	€ 60 million
Benefits M2	€ 310 million	€ 290 million	€ 250 million	€ 200 million	€ 80 million

Source: study team's calculation

The MaxEx[60] is at most 10 years for all non-cancer endpoints. For the increased turnover scenario, consisting of a doubling of the turnover of workers from 20 to 10 years, twice the workers are exposed within the MaxEx of the non-cancerous endpoints. The number of cancer cases do, however, not change, owing to a long MaxEx of 40 years and a latency of 30 years. Although more workers will be exposed to lead, additional cases of cancer will also occur beyond the 40-year time horizon of this study. Overall, however the increased turnover scenario leads to a doubling of the non-cancerous cases, which further leads to an increase in the benefits. For the BLVs of 200 and 300 µg/L, the benefits would even outweigh the costs. Finally, the order of magnitude of the benefits does not change.

With regards to the decreased workers' turnover scenario, the number of cases of the non-cancerous endpoints is halved. This leads to a decrease in the benefits, further increasing the cost-benefit ratio. The conclusion of the standard estimate that the costs outweigh the benefits, holds therefore also in this scenario. Furthermore, the assessment shows that the order of magnitude is similar to the standard estimate.

10.2.4 Declining discount rate

The use of a declining discount rate of 4% in the first 20 years, followed by 3% in the final 20 years increases the benefits of Method 1 and Method 2 by respectively 8% and 5% for all BLVs. The compliance costs increase however also for all BLVs, except for the BLV of

[60] The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase)

45 µg/L. The cost-benefit ratio does consequently not change to a notable degree, with the exception of the BLV of 45 µg/L, as a comparison with the cost-benefit ratio of the standard estimate in Table 10-5 below shows. This shows that the costs and benefits are somewhat equally distributed over time, as a reduced discounting rate in the future, which allocates more weight to future impacts, does not significantly alter the balance of the costs and benefits.

Table 10-5 Sensitivity of a declining discount rate. Benefits for M1 and M2, compliance cost, and resulting cost-benefit ratio for all BLV options, compared to the cost-benefit ratios of the standard estimate.

	45 µg/L	**100 µg/L**	**150 µg/L**	**200 µg/L**	**300 µg/L**
Declining discount rate of 4% for 20 years and then 3%					
Benefits M1	€ 340 million	€ 320 million	€ 280 million	€ 230 million	€ 90 million
Benefits M2	€ 470 million	€ 450 million	€ 380 million	€ 310 million	€ 120 million
Cost	€ 6,400 million	€ 1,800 million	€ 760 million	€ 360 million	€ 140 million
Cost-Benefit ratio M1	19	6	3	1.6	1.6
Cost-Benefit ratio M2	14	4	2	1.2	1.2
Standard estimate – static discount rate of 4%					
Cost-Benefit ratio M1	20	6	3	1.7	1.6
Cost-Benefit ratio M2	14	4	2	1.2	1.08

Source: study team's calculation

11. Comparing the options

The comparison of options entails the following sections:

- Section 11.1: Cost-benefit analysis (CBA)
- Section 11.2: Multi-criteria analysis (MCA)
- Section 11.3: Highlighted issues

11.1 Cost-benefit analysis (CBA)

11.1.1 Overview of the benefits (cost savings) for the BLV options

The table below summarises the benefits (cost savings from reduced ill health) associated with the BLV options, as assessed in chapter 5 above. The cost savings due to reduced ill-health are for the present value (PV) over 40 years with a static discount rate of 4%.

Table 11-1 Overview of the benefits (cost savings due to reduced ill health) per BLV

Impact	Stake-holders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Direct benefits – improved well-being - health							
Reduced cases of ill health (all end-points, excl. developmental toxicity)	Workers & families	12,000	11,000	10,000	8,100	3,200	0
Ill health avoided, incl. in-tangible costs (M1 to M2)	Workers & families	€200 - 310 million	€190 - 300 million	€160 - 250 mil-lion	€130 - 200 mil-lion	€52 - 80 million	€0
Avoided costs	Compa-nies	€6 million	€6 million	€5 million	€4 million	€2 million	€0
Avoided costs	Public sec-tor	€130 million	€120 million	€100 million	€90 million	€40 million	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free envi-ronment					
Direct benefits – improved well-being - environmental							
Environmental releases	All	No impact/limited impact					
Direct benefits – market efficiency							
Level playing field	Compa-nies	A harmonisation of the BLVs leads to a level playing field, as all compa-nies across all Member States follow a more symmetric requirement. The level-playing field increases with the stringency of BLVs					

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Indirect benefits							
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are sectors 1, 2, 3, 6, and 15.					
Synergy	Companies	Synergies in terms of exposure reduction to other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.					
Corporate Social Responsibility	Companies	Work with lead may be less perceived as a risky line of work associated with health issues. As a result of such an improved public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.					
No cost of setting BLV (savings for Member States for developing lower national BLVs)	Public sector	Benefit (MS would expectedly not implement lower BLV)			Small benefit (some MS would consider implementing lower BLV)	Limited benefit (many MS would consider the BLV too high)	No benefit

Source: study team's calculation

11.1.2 Overview of the costs for the BLV options

The table below summarises the costs associated with the BLV options, as also assessed in chapter 6 above. The costs are for the present value (PV) over 40 years with a static discount rate of 4%.

Table 11-2 Overview of the costs per BLV

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Direct costs - compliance							
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€6,300 million	€1,800 million	€750 million	€350 million	€130 million	€0
Monitoring (sampling and analysis)	Companies	€0	€0	€0	€0	€0	€0
Direct costs - administrative burdens							

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Company cost of additional administration	Companies	€0	€0	€0	€0	€0	€0
Direct costs - total							
Compliance and monitoring costs per company	Companies	€300,000	€82,000	€31,000	€15,000	€6,000	€0
Direct costs - enforcement costs							
Transposition costs	Public sector	€520,000	€520,000	€500,000	€480,000	€460,000	€0
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0
Indirect costs - other							
Firms exiting the market - No. of company closures	Companies	29	3	0	0	0	0
Employment – Jobs lost	Workers & families	1,800	130	0	0	0	0
Employment – Social cost	Workers & families	€150 million	€10 million	€0	€0	€0	€0
International competitiveness	Companies						
Consumers	Consumers	Limited impacts expected					
Internal market	Companies	Lowest/ highest BLV from 45 to 45	Lowest/ highest BLV from 100 to 100	Lowest/ highest BLV from 100 to 150	Lowest/ highest BLV from 100 to 200	Lowest/ highest BLV from 100 to 300	Lowest/ highest BLV from 100 to 700

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Specific MSs/regions - MSs that would have to change BLVs	Public sector	All MS	All MS	All MS except DE	All MS except DE, DK	All MS except DE, DK, FI	Only EE (not transposed)
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited					

Source: study team's calculation

11.1.3 CBA for the BLV options

The table below provides a direct comparison of the costs and benefits.

Table 11-3 Cost-Benefit of the BLV options

Impact	BLV options					
	45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Total benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million	€ 0
Total benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million	€ 0
Total costs	€ 6,300 million	€ 1,800 million	€ 750 million	€ 350 million	€ 130 million	€ 0
Cost benefit ratio M1	20	6.0	2.9	1.7	1.6	0
Cost benefit ratio M2	14	4.3	2.1	1.2	1.08	0

Source: study team's calculation

11.2 Multi-criteria analysis (MCA)

The table below summarises both the monetised and qualitative impacts.

Table 11-4 Multi-criteria analysis (all impacts over 40 years and additional to the baseline)

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Direct costs - compliance							
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€6,300 million	€1,800 million	€750 million	€350 million	€130 million	€0
Monitoring (sampling and analysis)	Companies	€0	€0	€0	€0	€0	€0
Direct costs - administrative burdens							
Company cost of additional administration	Companies	€0	€0	€0	€0	€0	€0
Direct costs - total							
Compliance and monitoring costs per company	Companies	€300,000	€82,000	€31,000	€15,000	€6,000	€0
Direct costs - enforcement costs							
Transposition costs	Public sector	€520,000	€520,000	€500,000	€480,000	€460,000	€0
Enforcement costs	Public sector	€0	€0	€0	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0	€0	€0	€0
Indirect costs - other							
Firms exiting the market - No. of company closures	Companies	29	3	0	0	0	0

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Employment – Jobs lost	Workers & families	1,800	130	0	0	0	0
Employment – Social cost	Workers & families	€150 million	€10 million	€0	€0	€0	€0
International competitiveness	Companies	Substantial negative impact	High negative impact	Moderate negative impact	Limited negative impact	Limited negative impact	No impact
Consumers	Consumers	Limited impacts expected					
Internal market	Companies	Lowest/ highest BLV from 45 to 45	Lowest/ highest BLV from 100 to 100	Lowest/ highest BLV from 100 to 150	Lowest/ highest BLV from 100 to 200	Lowest/ highest BLV from 100 to 300	Lowest/ highest BLV from 100 to 700
Specific MSs/regions - MSs that would have to change BLVs	Public sector	All MS	All MS	All MS except DE	All MS except DE, DK	All MS except DE, DK, FI	Only EE (not transposed)
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited					
Direct benefits – improved well-being - health							
Reduced cases of ill health (all endpoints, excl. developmental toxicity)	Workers & families	12,000	11,000	10,000	8,100	3,200	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€200 - 310 million	€190 - 300 million	€160 - 250 million	€130 - 200 million	€52 - 80 million	€0
Avoided costs	Companies	€6 million	€6 million	€5 million	€4 million	€2 million	€0
Avoided costs	Public sector	€130 million	€120 million	€100 million	€90 million	€40 million	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy towards a toxic-free environment					
Direct benefits – improved well-being - environmental							

Impact	Stakeholders affected	BLV options					
		45 µg/L	100 µg/L	150 µg/L	200 µg/L	300 µg/L	700 µg/L
Environmental releases	All	No impact/limited impact					
Direct benefits – market efficiency							
Level playing field	Companies	A harmonisation of the BLVs leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases with the stringency of BLVs					
Indirect benefits							
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones with facilities in different Member States will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are sectors 1, 2, 3, 6, and 15.					
Synergy	Companies	Synergies in terms of exposure reduction to other chemical substances used in production sectors may occur. The specific substances will vary between sectors. The level of synergy to be harnessed will also depend on the RMMs applied in each enterprise.					
Corporate Social Responsibility	Companies	Work with lead may be less perceived as a risky line of work associated with health issues. As a result of such an improved public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.					
No cost of setting BLV (saving for MS for developing lower national BLVs)	Public sector	Benefit (MS would expectedly not implement lower BLV)			Small benefit (some MS would consider implementing lower BLV)	Limited benefit (many MS would consider the BLV too high)	No benefit

Source: study team's calculation
Notes: All costs/benefits are incremental to the baseline (PV over 40 years). Internal market shows the ratio of highest BLV to lowest BLV before and after implementing the BVL option.

11.3 Highlighted issues

Relationship between levels of lead in air (PbA) and blood (PbB)

Blood lead concentrations are recognized as the main exposure metric in assessing occupational exposures in lead. The present study includes a full impact assessment of all BLV options as outlined in chapter 3. The assessment of the OEL options could not be performed in a corresponding manner due to missing and uncertain data regarding health effects related to airborne exposures. PbB and PbA relationships depend on various factors within an occupational setting and unambiguous correlation methods are not available (see sections 2.3.4 and 6.4.7).

The recognized best available method for estimating PbB based on exposure to airborne lead is the conversion method developed by the California Office for Environmental Health Hazard Assessment (OEHHA). This method has been applied by the RAC to derive the proposed OEL based on the proposed BLV. The conversion method showed to have limited value for the calculation of ill health cases in this study, as the validated conversion range and conversion values do not reflect relevant PbB and PbA concentrations of current occupational settings (section 4.16). For that reason, the steering group agreed that the study should evaluate the BLV quantitatively and the OEL qualitatively in relation to the BLV options. Data on compliance cost with OEL options have been collected during stakeholder consultation. Most companies focus on PbB management and found it challenging to provide data on PbA management. The OEL assessment has been conducted in a qualitative manner (sections 6.4.1, 6.4.5 and 6.4.7). Available data indicate the OEL option of 50 µg/m³ as an achievable level.

Groups at Extra Risk

RAC considers increased susceptibility to lead toxicity of certain groups; of occupational relevance are the groups "Women of childbearing age" as well as persons with "Pre-existing Conditions, Diseases, and Exposure to Other Substances" and "Genetic Polymorphism". The latter two groups have not been considered in the current study. The approach regarding women of childbearing age is outlined in section 4.2. RAC states that "*Neither the proposed BLV of 150 µg/L blood nor the proposed air limit value of 4 µg/m³ for lead and its inorganic compounds protects from developmental toxicity. No threshold for potential central nervous system effects in new-borns and infants can be identified at present. The exposure of fertile women to lead should therefore be avoided or minimised*". The present study does not discuss the relationship between setting protective limit values and gender equality. Data on adverse health effects of lead in women of childbearing age, exposure concentrations and numbers of female employees of childbearing age have been included in the study (see sections 2.2.4, 2.3.3, 4.6.3, 4.7), as well as information on how exposure of women is currently managed in industry (section 6.4.6). It is not within the scope of the study to provide conclusions on how/if limit values for women of childbearing capacity should be addressed in the CAD.

Development of future exposure concentrations

Data on exposure concentrations trends from various sources are presented in section 4.6.5. The available data show that blood lead levels have reduced drastically during the past decades, while the trend appears to have stagnated in recent years. Continuous efforts within the main lead producing and processing sectors indicate that further reductions are likely. However, these are not reflected in the exposure concentration trend data of the most recent years. Available information does not suggest exposure concentration reduction in sectors other than the main lead producing and processing sectors for the recent year. Since May 2021, companies in Germany, a significant proportion of the European lead industry, must comply with a BLV of 150 µg/L. No data are available yet to show the extent to which the newly introduced German BLV impacts the baseline and the benefits estimation. Future changes in exposure concentrations are therefore included as a variable in the sensitivity analysis. Future reductions in exposure concentrations result in a larger decrease of the benefits estimates compared to the decrease in cost estimates for the BLV options.

Level of compliance costs

The output data of the cost model should be interpreted with caution as the calculation is based on a number of assumptions and simplifications as outlined in section 6.3 and the methodological note. Nonetheless, the data give an indication of magnitude. Compared to companies' turnover (Table 7-5) compliance costs are generally of limited significance for most companies in most sectors for the BLV options ≥ 150 µg/L. This reflects the fact that the current EU BLV is regarded as outdated and most companies comply with lower national BLVs and/or work with voluntary industry targets. This also means that many measures for compliance with limit values below the current 700 µg/L are already in place, meaning the cost of implementing additional measures is limited.

A significant part of the compliance cost at the BLV options ≤ 100 µg/L is caused by discontinuations (see section 6.4.4 and 7.3.1). Discontinuation costs have to be interpreted with care, as the cost model offers limited opportunities to predict a company's alternative opportunities of reacting to lowered limit values other than discontinuing when costs for additionally required RMMs exceed profits. The cost of discontinuation may lead to an overestimation of the total compliance cost.

Time needed to achieve compliance with lowered BLV

Implementation of additional risk management measures depends, amongst others, on the required investment costs and availability of technical solutions. While airborne concentrations can be controlled immediately with the implementation of suitable risk management measures, the reduction of PbB levels is more time-consuming as PbB reductions depend, next to the effectiveness of risk management measures, on personal behaviour, on previous PbB levels and biological parameters. Time periods needed for achieving compliance with BLV options ≥ 150 µg/L were estimated at 3 months – 18 years. The BLV options < 150 µg/L were either regarded as unachievable or no information was available (section 6.4.1).

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Annex 1 Summary of the consultation

The number of consultation responses for lead and its compounds is summarised below.

Table A1-1: Number of responses relevant to lead and its compounds @ 12 July 2021

Response type	Number of responses
Questionnaire responses	84
Interviews and conference calls	41
Site visits	2 conducted under previous OELs studies
Total	127

The study team had conference calls with the following industry associations:

- REACH Lead Consortium/ILA and approximately 150 of their members involved in producing and using lead and its compounds
- The European Foundry Association (CAEF)
- Federation of European Explosives Manufacturers (FEEM)
- European Construction Industry Federation (FIEC) and three affiliates
- European Federation of Building and Woodworkers (EFBWW)

In addition, the following provided information during interviews and/or email exchanges:

- Eurometaux/ECI
- International Lead Association (ILA)
- European Trade Union Institute (ETUI)
- European Foundry Association (CAEF)
- Glass alliance Europe
- Copper Alliance Europe
- Federation of European Explosives Manufacturers (FEEM)
- European Federation of Building and Woodworkers (EFBWW)
- European Demolition Association (EDA)
- Euromines
- Danish Industry
- Romania Health Institute INSP
- German Non-ferrous metal industry association, VWMetalle
- Allgemeinen Unfallversicherungsanstalt Austria (AUVA)
- BG Bau Germany
- Company, Belgium

- Company, Austria
- Company, Bulgaria
- Company, several facilities within the EU and non-EU
- Company, several facilities within the EU
- Company, Italy
- Company, Slovenia
- Company, France
- Company, Czech Republic
- Company, EU (Member State not disclosed due to confidentiality)

Site visits
Due to the ongoing COVID-19 pandemic and associated travel restrictions, as well as difficulties in companies providing confidential images/recordings of their sites, no physical or virtual site visits were conducted in relation to lead and its compounds as a part of this study. Two site visits were however conducted for lead and its compounds under a previous OELs study, which provided useful information that could be used to inform the current study. These are summarised in the table below.

Table A2: Summary of site visits for lead and its compounds conducted under previous OELs studies

Substance	Sector	Member State	Status
Inorganic lead and its compounds	Primary lead producer	Germany	Undertaken June 2019
Inorganic lead and its compounds	Production of lead sheets and extruded products	Germany	Undertaken June 2019

.
These site visits were undertaken to obtain first-hand information on processes and activities where exposure is likely to occur, RMMs and costs of reaching the current exposure levels. These site visits were originally identified via the national sector association.

Annex 2 Lead questionnaire

Questionnaire for Companies: Asbestos

A consortium comprising RPA Risk & Policy Analysts (United Kingdom), COWI (Denmark), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), and EPRD (Poland) has been contracted by the European Commission's Directorate-General for Employment, Social Affairs and Inclusion to assess the impacts of establishing Occupational Exposure Limit values (OELVs) for a number of substances.

As part of the study, a baseline study is carried out for "Lead and its compounds". The collected information and subsequent analyses shall support the European Commission's work in the area of possible amendments of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. This part of the study is being carried out by COWI.

This questionnaire is intended for all companies where exposure to lead and its compounds may take place.

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

This questionnaire is intended for a single facility. If workers are exposed at multiple facilities, please complete the questionnaire for each facility or contact the study team.

The deadline for completion of the questionnaire is the 26th February 2021.

This questionnaire is available in English, French, German, Italian, Polish and Spanish. However, you are welcome to answer the questions in an official European language of your choice. Languages may be selected from the list in the top right corner of each questionnaire. This section also contains an accessibility mode for simplified reading, as well as the ability to download the questionnaire as a PDF.

If you have questions about the survey, please contact Marlies Warming, mrwa@cowi.com

Abbreviations used in the questionnaire:

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

	8h-TWA = (2 hours * 500 ppm + 5 hours * 100 ppm + 1 hours * 700 ppm) / (2 + 5 + 1 hours).

Publication privacy settings

By checking this box, I confirm that I have read the Privacy Statement and agree with the processing of my personal data for the purposes stated therein. I acknowledge that my views could be shared with the European Commission and published with information concerning the name and type of the organisation that I represent, to which I hereby give my consent.	☐

A) About your company

A1) Please provide the following details about your company	
Name of contact person	
Company	
Email address of contact person	
Telephone number of contact person	
Please provide the name and address of the facility for which you are completing this questionnaire	
Country of facility	

A2) Please define the sector in which your company is active (if possible, using a NACE code)	
A3) How many workers are employed in your company at this facility?	
A4) How many of the MALE workers employed in your company at this facility are exposed to lead or lead compounds?	
A5) How many of the FEMALE workers employed in your company at this facility are exposed to lead or lead compounds?	
A6) Have you any experience of workers having health issues resulting from occupational exposure to lead and its compounds at the workplace? (e.g., neurotoxicity, fertility	

issues, renal toxicity, cardiovascular effects, or brain cancer)	
A7) Have any workers left the company due to health issues associated with exposure to lead and its compounds?	
A8) What is the annual turnover in EUR at the facility for which you are filling out this questionnaire?	☐ < €2 million ☐ €2 – 10 million ☐ €10 – 50 million ☐ €50 – 100 million ☐ > €100 million

A9) If your workers are exposed to lead and its compounds, please specify the specific compounds that they are exposed to (e.g. lead monoxide, lead dinitrate, etc.)

Lead compound	**CAS No**	
Lead monoxide	1317-36-8; 7439-92-1	☐
Lead 2,4,6-trinitro-m-phenylene dioxide	15245-44-0	☐
Lead bis(tetrafluoroborate)	13814-96-5	☐
Lead tetraacetate	546-67-8	☐
Lead titanium trioxide	12060-00-3	☐
Pentalead tetraoxide sulphate	12065-90-6	☐
Lead cyanamidate	20837-86-9	☐
Lead	7439-92-1	☐
Lead di(acetate)	301-04-2; 6080-56-4	☐
Orange lead	1314-41-6	☐
Lead dinitrate	10099-74-8	☐
Trilead dioxide phosphonate	12141-20-7	☐
Trilead bis(carbonate) dihydroxide	1319-46-6	☐
Tetralead trioxide sulphate	12202-17-4	☐
Pyrochlore, antimony lead yellow	8012-00-8	☐
Dibasic lead sulphite	62229-08-7	☐
Lead diazide	13424-46-9	☐
Dibasic lead phthalate	69011-06-9	☐
Lead sulfochromate yellow	1344-37-2	☐
Dioxobis(stearato)trilead	12578-12-0	☐
Lead titanium zirconium oxide	12626-81-2	☐
Lead chromate molybdate sulfate red	12656-85-8	☐

Lead dichloride	7758-95-4	☐
Basic lead sulphate	12036-76-9	☐
Polybasic lead fumarate	90268-59-0	☐
Fatty acids, C16-18, lead salts	91031-62-8	☐
Neutral lead stearate	1072-35-1	☐
Others: [text box]		☐
Don't know which specific compounds		☐

B) Information about current exposure at your facility

Airborne concentrations

If you would like to report on more than four activities, please complete additional questionnaires.

	Activity 1	***Activity 2***	***Activity 3***	***Activity 4***
B1) Please specify the most important activities* during which exposure to lead and its compounds can occur.				
B2) Please provide the number of workers exposed during a typical working day				
**The most important activities in this context are those for which exposure to lead and its compounds gives you the most concern. This could be because the activity has low levels of exposure but affects many people. Or because the activity has high levels of exposure but for short periods. Or alternatively, an activity where it is very difficult or expensive to reduce exposure at all.*				
B3) Please provide data for <u>airborne concentrations</u> without PPE from your most recent measurements of air exposure concentration (8-hour Time Weighted Averages) in **µg Pb/m³**				
Lowest concentration (value)				
Highest concentration (value)				
Mean concentration (arithmetic mean; value)				
Median concentration (value)				
95th percentile concentration (value)				
Number of samples (n)				
Year of monitoring				
B4) Please confirm the unit for the data you have just entered	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*
B5) Please select the sampling method followed	☐ *Stationary sampling* ☐ *Personal sampling*	☐ *Stationary sampling* ☐ *Personal sampling*	☐ *Stationary sampling* ☐ *Personal sampling*	☐ *Stationary sampling* ☐ *Personal sampling*

	Activity 1	***Activity 2***	***Activity 3***	***Activity 4***
	☐ *Personal sampling of inhalation air inside the RPE*	☐ *Personal sampling of inhalation air inside the RPE*	☐ *Personal sampling of inhalation air inside the RPE*	☐ *Personal sampling of inhalation air inside the RPE*
B6) Are the workers wearing respiratory protective equipment (RPE) during the activity?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
B7) If you have other airborne concentration data than 8-hour Time Weighted Averages, please specify type of date and air exposure concentration				
Type of data, value				
B8) Please confirm the unit for the data you have just entered	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*	☐ *µg Pb/m³* ☐ *mg Pb/m³* ☐ *µg Pb/L* ☐ *mg Pb/L* ☐ *ppm*
B9) Please select the sampling method followed	☐ *Stationary sampling* ☐ *Personal sampling* ☐ *Personal sampling of inhalation air inside the RPE*	☐ *Stationary sampling* ☐ *Personal sampling* ☐ *Personal sampling of inhalation air inside the RPE*	☐ *Stationary sampling* ☐ *Personal sampling* ☐ *Personal sampling of inhalation air inside the RPE*	☐ *Stationary sampling* ☐ *Personal sampling* ☐ *Personal sampling of inhalation air inside the RPE*

Blood lead levels

	Activity 1	***Activity 2***	***Activity 3***	***Activity 4***
B10) Please provide data for blood lead levels from your most recent measurements				
Lowest concentration (value)				
Highest concentration (value)				
Mean concentration (arithmetic mean; value)				
Median concentration (value)				
95th percentile concentration (value)				
Number of samples (n)				
Year of monitoring				

B11) Please confirm the unit for the data you have just entered	☐ *µg Pb/L* ☐ *µg Pb/dL* ☐ *µg Pb/100 ml* ☐ *mg Pb/L* ☐ *mg Pb/dL* ☐ *mg Pb/100 ml*	☐ *µg Pb/L* ☐ *µg Pb/dL* ☐ *µg Pb/100 ml* ☐ *mg Pb/L* ☐ *mg Pb/dL* ☐ *mg Pb/100 ml*	☐ *µg Pb/L* ☐ *µg Pb/dL* ☐ *µg Pb/100 ml* ☐ *mg Pb/L* ☐ *mg Pb/dL* ☐ *mg Pb/100 ml*	☐ *µg Pb/L* ☐ *µg Pb/dL* ☐ *µg Pb/100 ml* ☐ *mg Pb/L* ☐ *mg Pb/dL* ☐ *mg Pb/100 ml*

Other information

B12) Do you have any other information on exposure to these substances at your facility?
If you are happy to provide more detailed information about numbers of workers exposed, exposure levels and/or further activities, please email this to Marlies Warming, mrwa@cowi.com, directly. This could e.g. be data that further specifies exposure concentrations of men, women and women of childbearing age

B13) Do you have any guidance on biological monitoring of blood lead levels? If so, please provide details or a link/reference.

Risk Management Measures in place

B14) Which Risk Management Measures are in place to control exposure of the lead and its compounds in the different activities at this facility? Please tick all that you use.				
	Activity 1	***Activity 2***	***Activity 3***	***Activity 4***
Restructuring operations/processes				
Temporary relocation of workers with high blood lead levels	☐	☐	☐	☐
Permanent relocation of workers with high blood lead levels	☐	☐	☐	☐
Reduced amount of substance used	☐	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐	☐

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

Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐	☐
Creating a culture of safety	☐	☐	☐	☐
Substitution or discontinuation in the past				
Partial substitution of lead and its compounds used in this activity in the past	☐	☐	☐	☐
Discontinuation of part of the activity using lead and its compounds	☐	☐	☐	☐
Other (please specify):	☐	☐	☐	☐

C) What are the lowest exposure levels that you could achieve

	Value	Unit
C1) What do you think is the lowest *technically possible* 8 hour TWA air concentration that can be achieved in this facility?		☐ µg Pb/m3 ☐ mg Pb/m³ ☐ µg Pb/L ☐ mg Pb/L ☐ ppm
C2) What do you think is the lowest *economically feasible* 8 hour TWA air concentration that can be achieved in this facility?		☐ µg Pb/m3 ☐ mg Pb/m³ ☐ µg Pb/L ☐ mg Pb/L ☐ ppm
C3) Any comments on above answers?		
C4) Do you have to comply with the European Workplace exposure standard EN 689?	☐ Yes ☐ No ☐ Don’t know	

D) Compliance with a new OEL or BLV and risk management measures

This section considers the Risk Management Measures (RMMs) that would have to be put in place to comply with a new OEL and BLV under the CAD.

Please fill out the section for the activity **with the highest exposure concentration.**

The following limit values and air concentrations given below are used as reference points for this questionnaire. For questions D1) to D6), please use the appropriate reference values for the substance in question.			
OEL		**BLV**	
OEL reference value 1 (Lowest national OEL in EU Member States (Bulgaria,	50 µg Pb/m³	***BLV reference value 1*** (Intermediate level of BLV in EU Member States)	300 µg Pb/L blood

Czech Republic, Denmark, Estonia, Latvia, Poland, Sweden))			
OEL reference value 2 (Intermediate level between lowest national level and OEL at the level proposed by RAC.)	20 µg Pb/m³	***BLV reference value 2*** (BLV at the level proposed by RAC)	150 µg Pb/L blood
OEL reference value 3 (OEL at the level proposed by RAC opinion for lead and its compounds)	4 µg Pb/m³	***BLV reference value 3**** (Biological guidance value related to background exposure of the general population) ****Please note that this limit would only apply to women of child-bearing age (under 50 years of age)***	45 µg Pb/L blood

The final policy option recommended for adoption is likely to encompass both an OEL and a BLV, potentially any combination of the reference values above. However, many respondents may be unable to provide the risk management measures (RMMs) details required for every combination. In addition, some RMMs reduce both blood lead levels and air exposure. Therefore, the questionnaire asks you to focus on either the BLV or OEL reference values by:

a) estimating the RMMs needed to achieve each BLV reference value, or

b) estimating the RMMs needed to achieve each OEL reference value.

D) Which type of limit value would you like to provide information on risk management measures?	☐ OEL	☐ BLV

If OEL, go to questions D1 D2 D3 D7

If BLV, go to questions D4 D5 D6 D8

D1) Please indicate which *additional* risk management measures (RMMs) would be the most important in helping you to achieve the OEL reference values?			
	50 µg Pb/m³	**20 µg Pb/m³**	**4 µg Pb/m³**
No action required as OEL already achieved	☐	☐	☐
Partial substitution of lead and its compounds	☐	☐	☐
Substitution of lead and its compounds	☐	☐	☐
Discontinuation of process using lead and its compounds	☐	☐	☐

Restructuring operations/processes			
Temporary relocation of workers with high blood lead levels	☐	☐	☐
Permanent relocation of workers with high blood lead levels	☐	☐	☐
Reduced amount of substance used	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐
Redesign of work processes	☐	☐	☐
Ventilation and extraction			
Closed systems	☐	☐	☐
Partially closed systems	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐
General ventilation	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐
Personal protective equipment (PPE)			
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐
Half and full facemasks (negative pressure respirators)	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐
Face screens, face shields, visors	☐	☐	☐
Safety spectacles, goggles	☐	☐	☐
Gloves	☐	☐	☐
Gloves with a cuff, gauntlets and sleeving that covers part or all of the arm	☐	☐	☐
Safety boots and shoes	☐	☐	☐
Rubber boots	☐	☐	☐
Conventional or disposable overalls, boiler suits, aprons	☐	☐	☐
Coveralls/hazardous materials suits	☐	☐	☐
Organisational and hygiene measures			
Training and education of workers	☐	☐	☐

Cleaning of working area	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐
Provision of separate storage facilities for work clothes	☐	☐	☐
Formal/external mask cleaning and filter changing regime	☐	☐	☐
Blood-lead monitoring	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐
Creating a culture of safety	☐	☐	☐
Other measures			
Other (please specify):	☐	☐	☐
Effective BLV			
In achieving these OELs, which BLV would you expect to also achieve?	700 µg Pb/L blood 300 µg Pb/L blood 150 µg Pb/L blood 45 µg Pb/L blood I don't know	700 µg Pb/L blood 300 µg Pb/L blood 150 µg Pb/L blood 45 µg Pb/L blood I don't know	700 µg Pb/L blood 300 µg Pb/L blood 150 µg Pb/L blood 45 µg Pb/L blood I don't know

D2) What is your estimated range of <u>total</u> <u>initial investment</u> likely to be incurred at this facility to achieve the following OEL reference values?

	50 µg Pb/m^3	20 µg Pb/m^3	4 µg Pb/m^3
< €10,000	☐	☐	☐
€10,000 - €100,000	☐	☐	☐
€100,000 - €1 million	☐	☐	☐
€1 -10 million	☐	☐	☐
€10 -100 million	☐	☐	☐
€100 -1 billion	☐	☐	☐
Over € 1 billion	☐	☐	☐
Don't know	☐	☐	☐

D3) What is your estimated range of total annual *recurrent costs* likely to be incurred at this facility to achieve the following OEL reference values?			
	50 µg Pb/m³	**20 µg Pb/m³**	**4 µg Pb/m³**
< €10,000	☐	☐	☐
€10,000 - €100,000	☐	☐	☐
€100,000 - €1 million	☐	☐	☐
€1 -10 million	☐	☐	☐
€10 -100 million	☐	☐	☐
€100 -1 billion	☐	☐	☐
Over € 1 billion	☐	☐	☐
Don't know	☐		

D7) How would the OEL reference values impact the competitiveness of your company…			
	50 µg Pb/m³	**20 µg Pb/m³**	**4 µg Pb/m³**
versus compet-itors in EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact
versus compet-itors outside of EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact

D4) Please indicate which *additional* RMMs would be the most important in helping you to achieve the BLV reference values?			
	300 µg Pb/L blood	**150 µg Pb/L blood**	**45 µg Pb/L blood** **Only applies to female workers under 50**
No action required as BLV already achieved	☐	☐	☐
Partial substitution of lead and its compounds	☐	☐	☐
Substitution of lead and its compounds	☐	☐	☐
Discontinuation of process using lead and its compounds	☐	☐	☐
Restructuring operations/processes			
Temporary relocation of workers with high blood lead levels	☐	☐	☐
Permanent relocation of workers with high blood lead levels	☐	☐	☐
Reduced amount of substance used	☐	☐	☐
Reduced number of workers exposed	☐	☐	☐
Rotation of the workers exposed	☐	☐	☐
Redesign of work processes	☐	☐	☐
Ventilation and extraction			
Closed systems	☐	☐	☐
Partially closed systems	☐	☐	☐
Open hoods over equipment or local extraction ventilation	☐	☐	☐
General ventilation	☐	☐	☐
Pressurised or sealed control cabs	☐	☐	☐
Simple enclosed control cabs	☐	☐	☐
Personal protective equipment (PPE)			
Self-contained breathing apparatus (with bottled air) or airline respirators (air supplied by hose)	☐	☐	☐
Powered air-purifying respirators	☐	☐	☐

Half and full facemasks (negative pressure respirators)	☐	☐	☐
Disposable respirators (FFP masks)	☐	☐	☐
Face screens, faceshields, visors	☐	☐	☐
Safety spectacles, goggles	☐	☐	☐
Gloves	☐	☐	☐
Gloves with a cuff, gauntlets and sleeving that covers part or all of the arm	☐	☐	☐
Safety boots and shoes	☐	☐	☐
Rubber boots	☐	☐	☐
Conventional or disposable over-alls, boiler suits, aprons	☐	☐	☐
Coveralls/hazardous materials suits	☐	☐	☐
Organisational and hygiene measures			
Training and education of workers	☐	☐	☐
Cleaning of working area	☐	☐	☐
Measures for workers' personal hygiene (e.g. daily cleaning of work clothing, obligatory shower)	☐	☐	☐
Provision of separate storage fa-cilities for work clothes	☐	☐	☐
Formal/external mask cleaning and filter changing regime	☐	☐	☐
Blood-lead monitoring	☐	☐	☐
Continuous measurement of air concentrations to detect unusual exposures	☐	☐	☐
Creating a culture of safety	☐	☐	☐
Other measures			
Other (please specify):	☐	☐	☐
Effective OEL			
In achieving these BLV, which OEL (airborne concentration without PPE) would you expect to also achieve?	150 µg Pb/m³ 100 µg Pb/m³ 50 µg Pb/m³ 20 µg Pb/m³ 4 µg Pb/m³ I don't know	150 µg Pb/m³ 100 µg Pb/m³ 50 µg Pb/m³ 20 µg b/m³ 4 µg Pb/m³ I don't know	150 µg Pb/m³ 100 µg Pb/m³ 50 µg Pb/m³ 20 µg Pb/m³ 4 µg Pb/m³ I don't know

D5) What is your estimated range of total <u>initial investment</u> likely to be incurred at this facility to achieve the following BLV reference values?

	300 µg Pb/L blood	**150 µg Pb/L blood**	**45 µg Pb/L blood** **Only applies to female workers under 50**
< €10,000	☐	☐	☐
€10,000 - €100,000	☐	☐	☐
€100,000 - €1 million	☐	☐	☐
€1 -10 million	☐	☐	☐
€10 -100 million	☐	☐	☐
€100 -1 billion	☐	☐	☐
Over € 1 billion	☐	☐	☐
Don't know	☐	☐	☐

D6) What is your estimated range of total annual <u>*recurrent costs*</u> likely to be incurred at this facility to achieve the following BLV reference values?

	300 µg Pb/L blood	**150 µg Pb/L blood**	**45 µg Pb/L blood** **Only applies to female workers under 50**
< €10,000	☐	☐	☐
€10,000 - €100,000	☐	☐	☐
€100,000 - €1 million	☐	☐	☐
€1 -10 million	☐	☐	☐
€10 -100 million	☐	☐	☐
€100 -1 billion	☐	☐	☐
Over € 1 billion	☐	☐	☐
Don't know	☐	☐	☐

D8) How would the BLV reference values impact the competitiveness of your company…

	300 µg Pb/L blood	**150 µg Pb/L blood**	**45 µg Pb/L blood** **Only applies to female workers under 50**

versus compet-itors in EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact
versus compet-itors outside of EU	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact	☐ Significant positive impact ☐ Moderate positive impact ☐ Limited/no impact ☐ Moderate negative impact ☐ Significant negative impact

E) Is your company working to meet voluntary industry targets?

E1) Is your company trying to meet voluntary industry targets?	
International Lead Association (ILA)	☐
Within your company	☐
None	☐
Other*:*	☐
E2) Please specify the targets (concentration, units)	

F) Is your company taking specific measures as regards reducing exposure of women of childbearing age

F1) Does your company have voluntary blood lead level targets for women of childbearing age?	☐ Yes	☐ No
If yes, please specify the targets (concen-tration, units)		
If yes, what kind of risk management measures are implemented to meet these targets?		
F2) Are some activities at this facility re-served only for male workers?	☐ Yes	☐ No

If yes, please specify the activities.		
F3) Do you have any issues with reserving certain activities for male workers only?	☐ Yes	☐ No
If yes, please explain these issues?		

G) Impacts of COVID-19

G1) Has COVID-19 had any impact on exposure levels of lead and its compounds or the numbers of workers exposed to lead and its compounds at this facility? (Examples could include: COVID-19 preventative measures have reduced your exposure levels or on the number of workers exposed has reduce/increased, or some of your operations have had to close due to COVID-19.)

H) Any other comments

H1) Do you have any other comments relevant to this study that you would like to make?

I) Further communication

I1) Please tick if you are happy for the study team to contact you for further clarification or discussion about your responses?	☐
I2) If you prefer this contact to be via a different email or phone number from those you provided at the start of the questionnaire, please provide the details here.	

Thank you for your answers!

Annex 3 Exposure concentrations and blood-lead levels organised by sources of information

1. Exposure data from the Lead REACH Consortium

Air exposure concentrations

Data on air exposure concentrations have recently been collected by the International Lead Association and were analysed by an external consultant (Grewe and Vetter, 2019) in the "Inhalation Monitoring Survey 2019", which was shared with the study team. The data collection covers the same sectors as shown for blood-lead levels below.

Data comprise both stationary and personal measurements. For each work task, data submitters were asked to provide information on RPE used, and anticipated exposure concentrations were calculated based on the personal measurements and the protection factors of used RPE. In Table A3-1, only personal measurement data (outside RPE) is displayed.

Data on exposure concentrations are reported in the Voluntary Risk Assessment Report (VRAR) for lead (LDAI, 2008) as the inhalable fraction. As the data in the VRAR are about 20 years old, and for most sectors are considered outdated, they are not reproduced in the sector specific sections, unless no other data are available.

Table A3-1 Air monitoring data for all workers by sector and workplace and across all samples from the period 2009 - 2019 (Grewe and Vetter, 2019). Personal samples, outside the RPE (mg/m^3).

Sector, workplace		Description	AM	Median	P90	Counts *
1. Primary lead producers, all			**0.39**	**0.11**	**1.04**	**182**
W1	Raw material handling	Ore/concentrate delivery, loading/unloading, and furnace feed mixing	0.61	0.27	1.24	9
W2	Sintering	Feeding/unloading, sinter plant operation	1.63	1.21	2.41	11
W3	Smelting	Furnace operation	0.68	0.29	1.79	16
W4	Refining and casting	Decopperisation, softening (As, Sb, Sn removal), silver separation, zinc distillation, casting of lead ingots/slabs or lead alloy ingots	0.30	0.14	0.58	85
W5	Internal logistics	Storage and shipment of finished goods, intra-facility transport	0.09	0.04	0.11	11
W6	Others	Repair, cleaning, and maintenance, quality control, and engineering	0.05	0.02	0.07	36
2. Secondary lead producers, all			**0.15**	**0.03**	**0.39**	**481**
W1	Raw material handling	Storage, transport and handling of batteries and other lead scrap	0.19	0.02	0.27	48

Sector, workplace		Description	AM	Median	P90	Counts *
W2	Shredding and sorting	For batteries, separation of sulphuric acid, shredding (breaking), grid-separation, elution of PbO-paste, also sorting of other lead scrap	0.11	0.02	0.32	44
W3	Desulphurisation	Sulphur removal from PbO-paste	n.a.	n.a.	n.a.	0
W4	Melting and smelting	Melting of grids, smelting and reduction of paste	0.14	0.03	0.28	190
W5	Refining and casting	Refining of lead, casting of ingots	0.23	0.06	0.63	111
W6	Storage, shipment and transport	Storage and shipment of finished goods, intra-facility transport	0.03	0.02	0.05	12
W7	Others	Repair, cleaning, and maintenance	0.11	0.02	0.25	49
3. Lead battery producers, all			**0.07**	**0.02**	**0.15**	**1553**
W1	Plate manufacturing	Casting/production of grids, oxide production, mixing, pasting, and curing operations	0.03	0.08	0.03	606
W2	Plate treatment	Jar/tank formation, plate washing, drying, cutting	0.17	0.13	0.07	84
W3	Assembly	Stacking, assembly, welding and joining operations	0.18	0.06	0.03	708
W4	Battery formation	Acid filling, formation (wet batteries), finishing	0.15	0.04	<0.01	40
W5	Internal logistics	Storage of raw materials and finished goods, intra-facility transport, shipment	0.10	0.01	<0.01	40
W6	Others	Cleaning and maintenance	0.02	0.05	<0.01	68
4. Lead sheet producers, all			**0.30**	**0.08**	**0.96**	**14**
W1	Raw material handling	Delivery, sorting, furnace loading	0.28	0.26	0.36	2
W2	Melting and refining	Melting, drossing and refining	0.37	0.09	1.28	10
W3	Milling	Milling operations	0.01	0.01	0.01	2
W4	Sawing and slitting	Sawing and slitting operations	n.a.	n.a.	n.a.	0
W5	Storage and shipment	Internal logistics, storage, shipment of finished goods	n.a.	n.a.	n.a.	0

Sector, workplace		Description	AM	Median	P90	Counts *
W6	Others	Repair, cleaning and maintenance	n.a.	n.a.	n.a.	0
6. Lead oxide and stabiliser producers, all			**0.15**	**0.04**	**0.32**	**0.03**
W1	Lead oxide production	Production of “crude” oxide, further oxidation/calcination, grinding/milling, packaging	0.04	0.03	0.08	14
W2	Lead stabiliser production (wet process)	Loading of lead oxide into reaction vessels, slurry formation by addition of water, catalysts and acid compounds, centrifuge operation, drying process, bagging/drumming operations	0.29	0.22	0.44	2
W3	Lead stabiliser compound production (dry/melting process)	Loading of lead oxide into reaction vessels, feeding of molten acid compound to reaction vessels, process control, cooling and forming of tablets, flakes etc., drying process, bagging/drumming operations	n.a.	n.a.	n.a.	0
W4	Mixing/blending of formulated stabiliser products	Material loading (manual or automated handling), operation of mixing/blending equipment, packaging operations	0.51	0.13	1.34	5
W5	Internal logistics	Storage (raw materials, finished goods) and shipment of finished goods	0.03	0.03	n.a.	1
W6	Others	Repair, cleaning, and maintenance, quality control, engineering	0.01	0.01	0.02	4
7. Lead crystal glass production, all			No data available			
8. Ceramic ware production, all			**0.02**	**0.02**	**0.03**	**3**
W1	Production of frits	Raw material handling, smelting, quenching, wet milling/grinding	0.01	0.01	0.02	2
W6	Others	Firing, cleaning and maintenance, quality control	0.03	0.03	n.a	1

* *Please note that the sum of counts for the individual workplace is less than the number for “all”, and the total include some data where the workplace is not specified.*

Blood-lead levels

A summary of the Lead REACH Consortium’s worker blood-lead analysis covering the four-year period from the beginning of 2013 to the end of 2016 is shown below. The data were collected by questionnaire from the 91 members of the Consortium. Furthermore, the questionnaire was distributed by relevant European sector organisations (e.g. Eurobat) to companies with workers exposed to lead, which are not members of the Consortium. For the three largest sectors, primary and secondary lead production and battery production, the survey covers most companies. For some sectors, such as lead crystal glass production, the percentage of companies represented by the survey is uncertain as the total number of companies using lead in these sectors is unknown.

Table A3-3 shows blood-lead levels by various statistical parameters for all workers. In the Consortium's analysis of worker blood-lead data, median blood-lead levels are calculated for a given worker for each year, to avoid bias of the database. For example, if a worker has six blood-lead measurements in a year, then the median of those six values is used in the statistical analysis to calculate the 90th percentile. Thus, every worker is represented once in the database for a given year and has a maximum of four values (annual medians – one per year) for the four-year period. As such, "counts" in the summary refer to the total number of annual median values used to calculate the 90th percentile for the period. Please note that the 90th percentiles are calculated from median values for each worker i.e. they represent 90th percentiles of the median values. This may describe the relative low distance between the P75 and the P90 as compared to the distance between the median (P50) and the P75. 90th percentiles calculated from the entire dataset, where all measurements were used in the calculation of the percentile, would likely be somewhat higher.

For a rough estimate of the number of workers represented by the data, the "counts" figure can be divided by four (which does of assume that each worker is employed at the same company for the full period in question). Data on number of workers by sectors are further described in section 4.5.

Table A3-3 shows the average blood levels of employed women and women of the child-bearing age.

Detailed data for each of the same exposure groups (SEGs) provided by the Lead REACH Consortium is shown in the table below.

Table A3-2 Blood-lead levels for all workers by sector across all samples reported in the Lead REACH Consortium 2013-2016 survey, µg/100 ml (Lead REACH consortium, 2019)

Sector (numbering with reference to this study)	Mean (AM)	Median	P75	P90	Min	Max	Counts *
1. Primary lead producers	14	12	20	27	0.4	62	8,487
2. Secondary lead producers	16	14	21	28	0.2	61	11,478
3. Lead battery producers	14	12	20	29	0.1	85	43,173
4. Lead sheet producers	17	16	24	30	1.0	52	1,438
4. Ammunition producers **	12	9	17	26	-	-	950
6. Lead oxide and stabiliser producers	16	14	22	28	0.5	58	1,540
7. Lead crystal glass production	11	12	19	24	0.1	48	1,047
8. Ceramic ware production	13	12	13	14	1.5	34	1,380

Note: figures have been rounded and are based on four years of data.

* *Each worker is represented by a maximum of four counts representing the median value of each years.*

** *Data for ammunition is for the period 2015-2017.*

Table A3-3 Blood-lead levels by sector for all women and women of childbearing age in the Lead REACH Consortium 2013-2016 survey, µg/100 ml (Lead REACH consortium, 2019)*

Sector	Average (AM) blood-lead levels – all women (µg/100 ml)	Average blood-lead levels – women of childbearing age* (µg/100 ml),	Number of legal entities with women of childbearing age
1. Primary lead producers	6.0	4.2	5 out of 7
2. Secondary lead producers	5.9	3.8	19 out of 27
3. Lead battery producers	9.4	9.9	29 out of 36
4. Lead sheet producers	4.1	4.1	3 out of 10
6. Lead oxide and stabiliser producers	6.2	6.2	5 out of 9
7. Lead crystal glass production	8.3	7.4	1 out of 1
8 Ceramic ware production	11.8	11.2	2 out of 4

Note: figures have been rounded and are based on four years of data (2013-2016)

* *Defined as <46 years*

The table below shows the AM, median and P90 blood-lead levels for each sector by workplace. For primary and secondary production, battery production, lead sheet production and lead oxide and stabiliser producers, the differences in P90 levels are remarkably low. The data reflect the fact that most workers in the production wear respiratory equipment of an efficiency depending on the exposure concentration. The data indicates that direct inhalation of fumes and dust is generally not the major exposure pathway. The blood-lead levels are to a large extent linked to the behaviour of workers and hygiene. Furthermore, many workers rotate between different workplaces. The data also indicate a relatively even level of contamination across the sites; entire sites are contaminated with lead from a large number of sources (such as dust from raw materials and waste handling, fumes from furnaces and smelting operations, dust from material handling). Glass making, raw material handling, forming processes and cutting processes result in significantly higher blood-lead levels.

Table A3-4 Blood-lead levels for all workers by sector and across all samples reported in the Lead REACH Consortium 2013-2016 survey, µg/100 ml (Lead REACH Consortium, 2019)

	Sector, workplace	Description	AM	Median	P90	Counts *
1. Primary lead producers, all			14.2	12.0	**27.0**	**8,487**
W1	Raw material handling	Ore/concentrate delivery, loading/unloading, and furnace feed mixing	15.9	13.3	30.0	318
W2	Sintering	Feeding/unloading, sinter plant operation	28.5	29.0	34.8	48
W3	Smelting	Furnace operation	14.4	12.3	27.0	3,250

	Sector, work-place	Description	AM	Median	P90	Counts *
W4	Refining and casting	Decopperisation, softening (As, Sb, Sn removal), silver separation, zinc distillation, casting of lead in-gots/slabs or lead alloy ingots	17.5	16.2	29.2	1,546
W5	Internal logistics	Storage and shipment of finished goods, intra-facility transport	15.1	13.9	28.4	334
W6	Others	Repair, cleaning, and maintenance, quality control, and engineering	11.6	10.0	22.5	2,889
2. Secondary lead producers, all			**15.5**	**14.4**	**28.0**	**11,478**
W1	Raw material handling	Storage, transport and handling of batteries and other lead scrap	14.6	13.4	25.0	893
W2	Shredding and sorting	For batteries, separation of sulphuric acid, shredding (breaking), grid-sepa-ration, elution of PbO-paste, also sorting of other lead scrap	15.4	14.2	27.0	1,423
W3	Desulphurisa-tion	Sulphur removal from PbO-paste	7.5	10.6	23.2	300
W4	Melting and smelting	Melting of grids, smelting and reduc-tion of paste	17.8	16.7	29.3	2,664
W5	Refining and casting	Refining of lead, casting of ingots	18.1	16.9	29.9	2,104
W6	Storage, ship-ment and transport	Storage and shipment of finished goods, intra-facility transport	13.6	12.9	26.9	409
	Others	Repair, cleaning, and maintenance	13.8	12.4	26.0	2,862
3. Lead battery producers, all			**14.3**	**12.0**	**29.0**	**43,173**
W1	Plate manufac-turing	Casting/production of grids, oxide production, mixing, pasting, and cur-ing operations	19.0	17.9	33.5	7,520
W2	Plate treatment	Jar/tank formation, plate washing, drying, cutting	20.1	19.8	32.9	1,708
W3	Assembly	Stacking, assembly, welding and join-ing operations	16.7	15.0	29.8	12,101
W4	Battery for-mation	Acid filling, formation (wet batteries), finishing	11.3	9.0	22.5	7,358
W5	Internal logistics	Storage of raw materials and finished goods, intra-facility transport, ship-ment	10.9	8.3	22.7	4,090
W6	Others	Cleaning and maintenance	12.3	9.0	27.9	6,517

	Sector, work-place	Description	AM	Median	P90	Counts *
4. Lead sheet producers, all			**16.1**	**17.3**	**30.0**	**1,438**
W1	Raw material handling	Delivery, sorting, furnace loading	29.5	30.0	38.9	26
W2	Smelting and refining	Melting, drossing and refining	20.6	19.0	31.7	222
W3	Milling	Milling operations	19.2	16.9	30.8	98
W4	Sawing and slitting	Sawing and slitting operations	18.2	17.6	28.0	514
W5	Storage and shipment	Internal logistics, storage, shipment of finished goods	15.6	15.2	29.0	151
W6	Others	Repair, cleaning and maintenance	16.6	15.4	29.3	161
6. Lead oxide and stabiliser producers, all			**15.7**	**14.3**	**28.0**	**1,540**
W1	Lead oxide production	Production of "crude" oxide, further oxidation/calcination, grinding/milling, packaging	21.7	21.4	31.0	331
W2	Lead stabiliser production (wet process)	Loading of lead oxide into reaction vessels, slurry formation by addition of water, catalysts and acid compounds, centrifuge operation, drying process, bagging/drumming operations	19.6	18.5	32.6	53
W3	Lead stabiliser compound production (dry/melting process)	Loading of lead oxide into reaction vessels, feeding of molten acid compound to reaction vessels, process control, cooling and forming of tablets, flakes etc., drying process, bagging/drumming operations	16.9	14.1	29.4	205
W4	Mixing/blending of formulated stabiliser products	Material loading (manual or automated handling), operation of mixing/blending equipment, packaging operations	12.9	10.8	24.9	334
W5	Internal logistics	Storage (raw materials, finished goods) and shipment of finished goods	14.9	14.0	26.2	75
W6	Others	Repair, cleaning, and maintenance, quality control, engineering	14.5	12.1	27.7	377
7. Lead crystal glass production, all			**12.8**	**12.1**	**24.0**	**1,047**
W1	Raw material handling	Raw material delivery, batch formulation, pot filling, melting	17.7	18.8	29.9	116

	Sector, workplace	Description	AM	Median	P90	Counts *
W2	Forming processes	Manual operation of multi-pot systems or semi-automated cold-top furnace, blowing operations	19.0	18.6	27.2	664
W3	Cutting processes	Finishing, manual and automated cutting operations	12.6	12.2	20.0	342
W4	Polishing processes	Acid polishing	6.6	5.0	10.3	185
W5	Others	Storage and shipment of finished goods, repair, cleaning and maintenance, quality control, engineering etc.	7.6	6.1	15.2	406
8. Ceramic ware production, all			**12.3**	**11.2**	**14.0**	**1,380**
W1	Production of frits	Raw material handling, smelting, quenching, wet milling/grinding	11.0	12.2	13.8	557
W2	Production and handling of pigments	Weighing, ball milling, filling	7.2	5.0	14.8	187
W3	Lithography	Manual transfer of lithographs	n/a	n/a	n/a	-
W4	Decoration	Manual painting and artwork, printing	n/a	n/a	n/a	-
W5	Glazing of ceramic	Dipping, spraying	12.7	12.7	14.2	79
W6	Others	Firing, cleaning and maintenance, quality control	12.6	12.7	14.2	557

* *Please note that the sum of counts for the individual workplace is less than the number for "all", and the total include some data where the workplace is not specified.*

2. Exposure data from Finland

In 2017, the Finnish Institute of Occupational Health published a booklet on lead exposure in Finland (FIOH, 2017). During the period between 2000 and 2014, almost 12,000 blood measurements and more than 900 urinary measurements on lead were monitored. The data were evaluated per year, sector (or "business field"), occupation and age of the workers.

Blood samples were collected from 226 different sectors, and the sectors contributing with most samples were "general public administration activities" (550 samples), "copper production" (1,626 samples), "casting of other non-ferrous metals" (599 samples) and "collection of non-hazardous waste" (655 samples). Urine samples were collected from 81 different sectors and the largest sectors contributing the total number of samples taken were "manufacture of ceramic household and ornamental articles" (84 samples) and "manufacture of non-domestic cooling and venting equipment" (76 samples). 50 sectors were presented by only 1 sample.

The measured concentrations were compared with the Finnish law-based biological limit values (BLV) of 39.3 and 49.7 µg Pb/100 ml[61] for blood-lead and the biological action limit (BAL) of 2.1 µg Pb/100 ml for urinary lead. Furthermore, the data were compared to the reference (background) concentrations derived from non-exposed workers of 1.9 and 0.17 µg Pb/100 ml for blood and urinary lead, respectively.

75% of all blood samples exceeded the reference background level for blood-lead. 2.1% and 0.9% of all blood samples exceeded the BLV of 39.3 and 49.7 µg Pb/100 ml, respectively.

51% of all urinary samples exceeded the reference level for urinary lead. 2.7% of all urinary samples exceeded the BAL.

Exposure concentrations per sector are presented in the table below.

Table A3-5 Blood-lead levels by sector in Finland 2000-2014 (FIOH, 2017)

Sector	Sector, this study	n	Blood-lead level, µg/100 ml			
			AM	Median	P95	Maximum
Production of lead, zinc and tin	2	311	8.3	6.2	20.7	31.7
Manufacture of cordage, rope, twine and netting	4	11	23.6	19.7	38.7	38.7
Manufacture of weapons and ammunition	4	291	11.4	9.7	26.3	42.3
Manufacture of other electronic and electric wires and cables	4	89	5.2	3.9	13.5	22.0
Manufacture of bearings, gears, gearing and driving elements	5	31	20.3	8.5	64.9	76.7
Casting of iron	5	201	19.9	11.2	55.1	109.2
Casting of other non-ferrous metals	5	599	25.3	25.1	43.9	66.9
Moulding of light alloy	5	54	11.4	11.2	21.5	23.8
Manufacture of basic iron and steel and of ferro-alloys	5	160	6.4	5.6	14.9	25.9
Manufacture of other taps and valves	5	109	4.8	4.4	8.9	15.3
Manufacturing of locks and hinges	5	70	3.1	2.9	7.5	8.1
Other non-ferrous metal production	5	26	3.5	3.1	6.0	13.3
Manufacture of tubes, pipes, hollow profiles and related fittings, of steel	5	17	6.4	5.0	16.8	16.8
Shaping and processing of flat glass	7	108	4.6	3.5	11.6	17.0

[61] All values are recalculated from µmol Pb/l in original document

Sector	Sector, this study	n	Blood-lead level, µg/100 ml			
			AM	Median	P95	Maximum
Manufacture of ceramic household and ornamental article	8	275	3.9	3.3	8.9	14.7
Manufacture of plastic plates, sheets, tubes and profiles	9	116	8.7	6.2	23.4	40.0
Artistic creation	9	15	8.1	6.0	18.9	18.9
Manufacture of builders' ware of plastic	9	42	7.3	6.6	14.3	21.1
Painting	9	21	5.2	4.6	8.7	14.1
Construction of roads and motorways	9	110	3.1	2.3	8.7	28.2
Manufacturing of other plastic products	9	117	1.9	1.9	4.1	6.4
Repair and maintenance of motor vehicles (excluding tires)	10	264	10.4	5.4	33.6	70.7
Manufacture of non-domestic cooling and ventilation equipment	10	12	15.3	16.0	31.3	31.3
Manufacture of communication equipment	10	28	4.4	2.5	11.6	12.2
Manufacture of electronic components	10	400	4.1	2.3	11.6	65.5
Manufacture of medical and dental instruments and supplies (excl. dentures)	10	10	5.2	4.1	9.9	9.9
Manufacture of electronic circuits	10	50	3.9	3.1	9.5	10.6
Manufacture of electric motors, generators and transformers	10	41	4.1	3.1	8.9	15.1
Roofing activities	10	13	1.9	1.5	7.5	7.5
Manufacturing of other electrical appliances	10	74	2.1	1.7	4.1	6.6
Manufacture of irradiation, electromedical and electrotherapeutic equipment	10	21	1.9	1.9	2.9	3.9
Activities of sport clubs	11	10	29.8	29.6	54.1	54.1
Police service	11	69	6.8	4.6	16.0	31.5
National defence/military	11	252	4.4	3.3	9.7	50.8
Recycling of assorted material	12	56	5.6	3.1	15.5	28.2
Dismantling of wrecks	12	32	10.8	10.4	23.6	27.8

Sector	Sec-tor, this study	n	Blood-lead level, µg/100 ml			
			AM	Median	P95	Maximum
Remediation activities and other waste management services	14	41	4.8	2.7	8.7	42.5
Treatment and disposal of hazardous waste	14	153	3.1	2.7	6.4	9.9
Treatment and disposal of non-hazard-ous waste	14	44	2.9	2.1	5.6	11.0
Collection of non-hazardous waste	14	655	2.3	1.9	4.6	23.0
Sewerage	14	29	2.1	1.7	4.6	5.2
Production of copper	15	1626	14.9	13.1	32.9	57.2
Medical research and development	15	31	8.3	7.0	18.0	42.1
Private doctors, medical clinics and simi-lar specialized medical services	15	391	4.4	2.5	15.1	66.1
Laboratory examinations	15	154	4.8	2.9	14.1	41.4
Research and development on other nat-ural sciences	15	86	3.9	3.3	9.1	11.6
Other printing	15	13	3.7	2.5	8.9	8.9
Other technical testing and analysis	15	78	2.5	1.9	7.0	9.9
Support activities for other mining and quarrying	15	98	1.7	1.2	3.9	6.4
Mining of other non-ferrous metals	15	28	1.9	1.9	3.1	3.3

n.e.c.: not elsewhere classified.

*** Sector numbering refers to study numbering (best estimate). For some of the sectors the most likely application of lead has been suggested.*

n = number of samples.

Description is translated from Finnish.

Furthermore, the evaluation of the data over time shows that blood and urinary lead levels decreased between 2000 and 2014. The 95th percentile of blood-lead levels decreased from 35 µg Pb/100 ml (n = 962) in 2000 to 17 µg Pb/100 ml (n=742) in 2014. The 95th percentile of urinary lead levels decreased from 4.6 µg Pb/100 ml (n = 36) in 2000 to 0.64 µg Pb/100 ml (n=60) in 2014.

3. Exposure data from France

Data from the two French occupational exposure databases COLCHIC (Occupational exposure to chemical agents database) and SCOLA have been provided for this study by the

French Ministry of Labour. The databases include data on lead workplace concentrations by sector.

A descriptive analysis and comparison of the COLCHIC and SCOLA databases has been published by Mater et al. (2016). The origin of the data in the two databases are different. The data collected in COLCHIC database come from measurement campaigns performed in companies under the national social security scheme. The choice of targets leading to the measurements in this database stems from general prevention programs defined by a period of 4 years by the national health insurance system, as well as from national sampling surveys. The data in the SCOLA database originates from certified laboratories, which take measurements at the request of companies in order to fulfil their regulatory obligations. COLCHIC and SCOLA include data measured from the same industrial settings and share a similar set of ancillary information. According to Mater et al. (2016), the duration of sampling was significantly shorter in COLCHIC than in SCOLA. Whereas SCOLA is related to regulatory compliance assessment, with strict sampling guidelines, COLCHIC data are measured in companies within industries targeted as potentially problematic. This may explain why the concentrations reported in the COLCHIC database are generally higher than the concentrations in SCOLA, as explained by the authors: "*The comparison empirical cumulative distribution curves show that the concentrations recorded in COLCHIC are higher than in SCOLA for the majority of the agents included in the comparison, with a median ratio of the 50th percentile of concentrations around 3. Higher exposure levels in COLCHIC is not implausible, since it contains data presumably measured in situations where potential risk was suspected, whereas compliance must be verified in all situations where a contaminant is deemed present in the workplace. Indeed, a majority (67%) of measurements in COLCHIC were undertaken with the reason for sampling being "possible risk of exposure". It is therefore possible that COLCHIC would reflect the higher tail of exposure distribution compared to what is found in SCOLA."* (Mater et al., 2016)

The lower concentrations reported in the SCOLA database are more likely to reflect 8h-TWA data; these data are presented here and in the sector-specific sections.

Table A3-6 Occupational exposure data by sector in France from 2009-2017, 8h-TWA in mg/m^3. Extract from the French SCOLA database, 2009-2017 (INRS, 2018b).

Code*	Sector**	Description	n	Exposure concentration, mg/m^3			
				AM	Median	P95	Max
2443Z	2	Metallurgy of lead, zinc or tin	1259	0.505	0.071	2.379	18.169
2720Z	3	Manufacture of batteries and accumulators	879	0.135	0.041	0.568	4.912
2432Z	4	Cold rolling of sheets	111	0.665	0.085	3.115	12.180
2814Z	4	Manufacture of other plumbing fixtures	20	0.036	0.017	0.139	0.287
2434Z	4	Cold wire drawing	55	0.047	0.007	0.134	0.867
2599B	4	Manufacture of other metal articles	110	0.048	0.009	0.105	2.862
2540Z	4	Arms and ammunition manufacturing	36	0.020	0.013	0.060	0.091

Code*	Sector**	Description	n	Exposure concentration, mg/m³			
				AM	Median	P95	Max
2732Z	4	Manufacture of other electronic or electric wires and cables	105	0.009	0.002	0.036	0.116
2511Z	4	Manufacture of metal structures and parts of structures	36	0.006	0.001	0.022	0.098
2442Z	5	Aluminium metallurgy	58	0.001	0.001	0.002	0.010
2453Z	5	Light metals foundry	24	0.001	0.001	0.001	0.002
2452Z	5	Steel foundry	21	0.017	0.003	0.093	0.093
2454Z	5	Foundry of other non-ferrous metals	34	0.018	0.020	0.037	0.050
2014Z	6	Manufacture of other organic basic chemicals	23	0.001	0.001	0.001	0.002
2012Z	6	Manufacture of dyes and pigments	24	0.044	0.034	0.095	0.120
3250B	7	Manufacture of glasses	57	0.001	0.001	0.003	0.006
2312Z	7	Shaping and processing of flat glass	5	0.056	0.030	0.185	0.480
2319Z	7	Manufacture of other glass articles, including technical glass	129	0.026	0.005	0.094	0.625
2313Z	7	Hollow glass manufacturing	144	0.096	0.002	0.081	6.030
2341Z	8	Manufacture of ceramics for domestic or ornamental use	45	0.011	0.001	0.052	0.154
2221Z	9	Fabrication of plates, sheets, tubes and profiles in plastics	37	0.003	0.001	0.007	0.056
4334Z	9	Painting and glazing	84	2.084	0.000	10.035	62.000
2030Z	9	Manufacture of paints, varnishes, inks and sealants	94	0.066	0.011	0.356	1.385
2016Z	9	Manufacture of basic plastic materials	159	0.013	0.001	0.047	0.379
2211Z	10	Manufacture and rethreading of tires	27	0.001	0.001	0.003	0.007
2712Z	10	Manufacture of dissecting and electric control equipment	54	0.001	0.001	0.003	0.007

Code*	Sec-tor**	Description	n	Exposure concentration, mg/m³			
				AM	Median	P95	Max
2711Z	10	Manufacture of electric motors, generators and transformers	23	0.002	0.001	0.005	0.035
2611Z	10	Manufacture of electronic components	107	0.002	0.000	0.005	0.095
4399B	10	Assembly work of metal structures	22	0.067	0.065	0.169	0.265
2651B	10	Scientific and technical instrumentation manufacturing	123	0.019	0.002	0.097	0.195
3250A	10	Manufacture of medical-surgical and dental equipment	26	0.012	0.003	0.071	0.088
2899B	10	Manufacture of other special machines	43	0.015	0.005	0.057	0.152
2790Z	10	Manufacture of other electrical equipment	34	0.018	0.014	0.053	0.090
2612Z	10	Manufacture of assembled electronic boards	120	0.007	0.001	0.051	0.111
8424Z	11	Public order and security activities	38	0.003	0.001	0.009	0.026
8422Z	11	Defence	131	0.063	0.023	0.238	0.397
9312Z	11	Activities of sports clubs	22	0.045	0.058	0.091	0.096
4311Z	13	Demolition work	25	0.349	0.002	1.764	3.160
3831Z	13	Dismantle wrecks	134	0.056	0.013	0.224	0.820
3811Z	14	Collection of non-hazardous waste	293	0.001	0.001	0.003	0.063
3821Z	14	Treatment and disposal of non-hazardous waste	634	0.025	0.001	0.015	3.731
3822Z	14	Treatment and elimination of hazardous waste	103	0.002	0.001	0.010	0.055
3900Z	14	Remediation and other waste management services	111	2.129	0.023	15.439	49.226
3832Z	14	Sorted waste recovery	769	0.037	0.003	0.112	3.520
3812Z	14	Collection of hazardous waste	30	0.024	0.018	0.050	0.056

Code*	Sector**	Description	n	Exposure concentration, mg/m^3			
				AM	Median	P95	Max
7219Z	15	Research and development in other physical and natural sciences	31	0.000	0.000	0.002	0.006
2051Z	15	Manufacture of explosive products	347	0.033	0.019	0.119	0.362
7120B	15	Analyses, tests and technical inspections	75	0.012	0.002	0.069	0.098

* *SCOLA database code. Description is here translated from French* n = number of samples

** *Sector numbering refers to study. For some of the sectors the most likely application of lead has been suggested.*

n = number of samples

4. Exposure data from the German MEGA database

The German institute for research and testing of the German Social Accident Insurance (IFA) regularly publishes data from the MEGA database.

Data on lead are published in two evaluations: the MEGA evaluations for lead (IFA, 2010) and the MEGA evaluations on lead as additives in polyvinyl chloride (PVC; IFA, 2011). The evaluations included both lead and its compounds.

Both stationary and personal samples were included in the evaluations if they were assessed to be representative for actual exposure. The criteria for inclusion of measured data into the evaluation were:

- Measured data relates to exposure
- Sampling time ≥ 1 hour
- Exposure time ≥ 6 hours
- Data sets contained ten or more measurements.

The data were evaluated per industry group (sector) and work area group, and presented either by sampling type (stationary and personal samples) or whether local exhaust ventilation (LEV) was used. In the following two sections, exposure concentration data by sector are presented with use of LEV and without use of LEV. The presented data contain approximately equal amounts of stationary and personal samples, but the sampling type is not available from the source data in this aggregation of data.

Concentrations are reported as median concentrations (P50), P90 and P95 concentrations. Arithmetic or geometric mean concentration values are not available.

Exposure data where LEV was used

The table below shows exposure data where LEV was used. However, no information about the efficiency of the LEV is provided. The data comprise roughly equal numbers of personal and stationary samples. Median concentrations comply with the current OEL of 0.15 mg/m^3 for all sectors where measurements were taken. 95th percentile concentrations exceed the OEL of 0.15 mg/m^3 occasionally, most pronounced in the sectors of "Porcelain, pottery, sanitary, tiles", "Hollow glass and flat glass, technical glass" and "Lead accumulators, nickel cadmium batteries".

Table A3-7 Exposure data from the German MEGA database, where LEV was used, including personal and stationary samples, 2000 - 2009. (IFA, 2010)

Sector/ occupation	Sector **	n	No of companies	Values < LOQ (%)	Exposure concentration, mg/m^3			Period
					Largest LOQ	Median	P95	
All sectors (apart from lead in PVC)		**2724**	**763**	**34.7**	**4.8**	**0.0059**	**0.35**	**2000-2009**
Lead accumulators, nickel cadmium batteries	3	364	18	1.9	0.0013	0.072	0.9	2000-2009
Foundry	5	177	54	10.2	0.0096	0.024	0.32	
Chemical industry	6	54	19	38.9	0.0056	0.0065	0.48	
Hollow glass and flat glass, technical glass	7	273	58	20.9	0.04	0.026*	0.56	
Porcelain, pottery, sanitary, tiles	8	334	82	34.4	0.015	0.0037*	0.23	
Processing and manufacture of plastics and rubber	9	105	44	32.4	0.0065	0.0059*	0.17	
Painting and varnishing	9	9	2	22.2	0.01	-	-	
Lead works	10	42	3	0	-	0.075	0.32	
Sports association, police	11	22	5	36.4	0.0027	0.0020*	0.32	
Cleaning of buildings, waste disposal	13	65	24	6.2	0.0064	0.048	0.25	
Manufacture and treatment of friction lining (brake lining and clutch lining)	15	37	6	29.7	0.0038	0.0023*	0.11	
Blast furnaces, rolling mills	15	57	15	1.8	0.014	0.026	0.93	
Electroplating	15	84	41	48.8	0.01	0.0017*	0.33	
Printing office	15	13	6	84.6	0.003	-	0.038	

* *Concentration below largest LOQ or largest LOQ unknown.*

** *Sector numbering refers to study numbering. For some of the sectors the most likely application of lead has been suggested.*

n=number of samples

Exposure data without LEV

The table below shows exposure data without use of LEV. Median concentrations (P50) comply with the current OEL of 0.15 mg/m^3 for all sectors where measurements were taken.

95th percentile concentrations often exceed the OEL of 0.15 mg/m³, most pronounced in the transport and construction sectors.

Table A3-8 Exposure data from the German MEGA database, without use of LEV, including personal and stationary samples, 2000 - 2009 (IFA, 2010)

Sector/ occupation	Sectors* *	n	No. of companies	Values < LOQ (%)	Exposure concentration, mg/m³			Period
					Largest LOQ	Median	P95	
All sectors (apart from lead in PVC)		**1,633**	**486**	**38.9**	**0.043**	**0.0035***	**0.22***	**2000-2009**
Lead accumulators, nickel cadmium batteries	3	47	9	0	-	0.051*	0.61*	
Foundry	5	123	29	11.4	0.0064	0.022	0.21	2000-2009
Chemical industry	6	21	14	47.6	0.01	0.0027*	0.066	
Hollow glass and flat glass, technical glass	7	275	53	14.9	0.0048	0.011	0.24	
Porcelain, pottery, sanitary, tiles	8	70	34	44.3	0.0025	0.0013*	0.034	
Processing and manufacture of plastics and rubber	9	77	30	27.3	0.0096	0.0046*	0.09	
Painting and varnishing	9	33	8	0	-	0.041*	0.20*	
Lead works	10	11	4	36.4	0.015	0.029	0.86	
Sports association, police	11	12	4	50	0.0029	0.0027*	0.52	
Cleaning of buildings, waste disposal	13	93	34	18.3	0.0048	0.0083	0.48	
Electroplating	15	17	8	41.2	0.0015	0.0010*	0.068	
Blast furnace, rolling mills	15	36	14	8.3	0.001	0.016	0.094	
Manufacture and treatment of friction lining (brake lining and clutch lining)	15	21	2	23.8	0.054	0.0057*	0.028*	

*   *Concentration below largest LOQ or largest LOQ unknown.*

**   *Sector numbering refers to study numbering. For some of the sectors the most likely application of lead has been suggested.*

5. Ireland

The Irish safety of lead at work guide (HSA, undated) provides a general description of works where significant exposure to lead is likely and works with less exposure; see the table below.

Table A3-9 Types of work and workplaces with potential to result in significant and low exposure, respectively (only works within the scope of this report included). (HSA, undated)

Lead work	Examples of industries and processes where such work could be carried out
Lead work where there is liable to be significant exposure to lead (unless the employer provides adequate controls)	
Lead dust, fumes and vapours. High-temperature lead work (above 500°C) e.g. lead smelting, melting, refining, casting and recovery processes, lead burning, welding and cutting.	Lead smelting and refining. Casting of certain non-ferrous metals, e.g. gun metal battery grids. Leaded steels manufacture. Scrap metal and wire-patenting processes. Burning of lead coated and painted plant and surfaces in demolition work. Ship-building, breaking and repairing. Chemical industry. Radiator repair.
Work with lead compounds which give rise to lead dust in air e.g. any work activity involving a wide variety of lead compounds.	Manufacture of lead-acid batteries, paints and colours, lead compounds, rubber products, fire assay, i.e. the use of lead oxides for the assay of precious metals by the process of cupellation. Certain mixing and melting processes in the glass industry. Certain colour preparations and glazing processes in the pottery industry. High-speed mixing and blending of plastics moulding powders containing lead stabilisers or colours. Work with low solubility lead compounds where poor working practices and standards of cleaning exist. Battery breaking. Manufacture of detonators (explosives industry).
Abrasion of lead giving rise to lead dust in air, e.g. dry discing, grinding, and cutting by power tools.	Miscellaneous industries, e.g. motor vehicle body manufacture and repair of leaded car bodies. Firing small firearms on indoor ranges. Blast removal and burning of old lead paint.
Spraying of lead paint and lead compounds and low solubility lead compounds.	Painting bridges, buildings etc. with lead paint.

Lead work	Examples of industries and processes where such work could be carried out
Work with low solubility inorganic lead compounds.	Work which is poorly controlled. This might be because of poor ventilation, housekeeping, personal hygiene or lack of proper welfare, eating drinking or smoking facilities.
Paint stripping.	Furniture and joinery restoration, e.g. removal of old lead paint from antique furniture, doors, window in frames etc. by immersion in a bath of caustic soda or dichloromethane, and scrapping off the residual sludge. May be followed by pressure washing and sanding.
Craft work.	Sculpture of bas relief in lead sheet.
Work with lead not liable to result in significant exposure	
Work with galena (lead sulphide).	Mining and working of galena when its character or composition is not changed.
Low temperature melting of lead (below 500 °C). Such low temperatures control the fume but some care is still required in controlling any dust from the dross.	Plumbing; soldering.
Work with materials which contain less than 1% lead.	
Work with lead in emulsion or paste form where the moisture content is such and is maintained so that lead dust and fume cannot be given off throughout the duration of the work.	Brush painting with lead paint and using some stabilisers for plastics.
Handling of clean solid lead metal e.g. ingots, pipes, sheets, etc.	Miscellaneous metal industries, stock holding, general plumbing with lead sheet.

6. Exposure data from Romania

Air exposure concentrations

A dataset on occupational exposure concentrations by sectors and years in Romania (CNMRMC, 2019) has been obtained as part of the stakeholder consultation for the previous OEL study (Lassen et al., 2019) . The same dataset has recently been published by Negru et al. (2020.)

The data are represented by ranges (min-max). The national Binding Limit Value in Romania (8-h TWA) is 0.15 mg/m^3.

Table A3-10 Exposure concentrations by sector and year in Romania (Negru et al., 2020)

Sector	Sector No *	Exposure concentrations, mg/m^3							
		2012	2013	2014	2015	2016	2017	2018	2019
Manufacture of batteries	3			0.01 – 0.18	0.004 – 0.16	0.009-0.096	N.D - 0.105	N.D - 0.167	
Manufacture of non-ferrous metal structures	4	0.006							
Production of electric and electronic components	4	0.007-0.0131	N.D*-0.074	0.0003 -0.002	0.0002 -0.005	0.0002-0.0004	0.0003	0.0007	0.0001
Manufacture of articles of metal wire	4				0.003 – 0.036			N.D	
Production and sale of dyes and additives for plastics	6		0.006 - 0.16						
Manufacture of thermal ceramic products (terra-cotta)	8		0.02-0.06		0.01 - 0.22			0.03 – 0.12	
Assembling of electronic components	10				0.03	0.0001-0.0007		0.002-0.004	0.01-0.02
Waste collection and treatment of electrical and electronic equipment	14			0.074					
Geochemical analysis laboratory	15								
Pantograph workshop (Bureau of Engraving)	15				0.013	0.016			
Computer repair	15				0.068				
Metalwork	?						0.0002-0.004		

Sector	Sector No *	Exposure concentrations, mg/m³							
		2012	2013	2014	2015	2016	2017	2018	2019
Production of auto compo-nents	?	0.008							
Mechanical re-pairs	?		0.017	0.075-0.125					
Research								0.16	

* *Sector numbering refers to the numbers used in the current study*

Blood-lead levels

Data on blood-lead levels for occupationally exposed workers in Romania are shown in the table below. PbB values above 40 µg/100 ml were found in the following sectors: production of lead, recovery of lead from waste batteries (recycling), manufacture of batteries, and manufacture of articles of metal wire.

Table A3-11 Blood-lead values for occupational exposed workers by sector by year in Romania (Negru et al., 2020).

Year	Sector	Sector No *	Number of workers	Sex	Mean (AM) ± SD µg/100 ml	Range µg/100 ml
2011	Production of lead	2	58	Men	18.74 ± 9.52	5.2 – 47.2
2012	Production and sale of dyes and additives for plastics	6	38	Men	5.23 ± 3.40	1.4 – 14.5
	Recovery of lead from waste batteries	2	75	Men (65) Women of child-bearing age (8) Women (2)	46.73 (average)	
	Manufacture of ther-mal ceramic products (terracotta)	8	31 (total number)	Men Women of child-bearing age Women	-	3.4-32.3 - 19.5 – 31.2
2013	Geochemical analysis laboratory	15	23	Men	-	0.9 – 13.2
	Recovery of lead from waste batteries	2	73	Men (64) Women of child-bearing age (8) Women (1)	45.34 (average)	

Year	Sector	Sector No *	Number of workers	Sex	Mean (AM) ± SD µg/100 ml	Range µg/100 ml
	Manufacture of thermal ceramic products (terracotta)	8	31 (total number)	Men Women of child-bearing age Women	-	21.6 – 30.5 21.1 – 34.8 8.5 – 38.5
2014	Manufacture of batteries	3	89	Men	-	37 – 57.8
			2	Women of child-bearing age	-	10.7- 11.7
			3	Women	-	12.0 – 12.9
	Manufacture of car batteries	3	277	Men	32.09 (average)	-
			10	Women	15.34 (average)	-
	Recovery of lead from waste batteries	2	73	Men (63) Women of child-bearing age (5) Women (5)	40.36 (average)	
	Manufacture of articles of metal wire	4	97	Men		4.0 – 45.0
2015	Production and sale of dyes and additives for plastics	6	59	Men	7.92 ± 5.52	0.8 – 32.9
			2	Women of child-bearing age	-	0.8 – 3.2
			1	Woman	-	2.8
	Manufacture of batteries	3	288	Men	-	3.6 – 58.9
			4	Women of child-bearing age	-	3.6 – 13.2
			12	Women	-	10.7 – 14.8
	Manufacture of car batteries	3	536	Men	18.30 (average)	
			96	Women	3.47 (average)	
	Recovery of lead from waste batteries	2	68	Men (58) Women of child-bearing age (5) Women (5)	34.32 (average)	
	Manufacture of articles of metal wire	4	97	Men	-	4.2 – 51.0

Year	Sector	Sector No *	Number of workers	Sex	Mean (AM) ± SD µg/100 ml	Range µg/100 ml
2016	Manufacture of thermal ceramic products (terracotta)	8	26 (total number)	Men Women of child-bearing age Women	-	19.5 – 26.4 23.2 – 39.9 11.5 – 39.9
	Manufacture of car batteries	3	543 94	Men Women	17.10 (average) 4.71 (average)	
	Recovery of lead from waste batteries	2	73	Men (62) Women of child-bearing age (5) Women (6)	33.96 (average)	
	Manufacture of articles of metal wire	4	97	Men		2.4 – 31.7
2017	Manufacture of thermal ceramic products (terracotta)	8	26	Men Women of child-bearing age Women	-	18.6 – 27.9 17.5 – 36.3 7.5 – 38.8
	Manufacture of car batteries	3	531 87	Men Women	16.94 (average) 3.62 (average)	
	Recovery of lead from waste batteries	2	78	Men (67) Women of child-bearing age (4) Women (7)	35.01(average)	
	Manufacture of articles of metal wire	4	97	Men		1.9 – 27.0
2018	Manufacture of thermal ceramic products (terracotta)	8	26	Men Women of child-bearing age Women	-	24.2 – 28.8 26.6 – 28.3 23.5 - 38.9

Year	Sector	Sector No *	Number of workers	Sex	Mean (AM) ± SD µg/100 ml	Range µg/100 ml
	Manufacture of car batteries	3	524	Men	16.04 (average)	
			90	Women	3.54 (average)	
	Recovery of lead from waste batteries	2	77	Men (65) Women of child-bearing age (4) Women (8)	32.84 (average)	
	Manufacture of articles of metal wire	4	97	Men		0.1 – 40.62
2019	Recovery of lead from waste batteries	2	77	Men (67) Women of child-bearing age (2) Women (10)	32.45 (average)	
2019	Manufacture of articles of metal wire	4	97	Men		0.6 – 54.5

* *Sector numbering refers to the numbers used in the current study*

7. Exposure data from Sweden

Julander et al. (2020) investigated the possible exposure routes in seven workers working in a brass foundry and, specifically, if metal cutting fluids used by the workers could lead to skin absorption of Pb. The different bronze alloys at the facility may contain up to 20% Pb. During work, the workers wore polycotton overalls and some used rubber gloves. No other personal protective equipment was used during the ordinary work tasks. In the foundry, local exhaust ventilation was installed at the workstations and workers were regularly informed on the importance of hand hygiene.

Julander et al. (2020) found Pb air concentrations (<0.1–3.4 µg/m^3) well below the Swedish occupational exposure limit value. Blood Pb was in the range of <0.72–33 µg/dl (personal sampling), and Pb on skin surfaces, after performing normal work tasks during 2 h, was in the range of 0.2–48 µg/cm^2. Two workers had higher amounts of Pb on their hands and in their blood (29 and 33.2 µg/dl) than the rest of the workers, possibly as a result of not wearing gloves.

The contributions of inhalation, skin absorption and transfer from hand-to-mouth to blood Pb levels were estimated. The results clearly show that hand-to-mouth behaviour gives the highest contribution to blood Pb (16.2 µg/dl), followed by skin absorption (3.44–6.33 µg/dl) and in-halation (2.02 µg/dl) in the studied brass foundry workers.

Table A3-12 Blood-lead levels in brass foundry in Sweden (from Julander et al. 2020).

Sector	Sector, this study	n	Blood-lead level (µg/dl)			
			AM	Median	P95	Maximum
Brass foundry	5	7	13.7*	7.7*	31.9*	33.2

** The blood level of one of the seven workers was below LOD (0.72 µg/dl); for statistical analysis the value was divided by square root of 2.*

8. Exposure data from the UK

Comprehensive data on occupational exposure to lead is available for UK (actually Great Britain) and reproduced below. Data on workplace exposure levels are not publicly available.

Blood-lead levels

In Great Britain, all workers with significant lead exposure – as defined in the Control of Lead at Work (CLAW) Regulations (SI 2002/2676) – are required to undergo medical surveillance, which includes measurement of blood-lead concentrations (HSE, 2019). Employers are responsible for deciding whether workers should be under medical surveillance, which is then carried out at least every 12 months by an HSE appointed doctor. The statistics shown in the tables below are compiled from annual summaries from appointed doctors of blood-lead levels among workers who have been examined under this surveillance regime. The reporting year is from April to March the following year; for example, 2011/12 includes the measurements from April 2011 to March 2012. Data on air exposure levels in the UK are not publicly available.

All statistics are based on the highest recorded blood-lead level for each individual. Please note that statistics from the Lead REACH Consortium shown in the previous section is based on median values for each worker, which will result in lower values. For the purpose of estimating total potential effects of the exposure of workers, median or mean (AM) values would better represent the actual exposure than the highest levels.

The CLAW regulations specify blood-lead concentration levels (measured in µg/100 ml) at which an appointed doctor must decide if a worker should no longer be exposed to lead (known as the "suspension level"). HSE's medical inspectors, HSE appointed doctors (who are the main group of doctors carrying out statutory medical surveillance of lead-exposed workers in the UK), and a body of scientific evidence indicate that individuals with blood-lead levels at or above the suspension limit and who are suspended from working with lead do not normally have symptoms described as “lead poisoning”. Such workers are removed from further exposure to lead to reduce the likelihood of such symptoms developing (HSE, 2019).

Table A3-13 Breakdown of male lead workers under medical surveillance by highest recorded blood-lead level and industrial sector – UK (2017/18). Please note that width of ranges is not the same. (HSE, 2019).

Sector	Sector No *	Highest blood-lead measurement (µg/100 ml) – male workers											Total male workers
		<10	10-19	20-24	25-29	30-34	35-39	40-49	50-59	60-69	70-79	>80	
Smelting, refining, alloying and casting	1, 5	292	182	75	49	34	34	36	35	8			745
Lead battery recycling	2	115	197	52	17	6	6	1					394
Lead battery manufacture	3	247	336	115	75	23	5	2					803
Manufacture of pigments and colours**	6	-	-	-									19
Manufacture of inorganic or organic lead compounds (including lead salts, fatty acids)	6	27	12	2	6	3	1		1	1			53
Badge and jewellery enamelling and other vitreous enamelling	7	4	1										5
Glass making (including cutting and etching)	7	74	18	10	6	11	4	2					125
Potteries, glazers and transfers	8	2	1										3
Painting of buildings and vehicles	9	174	17	5	5	5	1						207
Work with metallic lead and lead containing alloys	10	194	181	70	81	51	31	38	13	4			663
Demolition industry	12	179	36	14	2	3	5	1	1	2	1	2	246
Paint removal	12	284	58	25	16	14	8	12	7	1			425

Sector	Sec-tor No *	Highest blood-lead measurement (µg/100 ml) – male workers											Total male workers
		<10	10-19	20-24	25-29	30-34	35-39	40-49	50-59	60-69	70-79	>80	
Scrap industry (including pipes, flashing, cables)	12	342	84	21	11	2	2						477
Shipbuilding, repairing and breaking	12	57	3										60
Glass recycling (including TV and moni-tors)	14	25	70	27	23	9	5	7	1				167
Other processes ***	?	440	46	10	6	8	9	4	2			1	526
Total		2,475	1,242	426	297	178	113	105	62	16	1	3	4,918

* *Sector numbering with reference to the numbers used in the current study*

** *Data not reported*

*** *HSE has been asked about further information on “other processes” but this information is only available for each individual company and not summarised by the HSE.*

The proportion of male lead workers under medical surveillance with blood-lead levels at or above 25 µg/100 ml by industrial sector are shown in the figure below. Please note that the figure does not indicate the proportion of all workers in sectors with high blood levels, but the proportion of workers under medical surveillance. The highest proportions of workers under medical surveillance are in the sectors work with metallic lead and lead-containing alloys, glass making and smelting, refining, alloying and casting.

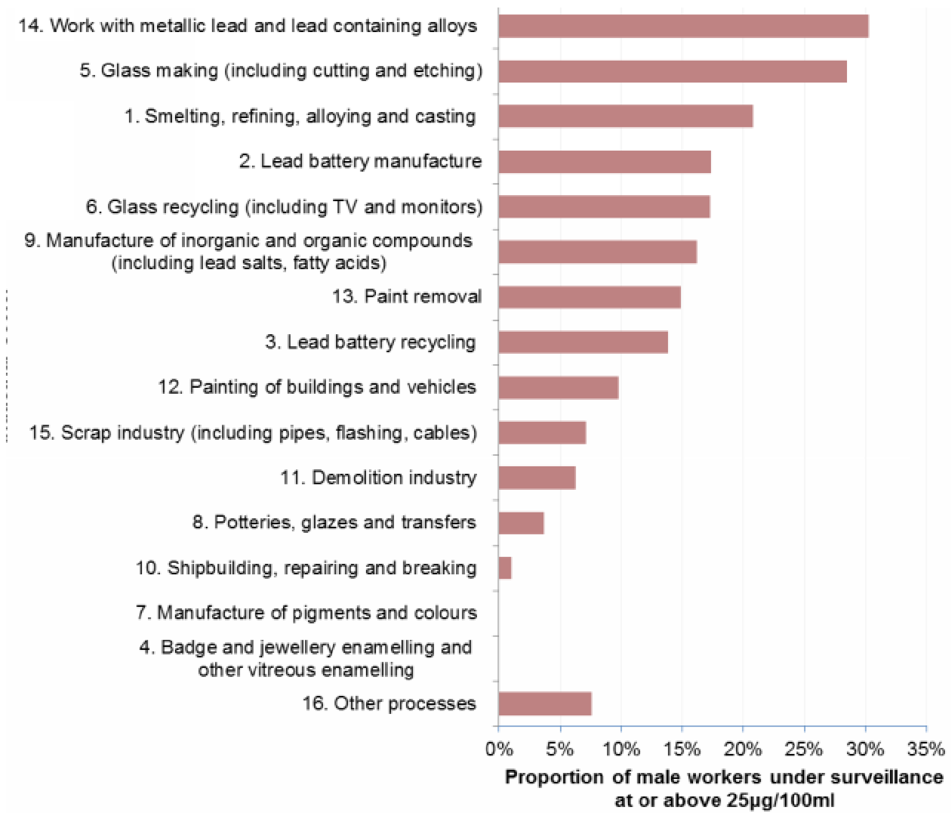

Figure 11-1 The proportion of male lead workers under medical surveillance with blood-lead levels at or above 25 µg/100 ml by industrial sector, three-year average 2015/16 – 2017/18 (HSE, 2019)

Table A3-14 Breakdown of female lead workers under medical surveillance by highest recorded blood-lead level and industrial sector (2017/18). Please note that width of ranges is not the same. (HSE, 2019).

Sector	Sector No *	Highest blood-lead measurement (µg/100 ml) – female workers				Total female workers
		<10	10-19	20-24	25-29	
Smelting, refining, alloying and casting	1, 5	38	6			44
Lead battery recycling*	2	-	-	-		5
Lead battery manufacture	3	17	3			20
Manufacture of pigments and colours	6					
Manufacture of inorganic or organic lead compounds (including lead salts, fatty acids)	6	3	1			4
Badge and jewellery enamelling and other vitreous enamelling	7					
Glass making (including cutting and etching)	7	10	2	1		13
Potteries, glazers and transfers	8					
Painting of buildings and vehicles	9					
Work with metallic lead and lead containing alloys	10	28	11		1	40
Demolition industry	12					
Paint removal*	12	-	-	-		7
Scrap industry (including pipes, flashing, cables)*	12	-	-	-		13
Shipbuilding, repairing and breaking	12					
Glass recycling (including TV and monitors)	14	-	-	-		1
Other processes	-	48	13			61
Total		**170**	**36**	**1**	**1**	**208**

Data on the statistical parameters (AM, median, P95) have been requested from HSE, however, data could not be provided because the original data does not allow for estimation of these statistical parameters. To compare the data with other datasets, approximate AM, median and 95th percentiles have been estimated for all workers for all data for the three periods: 2015/2016, 2016/2017 and 2007/2018. For each of the periods, the highest blood-lead measurement is included. The calculation method is indicated in the notes to the table. The parameters cannot be estimated using exact calculations but are approximated from the blood level distributions. Each worker is only represented by the highest measured value (for each year).

Table A3-15 Breakdown of all workers under medical surveillance by highest recorded blood-lead level (for each year) and industrial sector – based on data from 2015/2016, 2016/2017 and 2017/2018. Calculated from data in HSE (2019)

Sector	Sector No *	n ****	Highest blood-lead measurement (µg/100 ml) – approximate values for all workers		
			Average (AM)**	Median ***	95th percentile ***
Smelting, refining, alloying and casting	1, 5	2,654	12.8	11	32
Lead battery recycling	2	1,949	13.6	14	23
Lead battery manufacture	3	1,002	13.8	12	24
Manufacture of pigments and colours	6	65	6.4	<10	17
Manufacture of inorganic or organic lead compounds (including lead salts, fatty acids)	6	790	9.0	<10	23
Badge and jewellery enamelling and other vitreous enamelling	7	5	7.0	<10	17
Glass making (including cutting and etching)	7	406	10.8	<10	28
Potteries, glazers and transfers	8	61	6.4	<10	19
Painting of buildings and vehicles	9	702	8.8	<10	22
Work with metallic lead and lead containing alloys	10	1,697	14.9	15	34
Demolition industry	12	965	8.7	<10	23
Paint removal	12	1,338	9.8	<10	23
Scrap industry (including pipes, flashing, cables)	12	1,412	9.5	<10	22
Shipbuilding, repairing and breaking	12	255	5.6	<10	11
Glass recycling (including TV and monitors)	14	429	16.4	16	29
Other processes	-	1,555	7.9	<10	19

* *Sector numbering with reference to the numbers used in the current study*

***   Calculated using the midpoint of all concentration bands. For the concentration band "below 10", the value was set at 5 and for the concentration band "over 80", the value was set at 85.*

****   Calculated assuming a linear distribution within the concentration band that included the median or 95th percentile.*

***** Each data represent the maximum measured level for each worker for each period i.e. each worker may be represented by up to three measured levels.*

9. USA

The published blood-lead surveillance data with occupational exposure data by sector from the USA are shown in the tables below. The tables show data for occupational exposure only published for the years 2007 and 2016. The data aggregation and naming of the sectors (NAICS codes) have changed in between these two publications, therefore the data cannot be presented in one table.

In the current study, sectors for which the Lead REACH Consortium has provided data (primary and secondary lead production, battery productions, etc.), represent 58% of the workforce with blood-lead levels above 25 µg/100 ml in the USA dataset from 2007, and 39% of the workforce with blood-lead levels above 25 µg/100 ml in the USA dataset from 2016. Significant subsectors not covered by the Lead REACH Consortium appear to be within construction (Painting and wall covering contractors [related to removal of paint and wallpaper]), secondary smelting and refining of non-ferrous metals, "Highway, street, and bridge construction" (also related to removal of paint) and "All other amusement and recreation industries" (specific use not identified).

The data are not presented with statistical parameters (AM, median, P90, etc.) and consequently are not presented in the sector specific sections.

Table A3-16 Number and percentage of workers with elevated blood-lead levels (BLLs), by industry subsector. Adult Blood-lead Epidemiology and Surveillance (ABLES) program, United States 2007 (covering 34 States) (US DoH, 2009)

Occupational (Industry subsector)	2007 BLL ≥25 µg/100 ml		2007 BLL ≥40 µg/100 ml	
	No. of exposed	% of total	No. of exposed	% of surveyed for each category
Manufacturing, storage batteries	2,524	39.1%	207	8.2%
Metal mining, lead and zinc ores (Copper, nickel, lead, and zinc mining)	672	10.4%	127	18.9%
Construction, painting and paper hanging	399	6.2%	117	29.3%
Manufacturing, primary batteries	573	8.9%	126	22.0%
Manufacturing, secondary smelting and refining of nonferrous metals	447	6.9%	60	13.4%
Manufacturing, primary smelting and refining of nonferrous metals	128	2.0%	21	16.4%
Construction, special trade contractors	96	1.5%	20	20.8%
Manufacturing, copper foundries	78	1.2%	11	14.1%

Occupational (Industry subsector)	2007 BLL ≥25 µg/100 ml		2007 BLL ≥40 µg/100 ml	
	No. of exposed	% of total	No. of exposed	% of surveyed for each category
Construction, bridge, tunnel, and elevated highway construction	34	0.5%	5	14.7%
Manufacturing, nonferrous foundries, except aluminium and copper	75	1.2%	20	26.7%
Manufacturing, rolling, drawing, and extruding of nonferrous metals	56	0.9%	14	25.0%
Services, automotive repair shops	50	0.8%	9	18.0%
Manufacturing, steel works, blast furnaces (including coke ovens), and rolling mills	64	1.0%	5	7.8%
Other industries and unavailable information on industry	1,267	19.6%	215	17.0%
Total exposed at work	**6,463**	**100%**	**957**	**14.8%**

Table A3-17 Number and percentage of workers with elevated blood-lead levels (BLLs), by industry subsector. Adult Blood-lead Epidemiology and Surveillance (ABLES) program, United States 2016 (covering 18 States) (CDC, 2019)

Sector	Industry	2016 Number BLL ≥25 µg/100 ml	% of total*
Manufacturing	Total, manufacturing industries	910	52.1%
	Storage battery manufacturing	448	25.6%
	Nonferrous metal (except copper and aluminum) rolling, drawing, extruding, and alloying	206	11.8%
	Ship and boat building	49	2.8%
	Motor vehicle electrical and electronic equipment manufacturing	48	2.7%
	All other fabricated metal product manufacturing	41	2.3%
	Other manufacturing industries	118	6.8%
Construction	Total, construction industries	308	17.6%
	Highway, street, and bridge construction	103	5.9%
	Painting and wall covering contractors	90	5.1%

Sector	Industry	2016 Number BLL ≥25 µg/100 ml	% of total*
	Residential building construction	26	1.5%
	Commercial and institutional building construction	16	0.9%
	Other construction industries	73	4.2%
Services (except Public Safety)	Total, services (except public safety) industries	198	11.3%
	All other amusement and recreation industries	108	6.2%
	Remediation services	18	1.0%
	Automotive mechanical and electrical repair and maintenance	14	0.8%
	Other services (except public safety industries)	10	0.6%
	Other services industries	48	2.7%
Mining (except Oil & Gas Extraction)	Total, mining industries	29	1.7%
	Copper, nickel, lead, and zinc mining	27	1.5%
	Other mining industries	2	0.1%
Other/missing	Total, other/missing industry information	303	17.3%

* *Percentages of subsectors are calculated based on the reported number of adults.*

Additional information is available for bridge painting contractors (Guth et al., 2020). The objective of the study was to evaluate the effectiveness of exposure controls in preventing elevated blood lead levels (>25 µg/dl) during bridge painting projects. Different work tasks were evaluated 3times over a 4 month period, before and during bridge painting projects.

Geometric means (standard deviations) of all works for the 3 sampling periods can be seen in the table below. Twenty percent of workers in the high-intensity exposure work tasks experienced an incremental increase in BLL >10 µg/dl (maximum increases of 17, 48, 45 and 57 µg/dl). The large increases in BLL document that some high-intensity exposures were not adequately controlled during the first months of exposure, despite of use of recommended exposure controls. With the use of the bio-monitoring data, controls were modified, and lead exposures were adequately controlled 4 months after baseline testing.

BLLs for all sampling periods were log-normally distributed.

Table A3-18 Exposure concentrations (GM – geometric means, SD – standard deviation, µg/dl) in bridge painting workers (from Guth et al. 2020).

Work task/ Exposure group	Baseline		Follow-up 2-months*		Follow-up 4-months*	
	N	GM (SD)	N	GM (SD)	N	GM (SD)
All work tasks	289	8.0 (2.4)	283	11.0 (2.2)	141	12.1 (2.0)
High Exposure Intensity						
Abrasive Blaster	103	9.1 (2.1)	103	10.2 (2.3)	44	9.2 (1.8)
Abrasive Blaster/Painter	58	7.8 (2.7)	54	14.5 (2.2)	32	17.4 (1.8)
Laborer	51	6.0 (2.8)	49	13.1 (2.2)	30	16.9 (1.8)
Painter	6	16 (1.8)	6	14 (1.5)	1	8.0 (1.0)
Medium Exposure Intensity						
Equipment	3	4.2 (2.1)	3	6 (2.6)	2	9.5 (1.1)
Operator	3	19 (1.7)	3	18 (1.6)	5	10 (2.9)
Rigger	11	6.9 (1.8)	11	7.2 (2.1)	1	36.0 (1.0)
Low Exposure Intensity						
Competent Person	289	8.0 (2.4)	283	11.0 (2.2)	18	9.6 (1.8)
Foreman	41	8.1 (2.4)	41	9.0 (1.9)	44	9.2 (1.8)

** After initial exposure.*

10. Other

The Voluntary Risk Assessment Report for lead (LDAI, 2009) includes 31 occupational exposure scenarios, of which many have short descriptions. Description of the scenarios and occupational exposure data from the risk assessment are included in the sector specific sections under 4.4.2.

The IARC monograph on lead contains a wealth of data on exposure concentrations and blood-lead concentrations from around the world. Data has been extracted with a focus on data from EU Member States and other developed countries where exposure situations can be expected to be similar to exposure situations in the EU. Older data are included for application areas where newer, comprehensive data are not available or from non-industrial exposure settings where the exposure levels are less likely to have changed (e.g. shooting ranges or plumbing).

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