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Survey of lead and lead compounds

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version of LOUS from 2009 includes 40 chemical substances and groups of substances which have been classified as dangerous or which have been identified as problematic using computer models or due to other concerns. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding on-going activities under REACH, among others.

On the basis of the surveys, the Danish EPA will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns lead and lead compounds. These substances were included in the first list in 1998 and have remained on the list since that time.

The main reason for the inclusion in LOUS is the hazardous properties of the lead compounds which based on their lead content typically are classified as Repr 1A (may damage the unborn child and suspected to damage fertility); STOT RE2 (may cause damage to organs through prolonged or repeated exposure); Aquatic acute 1 (very toxic to aquatic life); Aquatic chronic 1 (very toxic to aquatic life with long lasting effects). Some lead compounds are further classified with Carc 2 (suspected of causing cancer) or carc 1B (may cause cancer).

The main objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process

The survey has been undertaken by DHI, Denmark, from March 2013 to October 2013

The project participants were:

- Poul Bo Larsen, DHI, Project manager
- Frank Leck Fotel, DHI, contributor
- Tina Slothuus, DHI, contributor
- Ole Hjelmar, DHI, contributor
- Helle Buchardt Boyd, DHI, Quality supervisor
- Jens Tørsløv, DHI, Quality supervisor

The work has been followed by an advisory group consisting of:

- Trine Thorup Andersen, Danish EPA, Chair of advisory group
- Lone Schou, Danish EPA
- Thilde Fruergaard Astrup, Danish EPA
- Susanne Simonsen, Danish Nature Agency
- Pia Vestergaard Lauridsen, Danish Working Environment Authority
- Dorthe Licht Cederberg, Danish Veterinary and Food Administration
- Ulla Hansen Telcs; Confederation of Danish Industry
- Michael Mücke Jensen, Energi og Olieforum
- Sabina Ricevuto, H.J.Hansen Genvindingsindustri A/S
- Steen Hansen, Stena Recycling
- Simon Stig-Gylling, The Danish Construction Association

Data collection

The survey and review is based on the available literature on the compounds, information from databases and if needed direct inquiries to resource persons from i.e. trade organisations or key market actors.

The data search included (but was not limited to) the following:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- On-going regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention, and the Basel Convention.
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Data on eco-labels from the Danish eco-label secretariat (Nordic Swan and EU Flower)
- Pre-registered and registered substances from ECHA's website

A large number of reports and assessments on lead and lead compounds are available from Danish authorities as well as international publications. The most recent and updated information have been found in:

- LDAI (2008). Voluntary Risk Assessment Report on lead metal, lead oxide, lead tetraoxide and lead stabiliser compounds. Lead Development Association International. (Use of the report permitted by the International Lead Association).
- Swedish Chemical Agency (2012a). CLH report: Proposal for Harmonised Classification and Labelling based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance name. Lead. Version 4, 20 September 2012. Dossier submitter: Swedish Chemicals Agency.

Swedish Chemical Agency (2012c). Annex XV restriction report proposal for a restriction. Lead and its compounds in articles intended for consumer use. Version 1, 21 December 2012.

Summary and conclusion

This report covers a survey of metallic lead and all types of organic and inorganic lead compounds and is a part of the review of the Danish EPA List of Unwanted Substances (LOUS), which is conducted from 2012-2015. It is the properties of the lead ion that has driven the inclusion of lead and lead compounds on the LOUS list due to the critical toxic effects on both human health and the environment.

Classification
Lead compounds are toxic substances and lead accumulate in the human body and in the environment.

In EU lead compounds in general are classified as toxic to reproduction due to adverse effects with respect to fertility and the development of the central nervous system of the unborn and developing child. Lead compounds are also classified as toxic following prolonged and repeated exposure due to adverse effects on several organs. Furthermore, they are classified for acute and long-term effects in the aquatic environment.

Until now there has not been any EU-harmonized classification of metallic lead, but currently it is discussed whether classification as toxic to reproduction should also apply for metallic lead.

Regulatory measures in DK and EU
Due to the adverse effects of lead, lead have for many years been regulated both at national level, at EU level and at a global level. Thus, lead and lead compounds may be considered as some of the most extensively regulated compounds in the world.

In EU, ban or strict restrictions have been implemented in a range of applications and sectors; paints, cosmetics, toys, packaging, jewelry, ceramics, electronic equipment, vehicles, petrol, feed, food, drinking water, etc.

Regulation of lead also applies to waste, industrial air-borne emissions, waste water emissions, quality criteria in soil/ sewage sludge/ambient air/ marine water/ and fresh water.

In the occupational environment strict measures apply for securing the safety of the workers including specific guidelines for occupational handling and through occupational limit values for lead and lead compounds. Also, specific measures are taken for protecting young workers and pregnant women towards lead exposure at the work place.

Manufacture and use
Even though lead and lead compounds are subjected to a great number of strict regulatory measures in both Denmark, EU and worldwide, metallic lead and lead compounds are used in very high quantities exceeding an annual consumption in EU of several million tonnes.

Especially *metallic lead* and *tetralead trioxide sulphate* are used in very high tonnages in EU and each of the compounds is registered under REACH at a tonnage level of 1-10 million tonnes per year.

Metallic lead production in EU is either from mining or from recovery of lead in the waste stream. In 2010 a total tonnage level of lead from mining in EU of 259,800 tonnes was reported. Data from 2001 indicate that of the refined lead production 65% was from secondary/recovery production.

On the global level China dominates the lead mining industry accounting for nearly half of the global production. Other major lead mining countries are Australia, USA and Peru.

In EU in 2000 the far highest quantity of lead and lead compounds was used for lead batteries (61%). Other very important uses were: Rolled and extruded products (14%), lead compounds in pigments, stabilisers a.o. (12%), ammunition (3%), alloys (2%), cable sheeting (2%), gasoline additives (1%), and other purposes (5%).

In Denmark, the pattern of consumption of lead has been analyzed in detail for the year 2000. For lead and lead compounds a total annual consumption of 14,900-19,000 tonnes was estimated. The primary uses were batteries (52%) and building materials (23%), while other important uses were fishing tools, keels, PVC, cathode ray tubes, cable sheets, alloys and crystal glass. Most of the lead used is recovered and 12,800-15,500 tonnes of lead was collected for recovery in Denmark in 2000.

In the Danish Product Registry 94 lead compounds were registered in 2011. For many compounds it is not possible to get information on the tonnage levels as this information is confidential since less than three companies have registered. Furthermore, it is not clear whether all registrations are "active". Four different lead pigments are registered with an annual use (2011) between 23 and 191 tonnes per year, whereas metallic lead is registered at a level of 78 tonnes. The use of metallic lead was mainly for welding/ soldering products. From 1997 to 2011 there has been an increasing trend in use of metallic lead and lead chromate (pigment), whereas the use of other lead compounds has declined.

A more exact knowledge concerning the trend in the uses for the various lead applications and the impact of the implementation of the Danish Statutory order on ban of the use of lead is however missing, as most of the Danish figures regarding use volumes refer back to year 2000.

Waste

Due to the EU-harmonised classification of the lead compounds, waste with a lead content above 0.5% should be considered as hazardous waste as this is the concentration limit for classifying lead compounds as toxic to reproduction according to the old classification system. Currently a classification of metallic lead down to a level of 0.03 % is discussed at EU level and adopting of this level would imply that waste containing more than 0.03% (300mg Pb/kg) of metallic lead should be considered as hazardous. Several municipalities in Denmark currently apply limit values of 40 mg Pb/kg and 2500 mg Pb/kg as the limits for clean waste and hazardous waste, respectively.

It can be anticipated that a lower limit for metallic lead may cause problems in terms of classification of large fractions of waste as hazardous.

From appendix 7 it can be seen that in year 2000 the estimated amount of lead included in municipal waste (not subject to recovery) was in the range of 510-1,400 tones. The largest fractions of lead in the waste stream came from fishing tools (210-420 tonnes), lead crystal glass (97-220 tonnes), pigments in paint and plastic 56-170 tonnes, ceramic products (40-150 tonnes), lead sheets (10-100 tonnes); stabilizer in PVC (26-86 tonnes), and from various other metallic parts.
Of this, 290-930 tonnes of lead were directed to incineration and from this an estimated amount of 220-480 tonnes lead were landfilled in deposits.

However, data from 2011 indicate that the lead content in shredder waste due to the high annual tonnage level of this type of waste may contribute significantly to the mass balance of lead in waste.

With a lead content in the range of 3,800- 13,000 mg Pb/ kg this may imply a total lead amount in the shredder waste of 703- 2405 tonnes. The Danish EPA has during the last couple of years initiated several projects in order to gain more knowledge on this field with the aim of optimising the treatment of shredder waste.

Extensive recovery of waste containing lead metal and dust takes place in Denmark. In year 2000 a total of 12,800-15,600 tonnes of lead was collected and recovered. Recent data showed recycling of 16,134 tonnes of lead from batteries in 2009.

In year 2000 about 1,300-2,300 tonnes of lead were landfilled. The mains sources were residues from solid waste incineration (630-980 tonnes), shredder waste (380-700 tonnes) and fishing tools (170-340 tonnes). This may have changed due to changes in landfilling conditions.

Further it was estimated that in connection with waste incineration 1.2-3.7 tonnes were emitted into ambient air.

The majority of the data from 2000 are data pertaining to the period before the Danish statutory order on the ban on lead was introduced in 2000/2001. The implementation of this ban is considered to have affected the use of lead and lead compounds and this would also be reflected in the waste streams, however, with some delay. As an updated analysis on the lead mass flow in the Danish society is not available, it is not possible to give an updated detailed picture of today of the use and the waste flow of lead.

Environment effects, exposure and impact
From the risk assessment report performed by the international lead industry in 2008, the total lead emissions to the environment was estimated to 2,672,114 kg Pb/year in EU15. The emissions were rather evenly distributed to air, soil and water.

Data from the Danish EPA in 2004 lead to the following figures for the Danish emissions in year 2000:

Air: 5-19 tonnes lead
Water: 170-600 tonnes lead
Soil: 480-2,200 tonnes lead
Landfills; deposits: 1,300-2,300 tonnes lead

These numbers are quite large compared to numbers for the. Based on the sources applied in this risk assessment it has, however, not been possible to identify the reasons for these disagreements.

Danish monitoring data have shown a dramatic decline in the lead content in air from around 1000 ng Pb/m^3 in towns in 1982 to 4-5 ng Pb/m^3 in 2011. This decline is explained by the phase out of lead additives in gasoline in the late seventies and forward. The average background level in Danish soil has been measured to 16 mg/kg for unpolluted soil whereas soil in the cities and polluted areas may reach levels of several hundred mg Pb/kg.

In Danish streams concentrations of 0.2-1.6 µg Pb/L are reported, whereas the concentration of lead in marine waters has been reported as 0.01-0.2 µg Pb/L (Danish EPA, 1998).

In the recent very comprehensive risk assessment report made by the lead industry (LDAI 2008) Predicted No Effect Concentrations (PNECs) have been derived for the environmental compartments: Water, sediment, soil as well as for sewage treatment plants ($PNEC_{microorganism}$). These values have been compared to modeled- and monitoring data on the environmental concentration of lead.

Measured environmental concentrations reported are below the PNEC values for these compartments. Therefore no risk has been identified for the environmental compartment.

Human health hazards
Lead that enters into the human body either by oral, dermal or inhalational exposure progressively accumulates in the human body tissues. Lead in blood and soft tissue have a half-life of approximately 40 days in the tissue, whereas lead accumulated in bone has a half-life of several decades. Stored lead in bones may be liberated to other body compartments in persons with low calcium status e.g. in lactating mothers or people suffering from osteoporosis.

The most critical effects of lead (i.e. effects which occur at the lowest exposure levels) are the neurodevelopmental effects which cause impaired brain function in children and for adults haematological effects (increased blood pressure) and the adverse effects on the kidneys.

No lower threshold for the adverse effects of lead has been identified. Thus, in a recent evaluation made by EFSA (the European Food Safety Authority) no-effect-levels and acceptable levels could not be identified, so instead so-called bench mark dose levels for the critical effects were derived. For neurodevelopmental effect (impaired IQ children) a lowest benchmark dose (BMDL01) of 0.50 µg Pb/kg bw/day was derived (i.e. a 1% effect level which corresponds to a loss of 1 IQ point in children with a normal IQ at 100 point).

In relation to the recent EU restriction from 2011 on lead in jewelry the maximum acceptable exposure to lead from jewelry for children was concluded to be 0.05 µg Pb/kg bw/day (i.e. ten times lower than the BMDL01 level).

This tolerable dose level established in 2011 is a factor 70 lower than the previous tolerable dose level at 3.6 µg Pb/kg bw/day. This of course further impacts the risk assessment of lead as human exposure to lead may not have declined at the same magnitude.

Human exposure
The general population is primarily exposed to lead through food, although lead levels in food have decreased during the last decade. Thus, the European Food Safety Authority, EFSA concluded based on surveillance data that from 2003 to 2010 an overall decrease of 23% in the lead content of food items in the EU.

Recent data from the National Food Institute, Technological University of Denmark (DTU Food) estimated daily lead exposure levels for Danish adults and children to 0.25 µg Pb/kg bw/day and 0.30 µg Pb/kg bw/day, respectively (mean values). These figures that were based on food analyses in the period 2004-2011 were approximately 21% lower compared to the exposure calculated from food analyses in the period of 1998-2003. Beverages, sugar and confectionary, cereals, vegetable and fruit, all together accounted for more than 90% of the lead exposure from food.

Exposure to lead from drinking water may also contribute significantly to the lead exposure especially if release of lead from taps, pipes and fitting occur because of the use of lead containing alloys or because of lack of quality control the taps, pipes and fittings. In Denmark the content of lead in drinking water including the release of lead from drinking water installations is not regarded as problematic by the authorities. Denmark has an approval scheme for construction products in contact with drinking water which sets limits for the release of lead. For children, lead exposure from ingestion of soil and dust particles may further be an important source for lead exposure.

A recent Swedish restriction proposal focusing on lead in consumer products provide data showing that lead migration from various articles may occur, especially when mouthed by children. This further contributes to the overall lead exposure and in order to control the exposure down to a level of 0.05 Pb/kg bw/day a maximum lead content of 500 mg/kg in the articles is proposed in the Swedish restriction proposal.

For adults, specifically sport shooters may be exposed to lead which have resulted in highly increased blood lead levels due to the diffuse exposure from the lead content in the ammunition.

Also in workers occupational exposure may occur in various occupational areas which also results in increased blood lead levels.

Because of the high number and rather diffuse sources of lead exposures it is very difficult to perform a valid estimate of the total lead exposure of the population, as this may vary a lot due to different preferences in food choice and the control and use of various products and metallic parts containing lead. The exposure through drinking water, soil and dust may also vary a lot.

Human Health impact assessment

Only few health impact assessments have been made regarding the current lead exposure and its consequences to human health by using EFSA´s recent risk estimates for lead exposure:

In the current Swedish restriction proposal of maximum lead content of 0.05% for all types of consumer products/articles is proposed. It was estimated that compared to the present situation with the existing lead levels in these types of consumer products there would be a gain of 208,000 IQ points among 6-36 months old children in EU due to the reduced lead exposure by mouthing these articles.

The increased blood lead levels in shooters exposed to lead from the ammunition may cause increased risk for adverse hematological effects and kidney effects.

Recently, a French study has assessed the impact of the current blood lead levels of French children. When looking at the fraction of French children having a blood lead level exceeding 1.5 µg Pb/dL (50% of the children) it was estimated that these higher blood lead levels were associated with an overall IQ loss of 3.1 million IQ points among the French children. In socioeconomic terms this was estimated to a cost of 54 billion Euros.

Scaled to the size of the Danish population this calculation would imply an overall IQ loss of 279,000 points among Danish 1-6 year old children and a socioeconomic cost of 4.85 billion Euros.

Although the blood lead level of children in Western Europe has decreased to a level of 1.5-2 µg PB/dL this is still to be considered to be within an effect level. Thus, the present lead exposure still contributes to adverse effects such as impaired IQ in the population. Therefore, further limitations of the lead exposure would still have beneficial effects even though substantial benefits already have been obtained due to the gradual and continuous decrease in the lead exposure (and the blood lead levels) over the last decades.

Alternatives to lead and lead compounds

Great efforts have been made - both from authority site and industry site - in order to replace lead and lead compounds with alternative substances and materials.

The main consumption of lead is currently the battery sector. Although several alternative battery technologies exist, it is highly unlikely that lead batteries will be phased out completely as several alternatives have undesirable health and safety profiles. It should be noted that today there is a complete recycling of lead batteries. However the battery technology is constantly developing, possibly bringing new alternatives to lead batteries.

Previously the construction sector was a significant consumer of lead as lead sheets for roofing and flashing. In Denmark this use has been almost eliminated, except in historical buildings. Several alternatives to lead sheets are available on the market.

The fishing industry was previously also an important consumer of lead for weights and sinks. These uses are to a great extend replaced by iron and zinc. For sink-lines, work is still ongoing in order to further improve current lead free alternatives. In the sports fishing industry lead has been almost completely replaced with zinc, tin and wolfram.

Lead is gradually replaced as heat stabilizer in PVC and elastomers, primarily with calcium-zinc systems. Lead is used for moisture protection in cables. It has been replaced in ground cables, but no useful alternative have been identified for sea cables.

In ammunition lead is replaced primarily by steel, copper, wolfram and bismuth, the latter two when the gun does not tolerate the toughness of steel and copper. Lead in the form of lead styphnate is still used in gunpowder and other explosives, for containing the explosion. Alternatives are known and developed, but to what extend lead styphnate is exchanged, is unclear.

Lead compounds were traditionally used in several different pigments. This use is now to a large extent replaced by hundreds of other types of pigments.

In conclusion, many of the traditional high volume uses of lead have been phased out more or less completely; however, several uses are still not possible to phase out. This is primarily the use in batteries, but also other uses, such as in alloys and high flexibility cables.

Main findings/ conclusions

Overall, the intense focus on lead and lead compounds including strict regulation, substitution efforts and the increased degree of waste management and recycling have been a success as lead levels in the environment and diffuse lead exposure of the population (e.g. through and air) food has declined significantly in the last decades.

Still, the following observation and findings should be noted:

- There are still very high production and use volumes in EU of lead (metallic lead and lead oxides at an annual tonnage level above 1 million tonnes each). In Denmark metallic lead is used at an annual tonnage level above 10,000 tonnes.

- In order to evaluate the impacts and benefits from the lead ban introduced in Denmark a more detailed assessment of the mass balance of lead in DK (use volume, various uses, emissions, and waste fractions) would be needed.

- Large efforts have already been made to make substitutions for the use and recycling of lead. Still awareness should be paid towards substitution of remaining uses of lead and also in relation to lead as an impurity in various materials/ products to further decrease diffuse lead emissions into the environment.

- The proposed harmonized classification of metallic lead with a specific concentration limit of 0.03% may if agreed on EU level have an impact on the handling of waste, as waste with a higher content than 0.03% could then be considered as hazardous. However, this depends on to what extent the CLP classification rules are used in the forthcoming revision of the waste classification system.

- In eco toxicological terms there are in general low lead levels in the environment in Denmark i.e. no adverse effects in the environment are to be expected.

- There is a decreasing trend in human exposure to lead in EU and in DK. Still exposure from food, although declining, is on an overall basis considered to be the dominant exposure pathway for human exposure to lead.

- Significant lead exposures may occur on a case by case basis due to lead content in consumer products/articles; from drinking water installations; from soil and from dust.

- Especially data on the lead content in house dust is missing in order to evaluate the exposure from the indoor climate.

- The Swedish restriction proposal for a maximum level of lead of 0.05% in articles may contribute significantly to reduced lead exposure in children and may on an overall basis affect the IQ level in children in a positive direction.

- Large human health benefits from the last decades overall reduced lead exposure (and reduced blood lead levels) have presumably been gained.

- Recently it has been concluded that no lower exposure threshold for the adverse effects of lead exists. Thus, based on the newly established dose-response relationship for lead it can be concluded that further health benefits may still be obtained when the current lead exposure from the various sources is further reduced.

- In order to further assess the adverse health impact of existing lead levels/ lead exposures, bio-monitoring data (blood lead levels) of the various population subgroups in the Danish population would be needed, as the blood lead level is the best measure for estimating the impact on health.

Sammenfatning og konklusion

Denne rapport omfatter en undersøgelse af metallisk bly og uorganiske og organiske blyforbindelser. Rapporten er et led i gennemgangen af Miljøstyrelsens Liste Over Uønskede Stoffer (LOUS), som gennemføres fra 2012 til 2015. Det er bly-ionens egenskaber, der har ført til, at bly og blyforbindelser er blevet inkluderet på LOUS listen, på grund af bly-ionens problematiske toksiske effekter på mennesker og miljø.

Klassificering
Blyforbindelser er giftige stoffer, som ophobes i mennesker og i miljøet.

I EU skal blyforbindelser klassificeres som reproduktionstoksiske som følge af skadelige virkninger på fertiliteten og på udviklingen af centralnervesystemet hos fostre og børn. Blyforbindelser er også klassificeret som skadelige ved længerevarende eller gentagen eksponering på grund af skadelige virkninger på flere organsystemer. Desuden er stofferne klassificeret for akutte og kroniske effekter i vandmiljøet.

Indtil nu er metallisk bly ikke omfattet af en EU-harmoniseret klassificering, men det drøftes i øjeblikket i EU, om metallisk bly også skal klassificeres som reproduktionstoksisk.

Lovgivningsforanstaltninger i DK og EU
På grund af blys skadelige virkninger har bly været reguleret i mange år både nationalt, internationalt og på EU-niveau. Således kan bly (som metal og som kemiske forbindelser) betragtes som måske det mest omfattende regulerede stof i verden.

I EU er der blevet gennemført forbud eller strenge anvendelsesbegrænsninger for en række anvendelsesområder og sektorer: maling, kosmetik, legetøj, emballage, smykker, keramik, elektronisk udstyr, køretøjer, benzin, foder, fødevarer, drikkevand osv. Reguleringen af bly gælder også affald, industrielle luftbårne emissioner, spildevandsudledning, og kvalitetskriterier (eller grænseværdier) i jord/slam/luft/havvand/og ferskvand.

I arbejdsmiljøet gælder strenge foranstaltninger til sikring af arbejdernes sikkerhed, herunder specifikke retningslinjer for erhvervsmæssig håndtering samt grænseværdier i arbejdsmiljøet for bly og blyforbindelser. Desuden er der særlige krav for at beskytte unge arbejdere og gravide kvinder mod blyeksponering i arbejdsmiljøet.

Fremstilling og anvendelse
Selvom bly og blyforbindelser er underlagt et stort antal strenge lovgivningsmæssige tiltag i både Danmark, EU og på verdensplan, anvendes der metallisk bly og blyforbindelser i meget store mængder. I EU overstiger det årlige forbrug af bly og blyforbindelser flere millioner tons.

Især *metallisk bly* og *tetrablytrioxidsulphat* anvendes i meget store mængder i EU, og stofferne er i forbindelse med deres REACH registrering registreret i et tonnageniveau på 1-10 millioner tons pr. år.

Produktionen af metallisk bly i EU stammer enten fra minedrift eller fra genindvinding af bly i affaldsstrømmen. I 2010 blev der i EU rapporteret et samlet tonnageniveau af bly fra minedrift på

259.800 tons. Data fra 2001 viser, at 65 % af den raffinerede blyproduktion var fra sekundær produktion/genindvinding.

På globalt plan dominerer Kina imidlertid blyproduktionen, og varetager næsten halvdelen af den globale produktion. Australien, USA og Peru og andre væsentlige blyproducenter på det globale marked..

I år 2000 i EU (dvs. EU15) blev langt den største mængde bly og blyforbindelser brugt til blybatterier (61 %). Andre meget vigtige anvendelser var: valsede og ekstruderede produkter (14 %), blyforbindelser i pigmenter, som stabilisatorer (12 %), ammunition (3 %), legeringer (2 %), kabelbeklædning (2 %), benzinadditiver (1 %) og andre formål (5 %).

I Danmark er forbrugsmønstret af bly for år 2000 blevet belyst meget detaljeret i en Miljøstyrelsesrapport fra 2004. I rapporten blev der anslået et samlet årligt forbrug af bly (metallisk bly + blyforbindelser) på 14.900-19.000 tons. De primære anvendelser var batterier (52 %) og byggematerialer (23 %), mens andre vigtige anvendelser var fiskeredskaber, skibskøle, PVC, katodestrålerør, kabler, legeringer og krystalglas. Det meste af det anvendte bly genanvendes, og der blev i år 2000 indsamlet 12.800-15.500 tons bly til genanvendelse i Danmark.

I det danske produktregister var der i 2011 registreret 94 blyforbindelser. For mange forbindelser er det imidlertid ikke muligt at få oplysninger om mængdeniveauer, da disse oplysninger er fortrolige, når mindre end tre virksomheder har registreret. Endvidere står det ikke klart, om alle registreringer er ”aktive". Fire forskellige blypigmenter er registreret med en årlig anvendelse (2011) på mellem 23 og 191 tons, mens metallisk bly er registreret med 78 tons. Metallisk bly anvendes hovedsageligt til svejse-/lodde-produkter. Fra 1997 og frem til 2011 har der været en øget anvendelse af metallisk bly og blychromat (farvepigment), mens anvendelsen af andre blyforbindelser er gået ned..

Der mangler dog for en række anvendelsesområder en mere kvantitativ, præcis viden om udviklingen siden år 2000. Ikrafttrædelsen af den danske blybekendtgørelse i 2001 må således forventes at have haft betydelig indflydelse for udviklingen.

Affald
På grund af den EU-harmoniserede klassificering af blyforbindelser som reproduktionstoksiske skal affald med et indhold af blyforbindelser over 0,5 % betragtes som farligt affald. Fremover vil grænsen for farligt affald for metallisk bly måske blive sat til 0,03 %, da denne koncentrationsgrænse for klassificering af metallisk bly i øjeblikket drøftes på EU-plan. Flere kommuner i Danmark anvender i øjeblikket grænseværdier på 40 mg Pb/kg og 2500 mg Pb/kg (0,25 %) som de grænser, der definerer henholdsvis rent affald og farligt affald.

Af appendix 7 kan det ses, at i år 2000 var den anslåede mængde bly i husholdningsaffald (den del, der ikke genindvindes) i størrelsesordenen 510-1.400 tons. De største blyfraktioner i affaldsstrømmen kom fra fiskeredskaber (210-420 tons), blyholdig krystalglas (97-220 tons), pigmenter i maling og plast (56-170 tons), keramiske produkter (40-150 tons), blyplader (10-100 tons), stabilisatorer i PVC (26-86 tons) og fra forskellige andre metalliske dele. Af denne mængde bly i affaldet kom 290-930 tons til forbrænding, og ca. 220-480 tons bly blev deponeret.

Data fra 2011 viser, at blyindholdet i shredderaffald kan bidrage væsentligt til massebalancen af bly i affald på grund af det høje årlige tonnageniveau af affaldet. Med et blyindhold på 3.800-13.000 mg Pb/kg kan shredderaffaldet således bidrage med 703-2405 tons bly. Miljøstyrelsen har derfor gennem de senere år iværksat flere projekter med henblik på at få mere viden om dette område for at optimere behandlingen af shredderaffald.

I Danmark er der en omfattende genvinding af affald, der indeholder bly og blystøv. I 2000 blev i alt 12.800-15.600 tons bly indsamlet og genindvundet. De seneste data fra 2009 angiver genanvendelse af 16.134 tons bly fra batterier.

I 2000 blev i alt omkring 1.300-2.300 tons bly deponeret. De primære kilder hertil var rester fra forbrænding af fast affald (630-980 tons), shredderaffald (380-700 tons) og fiskeredskaber (170-340 tons). Dette kan have ændret sig på grund af ændringer i betingelserne for deponering.

Yderligere blev det anslået, at der i forbindelse med affaldsforbrænding i år 2000 blev udledt 1,2-3,7 tons bly i luften.

Hovedparten af ovenstående data er fra år 2000, dvs. før den danske bekendtgørelse om forbud mod bly trådte i kraft i 2000/2001. Implementeringen af dette forbud anses for at have påvirket anvendelsen af bly og blyforbindelser væsentligt, og dette må forventes også at afspejle sig i affaldsstrømmen, - dog med en vis forsinkelse. Da en opdateret analyse af bly-massestrømmen i Danmark ikke er tilgængelig, er det ikke muligt at give et opdateret og mere detaljeret billede af anvendelsen og affaldsstrømmen af bly i dag.

Miljøeffekter, eksponering og påvirkning
Fra en risikovurderingsrapport udarbejdet af den internationale blyindustri i 2008 blev de samlede blyemissioner til miljøet anslået til 2.672 tons Pb/år i EU15. Emissionerne var ret jævnt fordelt på luft, jord og vand.

Data fra Miljøstyrelsen i 2004 viste følgene tal for danske emissioner i 2000:

Luft: 5-19 tons bly
Vand: 170-600 tons bly
Jord: 480-2.200 tons bly
Deponeringsanlæg: 1.300-2.300 tons bly

Disse tal er forholdsvis store i forhold til tallene for EU. Ud fra de anvendte kilder har det imidlertid ikke været muligt at afklare denne ”uoverensstemmelse” nøjere.

Danske overvågningsdata har vist en dramatisk nedgang i blyindholdet i luften fra omkring 1000 ng Pb/m^3 i byerne i 1982 til 4-5 ng Pb/m^3 i 2011. Denne nedgang kan forklares med udfasningen af blyadditiver i benzin i slutningen af halvfjerdserne og frem.

Det gennemsnitlige baggrundsniveau i dansk jord er blevet målt til 16 mg/kg for ikke-forurenet jord, hvorimod jord i byer og forurenede områder kan nå niveauer på flere hundrede mg Pb/kg.

I danske vandløb er der rapporteret koncentrationer på 0,2-1,6 mg Pb/L, mens koncentrationen af bly i havvand er blevet rapporteret til 0,01-0,2 µg Pb/L (Miljøstyrelsen, 1998).

I den meget omfattende risikovurderingsrapport foretaget af blyindustrien (LDAI, 2008) er der blevet udledt beregnede nuleffektkoncentrationer (PNEC) for vand, sediment, jord og i rensningsanlæg. Disse værdier er blevet sammenlignet med modellerede data og overvågningsdata mht. blykoncentrationerne i disse miljøer. Sammenstillingen viser, at de estimerede og målte blyværdier i miljøet ligger under PNEC-værdierne, hvorfor der ikke er fundet at være risiko for påvirkning af miljøet.

Sundhedsfarer
Bly ophobes i kroppen, efter det optages enten i forbindelse med indtagelse, ved hudkontakt eller ved indånding. Bly i blodet og blødt væv/organer har en halveringstid på omkring 40 dage, hvorimod bly akkumuleret i knoglerne har en halveringstid på adskillige årtier. Bly ophobet i

knoglerne kan frigives til blodet og fordeles til andre dele af kroppen hos personer med øget calciumbehov eller calciummangel, f.eks. ammende mødre eller personer, der lider af knogleskørhed.

De mest kritiske virkninger af bly (dvs. virkninger, som optræder ved de laveste eksponeringsniveauer) er de neurologiske virkninger, der forårsager nedsat hjernefunktion hos børn, og hæmatologiske virkninger (forhøjet blodtryk) og nyrebeskadigelse hos voksne.

Der er ikke identificeret nogen nedre grænse for de skadelige effekter af bly. Således kunne der ikke identificeres et *ikke-effekt-niveau* eller et *acceptabelt eksponeringsniveau* i en nylig vurdering foretaget af EFSA (Det Europæiske Fødevareagentur). I stedet udledte man såkaldte benchmark dosisniveauer for de kritiske effekter. For neurologisk virkning (nedsat IQ hos børn) afledtes en benchmark dosis (BMDL01) på 0,50 mg Pb/kg legemsvægt/dag (dvs. den dosis der et knyttet til et 1 % effektniveau, som svarer til et tab på 1 IQ point hos børn med et IQ niveau på 100.

I forbindelse med den seneste EU-anvendelsesbegrænsning vedr. bly i smykker fra 2011 er den maksimale, acceptable eksponering for bly fra smykker til børn blevet udledt til at være 0,05 mg Pb/kg legemsvægt/dag (dvs. ti gange lavere end BMDL01 niveauet).

Dette tolerable dosisniveau fastsat i 2011 *er en faktor 70 lavere* end det tidligere anvendte tolerable dosisniveau på 3,6 µg Pb/kg legemsvægt/dag. Dette har selvfølgelig stor betydning for risikovurderingen af bly, da den humane eksponering for bly ikke er faldet i samme størrelsesorden.

Human eksponering
Den almindelige befolkning er primært udsat for bly gennem fødevarer, selv om blyniveauet i fødevarer er faldet i løbet af det seneste årti. Således konkluderede det Europæiske Fødevareagentur, EFSA, baseret på overvågningsdata, at der fra 2003 til 2010 er et samlet fald på 23 % i blyindholdet i fødevarer i EU.

De seneste beregninger fra Fødevareinstituttet i Danmark angiver daglige blyeksponeringsniveauer for danske voksne og børn til henholdsvis 0,25 µg Pb/kg legemsvægt/dag og 0,30 mikrogram Pb/kg legemsvægt/dag (middelværdier). Disse tal, der er baseret på fødevareanalyser i perioden 2004-2011, er cirka 21 % lavere sammenlignet med eksponeringen beregnet ud fra fødevareanalyser i perioden 1998-2003. Drikkevarer, sukker og konfekture, kornprodukter, grøntsager og frugt tegnede sig tilsammen for mere end 90 % af blyeksponeringen fra fødevarer.

Eksponering for bly gennem drikkevandet kan også bidrage væsentligt til blyeksponering, især hvis frigivelse af bly fra vandhaner, rør og armaturer opstår på grund af anvendelse af blyholdige legeringer eller på grund af manglende kvalitetskontrol af vandhaner, rør og armaturer. I Danmark vurderer myndighederne generelt ikke, at der er problemer med blyindholdet i drikkevand, herunder frigivelse fra installationer. Danmark har en godkendelsesordning for byggevarer i kontakt med drikkevarer som sætter grænser for frigivelsen af bly. For børn kan blyeksponering fra indtagelse af jord og støvpartikler endvidere være en vigtig kilde til blyeksponering.

I et nyt svensk forslag til forbud mod bly i forbrugerprodukter påpeges det, at uacceptabel blyafgivelse fra forskellige artikler kan forekomme, især når de puttes i munden af børn. Denne form for blyeksponering vil bidrage til den samlede blyeksponering, og for at eksponeringen fra artikler ikke skal overstige 0,05 Pb/kg legemsvægt/dag foreslås der en grænseværdi for blyindhold på 500 mg/kg i artiklerne.

Mht. voksne vides, at især sportsskytter kan være udsat for bly, hvilket har resulteret i stærkt forhøjet blyindhold i blodet på grund af den diffuse eksponering fra blyindholdet i ammunitionen.

Hos arbejdere kan der forekomme erhvervsmæssig eksponering inden for forskellige fagområder, hvilket også medføre forhøjet blyindhold i blodet.

På grund af det høje antal og de temmeligt diffuse kilder til blyeksponering er det meget vanskeligt at lave et præcist skøn over befolkningens eller befolkningsgruppers samlede blyeksponering, da dette kan variere meget på grund af forskellige præferencer i fødevarevalg, forskelligt indhold i drikkevand og anvendelse af forskellige forbrugerprodukter, der kan indeholde rester af bly. Desuden kan eksponering via jord og støv, der er særligt relevant for børn, også variere meget.

Påvirkning af befolkningens sundhed
Der er kun foretaget få konsekvensvurderinger vedrørende den aktuelle blyeksponering og dens betydning for menneskers sundhed ved hjælp af de nyeste risikoestimater, der som nævnt ikke anvender nogen nedre grænse for blys skadelige effekter. Nedenfor er gengivet et par eksempler:

For nylig har en fransk undersøgelse vurderet konsekvenserne af det nuværende blyindhold i franske 1-6 årige børns blod. Når man så på halvdelen af de franske børn (ca. 2,35 millioner), der havde et blyindhold i blodet over 1,5 mg Pb/dL, blev det anslået, at det højere blyindhold i denne gruppe børn var forbundet med et samlet IQ-tab på 3,1 millioner IQ point. Dette fald i IQ blev estimeret til igennem børnenes levetid at udgøre en samfundsøkonomisk omkostning på 54 mia. euro.

Skaleret til størrelsen af den danske befolkning ville denne beregning indebære et samlet IQ-tab på 279.000 points blandt danske 1-6 årige børn og en samfundsøkonomisk omkostning på 4,85 mia. euro.

I det nuværende svenske forslag mht. anvendelsesbegrænsning af bly i forbrugerprodukter foreslås et maksimalt blyindhold på 0,05 % for alle typer forbrugerprodukter/artikler. Det blev beregnet, at i forhold til den nuværende situation med de eksisterende blyniveauer i disse typer forbrugerprodukter, ville der være en gevinst på 208.000 IQ point blandt børn i EU i alderen 6-36 måneder på grund af den reducerede blyeksponering ved at putte disse artikler i munden.

Selvom blyindholdet i vesteuropæiske børns blod er faldet til et niveau på 1,5-2 µg PB/dL, anses dette stadig for at udgøre et effektniveau. Således vurderes den nuværende blyeksponering stadig at bidrage til skadelige virkninger, først og fremmest mht. nedsat IQ hos børn. Derfor vil yderligere begrænsninger af blyeksponering fortsat have gavnlig effekt, selvom der allerede er opnået væsentlige gavnlige effekter på grund af det gradvise og konstante fald i blyeksponering (og i blyindholdet i blodet) i løbet af de seneste årtier.

Alternativer til bly og blyforbindelser
Der er gjort en stor indsats - både fra myndighedernes og erhvervslivets side - for at erstatte bly og blyforbindelser med alternative stoffer og materialer.

Den væsentligste anvendelse af bly er i øjeblikket inden for batterisektoren. Selvom der findes flere alternative batteriteknologier, er det højst usandsynligt, at blybatterier vil blive udfaset fuldstændigt, da flere alternativer har uønskede sundheds- og sikkerhedsmæssige egenskaber. Det skal dog tilføjes at der i dag pågår en effektiv genanvendelse af blybatterierne. Men batteriteknologien er i konstant udvikling, hvilket eventuelt kan skabe nye alternativer til blybatterier.

Tidligere var der et betydeligt forbrug af bly i byggesektoren i forbindelse med blyplader til tagdækning og inddækning. Denne brug er ikke tilladt længere, undtagen til restaurering/ vedligeholdelse af historiske bygninger. Flere alternativer til blyplader er tilgængelige på markedet.

Fiskeindustrien har haft et betydeligt blyforbrug til lodder og synk. Disse anvendelser er i stor udstrækning erstattet af jern og zink. Med hensyn til erstatning af bly i synkeliner pågår der fortsat et arbejde med at forbedre de blyfrie alternativer. I sportsfiskeindustrien er bly blevet næsten helt erstattet med zink, tin og wolfram.

Bly er gradvist erstattet som varmestabilisator i PVC og elastomerer, primært med calcium-zink-systemer. Bly anvendes til fugtbeskyttelse for kabler. Denne brugt er blevet erstattet i jordkabler, men der er ikke fundet noget brugbart alternativ for havkabler.

I ammunition kan bly primært erstattes af stål, kobber, wolfram og bismuth; hvor de to sidstnævnte anvendes når våbnet ikke kan tåle ståls og kobbers hårdhed. Bly i form af blystyphnat bruges stadig i krudt og sprængstoffer til at kontrollere eksplosionen. Alternativer er kendt og udviklet, men det er uklart, i hvilket omfang blystyphnat er under udskiftning.

Blyforbindelser er traditionelt blevet anvendt i flere forskellige farvepigmenter. Denne anvendelse er nu i stor udstrækning erstattet af hundredvis af andre typer farvepigmenter.

Sammenfattende er mange af de traditionelle højtonnageanvendelser af bly blevet udfaset mere eller mindre fuldstændigt. Nogle typer af anvendelse er stadig ikke mulige at udfase, hvilket primært gælder anvendelsen i batterier, men også i fx metallegeringer og til visse typer kabler.

Vigtigste resultater/konklusioner
Det sammenfattende billede fra denne rapport viser, at den intense fokus der har været på bly og blyforbindelser, i forbindelse med den strenge lovgivning, substitutionsbestræbelserne og den øgede grad af affaldshåndtering og genvinding, har været en succes. Dette har medført, at blyniveauerne i miljøet og den diffuse blyeksponering af befolkningen (fx via fødevarer og luft) er faldet betydeligt i de seneste årtier.

Gennemgangen i denne rapport giver imidlertid grundlag for at fremhæve følgende:

- Der er fortsat en meget høj produktion og et højt anvendelsesvolumen af bly i EU (fx metallisk bly og blyoxider, der har et årligt tonnageniveau på over 1 million tons hver især). I Danmark anvendes metallisk bly i et årligt tonnageniveau på over 10.000 tons.

- For at kunne vurdere effekten og fordelene af det danske blyforbud vil det være nødvendigt med en opdateret og detaljeret vurdering af massebalancen for bly og blyforbindelser i Danmark (anvendelsesvolumener ved forskellige anvendelser, emissioner og indhold i affaldsstrømme).

- Der er allerede gjort en stor indsats for at substituere og genanvende bly. Alligevel bør man være opmærksom på fortsat at substituere på anvendelsesområder, hvor bly stadig anvendes, og på områder, hvor bly findes som urenhed i forskellige materialer/produkter, og hvor dette kan bidrage til diffuse blyemissioner til miljøet.

- Den foreslåede harmoniserede fareklassificering af metallisk bly helt ned til et blyindhold på 0,03 % kan, hvis vedtaget på EU-plan, have stor indflydelse på affaldshåndteringen. Affald med et højere indhold end 0,03 % vil derefter kunne betragtes som farligt affald. Dette afhænger dog af I hvor stor udstrækning CLP klassificeringsreglerne vil blive anvendt i den kommende revision af affaldsklassificerings systemet.

- Med hensyn til miljøet er der generelt lave blyniveauer i Danmark, dvs. bly forventes ikke at medføre skadelige effekter i miljøet.

- Blyeksponeringen af befolkningen viser en faldende tendens både i EU og i Danmark. Den primære overordnede kilde til befolkningens blyeksponering er gennem fødevarer, selvom niveauerne i fødevarerne er faldende.

- Bidrag fra blyindholdet i forbrugerprodukter/artikler, fra drikkevandsinstallationer samt fra jord og støv udgør også en baggrundskilde for blyeksponeringen og kan i visse tilfælde medføre en betydelig øget blyeksponering.

- Der mangler især data om blyindholdet i husstøv for at kunne vurdere eksponeringen fra indeklimaet mere detaljeret.

- Det svenske EU-forslag til blyforbud i artikler, hvor der foreslås en grænseværdi på 0,05 % bly i artikler, kan bidrage væsentligt til reduceret blyeksponering hos børn, og kan dermed medvirke til at påvirke IQ-niveauet hos børn i positiv retning.

- For nyligt har den videnskabelige komité i EU's Fødevareagentur konkluderet, at der ikke findes noget nedre eksponeringsniveau for blys skadelige virkninger. Det betyder, at yderligere sundhedsmæssige fordele stadig kan opnås, hvis den aktuelle blyeksponering fra de forskellige kilder fortsat reduceres.

- På den baggrund må det også konkluderes, at de hidtidige tiltag til at reducere blyeksponeringen, og den dermed lavere blyeksponering vi har i dag, har betydet store sundhedsmæssige fordele.

- For mere præcist at kunne vurdere de sundhedsmæssige konsekvenser af eksisterende blyniveauer/blyeksponeringer, og vurdere fordelene af en yderligere reduktion af blyeksponeringen, vil det være nødvendigt med biomoniteringsdata med målinger af blyindholdet i blodet for udvalgte befolkningsgrupper, da blyindholdet i blodet er det bedste mål for vurdering af de sundhedsmæssige konsekvenser.

1. Introduction to the substance group

1.1 Definition of the substances

The substance group covers metallic lead and lead compounds. There are numerous organic and inorganic lead compounds. The primary focus in this report is on lead as an element as it is the properties and effects of elemental lead and the lead ion that are of concern with respect to human health and the environment. The hazardous properties are driven by the lead content or the liberation of the lead ion. However, some lead compounds have other or additional hazardous properties compared to elemental lead which may be addressed on a case by case basis, however, this is outside the scope of this report.

Identifiers for metallic lead are given in Table 1-1.

TABLE 1-1 NAME AND OTHER IDENTIFIERS OF LEAD

	Lead
Synonyms	Lead metal; Lead element; Pigment 4; Plumbum
EC number	231-100-4
CAS number	7439-92-1
Molecular formula	Pb
Molecular weight	207.2 g/mol

This survey also covers all inorganic as well as organic lead compounds on the market and 65 lead compounds have been registered under REACH of which 30 compounds are registered as intermediate compounds (see appendix 1). From this appendix the importance of lead compounds can be seen by the very high volumes that are registered for use in the EU, thus, metallic lead and tetralead trioxide sulphate have been registered in the tonnage range of 1,000,000-10,000,000 tonnes per year.

1.2 Purity

With respect to metallic lead of high purity CEN standard EN 12659 sets out official European specifications for four key grades of metallic lead in a purity range of 99.94-99.99% lead (LDAI, 2008).

For technical grades of metallic lead the Swedish Chemical Agency (2012a) reports a typical content of 95% metallic lead with a lower limit of 80%. A great variety of impurities may occur in metallic lead at maximum levels of 2 – 15%: antimony, tin, sulphur, oxygen, copper, aluminium, zinc, iron, chromium, magnesium, manganese, sodium, barium, strontium, indium, gallium, tellurium, calcium, silicon, potassium, bismuth.

The REACH registration covers qualities of metallic lead with a stated purity of 92% and above. In the lead registration also lead qualities with arsenic as an impurity are reported.

Lead in alloys
Lead is often added in concentrations of around 2% to enhance the machinability of brass. The most common brass quality CW602N has a lead content of 3%. There are other qualities such as CW612N which has a lower lead content (2%), but in principle the same characteristics (Swedish Chemical Agency, 2012c).

Further, alloys of cobber have a typical content of 2-6% of lead (gunmetal), and alloys of aluminium may contain 0.2-2% lead. Zink for galvanising may contain approx. 1% lead, and steel for machinery 0.4% lead (Danish EPA, 2004).

1.3 Physical chemical properties

The physical chemical properties of the lead compounds may vary depending of the specific lead species. Below in Table 1-2 physical chemical data are given for four selected lead compounds to illustrate the variability in the properties.

TABLE 1-2 PHYSICAL-CHEMICAL PORPERTIES OF LEAD AND SELECTED LEAD COMPOUNDS

Property	Metallic lead powder[1]	Lead oxide[1]	Lead dichloride[2]	Tetraethyllead[2]
CAS no.	7439-92-1	1317-36-8	7758-95-4	78-00-2
Physical state	Solid, powder	solid	solid	liquid
Melting point	>600 °C	>600 °C	501°C	-136 °C
Boiling point	1,725-1,745 °C	ND	ND	>110°C
Relative density	11.45 g/cm3	9.96 g/cm3	5.9 g/cm3	1.6 g/cm3
Vapour pressure	0 mbar at 20 °C 1.33 mbar = 1.33 Pa at 1000 °C	ND	ND	63.7 Pa at 25°C
Water solubility	185 mg/L [20 °C, at pH = 10.96]	70 mg/L	10,000 mg/L	0.29 mg/L
Log P (octanol/water)	ND	ND	ND	4.88

1) Data from LDAI (2008), 2) Data from the REACH registration

Although the concern for the lead compounds generally relates to the lead ion, the concern and the problematic aspects of these compounds may vary as the different physical-chemical properties have an influence on how and to which extent the lead ion is liberated when the compound is emitted to the environment or when entering into the human body.

2. Regulatory framework

This chapter provides an overview of how lead and lead compounds are addressed in the existing legislation in EU and in Denmark. Further, international agreements as well as eco-labelling in the EU and Denmark are covered as well. Regulation in pipe-line or in the implementation phase will also be covered.

For readers not used to dealing with legislative issues, Appendix 2 provides a brief overview and connections between legislatives instruments in EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, explanation for lists referred to in chapter 2, as well as a brief introduction to international agreements and relevant eco-labelling schemes.

2.1.1 Existing legislation

In this section specific guidance and existing legislation addressing lead and lead compounds in EU as well as in Denmark are listed in Table 2-1.

TABLE 2-1 SPECIFIC LEGISLATION ADRESSING LEAD AND LEAD COMPOUNDS

Legal instrument	EU/national	Requirements for lead and lead compounds
Regulation addressing products		
Regulation No 1907/2006 (EC) on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	EU	Lead compounds and lead sulphates: Shall not be used as substances and a constituent of preparations intended for use as paints, except for the restoration and maintenance of works of art and historic buildings and their interiors, where Member States wish to permit this on their territory, in accordance with the provisions of ILO Convention 13 on the use of white lead and sulphates of lead in paint.
COMMISSION REGULATION (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards lead	EU	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, unless it can be demonstrated that the rate of lead released does not exceed the limit of 0,05 µg/cm 2 /h (0,05 µg/g/h).

Council Regulation (EEC) 304/2003 on the export and import of dangerous chemicals (Rotterdam Convention)	EU	Sets out the requirements for classification, packaging and labelling of dangerous substances and preparations, including lead compounds, when put on the market in non-EU countries or imported from non-EU countries.
Danish Statutory Order: BEK nr. 856 af 05/09/2009	DK	The statutory order bans the import and sale of products that contain lead. Products are covered by this regulation when lead represents more than 100 ppm (mg/kg) of their homogeneous components (certain exemptions apply).
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste Danish Statutory Order Bekendtgørelse om visse krav til emballager BEK nr. 1049 af 10/11/2011	EU	The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight. The concentration levels referred to in paragraph 1 shall not apply to packaging entirely made of lead crystal glass as defined in Directive 69/493/EEC (1). Danish Statutory Order stipulates in addition: Lead may not be added intentionally in the production of plastic boxes or pallets. By derogation of the general requirements, glass packaging may be used if the sum of the substances does not exceed 250 ppm in weight, in glass packaging based on recycled glass where the substances are not intentionally added.
Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys Danish Statutory Order Bekendtgørelse om sikkerhedskrav til legetøj og produkter, som på grund af deres ydre fremtræden kan forveksles med levnedsmidler BEK nr. 1116 af 12/12/2003 (Legetøjsbekendtgørelsen)	EU/DK	Bioavailability of lead resulting from the use of toys must not, as an objective, exceed the following level per day: 0.7 µg/day. Part of this Directive was repealed in July 2011. The Directive is to be completely repealed by 20 July 2013 - please see below. Part of this statutory order is repealed by July 2011. The directive is completely repealed by 20 July 2013 - please see below.

Directive 2009/48/EC relating to toy safety Danish Statutory Order: Bekendtgørelse om sikkerhedskrav til legetøjsprodukter BEK nr. 13 af 10/01/2011	EU/DK	The specific limit values laid down in Directive 88/378/EEC for certain substances should also be updated to take account of the development of scientific knowledge. Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present. Limit values for lead in toys (Commission Directive 2012/7/EU of 2 March 2012 to be adopted by 20 Jan. 2013 at the latest): - In dry, brittle, power-like or pliable toy material: 13.5 mg/kg - In liquid or sticky toy material: 3.4 mg/kg - In scrapped-off toy material: 160 mg/kg Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and Part 3 of Annex II thereto are repealed with effect from 20 July 2013. By 31 Aug 2012 the Danish Statutory order still included old limit values: - In dry, brittle, power-like or pliable toy material: 1.5 mg/kg - In liquid or sticky toy material: 0.5 mg/kg - In scrapped-off toy material: 23 mg/kg Statutory Order No. 1116 of 12. December 2003 is partly repealed by 20 July 2011. §4 item 1.1 and annex 2, part II, item 3 are repealed 20 July 2013.
Regulation (EC) No 1223/2009 of the on cosmetic products Danish Statutory Order: Bekendtgørelse om kosmetiske produkter BEK nr. 422 af 04/05/2006 (Kosmetikbekendtgørelsen)	EU/DK	Lead and its compounds are included in the list of substances prohibited in cosmetic products.
Directive 2012/19/EU OF THE EUROPEAN	EU	Sets out requirements for manufacturers of electrical and electronic equipment to identify

PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast) (Text with EEA relevance)		dangerous substances and preparations, including lead compounds, in new electrical and electronic equipment.
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) [RoHS Directive] Danish Statutory Order; Bekendtgørelse om begrænsning af import og salg samt fremstilling til eksport inden for EU af elektrisk og elektronisk udstyr, der indeholder visse farlige stoffer BEK nr. 284 af 24/03/2011	EU/DK	New electrical and electronic equipment put on the market shall not contain lead in concentrations over 0.1 w% in electrical equipment. However exemptions are made on 35 specific uses. Further, the use of lead in equipment utilizing or detecting ionising radiation and sensors, detectors and electrodes are further specified in ANNEX IV Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments.
COMMISSION DELEGATED DIRECTIVE 2012/50/EU of 10 October 2012	EU	Amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing lead. Whereas: (1) Directive 2011/65/EU prohibits the use of lead in electrical and electronic equipment placed on the market. (2) The substitution of lead in PZT based dielectric ceramic materials for capacitors, which are part of integrated circuits or discrete semiconductors, is still technically impracticable. The use of lead in those materials should therefore be exempted from the prohibition.
Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [ELV Directive]	EU/DK	Prohibits the use of lead in materials and components of vehicles in concentrations above 0.1 weight percent. However various specific exemptions apply for minor metal parts, alloys and electronics. In Annex II a list of exemptions for certain uses

Danish Statutory Order: Bekendtgørelse om begrænsning af import, salg samt fremstilling til eksport inden for EU og til EFTA-lande af person- og varebiler m.v., der indeholder visse farlige stoffer BEK nr. 1257 af 11/12/2008		such as lead as an alloying element in steel and copper, and lead in batteries and vibration dampers are presented. The exempted concentration ranges from 0,35% in steel for machining purposes and galvanized steel to 4% lead in copper alloy.
Council 85/210/EEC on the approximation of the laws of the Member States concerning the lead content of petrol	EU	Restricts the content of content of lead in petrol. Unleaded petrol is defined here as having less than 0.013 g Pb/l, and leaded petrol is defined as having not less than 0,15 g Pb/l and not exceeding 0.4 g Pb/l.
Danish Statutory Order: Bekendtgørelse om begrænsning i anvendelse af visse farlige kemiske stoffer og produkter til specielt angivne formål BEK nr. 857 af 05/09/2009	DK	Petrol where lead compounds are added can only be used as fuel in internal combustion engines. At the distribution apparatus and loose containers where leaded petrol is handled it shall be clearly indicated that the petrol is leaded.
Regulation (EC) No 689/2008 the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals	EU	Tetraethyl lead and tetramethyl lead are included in list of chemicals subject to export notification procedure (implementation of the PIC-procedure in EU - reference is made to the Rotterdam Convention). Please refer to PIC circular at www.pic.int/ The regulation replaces Regulation (EC) No 689/2008 with effect as of 1 March 2014.
Regulation addressing waste		

Regulation (EC) No 1013/2006 on shipments of waste	EU	Waste containing lead is subject to a Prior inform consent procedure in connection with trans-boundary movement in the EU and in OECD. Lead containing waste to non-OECD countries is subject to an export prohibition: Waste subject to export prohibition (included in Annex V) includes: - Metal wastes and waste consisting of alloys of lead. -Waste having as constituents or contaminants, excluding metal waste in massive form, lead and lead compounds. -Waste zinc residues not included on List B, containing lead in concentrations sufficient to exhibit certain characteristics. -Waste lead-acid batteries, whole or crushed. -Waste electrical and electronic assemblies or scrap; (1) containing components such as accumulators and other batteries included on list A, mercury-switches, glass from cathode‑ray tubes and other activated glass and PCB-capacitors, or contaminated with Annex I constituents (e.g. cadmium, mercury, lead, polychlorinated biphenyl) to an extent that they possess any of the characteristics contained in Annex III (note the related entry on list B, B1110); (2) Waste metal cables coated or insulated with plastics containing or contaminated with coal tar, PCB (3), lead, cadmium, other organohalogen compounds or other Annex I constituents, to the extent that they exhibit Annex III characteristics. - Wastes which contain, consist of or are contaminated with leaded anti-knock compound sludges. Clean, uncontaminated metal scrap, including alloys, in bulk finished form (sheet, plate, beams, rods, etc.): Lead scrap (but excluding lead-acid batteries). - Waste electrical and electronic assemblies or scrap (1)(including printed circuit boards) not containing components such as accumulators and other batteries included on list A, mercury-switches, glass from cathode-ray tubes and other activated glass and PCB-capacitors, or not contaminated with Annex I constituents (e.g. cadmium, mercury, lead, polychlorinated biphenyl) or from which these have been removed, to an extent that they do not possess

		any of the characteristics contained in Annex III (note the related entry on list A, A1180). - Wastes from lead thermal metallurgy - Lead batteries - Lead
Directive 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives and replaces Council Directive 91/689/EEC	EU	This Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use.
Danish Statutory Order: Bekendtgørelse om affald, BEK nr. 1309 af 18/12/2012	DK	This statutory order lays down measures for handling of waste that are regulated elsewhere, including waste contaminated with lead.
Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries	EU	Sets conditions for export of lead in waste to certain non-OECD countries.
Danish Statutory Order: Bekendtgørelse om deponeringsanlæg BEK nr. 719 af 24/06/2011	DK	Sets down limit values for leaching of trace elements, including lead in deposited waste.
Danish Statutory Order: Bekendtgørelse om håndtering af affald i form af motordrevne køretøjer og affaldsfraktioner herfra BEK nr. 1213 af 19/12 2012	DK	Sets up measures for handling of waste related to End Of Life vehicles, including materials and components that contain lead.
Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators	EU/DK	Specific recycling requirements should be established for cadmium and lead batteries and accumulators in order to attain a high level of material recovery throughout the Community and to prevent disparities between Member States.

Danish Statutory Orders: Bekendtgørelse om import og salg samt eksport af batterier og akkumulatorer BEK nr. 943 af 23/09/2008 - regarding restriction on the Use		Batteries, accumulators and button cells containing more than 0,004 % lead, shall be marked with the chemical symbol Pb.
Bekendtgørelse om batterier og akkumulatorer og udtjente batterier og akkumulatorer BEK nr. 1186 af 07/12/2009 - regarding recycling of the batteries		Recycling of 65 % by average weight of lead-acid batteries and accumulators, including recycling of the lead content to the highest degree that is technically feasible while avoiding excessive costs.
Regulation addressing Industry and emissions/ levels in the environment		
Commission Decision 2000/479/EC on the implementation of a European pollutant emission register (EPER)	EU	Sets out the requirements for reporting environmental releases of pollutants, including lead and lead compounds, from industrial facilities regulated under Council Directive 96/61/EC on integrated pollution prevention and control (IPPC).
Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe	EU	Sets out objectives, assessment and management of ambient air quality in relation to pollutants including lead compounds. Lead ambient air limit value 0.5 µg/m^3 as a yearly average.
Council Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy	EU	Sets out objectives in the field of water policy including priority status and quality standard requirements for lead.
Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	EU/DK	Limit values for lead concentration in soils; 50-300 mg/kg soil dry weight. Limit value for lead concentration in sewage sludge for use in agriculture: 750-1200 mg/kg dw. Limit value for amounts of lead added annually to agricultural land based on 10-years average: 15 kg/ha/year.

Danish Statutory Order: Bekendtgørelse om anvendelse af affald til jordbrugsformål (Slambekendtgørelsen)		Danish Statutory order: Limit value for lead in sewage sludge for use in agriculture: 120 mg/kg DM.
Danish Statutory Order: Bekendtgørelse om anvendelse af restprodukter og jord til bygge- og anlægsarbejder og om anvendelse af sorteret, uforurenet bygge- og anlægsaffald BEK nr. 1662 af 21/12/2010	DK	This statutory order sets down the rules concerning use of waste products and soil for building and construction work, and about the use of sorted, unpolluted building and construction waste, with the aim of reducing the amount of waste for landfill or incineration, and to reduce the consumption of raw materials. Restrictions are made regarding lead content above 40 mg/kg DM, and 10 mg/l in eluate.
Danish Statutory Order: Bekendtgørelse om anvendelse af bioaske til jordbrugsformål (Bioaskebekendtgørelsen) BEK nr. 818 af 21/07/2008	DK	Limit values for lead; 120 mg/kg DM, 250 mg/kg DM for wood ash used in forestry.
Danish Statutory Order: Bekendtgørelse om anlæg, der forbrænder affald BEK nr 1451 af 20/12/2012 Transposes part of the provisions of Directive 2010/75/EU on industrial emissions	DK	Emission limit for lead; 0.5 mg/m3. Waste water from cleaning of flue gas: 0.2 mg/L.
Danish Statutory Order: Bekendtgørelse om anmeldelse og dokumentation i forbindelse med flytning af jord BEK nr. 1479 af 12/12/2007 (Jordflytningsbekendtgørelsen)	DK	Stipulates rules for notification and documentation when soil containing lead above the limit values is displaced under certain conditions. Limit values: Category 1: ≤ 40 mg/kg Category 2: ≤ 400 mg/kg

Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (PRTR Regulation)	EU	Releases of lead and lead compounds shall be reported by operators with activities above a certain activity threshold if the releases are above a certain threshold releases: To air: 200 kg/year To water: 20 kg/year To land: 20 kg/year
Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (Recast)	EU	Emission values for lead and its compounds (expressed as Pb): Air emission limit values for waste incineration plants: 0.5 mg/Nm3. Emission limit values for discharges of waste water from the cleaning of waste gases from incineration of waste: 0.2 mg/L.
Danish Statutory Order: Bekendtgørelse om vurdering og styring af luftkvaliteten BEK nr. 1326 af 21/12/2011 (Luftkvalitetsbekendt-gørelsen)	DK	Determines common methods and criteria for the assessment of concentrations of lead in ambient air and deposition. Danish Statutory Order: Deadline for assessment of measure 31 December 2012. 4. Bly – Yearly average Upper assessment level: 70 % (0,35 µg/m^3) of limit value of 0.5 µg/m^3 Lower assessment level: 50 % (0,25 µg/m^3 of limit value of 0,5 µg/m^3
Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy [Water framework Directive] Danish Statutory Order: Bekendtgørelse om miljøkvalitetskrav for vandområder og krav til udledning af forurenende stoffer til vandløb, søer eller havet BEK nr. 1022 af 25/08/2010	EU	Lead included in list of priority hazardous substance. Specific environmental quality standards (EQS) for lead and its compounds (depending on water hardness classes). AA: annual average; MAC: maximum allowable concentration; Unit:µg/L: AA-EQS (2)Inland surface waters (3); 7.2 AA-EQS (2)Other surface Waters; 7.2 MAC-EQS (4) Inland surface(3); waters not applicable MAC-EQS (4) Other surface waters; not applicable AA: Annual average; MAC: Max. Concentration. Environmental quality criteria for lead in water; General quality criteria; 0.34 µg Pb/l for fresh and marine waters. Short term quality criteria; 2.8 µg Pb/l for fresh and marine waters.

Bekendtgørelse om fastsættelse af miljømål for vandløb, søer, kystvande, overgangsvande og grundvand BEK nr. 1433 af 06/12/2009	DK	Lead is mentioned in the minimum list of substances for which a threshold value should be established.
Bekendtgørelse om kvalitetskrav til miljømålinger BEK nr. 900 af 17/08/2011	DK	Sets action levels by quality control and requirements regarding the quality of analyses.
Directive 2006/118/EC on the protection of groundwater against pollution and deterioration Danish Statutory Order: Bekendtgørelse nr. 1434 af 06/12/2009 om overvågning af overfladevand, grundvand, beskyttede områder og om naturovervågning i internationale naturbeskyttelsesområder mv. Bekendtgørelse om kvalitetskrav for skaldyrvande BEK nr. 38 af 19/01/2011 Bekendtgørelse nr. 41 af 19/01/2011 Bekendtgørelse om ændring af bekendtgørelse om overvågning af overfladevand, grundvand, beskyttede områder og om naturovervågning i internationale naturbeskyttelsesområder mv.	EU/DK	Lead is mentioned in the Minimum list of pollutants and their indicators for which Member States have to consider establishing threshold values in accordance with Article 3. Establishes rules for monitoring of groundwater (lead not mentioned). Sets quality values for shellfish waters for lead and other substances. Lead is in the list of parameters for the evaluation of quality criteria for shell fish waters, also sampling frequency is given (at least every 6 months). The statutory order is an implementation of Directive 2006/113/EC mentioned below.

Directive 2006/113/EC on the quality required of shellfish waters (codified version)	EU	Sets quality values for shellfish waters for lead and other substances.
Bekendtgørelse af lov om beskyttelse af havmiljøet (Havmiljøloven) BEK nr. 929 af 24/09/2009	DK	Lead is on the list of substances that may only be found in insignificant amounts and concentrations in dredging material.
Danish Statutory Order: Bekendtgørelse om definition af lettere forurenet jord (BEK nr. 554 af 19/05/2010)	DK	Values for lead are established here. Soil with concentrations of lead from 40 to 400 mg Pb/kg is considered slightly polluted.
Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II) Danish Statutory Orders: Risikobekendtgørelssen BEK nr. 1666 af 14/12/2006 Gældende Arbejdstilsynets risikobekendtgørelse BEK nr. 20 af 12/01/2006 Gældende	EU/DK	Sets out the requirements for the preparation of accident prevention policies, safety reports and emergency plans for sites storing dangerous substances, including lead compounds, in volumes greater than defined thresholds. The two statutory orders implement the Council Directive 96/82/EC.
Danish Statutory Order: Bekendtgørelse om godkendelse af listevirksomheder. BEK nr 14564 af 20/12/2012	DK	Sets out criteria for the authorisation of industrial facilities handling substances that may pose a risk when emitted into the environment. If substances on the "List of unwanted substances" are used it shall be justified why substitution is not possible.
Regulation addressing food, feed and drinking water		
Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs	EU	Sets maximum levels for lead in a number of different foodstuffs. In various food items the maximum level are between 0.02 and 1.5 mg/kg.
Regulation 1935/2004 materials and articles	EU	Lead not specifically mentioned, but article 13 says food contact materials must not endanger

intended to come into contact with food		human health.
Regulation 10/2011 on plastic materials and articles intended to come into contact with food	EU	Lead is only specifically mentioned in the purity specifications for one copolymer. Limit: 2 mg Pb/kg plastic. However, no lead or lead compounds are on the Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids.
Danish statutory order no. 822/2013 on food contact materials	DK	https://www.retsinformation.dk/Forms/R0710.aspx?id=152320 Sets a limit of migration from ceramics, enameled food contact materials, and glass. Note that metal grills and hot drink machines may contain lead, and this needs to be addressed in legislation, and enforced.
COMMISSION REGULATION (EU) No 744/2012 of 16 August 2012	EU	Sets the maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 % for lead; feed materials: 10 (With exemptions).
Directive 2002/32/EC on undesirable substances in animal feed as regards lead, fluorine and cadmium Danish Statutory Order: Bekendtgørelse 998 af 12/10/2004 om foderstoffer	EU/DK	Sets maximum content of lead in different types of feed materials, between 5 and 40 mg Pb/kg.
Council Directive 98/83/83/EC on the quality of water intended for human consumption		Limit value for lead 10 µg/l (note that a limit value of 25 µg/l applies until the end of 2013) .
BEK 1024 af 31/10/2011 Bekendtgørelse om vandkvalitet og tilsyn med vandforsyningsanlæg	DK	Sets limit value for lead in drinking water to 5 µg/lwhen entering households and 10 µg/l when leaving the tap.
BEK nr 31 af 21/01/2013; Executive Order no. 31 of 21 January 2013	DK	Sets special requirements for release of lead from taps to 5 µg (to be fulfilled at the latest by April 2016, until then a requirement of 20 µg is accepted).

Executive Order on issue of approvals for building components that come into contact with drinking water		
Commission Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters Danish Statutory Order: Bekendtgørelse om naturligt mineralvand, kildevand og emballeret drikkevand BEK nr. 1015 af 10/12/2003 (Mineralvandsbekendt-gørelsen)	EU DK	Limit value of lead in mineral water: 0.01 mg/L.
Regulation addressing the working environment		
Danish Statutory order: Bekendtgørelse om arbejde med stoffer og materialer med senere ændringer BEK nr. 292 af 26/04/2001	DK	This Executive Order applies to any work with substances and materials, including their manufacture, use and handling. The Order demands the employer to ensure that dangerous substances and materials at the workplace are eliminated, replaced or reduced to a minimum. Annex 1 set specific requirements for work, where a risk of exposure to lead and its compounds, is expected.
Council Directive 98/24/EC and amending Commission Directive 2000/39/EC	EU	Establish indicative occupational exposure limits for chemical agents Occupational Exposure Limit (OEL): 0.15 mg Pb/m3 (8 hour) ANNEX II BINDING BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES 1. Lead and its ionic compounds 1.1. Biological monitoring must include

		measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is: 70 lg Pb/100 ml blood 1.2 Medical surveillance is carried out if: Ð exposure to a concentration of lead in air is greater than 0,075 mg/m3, calculated as a time-weighted average over 40 hours per week, or Ð a blood-lead level greater than 40 lg Pb/100 ml blood is measured in individual workers.
Danish Statutory Order; Bekendtgørelse om ændring af bekendtgørelse om grænseværdier for stoffer og materialer BEK nr. 1134 af 01/12/2011	DK	Limit value for lead: 0.05 mg/m^3 Biological limit value: 20 µg Pb/dL blood.
Danish Statutory Order: Bekendtgørelse om foranstaltninger til forebyggelse af kræftrisikoen ved arbejde med stoffer og materialer BEK nr. 908 af 27/09/2005	DK	Sets conditions for certain working processes with specific lead compounds above a concentration of 0.1% lead or lead compound.
Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health of pregnant workers and workers who have recently given birth or are breast-feeding	EU	Sets out measures to protect pregnant workers and workers who have recently given birth or are breast-feeding, including requirement to assess exposure to health risks, also specifically addressing lead and lead compounds.
Council Directive 94/33/EC on the protection of young people at work	EU	Prohibits the use of chemical agents, including lead compounds, by young workers.

2.1.2 Classification and labelling

Substances and mixtures placed on the market in EU shall be classified, labelled and packaged according to the CLP regulation (1272/2008/EC).

2.1.2.1 Harmonised classification in the EU

Besides the harmonised classification for “lead compounds” as such there are harmonised classifications for 16 lead compounds according to Annex VI of the CLP Regulation.

The classification of lead compounds depends of the intrinsic properties of Pb-cation as well as the intrinsic properties of the anion of the compound.

A harmonised classification applies to 9 of the 65 compounds registered under REACH. Some examples of harmonized classified compounds are provided in Table 2-2.

From the table it can be seen that the most critical classifications for lead compounds in general are: Repr. 1A, H360Df (May damage fertility or the unborn child); STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure) and Aquatic Acute 1, H400 (Very toxic to aquatic life); Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects).

The harmonised classification as Carc 1B; H350 (May cause cancer) of Pigment yellow is due to the content of Cr(VI) in the chromate ion.

TABLE 2-2 HARMONIZED CLASSIFICATION OF SELECTED LEAD COMPOUNDS ACOORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International chemical identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
082-001-00-6	Lead compounds with the exception of those specified elsewhere in this Annex	-	Acute tox. 4 Acute tox. 4 Repr. 1A STOT RE2 Aquatic Acute 1 Aquatic Chronic 1	H302 H332 H360Df (Repr. 2; H361f ≥2.5%) H373 (STOT RE2 ≥ 0.5%) H400 H410
082-005-00-8	Lead di(acetate) (1-10 tonnes/ year)	301-04-2	Repr. 1A STOT RE2 Aquatic Acute 1 Aquatic Chronic 1	H360Df H373 H400 H410
082-003-00-7	Lead azide Lead diazide (10-100 tonnes/year)	13424-46-9	Unst. Expl. Acute tox. 4 Acute tox. 4 Repr. 1A STOT RE2 Aquatic Acute 1 Aquatic Chronic 1	H200 H302 H332 H360Df H373 H400 H410
082-009-00-X	C.I. Pigment Yellow 34 [This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77603.] lead sulfochromate yellow (1,000-10,000 tonnes/ year)	1344-37-2	Carc. 1B Repr. 1A STOT RE2 Aquatic Acute 1 Aquatic Chronic 1	H350 H360Df H373 H400 H410

H200 Unstable explosives
H302 Harmful if swallowed
H332 Harmful if inhaled

H350 May cause cancer
H360 May damage fertility or the unborn child
H373 May cause damage to organs through prolonged or repeated exposure
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

Currently no harmonised classification applies for *metallic lead*.

However a proposal for harmonised classification of metallic lead has been submitted to ECHA in 2012 and has undergone public consultation in 2012. An opinion from the Risk Assessment Committee is expected during 2014 at the latest. According to this proposal metallic lead should be classified as Repr 1A; H360Df (May damage fertility; May damage the unborn child) similar to the classification that apply for "lead and lead compounds". Further the classification is proposed to apply down to a specific concentration limit of 0.03% metallic lead in a mixture.

2.1.2.2 Self-classification in the EU

The classification inventory at the ECHA web-site contains classification and labelling information on notified and registered substances received from manufacturers and importers. These are self-classifications which are used by the suppliers of the chemicals. A total of 164 different lead compounds have been notified.

Below the self-classifications are given for selected lead compounds registered at very high or high tonnage levels, Table 2-3. It can be seen from the table that the same compounds may be classified differently by different notifiers. This may be due to e.g. different data sources for the notifications or different interpretation of the data by the notifiers, or maybe errors. It can be seen that the harmonized classification of lead compounds in general is reflected in the self-classification of the specific compounds.

TABLE 2-3 NOTIFIED SELF-CLASSIFICATION OF SELECTED LEAD COMPOUNDS (FROM ECHA CLASSIFICATION INVENTORY)

Compound	CAS No	Classification		No. of notifiers
		Hazard Class and Category Code(s)	Hazard statement Code(s)	
Lead (1,000,000-10,000,000 tonnes / year)	7439-92-1	Acute tox. 4 Acute tox. 4 Repr. 1A STOT RE2 Aquatic Acute 1 Aquatic Chronic 1 ----------------------- Muta.2 Carc. 2 Repr.2	H302 H332 H360Df (Repr. 2 ≥2.5%) H373 (STOT RE2 ≥ 0.5%) H400 H410 --------------------- H341 H351 H361	Most widely used classification (296 of 1498) notifiers) ------------ additional classifica-tions which have been used in

		Repr.1B STOT SE2 STOT RE1 Acute tox.3 Not classified	H360 H371 H372 H301	various combina-tions by the remaining notifiers. 223 notifiers
Lead monoxide (100,000-1,000,000 tonnes / year)	1317-36-8	Acute tox. 4 Acute tox. 4 Repr. 1A STOT RE 2 Aquatic Chronic 1 -------------------- Carc. 2 STOT RE 1 Aquatic Acute 1	H302 H332 H360 (Repr. 2 ≥2.5%) H373 (STOT RE2 ≥ 0.5%) H410 --------------------- H351 H372 H400	Most widely used classification (121 of 540) notifiers) --------------- Additional classifica-tions that have been used in various combina-tions by the remaining notifiers.
Lead oxide sulphate (100,000-1,000,000 tonnes / year)	12065-90-6	Acute tox. 4 Acute tox. 4 Carc. 2 Repr. 1A STOT RE1 Aquatic Chronic 1 ------------------------ STOT RE 2	H302 H332 H351 H360Df (Repr. 2 ≥2.5%) H372 (STOT RE2 ≥ 0.5%) H410 M=1 -----------------------	Most widely used classi-fication (33 of 35) noti-fiers) --------------- Additional classification by the remaining 2 notifiers not using Carc. 2 classification
Tetraethyl lead (1,000-10,000	78-00-2	Acute tox. 4	H302	Most widely used

tonnes / year)		Acute tox. 1 Acute tox. 4 Repr. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1 ----------------------- Acute tox. 1 Acute tox. 2 Acute tox. 1 Acute tox. 2	H310 H332 H360 H373 H400 H410 --------------------- H300 H300 H330 H330	classification (23 of 51) notifiers) --------------------- additional classifica-tions which have been used in various combinations by the remaining notifiers.
Fatty acids, C16-C18, lead salts (10,000-100,000 tonnes / year)	91031-62-8	Acute tox. 4 Acute tox. 4 Carc. 2 Repr. 1A STOT RE 1 Aquatic Chronic 1	H302 H332 H351 H360 (Repr 2 ≥2.5%) H373 (STOT RE1 ≥0.5%; STOT RE2 ≥0.05%) H410	7 of 7 notifiers. SCL for Repr. and STOT RE classification

H200 Unstable explosives
H300 Fatal if swallowed
H301 Toxic if swallowed
H302 Harmful if swallowed
H310 Fatal in contact with skin
H330 Fatal if inhaled
H332 Harmful if inhaled
H341 Suspected of causing genetic defects
H350 May cause cancer
H351 Suspected of causing cancer
H360 May damage fertility or the unborn child
H361 Suspected of damaging fertility or the unborn child
H371 May cause damage to organs
H372 Causes damage to organs
H373 May cause damage to organs through prolonged or repeated exposure

H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

2.1.3 REACH

Registration
A total of 65 lead compounds have been registered under REACH by 2013. Of the 65 registered lead compounds 30 are registered as intermediates (see tonnage for the other registrations in appendix 1). The registered substances currently cover substances produced or imported in volumes exceeding 100 tonnes/year. Additional lead compounds may be registered by the last registration deadline in 2018, which applies to substances marketed in volumes exceeding 1 ton/year.

Authorization
Three lead compounds have been placed on the authorisation list, REACH Annex XIV:

TABLE 2-4 LEAD COMPOUNDS UNDER AUTHORISATION IN REACH

Compound Name	CAS Number	Sunset date	Latest application date
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2	21/05/2015	21/11/2013
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	12656-85-8	21/05/2015	21/11/2013
Lead chromate	7758-97-6	21/05/2015	21/11/2013

Candidate list
30 lead compounds are placed on the candidate list for authorization as they are defined as Substance of Very High Concern due to their classification as Repr. 1A, (see full list in Appendix 3). A proposal for inclusion for yet another lead compound, lead di(acetate), on the candidate list is currently in public consultation (September 2013).

Restriction
Currently there are REACH annex XVII restrictions (ban) on:
- Lead carbonates and lead sulphates for the use in paints
- Metallic lead and lead compounds in in concentration of more than 0.05% in jewellery

Furthermore a restriction proposal for banning lead and lead compounds in articles intended for consumer use (with a Pb content above a level of 0.05 w/w %) are under discussion in ECHA. The proposal is currently under public consultation and will be concluded upon by the ECHA committees during 2014.

2.2 International agreements

Lead in the form of tetraethyl and tetramethyl lead is on the OSPAR list of substance of possible concern, with intentions of reducing discharges in order to reach near-background concentrations in the OSPAR maritime area (the North-East Atlantic), whereas lead and 8 organic lead compounds are on the Priority action list of OSPAR.

HELCOM, The Helsinki Commission has issued a range of recommendations regarding lead. This includes but are not limited to recommendations on the reduction of emission of lead from leaded fuel, restriction of discharge and emission of lead from treated metal surfaces, proper handling of waste and reduction of discharge from urban areas by the treatment of storm water.

Lead is listed in Annex II of the Barcelona convention, the Annex regards Harmful or Noxious Substances and Materials for which the disposal in the Protocol Area is subject to a special permit.

The Bucharest convention on the protection of the Black Sea, lists heavy metals and its compounds, herein lead and its compounds, with the aim of reducing, controlling, and eliminating use and release of harmful substances in order to prevent the environment of the Black Sea.

The Basel convention set out control measures of the movements of hazardous waste incl. waste containing lead between nations, and restricts transfer of hazardous waste from developed to less developed countries (non-adopted). The convention also intends to minimize the amount and toxicity of wastes generated, to ensure their environmentally sound management as closely as possible to the source of generation, and to assist least developed countries (LDCs) in environmentally sound management of the hazardous and other wastes they generate.

Lead is not directly covered by the Rotterdam Convention on prior informed consent (the PIC-procedure), but tetraethyl lead and tetramethyl lead are, however, covered by Regulation (EC) No 689/2008 implementing the Convention in the EU.

Lead compounds are not listed in the Stockholm convention on persistent organic pollutants.

2.3 Eco-labels

Eco-labels are voluntary labeling schemes that can be applied to a range of products and services to document compliance with a specific set of criteria. This section will focus on the Nordic Swan, the EU flower and the German Blue Angel, which represent the eco-labels most often encountered on products on the Danish market. The Nordic Swan and the EU flower can largely be regarded as having the same criteria, and the EU flower is therefore considered as covered by the description of the Nordic Swan.

The use of lead is generally prohibited or restricted in eco-labelled products. The Nordic eco-label, the Nordic Swan covers more than 60 different consumer product groups, ranging from alternatives to dry cleaning to dishwasher machines and vehicle tires. When lead is mentioned in the criteria it is generally not allowed to be present or used in the production of the product group. In cases where lead can be present as an impurity, for example in zinc oxide, certain restrictions apply for the level of impurities. This is the case for the use of zinc oxide in vehicle tires, where lead should be present as less than 0.1% of the zinc oxide, or 0.00155% of the final tires. The German Blue Angel sets criteria for the presence of lead in several product groups, for example paper products where lead is prohibited. The same applies for plastic used in consumer products, wood products, pigments and dyes.

2.4 Summary and conclusions

In EU lead compounds in general should be classified as Repr 1A, H360Df (May damage fertility or the unborn child) due to adverse effects with respect to fertility and the development of the central nervous system of the unborn and developing child. Furthermore classification as STOT Re2;H373 (May cause damage to organs through prolonged and repeated exposure) due to adverse effects on several organs. Environmental classification with Aquatic Acute 1, H400 (Very toxic to aquatic life) and Aquatic Chronic 1;H410 (Very toxic to aquatic life with long lasting effects) also applies to lead compounds.

Furthermore, lead accumulates in the human body and in the environment which enhance the toxicity of the compound.

Until now there has not been any EU-harmonized classification of metallic lead, but currently it is discussed whether classification with Repr 1A, H360Df (May damage fertility or the unborn child) should also apply for metallic lead in association with a specific concentration limit for classification of metallic lead in mixtures down to a concentration level at 0.03 wt% or 300 mg/kg.

Due to these adverse effects of the compounds the lead compounds (and metallic lead) have for many years been regulated at both national level, EU level and at global level and thus, lead and the lead compounds may be considered as maybe the most extensively regulated compounds in the world.

In EU, ban or strict restrictions have been implemented for lead/ lead compounds in e.g. paints, cosmetics, toys, packaging, jewellery, ceramics, electronic equipment, vehicles, petrol, feed, food, drinking water, etc.

Regulation regarding lead also applies to waste, industrial air-borne emission, waste water emissions, quality criteria in soil/ sewage sludge/ambient air/ marine water/ and fresh water.
In the occupational environment strict measures apply for securing the safety of the workers through occupational limit values including specific guidelines for occupational handling of lead and lead compounds. In addition to this specific measures are taken for protecting young workers and pregnant women at the work place.

A total of 65 lead compounds have been registered under REACH and 30 lead compounds have been put on the REACH candidate list. Until now, three lead compounds (C.I. Pigment Yellow 34 (lead sulfo chromate yellow); C.I. Pigment Red 104 (Lead chromate molybdate sulphate red) and lead chromate) are subject to the authorization process in REACH.

Two organic lead compounds are on the OSPAR list of compounds of possible concern, whereas further 8 organic lead compounds are on the priority action list. Also HELCOM has focus on lead and lead compounds and has in connection with this issued a range of recommendations.
Substances and mixtures placed on the market in EU shall be classified, labelled and packaged according to the CLP regulation (1272/2008/EC).

3. Manufacture and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

Lead is found at low concentrations in the earth's crust, mainly as lead sulfide (galena, PbS). Lead is usually found in ores with zinc, silver and (most abundantly) copper, and is extracted together with these metals. The main lead mineral, lead sulfide, contains approximately 85% lead. Other common varieties are lead carbonate (cerussite, $PbCO_3$) and lead sulfate (anglesite, $PbSO_4$).

Most ores contain less than 10% lead, and ores containing as little as 3% lead can be economically exploited. Sulfide ores are roasted (treated with hot air), producing primarily lead oxide and a mixture of sulfates and silicates of lead and other metals contained in the ore. Lead oxide from the roasting process is then reduced in a coke-fired blast furnace where most of the lead is converted to its metallic form.

Metallic lead can then be further processed to produce e.g. lead batteries, lead sheets, lead powder, leaded steels, lead oxide and other lead compounds, and in the production of other articles containing lead (Swedish Chemical Agency, 2012a).

The manufacturing processes of the high volumes of lead oxides (PbO and Pb3O4) use highly refined metallic lead (99.9%) as raw material. The chemistry of the process is an oxidation of lead with atmospheric oxygen. The oxidation of lead is exothermic and the process temperature can be maintained without additional heating. The final oxidation products are as powders.
(LDAI, 2008)

3.1.2 Manufacturing sites and volumes

LDAI (2008) lists 32 production plants in EU-15 which have a refined production of metallic lead exceeding an annual tonnage of 1000 t/year. Overall manufacturing volumes were also given for EU15 in the period of 1998-2001, Table 3-1:

TABLE 3-1 PRODUCTION AND CONSUMPTION OF LEAD WITHIN THE EU-15 (LDAI, 2008)

	1998	1999	2000	2001
Mine production (tonnes) 1)	200,000	210,000	234,000	200,000
Refined metal production (tonnes)2)	1,547,000	1,564,000	1,598,000	1,567,000
Refined metal consumption (tonnes)	1,653,000	1,662,000	1,728,000	1,733,000

1) Tonnage by lead content
2) From mining + recycling

The Swedish Chemical Agency (2012c) has more recently compiled mine production tonnage levels from the various countries in EU, showing that Sweden has far the highest production volume, Table 3-2.

TABLE 3-2 MINE PRODUCTION OF LEAD IN EUROPE, TONNES OF LEAD (SWEDISH CHEMICAL AGENCY, 2012C)

Country	2006	2007	2008	2009	2010
Bulgaria (a)	19 571	17 768	14 577	12 981	12 705
Greece	11 400	13 400	14 000	10 000	12 200
Ireland	61 800	56 800	50 200	49 500	39 100
Italy	6 000	3 000	3 000	2 000	3 000
Macedonia	11 531	36 039	49 877	46 788	41 300
Poland	77 450	61 330	67 070	62 910	44 200
Romania	6 269	784	-	-	-
Spain	-	-	-	1 000	300
Sweden	55 644	63 224	63 489	69 293	67 697
Turkey	11 000	20 800	31 800	21 600	39 000
United Kingdom	400	300	300	243	251
EU34 Total	261 100	273 400	294 300	276 300	259 800

On a global level, however, China dominates the lead mining industry, accounting for nearly half of the global lead production. Other major lead mining countries are Australia, USA and Peru (LDAI, 2008).

3.2 Import/export and recovery

3.2.1 Import/ export and recovery in EU

Specific import/ export figures are given in LDAI (2008):

TABLE 3-3 IMPORTS AND EXPORTS OF LEAD TO FRANCE, GERMANY, ITALY AND THE UK (LDAI, 2008)

	1998	1999	2000	2001
Concentrates imports (tonnes) 1)	208,000	248,000	239,000	212,000
Concentrates exports (tonnes) 1)	0	0	0	0
Refined metal imports (tonnes)	85,000	99,000	153,000	120,000
Refined metal exports (tonnes)	54,000	52,000	56,000	50,000

1) Tonnage by lead content

These figures have been updated by the Swedish Chemical Agency (2012c):

TABLE 3-4 IMPORT, EXPORT AND INTRA-EU TRADE OF LEAD RAW MATERIALS. AVERAGE VALUES 2005-2010 (SWEDISH CHEMICAL AGENCY, 2012C)

	Lead ores and concentrates. Tonnes of lead per year	Lead waste and scrap tonnes per year
Imports to EU27	245,000	264,000
Exports from EU27	124,000	399,000
Intra EU trade	298,000	157,000

Secondary production (recovery) constitutes around 65% of refined lead metal production in the EU. The data for secondary lead recovery as a percentage of refined metal production are presented in Table 3-5.

TABLE 3.5 RECOVERY OF SECONDARY LEAD WITHIN THE EU-15 (LDAI, 2008)

	1998	1999	2000	2001
Refined metal production (tonnes)	1,547,000	1,564,000	1,598,000	1,567,000
Secondary lead production (tonnes)	914,000	956,000	1,034,000	1,024,000
Percentage secondary production	59 %	61 %	65 %	65 %

The figures in Table 3-5 do not include lead which is recovered simply as a result of re-melting rather than secondary refining.

Most recycled lead is recovered from batteries and from applications in construction including lead sheets and piping. Lead is also recovered from electronic equipment and from the automotive industry. Recycling rates for process scrap are about 100%. The wide range of product lifetimes (up to hundreds of years) makes estimation of old scrap recycling rates difficult (LDAI, 2008).

3.2.2 Import/ export and recovery in Denmark

In 2000 it was estimated that the *import* of lead in connection with raw materials, semi-finished products and finished products was in the range of *18,000-22,700 tonnes*. Further an *import of 64-130 tonnes* was considered due to trace amounts of lead (Danish EPA, 2004a).

Export in semi-finished and finished products was estimated in the range of *3,100-3,900 tonnes*. *Export* in waste and scrap was estimated to *12,400-14,800 tonnes*.

Recovery was estimated to *340-570 tonnes* (Danish EPA, 2004a). Detailed figures on import/export of metallic lead in various product categories are given in appendix 4.

In 2011 it was estimated that 18 576 tons of batteries containing lead acid was sent for recovery. The recovery rate was assessed to 100% (DPA system, 2012). Data from 2009 indicate export of 17,455 tonnes of used lead batteries (Danish EPA, 2011a).

3.3 REACH registration, volumes and uses.

Based on the data from the REACH registrations, see appendix 1, the lead compound can be split into the tonnage bands given in Table 3-6.

TABLE 3-6 TONNAGE BAND AND USES OF REGISTERED LEAD COMPOUNDS (ECHA WEBSITE, JUNE 2013)

Tonnage level/ year	Registered Lead compounds (CAS no.)	Registered uses
1,000,000 – 10,000,000	Metallic lead (7439-92-1)	Metals, alloys, metal articles, batteries, lead sheet, welding products, ammunition, manufacture of lead oxide

	Tetralead trioxide sulphate (12202-17-4)	Lead battery production, PVC processing/ stabiliser
100,000 - 1,000,000	Lead monoxide (1317-36-8) Pentalead tetraoxide suphate (12065-90-6) Trilead dioxide phosphonate (12141-20-7) Dioxibis(stearato)trilead (12578-12-0) Slags, lead-zinc smelting (93763-87-2)	Mainly for battery production; manufacture of rubber protection, and for PVC stabiliser production Lead battery production, PVC processing/ stabiliser PVC processing PVC processing Zn Waeltz slag production/ additive as fluxing agent in pyrometallurgical processes
10,000 - 100,000	Orange lead, (1314-41-6), Fatty acids, C16-18, lead salts (91031-62-8)	Battery production , rubber protection PVC processing (stabiliser)
1,000 - 10,000	Tetraethyllead (78-00-2) Lead sulfochromate yellow (1344-37-2) Lead chromate molybdate sulphate red (12656-85-8)	Fuel additive , fuel blends Pigment production Pigment production
100-1,000	Silicic acid, lead salt (11120-22-2) Lead oxide sulphate (12036-76-9) Lead titanium zirconium oxide (12626-81-2) Sulfourous acid, lead salt, dibasic (62229-08-7) Phthalate(2-)dioxotrilead (69011-06-9)	Lead crystal ware PVC processing Manufacture of piezoceramic, processing into electro-ceramic components PVC processing PVC processing
10-100	11 lead compounds	-

1-10	5 lead compounds	-
Intermediate use only	31 lead compounds	-
Tonnage confidential	2 lead compounds	-

Overall the REACH registration data indicate a total annual tonnage level of lead compounds in the EU in the range of 2,500,000 – 25,000,000 tonnes. However, it may be assumed that some of the volumes may be double-counted, e.g. first counted as metallic lead and then as lead oxide, as metallic lead is used for the production of lead oxide.

3.4 Use, globally and in EU

The Swedish Chemicals Agency (2012c) gives an overview of the global use of lead, Table 3-7.

TABLE 3-7 WORLD END USES OF LEAD 2011 (SWEDISH CHEMICALS AGENCY, 2012C)

Area of application	Volume in 1000 tonnes
Batteries	8500
Pigments and other compounds	560
Rolled and extruded products	360
Miscellaneous	210
Shot and ammunition	140
Alloys	130
Cable sheathing	90
Fuel additives	9

Data from LDAI (2008):

TABLE 3-8 ESTIMATED USE OF LEAD BY SECTOR IN THE EU (LDAI, 2008)

	1998 (tonnes)	1999 (tonnes)	2000 (tonnes)	Percentage use in 2000
Batteries[1)]	976,600	1,001,200	1,008,900	61 %
Rolled and extruded products	245,700	235,800	242,400	14 %
Pigments and other compounds[2)]	204,200	195,300	200,800	12 %
Shot and ammunition	61,900	58,400	56,600	3 %
Alloys	33,900	36,900	39,600	2 %
Cable sheathing	37,100	35,300	31,300	2 %
Fuel additives[3)]	24,800	21,500	19,400	1 %
Miscellaneous	68,800	77,600	78,200	5 %

1) Includes oxides for battery manufacture

2) Includes oxides for uses other than battery manufacture

3) Refers to the consumption of lead in the production of petrol additives in one EU plant.

From the registered use given in Table 3-6 it can be seen that the main applications for metallic lead are in batteries, rolled and extruded products, shot and ammunition, alloys, and cable sheeting. Lead sulphates and oxides are used in battery production and in PVC processing as stabilisers. Other lead compounds are used as fuel additives, in lead glassware, as pigments, in ceramics and in electronics.

In appendix 5 all the lead compounds REACH registered for use as pigments or PVC stabilisers are given.

3.4.1 Denmark

In the Nordic SPIN database 94 lead compounds are registered. According to the SPIN database the use of many compounds is either very low or has stopped e.g. for lead oxide sulphate (very high volume in EU) no use in Denmark has occurred since 2003. For lead oxide (blymønje, CAS 1314-41-6) a very low tonnage level of 0.1 tonnes has been registered in Denmark in 2011. For many other compounds the volumes are confidential because the tonnage levels are not available when less than three companies have registered the compound.

The relatively low tonnages regarding use of metallic lead and lead compounds (as also seen below) may be seen in the context of the Danish ban on the use of lead that was implemented in 2001.

No systematic review for the 94 compounds in the SPIN database has been made. Based on searches on metallic lead, the pigments and some of the acids, the following consumption and uses have been found for 2011:

Metallic lead (CAS 7439-92-1)
In Denmark the registered use of metallic lead had a tonnage level of 78 tonnes in 2011 was covered by 303 preparations. 41 tonnes were used for welding products whereas the use of the rest of the tonnage cannot be seen in the register.

Chromic acid lead salt or Lead (II) chromate (CAS 7758-97-6)
In Denmark 37 tonnes was registered in 2011 covered by 15 preparations. 10 preparations were in the group of paint and laquers having a tonnage level of 0.3 tonnes. The use of the remaining tonnage cannot be retrieved by the register. Note that this substance is on the authorization list under REACH (Sunset date 21/5-2015).

Lead sulfochromate yellow or C.I. Pigment Yellow 34 (CAS 1344-37-2)
In Denmark a tonnage level of 191 tonnes was registered in 2011 distributed on 126 preparations. 136 tonnes were used as colouring agents and 4.7 tonnes in paint and laquers. Note that this substance is on the authorization list under REACH (Sunset date 21/5-2015).

Lead chromate molybdate sulfate red or C.I. Pigment Red 104(12656-85-8)
In Denmark a tonnage level of 22.8 tonnes was registered in 2011 distributed on 82 preparations. 10.8 tonnes were used as coloring agents and 2.3 tonnes in paint and laquers. Note that this substance is on the authorization list under REACH (Sunset date 21/5-2015).

Tetralead trioxide sulphate (12202-17-4)
Although registered at a very high level in REACH no use of this compound could be found in Denmark.

The SPIN database and the Danish Product Register does not cover lead and lead compounds incorporated in articles (such as batteries) which are imported to the Nordic countries/Denmark.

The Danish EPA (2004) gives an overall view of the consumption of lead compounds and lead in articles in Denmark in 2000 as shown in Table 3-9 below. The total consumption of lead was in

2000 estimated to be in the range of *14,900 – 19,000 tonnes*. The principal uses of metallic lead were: lead for accumulators, building materials (flashing and roofs), keels, copper and tin alloys, fishing tools and balancing weights.

TABLE 3-9 CONSUMPTION OF LEAD IN DENMARK IN 2000. (DANISH EPA, 2004A)

Consumption of lead in Denmark in 2000			
Product group	**Consumption tonnes Pb/year**	**% of total**	**Trend, year up to 2000**
Lead metal			
Accumulators*	8,300-9,300	52	Increasing
Building materials**	3,700-4,100	22.9	Stagnant
Ammunition*	110-200	1.0	Decreasing
Keels	240-740	3.0	Varying
Cable sheets**	353-383	2.2	Decreasing
Lead-tin alloys	190-350	1.6	Stagnant
Other alloys	170-350	1.5	Stagnant
Fishing tools	530-910	3.8	Decreasing
Other uses as metal	76-160	0.4	Stagnant
Chemical compounds			
Red lead**	0.5-2	< 0.1	Decreasing
Pigments**	17-70	0.3	Decreasing
Cathode ray tubes**	520-640	3.0	Stagnant
Other glass (mainly crystal glass)**	140-340	1.4	Stagnant
PVC	440-570	3.0	Stagnant
Ceramics**	40-150	0.6	Stagnant
Other uses as chemical	15-76	0.3	Different
Turnover as impurity			
Coal	40-67	0.3	Decreasing
Oil products	< 0.12	< 0.1	Stagnant
Biofuels	2.7-5.1	< 0.1	Increasing
Cement	13-26	0.1	Stagnant
Fertilizers and feedstuff	3.5-9.7	< 0.1	Stagnant
Lime	0.5-1.1	< 0.1	Decreasing
Sand blasting	2.9-6.1	< 0.1	Stagnant
Other turnover	4-24	< 0.1	Different
Total (rounded)	14,900-19,000	100	

*Not covered by the general ban on lead in the Danish legislation. Specific legislation applies to the use where lead is still in use.

** Covered by the general ban on lead in the Danish legislation but specific derogations for continued use of lead apply (see appendix 4)

No more recent Danish overviews are available for updated figures. Thus, the data in the table pertain to a period just before the Danish statutory order on the restrictions on lead had entered into force and therefor the use pattern today should have changed quite a lot e.g. the use in cathode ray tubes may have declined significantly due to the shift in technology into television flat screens.

New data on batteries indicate that the consumption of car batteries with lead acid was 11,145 tonnes of batteries in 2011 while the consumption of industrial batteries with lead acid was 8,703 tonnes of batteries. (It may be difficult to make a direct comparison of this figure to the battery/accumulator figure in Table 3-9 as the value in Table 3-9 refers to tonnes of lead and not to tonnes of batteries).

3.5 Historical trends in use

From the lead manufacturing data in Europe (Table 3-2) it can be seen that lead production has been quite stable in the period from 2006 to 2010 at a level in the range of 260.000 – 294.000 tonnes.

The trend for the use of lead and lead compounds in Denmark up to year 2000 is given in Table 3-9. However, this was before the Danish statutory order on lead restriction went into force in November 2000.

An assessment of the statutory order was made in 2006 by the Danish EPA, however, without specific quantitative data. On a qualitative basis it was concluded that the previous use of lead in pigments for plastic and lead compounds as stabilizer in PVC in 2006 had nearly stopped. Generally for many other uses it was concluded that there had been a significant trend from the use of lead to alternatives because of the introduction of the statutory order (Danish EPA, 2006a).
Although a decreasing trend of the use of lead since 2000 may be anticipated, it has not been possible to find more detailed updated consumption figures for the various product categories except batteries and aviation fuel. Especially for use areas where lead may still be used (or partly used), e.g. in ammunition, in building materials for historic repair of buildings, in batteries, and in fishing tools, updated data may be useful for describing the trend in use. However, in 2007 it was anticipated that the statutory order on lead would result in a reduced use of lead of about further 4000 tonnes per year Danish EPA (2007).

For *batteries* during the period 2009 to 2011, a decreasing trend for the use of lead portable batteries containing lead acid (down to 61 tonnes of batteries in 2011) has been seen, whereas there has been an increase in the use of industrial batteries containing lead acid from approximately 5800 tonnes of batteries in 2009 to 8700 tonnes in 2011. The level of use of car batteries was rather stagnant (approximately 11200 tonnes of batteries in 2011) (DPA system, 2012).

In *aviation fuel* the organic lead substance tetraethyl lead is still used as an additive in fuel for small and older planes at a maximal concentration level of 0.56 g/L. The consumption for this purpose is gradually declining. Thus the consumption of fuel with tetraethyl lead in 2001 was at a level of 3,694 m^3 of fuel compared to 2,167 m^3 in 2012 (EOF 2013, personal communication).

A trend up to today can be given for other *specific lead compounds* which were considered most important in the Denmark in 2000, and for which the use volumes from year 2000 was gathered from the Danish Product Registry (Danish EPA, 2004a). Making an updated search on these compounds gives the following picture of the trend during the period, see Table 3-10.

From this it can be seen that there has been a decline in the use of pigments especially C.I Pigment Yellow 74. One exception for the pigments is an increase of the use of lead(II)chromate. Also for metallic lead an increase for the use in welding and soldering agents soldering products can be seen.

TABLE 3-10 TREND IN USE OF SELECTED LEAD COMPOUNDS (DANISH EPA 2000, AND UPDATED DATA FROM THE DANISH PRODUCT REGISTRY/ SPIN)

CAS Number	Compound Name	Use	Tonnage 1997	Tonnage 2006	Tonnage 2011	Trend 1997-2011
1072-35-1	Lead (II)stearate	Stabiliser	32	25	confidential	-
1344-37-2	C.I. Pigment Yellow 34	Pigment	346-354	521	191	decrease
1344-40-7	Lead oxide phosphonate (PB3O2(HPO3)), hemihydrate	Stabiliser	5-7	16.5	0	decrease
6358-31-2	C.I. Pigment Yellow 74	Pigment	4.025-4.507	1076	86	decrease
7439-92-1	Metallic lead	Welding/ soldering	2	17.4	78	increase
7758-97-6	Lead (II)chromate	Pigment	1-2	2.8	37	increase
12656-85-8	C.I. Pigment Red 104	Pigment	178-180	108	23	decrease

3.6 Summary and conclusions

Even though lead and lead compounds are subject to a great number of strict regulatory measures in Denmark, in EU and worldwide, metallic lead and lead compounds are used in very high quantities exceeding several million tonnes per year in the EU. Especially *metallic lead* and *tetralead trioxide sulphate* are used in very high tonnages above 1 million tonnes per year.

The metallic lead production in EU is either from mining and refining or from recovery of lead in the waste stream. In 2010 a total tonnage level of lead from mine production in EU of 259 800 tones was indicated. Figures from 2001 show that of the total refined lead production in Europe (EU15) 65% were from secondary/recovery production.

In EU in 2000 the far highest quantity of lead and lead compounds was used for lead batteries (61%). Other very important uses were: rolled and extruded products (14%), lead compounds in pigments, stabilisers a.o. (12%), shot/ammunition (3%), alloys (2%) cable sheeting (2%), gasoline additives (1%) and other purposes (5%).

In Denmark the pattern of consumption of lead has been analysed in details for year 2000. For lead and lead compounds a total annual consumption of 14,900-19,000 tonnes was estimated divided into the following uses: 52% for batteries; 23% for building materials, 3.8% for fishing tools, 3% for keels, 3% for PVC, 3% for catode ray tubes, 2.2% for cable sheets, 1.5% for alloys, 1.4% for crystal glass, 0.6% for ceramics, 0.4% for other metallic uses, and 0.3% for pigments.
In total 12,800-15,500 tonnes of lead were collected for recovery in Denmark in 2000.

In the Danish Product Registry, 94 lead compounds were registered in 2011. Four different lead pigments are registered with an annual use (2011) between 23 and 191 tonnes per year, whereas metallic lead is registered at a level of 78 tonnes. The use of metallic lead was mainly for welding/

soldering products. From 1997 to 2011 there has been an increasing trend in the use of metallic lead and lead chromate (pigment), whereas the use of other lead compounds has declined.
Overall, the cumulated use of the four lead pigments have declined in connection with the Danish ban on lead, from approximately 5000 tonnes in 1997 to approximately 1700 tonnes in 2006 and to 337 tonnes in 2011.

A more exact knowledge concerning the trend in the uses for the various lead applications and the impact of the implementation of the Danish Statutory order on ban of the use of lead is, however, missing, as most of the Danish figures regarding use volumes refer back to year 2000.

4. Waste management

Heavy metals that are extracted from mining and used for technology will sooner or later be discharged to the environment or end up in the waste stream. Heavy metals may end up in solid waste during all life cycle phases of the products as illustrated in Figure 4-1 below.

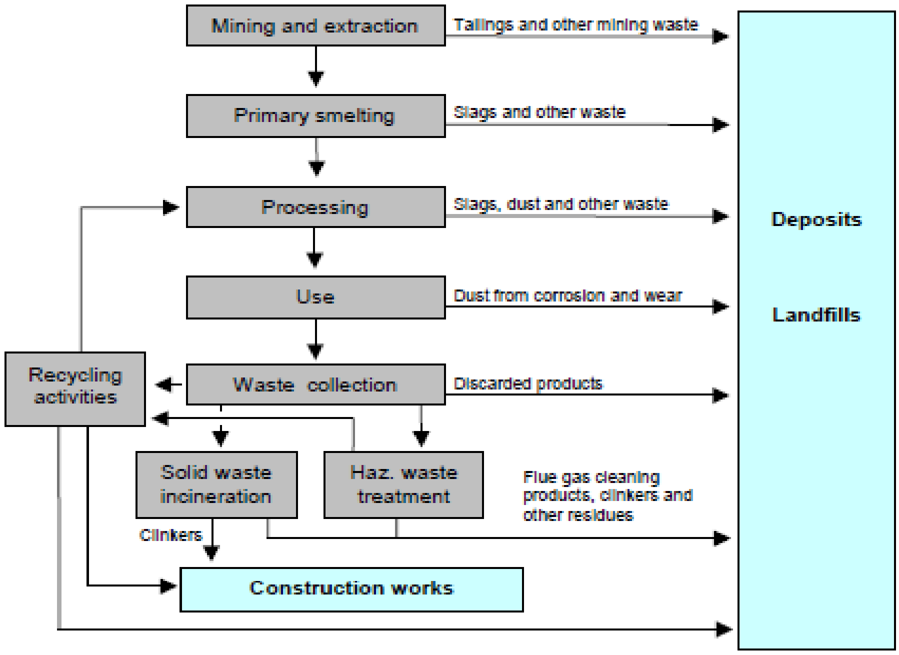


FIGURE 4-1 SCHEMATIC ILLUSTRATION OF THE OVERALL FLOW OF HEAVY METALS TO WASTE (COWI 2002)

For lead waste it may be noted that some fraction from the waste treatment will in the end and after the recycling activities either end up in deposits/ landfills or for use in construction works.

The data in this section is to a large extent based on Danish EPA (2004). For illustrative purposes the reader is referred to Figure 5-2 which also contains data on lead emission from waste treatment and data on recycling.

4.1 Regulatory practices

In Denmark waste is treated according to the statutory order on waste (Danish Ministry of the Environment, 2012). The statutory order i.e. includes waste streams where lead typically may occur. It is stated that PVC waste, waste containing heavy metals (e.g. fishing sinkers and nets) and waste from x-ray wards are not suitable for incineration.

In the statutory order several waste categories (cf. the European Waste Catalogue) are given for specific waste fractions that may contain lead.
It has to be noted that EWC code 17 04 04 specifically covers metallic lead and that this fraction is *not* regarded as hazardous waste according to European waste legislation.. This classification is

used on waste fractions solely containing metallic lead from constructions. If lead or lead compounds are found as a contaminant or as a pollution to one other waste fraction e.g. shredder waste, the waste will be classified as hazardous and will fall in under one of the EWC codes describing the waste containing hazardous substances

As an overall rule all waste fractions containing hazardous compounds at a concentration level that, according to the classification rules for chemical compounds and preparations would require classification as hazardous, should be considered and treated as hazardous waste. However, specific other rules may apply as well.

Acccording to the current regulation, waste containing lead compounds is considered as hazardous waste if the compounds of the lead compounds exceeds 0.5% as this was the classification limit for Rep1 classification of the lead compounds according to the old chemical classification system and the waste classification system refers to these “old” classifications. Currently a classification proposal on metallic lead is discussed at EU-level. If this proposal is agreed and implemented, metallic lead should be classified as Repr 1A H360D down to a lead content of 0.03% in lead containing mixtures (or 300 mg Pb/kg). Depending on the revision of the waste classification system it might be that this classification would thus give significant impact as all metallic waste fractions containing more than 300 mg Pb/kg should then be treated as hazardous.

At municipal level several municipalities in Denmark consider waste with a lead content above 0.25% (or 2,500 mgPb/kg) as hazardous waste that should be directed for special treatment (e.g. the municipalities of Copenhagen and Hillerød). Waste containing lead in the range of 40-2500 mg Pb/kg should be incinerated or disposed whereas waste with a lead content below 40 mg Pb/kg is considered as waste without any specific restrictions with respect to recycling (Cph Municipality, 2013; Hillerød Municipality, 2013).

Further, the municipality of Copenhagen instructs that industrial PVC waste with a lead content above 100 mg Pb/kg is not suitable for recovery, but should instead be disposed of (Cph Municipality, 2012).

4.2 Lead in waste from industry

In 2003 the Danish EPA analysed various industrial activities where lead may be a part of the waste and guides were elaborated in order to provide instructions on how to identify heavy metals in waste and ideas on how to achieve a *higher degree of sorting and recycling of heavy metals*. The guide comprises instructions for 16 types of enterprises:

metal-processing enterprises, plastics-processing enterprises, carpenters/joiners, plumbing and heating firms, plumbers and locksmiths’ shops, electricians, bricklayers , damage services, demolition enterprises, scrap dealers, electronics scrap dealers, cable-processing enterprises, sorting plants, garages, fishery, hospitals and dental clinics

The specific guidance regarding optimal treatment of industrial waste containing lead can be seen in the Danish EPA (2003).

Lead as traces in industrial waste
Several industrial activities result in waste fractions containing lead originating from trace amounts of lead in the raw materials. Such waste fractions may be of importance either due to high concentrations of lead or due to high volumes. The most significant contributors are mentioned below.

Waste incineration

When incinerating waste, the largest fraction of lead can generally be found in the bottom ashes (70% - high volume, moderate concentrations) compared to the air pollution control residues, including fly ashes (30% - low volume, high concentrations) according to Chandler et al. (1997). Typical average reported lead concentrations in fly ashes range from 2,000 to 11,000 mg Pb/kg dry wt. Average lead concentrations in bottom ash are lower at 600-1,600 mg Pb/kg dry wt (LDAI, 2008).

New data on lead content in municipal waste incineration bottom ash show an average median level of 1058 mg Pb/kg and a 95-percentile level of 3669 as an average in Europe. In Denmark a median level of 970 mg/kg and a 95-percetile level of 2400 mgPb/kg have been found based on analysis of approximately 1300 samples of incinerator bottom ash during the period 1998 to 2010 (Hjelmar *et al.*, 2013).

For Denmark in 2000 a yearly volume of 630-980 tonnes of lead was estimated to be landfilled in fly ashes from solid waste incineration, whereas 380-700 tonnes lead was landfilled from shredder waste and 170-340 tonnes from fishing tools. Further 1.2-3.7 tonnes of lead were estimated to be emitted yearly into ambient air from the waste incineration plants (Danish EPA, 2004a).

Energy production, coal
Coal contains an average amount of lead of 6-10 mg Pb/kg. About 94% of this lead ends up in fly ashes in connection with the use of coal for energy production. In Denmark it was estimated that the annual production of fly ashes contained 49 tonnes of lead (estimated for year 2000).
The majority of the fly ashes with a lead content of 18-59 mg Pb/kg are used for cement production, asphalt and concrete production and about 30% was disposed or used for landfilling.

Cement production
White and grey cement contains about 6-36 mg Pb/kg depending on the type of cement (highest levels in grey cement where waste fractions are used in the production). It is estimated that an amount of 5.3 tonnes of lead is included in the waste from the cement production, primarily in the filter dust.

Also waste from other industries contains lead, however, at lower levels/quantities (Danish EPA 2004a).

Shredder waste
Recent Danish data indicate that the lead content in shredder waste may contribute with a significant amount of lead in the waste stream. The shredder waste consists of foam, rubber, plastic, iron and metals, and has a high energy content. Measurements indicate lead levels in non-metallic shredder waste of 3,800- 13,000 mg Pb/ kg. When considering a yearly tonnage of shredder waste of up to 185,000 tonnes this may imply a lead amount in this waste fraction in the range of 703-2405 tonnes lead (Danish EPA, 2011b). The Danish EPA has during the last couple of years initiated several projects in order to gain more knowledge on this field with the aim of optimising the treatment of shredder waste.

4.3 Lead in municipal waste

4.3.1 Lead volumes in municipal waste

The following estimates have been given regarding lead in waste from the various uses of lead and lead compounds, Table 4-1 (COWI, 2002).

TABLE 4-1 LEAD CONSUMPTION BY APPLICATION AREA, AND SOURCES OF LEAD TO MUNICIPAL SOLID WASTE INCINERATION (MSWI) OR TO LANDFILL IN DENMARK 1994 (COWI, 2002)

Application area	Consumption tonnes Pb/year	% of total	Total to MSWI or landfill tonnes Pb/year	% of total
Metal				
Batteries	8,100-8,900	48	< 100	2
Flashing and sheets	2,600-3,700	18	50-200	5
Cable sheets	2,000-2,300	12	6-23	0.6
Fishing tools (sinkers)	375-725	3.6	230-300	11
Ammunition	350-460	2.7	10-15	0.5
Roofs	250-400	2	-	-
Solders	260-380	2	120-210	7
Other alloys	150-300	1.3	-	-
Balancing weights	200-250	1.3	-	-
Keels	50-150	0.6	-	-
Seals	5	< 0.1	5	0.1
Lead foil for flower decorations and toys (miniatures)	5.5-12	< 0.1	5.5-12	0.4
Curtains, wine bottle foils, and other products of metallic lead	80-270	1.0	10-100	2
Chemicals/minerals				
Cathode ray tubes (lead glass)	550-900	4	450-750	25
Ceramics (glazing)	25-150	0.5	25-150	4
Glass others than cathode ray tubes	70-80	0.4	50-100	3
Pigments in paint and plastic	35-110	0.4	150-250	8
Stabilisers in PVC	300-400	2	30-100	3
Gasoline additives	2-10	< 0.1	-	-
Other chemicals	12-40	0.2	-	-
Trace element and contaminant				
Waste from cable reclamation			10-13	0.5
Shredder fluff			200-1,000	25
Residues from steel reclamation			45	2
Sewage sludge			3	0.1
Residues from chemical waste treatment			97	2
Total (rounded)	**15,000-20.000**	**100**	**1,500-3,500**	**100**

Updated figures for year 2000 are given in a table in Danish in appendix 5 (from the Danish EPA, 2004a).

However, there are no Danish data on the actual content of lead in the various waste fractions, thus the estimations are based on assumptions regarding the lead content in the various waste fractions.

Data from other countries
In the EU risk assessment from the lead industry data on measured as well as estimated levels of the lead content in municipal solid waste were given from various EU countries. The analysis all together revealed mean values between 100 to 800 mg Pb/kg wastes (dry weight). Highest concentrations were found in metallic waste followed by “other waste”, glass, and plastic waste. Low levels (generally below 50 mg Pb/kg dry weight) were found in paper/cardboard waste, organic waste and textiles (Figure 3.1-35 in LDAI, 2008). In general it was concluded that no tendency could be found that the lead concentration in waste today (based on figures up to year 2000) was lower than in the past (LDAI, 2008).

Lead in various articles in municipal waste
Overall, lead may occur in municipal waste from various articles: decoration items of metallic alloys, jewellery, buttons, zippers, rivets, and studs in clothes, accessories, keys, key rings, bags, belts, ammunition (e.g. lead pellets), pigments and pigment treated surfaces, PVC waste, glass and crystal waste, domestic household machines, radios, televisions, computers, electronics and electric equipment, cables and lightening, water pipes/ fittings/ taps/mixers, waste from abrasion of old paints etc. (Danish EPA, 2003; Danish EPA, 2004a; Swedish Chemical Agency, 2012c).

4.4 Recycling

Recycling
Extensive collection of waste containing metal and dust takes place in Denmark. Besides ashes and dust from steel reclamation and foundries (490-670 tonnes lead) considerable amounts of lead accumulators/ batteries (10,000-11,000 tonnes of lead), lead flashing (600-1,200 tonnes of lead), copper alloys (370-650 tonnes) and cables (580-690 tonnes of lead) were collected. Collection of lead glass from cathode ray tubes for recovery abroad accounted for 90-260 tonnes, whereas 18-50 tonnes of lead were collected with PVC for recovery.

In total 12,800-15,600 tonnes of lead were collected for recovery in Denmark in 2000.

A major part of the collected waste was exported for recovery abroad. However, a significant part of the cables were recovered in Denmark, and cables were imported as well for recovery in Denmark. The products of the recovery process were mainly exported. Recycling of lead within the Danish society is estimated at 340-570 tonnes (Danish EPA 2004a).

For 2009 recycling of 16.134 tonnes and disposal of 1322 tonnes of *lead batteries* was reported (Danish EPA 2011a).

Recent data from Denmark indicate recycling of 18,495 (or 100%) of batteries containing lead acid in 2011 (DPA 2012).

4.5 Disposal

Landfilling or use in construction work
According to figures referring to 2000 about 1,300-2,300 tonnes of lead was landfilled (including deposits, construction work etc.). The main sources were residues from solid waste incineration (630-980 tonnes of lead) and shredder waste (380-700 tonnes of lead) and fishing tools (170-340 tonnes of lead) (Danish EPA 2004a). These data should be regarded with caution since the amount

and types of waste landfilled as well as the conditions of landfilling have changed substantially since the beginning of the millennium.

4.6 Release of lead from waste disposal or construction works

Leaching experiments (batch leaching tests according to EN-12457) have been made for 1253 samples of bottom ashes collected from 24 Danish incineration plants during the period of 1998-2010.
A median level of 970 mg/kg and a 95-percetile level of 2400 mgPb/kg have been found for the ashes. The leaching data indicated a very low degree of leaching showing a median leaching of 0.008 mg pb/kg and a 90-percentile leaching of 0.036 mg Pb/kg (the pH was in the range of 10.3-11.4) Hjelmar 2013).

In general the leaching potential for lead and lead compounds is considered to be low in connection with disposal of waste containing lead, due to the generally low water solubility of the substance-compounds and as the lead compounds often are embedded in an insoluble matrix, e.g. alloys, glass, PVC, etc. Furthermore, lead has a very low mobility in soil and groundwater.

4.7 Summary and conclusions

Due to the EU-harmonised classification of the lead compounds, waste with a lead content above 0.5% should be considered as hazardous waste as this is the concentration limit for classifying lead compounds as toxic to reproduction according to the old classification system. Currently a classification of metallic lead down to a level of 0.03 % is discussed at EU level and adopting of this level would imply that waste containing more than 0.03% (300mg Pb/kg) of metallic lead should be considered as hazardous. However, this depends on the forthcoming revision of the waste classification system. Several municipalities in Denmark currently apply limit values of 40 mg Pb/kg and 2500 mg Pb/kg as the limits for clean waste and hazardous waste, respectively.

It can be anticipated that a lower limit for metallic lead may cause problems in terms of classification of large fractions of waste as hazardous.

From appendix 7 it can be seen that in year 2000 the estimated amount of lead included in municipal waste (not subject to recovery) was in the range of 510-1,400 tones. The largest fractions of lead in the waste stream came from fishing tools (210-420 tonnes), lead crystal glass (97-220 tonnes), pigments in paint and plastic 56-170 tonnes, ceramic products (40-150 tonnes), lead sheets (10-100 tonnes); stabilizer in PVC (26-86 tonnes), and from various other metallic parts.
Of this, 290-930 tonnes of lead were directed to incineration and an estimated amount of 220-480 tonnes lead were landfilled in deposits.
Recent data indicate that the lead content in shredder waste due to the high annual tonnage level of shredder waste may contribute significantly to the mass balance of lead in waste. With a lead content in the range of 3,800- 13,000 mg Pb/ kg this may imply a total lead amount in the shredder waste of 703- 2405 tonnes. The Danish EPA has during the last couple of years initiated several projects in order to gain more knowledge on this field with the aim of optimising the treatment of shredder waste. However, extensive recovery of waste containing lead metal and dust takes place in Denmark. In year 2000 a total of 12,800-15,600 tonnes of lead was collected and recovered. Recent data showed recovery of 16.134 tonnes of lead from batteries in 2009.

In year 2000 about 1,300-2,300 tonnes of lead were in total landfilled (including desposits, use in construction works etc.). The main sources were residues from solid waste incineration (630-980 tonnes), shredder waste (380-700 tonnes) and fishing tools (170-340 tonnes). This may have changed due to changes in landfilling conditions.

Further it was estimated that in connection with waste incineration 1.2-3.7 tonnes were emitted into ambient air. If this source has not declined, this may together with fireworks be the most prominent source for lead emission into the air in Denmark.

The data from year 2000 are data pertaining to the period before the Danish statutory order on the ban on lead was introduced. The implementation of this ban is considered to have affected the use of lead and lead compounds and this would also be reflected in the waste streams, however, with some delay. As an updated analysis on the lead mass flow in Denmark is not available, it is not possible to give an updated detailed picture of today of the use and the waste flow of lead. However, due to increasing efforts regarding recovery and due to the phasing out of lead and lead compounds it may be assumed that lead in the waste fractions for incineration and for disposal has declined further in Denmark since year 2000.

5. Environmental effects and exposure

5.1 Environmental hazard

5.1.1 Classification

As can be seen from the overview of existing legislation in Chapter 2, section 2.1.2.1, a range of classifications are available for lead compounds. Most lead compounds are classified for acute and chronic hazards to the aquatic environment: Aquatic acute 1, H400 (Very toxic to aquatic life) and Aquatic chronic 1, H410 (Very toxic to aquatic life with long lasting effects) compound.

5.2 Environmental exposure

5.2.1 Sources of release

Lead is present in the environment due to natural processes (resulting in a natural background concentration of Pb in all environmental compartments, including organisms). It is, however, the chemical processes that affect the speciation of lead in the environment and which have implications for the environmental exposure and effects (LDAI, 2008).

The environment may be exposed to chemical compounds during all stages of the life cycle from production to disposal or recovery:

- production
- processing
- transportation and storage
- formulation (blending and mixing of compounds in preparations)
- use:
  - professional large scale use (industry)
  - professional small scale use (trade)
  - private or consumer use
- disposal, including waste treatment (e.g. incineration, landfill and recycling)

These environmental exposures (emissions to the environment) are further illustrated in Table 5-1 and Figure 5-2.

The releases of lead (kg Pb/year) to water, air and soil was estimated by the Lead Development Association International (LDAI) for the European countries (EU15) and is presented in Table 5-1 below (not taken into account cumulative nor historical emissions).

All in all an emission to the environment corresponding to 2,672,114 kg Pb/year is estimated in the EU (EU15). Total emission from industry was 879,351 kg Pb/year accounting for the highest single contribution to the environment, followed by households (557,202 kg Pb/year) ammunition (336,410 kg Pb/year) agricultural fertilizers etc. (275,827 kg Pb/year), lead from waste management (188,383 kg Pb/year), and lead from traffic tires, wheel weights, rail transports etc. (181,309 kg Pb/year).
It can be seen that industry is responsible for the main lead release to the air compartment (704,493 kg Pb/year) but also to the water compartment (174,858 kg Pb/year).

Contributions to the water compartment are also due to a release from the use of lead in households (295,664 kg Pb/year), waste management and miscellaneous sources (173,612 kg Pb/year). The release from households includes fishing sinkers (202,575 kg Pb/year).

The soil compartment is exposed due to releases from household (199,491 kg Pb/year), agriculture (275,700 kg Pb/year), traffic (108,412 kg Pb/year) and miscellaneous sources (314,430 kg Pb/year). Here, miscellaneous sources are solely covered by ammunition.

TABLE 5-1 ESTIMATED RELEASE OF LEAD INTO THE ENVIRIONMENT IN EU (EU15), NOT TAKING INTO ACCOUNT CUMULATIVE OR HISTORICAL EMISSIONS (LDAI, 2008)

	Water (kg Pb/year)	Air (kg Pb/year)	Soil (kg Pb/year)	Total (kg Pb/year)
Industry	**174,858**	**704,493**	**0**	**879,351**
Combustion processes industry	**0**	**102,000**	**0**	**102,000**
- Power production	0	78,000	0	78,000
- Others	0	24,000	0	24,000
Households	**295,664**	**62,047**	**199,491**	**557,202**
- Residential heating	0	61,943	0	61,943
- Corrosion of lead sheets	22,459	0	164,703	187,162
- Domestic waste water	70,630	0	34,788	105,418
- Lost fishing sinkers	202,575	0	0	202,575
- Other sources	0	104	0	104
Waste management	**173,214**	**15,169**	**0**	**188,383**
- Sewage treatment plants	144,850	0	0	144,840
- Waste incineration	10,846	15,169	0	26,015
- Landfills	17,528	0	0	17,528
Agriculture	**8**	**119**	**275,700**	**275,827**
- Use of manure, fertilisers,...on agricultural soil	0	0	275,700	275,700
- Other sources	8	119	0	127
Traffic	**40,838**	**32,059**	**108,412**	**181,309**
- Tyre wear	29,079	1,884	16,418	47,381
- Exhaust fumes (road, air, navigation)	0	12,244	0	12,244
- Loss and corrosion of wheel weights	4,860	0,	32,670	37,530
- Wear of collector shoes (rail transport)	3,941	15,867	52,043	71,851
- Other sources	2,958	2,064	7,281	12,303
Miscellaneous sources	**173,612**	**0**	**314,430**	**488,042**
- Sewage system- overflows	77,793	0	0	77,793

- Sewage system separate sewage systems	73,839	0	0	73,839
-Use of Pb-containing ammunition	21,980	0	314,430	336,410
TOTAL	**858,194**	**915,887**	**898,033**	**2,672,114**

(The figure does not take into account the cumulative and historical emissions from the use of Pb-containing ammunition but pertains to 2008 estimated release).

5.2.2 Exposure from emissions and airborne deposition in Denmark

Overall national sources for lead release to the environment in Denmark
The lead balance for the Danish society has been established by the Danish EPA (2004) and is presented in Figure 5-1 below. Here the national sources to emissions into the air can be seen as well as the desposition from the air (Note that the deposition is much higher than the national emission due to long- range transport of particulate matter in air).

Also the various sources for lead emissions to soil and water is given . The total annual environmental lead emissions in 2000 were calculated to:

Air: 5-19 tonnes
Water: 170-600 tonnes
Soil: 480-2,200 tonnes
Landfills; deposits: 1,300-2,300 tonnes

It can be seen that the relative contribution to air is quite low compared to European levels in general as displayed in Table 5-1. This is probably due to the fact that there is no large production of lead containing products in Denmark. In Denmark the main contribution to lead in air is from transport and from lead industry in other countries (DMU, 2004). It must also be noted that for water and soil the emission values derived for Denmark , which are reported as tonnes/year, are very high compared to the total values for Europe, which are reported as kg/year (Table 5-1). An explanation for this has, however, not been identified, when revieveing the information on the applied methods in the LDAI report (2008) and DMU report (2004). Therefore applying the figures and comparing the data should be done with care and considering this.

No such detailed analysis from Denmark is available since year 2000; however a decline may be assumed due to the implementation of the Danish ban on lead in products and articles which was implemented in year 2000.

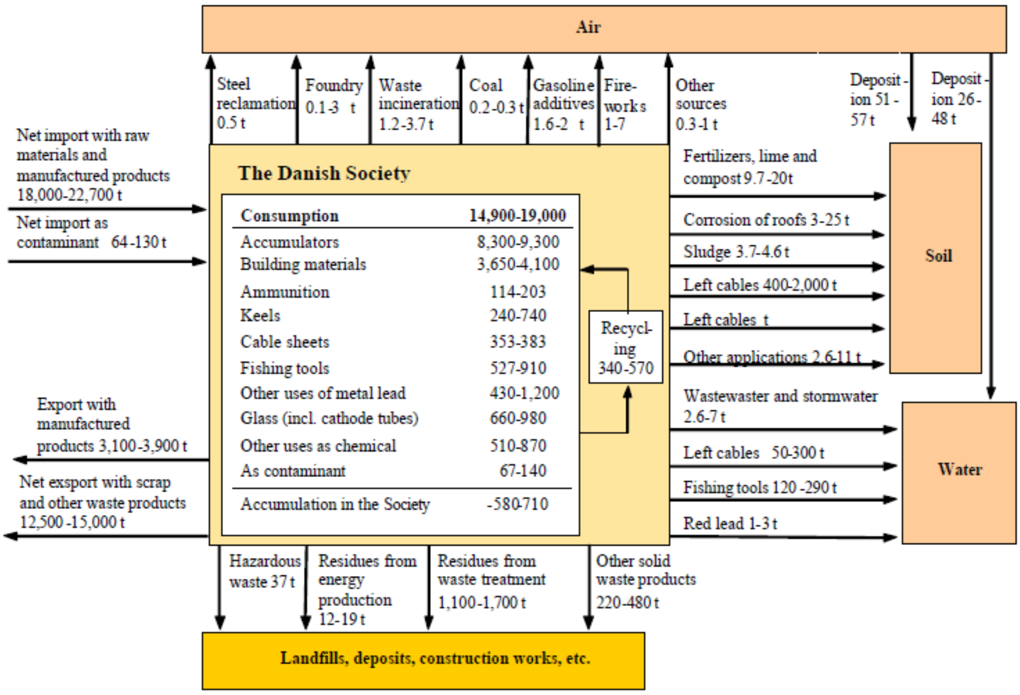


FIGURE 5-1 LEAD BALANCE FOR THE DANISH SOCIETY (YEAR: 2000). ALL FIGURES ARE IN TONNES PB/YEAR DANISH EPA (2004)

Deposition
The lead deposition from air (just below 1 mg Pb/m²/year) and the concentrations in air (3-5 ng Pb/m³) in 2011 do not differ significantly from recent years. However, over the last 20 years there has been a continuous decrease in heavy metal levels in air. The greatest decline is among others observed for lead. For most of the heavy metals the decline has been greatest in the period until the second half of the 1990es, hereafter the changes have been relatively small (Danish Centre for Environment and Energy (2012a).

The total deposition of lead (the sum of the dry and wet-deposition) to the Danish coastal waters and land area can be estimated based on measurements of wet deposition and calculation of the dry deposition based on measurements of the content of particle bound lead in the atmosphere (Table 5-2). The variation in deposition from year to year depends on several factors. The main factor is the actual emissions from the source areas via atmospheric transport, which contributes to heavy metal fallout over Denmark. The emission has generally been decreasing in recent decades. Most significant are the removal of lead from gasoline (late seventies and forward) and a generally better cleaning of flue gases Danish Centre for Environment and Energy (2012a).

TABLE 5-2 ANNUAL DEPOSITION OF LEAD. ESTIMATATIONS BASED ON MEASUREMENTS. THE LAST COLUMN SHOWS THE ANTHROPOGENIC EMISSIONS OF HEAVY METALS TO THE ATMOSPHERE FROM DANISH SOURCES IN 2010 (DANISH CENTRE FOR ENVIRONMENT AND ENERGY (2012A)

Deposition	Deposition to land µg/m²	Deposition to water µg/m²	Estimated deposition		Emission from Danish sources ton/year
			Land area (43.000 km²) ton/year	Coastal waters (31.500 km²) ton/year	
Lead	840	760	36	24	11

5.3 Environmental fate

Being an element lead is persistent and will remain in circulation once it enters the environment. Both organic and inorganic lead compounds may be transformed by normal environmental processes which either increases or decreases the availability of the toxic species.

Aquatic compartment
Lead enters the aquatic environment via municipal and industrial wastewater, runoff and leaching from natural and anthropogenically burdened soils, atmospheric deposition and corrosion and abrasion of lead containing materials.

The amount of lead that remains in solution in surface waters depends on the pH of the water and the dissolved salt content; solid lead is virtually insoluble, whereas the solubility of lead oxide is 107 mg/l at 25°C. At pH values at or below 6.5 most of the dissolved lead is in the form of free Pb^{2+} ion. In waters with high amounts of natural organic matter (NOM), corresponding to a dissolved organic carbon content of 10 mg/l, organically bound lead becomes more important. Sulfate ions limit the lead concentration in solution through the formation of poorly soluble lead sulphate. At higher pH levels the lead carbonates, $PbCO_3$ and $Pb_2(OH)_2CO_3$, determine the amount of Pb in solution. The carbonate concentration is in turn dependent upon the partial pressure of carbon dioxide, pH, and temperature. In most surface waters and ground waters, the concentration of dissolved lead is low because the lead will form complexes with anions in the water such as hydroxides, carbonates, sulfates, and phosphates that have low water solubility and these complexes will precipitate out of the water column. A significant fraction of lead carried by river water is expected to be in an undissolved form, which can consist of colloidal particles or larger undissolved particles of lead carbonate, lead oxide, lead hydroxide, or other lead compounds incorporated in other components of surface particulate matters from runoff. Lead may occur either as sorbed ions or surface coatings on sediment mineral particles, or it may be carried as a part of suspended organic matter in water. The ratio of lead in suspended solids to lead in dissolved form has been found to vary from 4:1 in rural streams to 27:1 in urban streams (LDAI, 2008).

Waste water treatment plants
Removal of lead in waste water treatment plants may take place by adsorption to particles and only Pb ion and Pb bound to ligands are to be released by the effluent. The proportion of lead that either remains in the solution (and thus is released in the effluent) or becomes associated with suspended solids (and removed with sludge) is in part dependent on the chemical form and speciation of the metal in the incoming sewage. Table 5-3 reports input and output data for lead in sewage treatment plants in the Netherlands and Belgium and the corresponding removal. Based on the available data, the value of 84% removal represents a reasonable worst case removal of Pb in waste water treatment plants in EU (LDAI, 2008).

TABLE 5-3 PB INPUT, OUTPUT DATA (TONNES PB/YEAR) AND REMOVAL DATA (%) FOR SEWAGE TREATMENT PLANTS IN THE NETHERLANDS AND BELGIUM (LDAI, 2008)

Sewage Treatment Plant, year	Total input (T Pb/year)	Total output from STP (T Pb/year)	Removal
The Netherlands			
1993	81.7	12.7	84.4%
2000	59.4	8.6	85.6%
2001	66.3	10.2	84.5%
2002	55.2	8.1	85.4%
2003	50.7	8.5	83.3%
2004	49.3	6.6	86.7%
Belgium			
Flanders, 2000	3603.3	648.6	82%
Flanders, 2001	2323.3	418.2	82%
Flanders, 2002	960	172.8	82%

According to information on the concentration in the in- and outlet of Danish sewage treatment plants is reported as 13 µg/L and 1.8 µg/L (based on data from 1998-2009) respectively corresponding to a removal of approximately 86% (Danish Nature Agency, 2011).

Terrestrial compartment

Lead can be present in soils as free ion (Pb^{2+}) in solution, adsorbed onto soil solids (clay minerals, Fe and Mn oxides and soil organic matter) or in a precipitate (formation of soil minerals, e.g. anglesite, jarosite). The distribution of Pb over these various forms depends on soil properties (e.g. pH, % organic matter, parent material), the source of the Pb contamination (lead shot, residues from mining etc.) and the time since contamination. Reported average Pb concentrations in soils located away from point sources range between 16 and 41 mg/kg dw. Anthropogenic sources of Pb in soil are mining operations, metal processing, the manufacture, use and disposal of Pb-containing products (e.g. Pb sheets, batteries, piping) and the former use of leaded petrol. Large amounts of metallic Pb from the use of lead pellets (bullets and shot) as ammunition have been deposited on the soil of shooting ranges worldwide (LDAI, 2008).

Atmosphere

The most important anthropogenic sources of lead entering the atmosphere are combustion of fossil fuels and releases during production processes (smelters and chemical production). The transport and distribution of lead from major emission sources is mainly atmospheric. Most of the lead discharged to the atmosphere is deposited near the source and approximately 20% is widely dispersed. The extent of long-range transport is dependent on the particle size. Small particles can travel 10-30 days before settling. Lead can be removed from the atmosphere by wet and dry deposition, wet deposition being the more important (LDAI, 2008).

Partitioning of lead

Dissolved lead concentrations in the water column are determined by the adsorption of the metal to suspended particulate matter (SPM) and/or sediment phase. The affinity of Pb to SPM and sediment is reflected in the $K_{D,SPM}$ and $K_{D,sed}$ values, respectively. Log $K_{D,SPM}$ values for lead for fresh water and estuarine surface waters in Europe are in the rage: 4.45-6.25. Corresponding values for marine surface waters are in the range: 4.7-7.25.

Only a few studies have reported Pb partition coefficients between the aqueous phase and the sediment. Log K_D values ranged between 4.4 and 5.66.

Volatilisation

Considering the high boiling point for lead (1,725-1,745°C), volatilisation is not considered relevant except when considering lead production processes (LDAI, 2008).

5.4 Monitoring data

Soil

Based on monitoring data on the lead content in soil form, various EU countries LDAI (2008) estimated an overall median lead concentration in agricultural soil of 29.7 mg Pb/kg soil. However, soil levels of several thousand mg Pb/ kg soil have been measured in countries in connection with polluted areas.

The median background concentration of lead in agricultural soil in Denmark has been measured to 11.3 mg Pb/kg soil from 393 measurement distributed through-out the country with a 5-95% percentile interval of 4.5-19.2 mg Pb/kg (DMU, 1996).

For diffuse polluted soil near busy roads, maximum lead levels up to 540 mg Pb/kg have been measured in the top soil. Medium levels for various depth 0-30 cm and distances (0-30 meters) are generally below 300 mg Pb/kg soil (Danish EPA, 2004b).

For diffuse polluted soil near a former rolling mill a median lead level of approximately 200 mg PB/kg and a 95 percentile level of approximately 400 mg/kg soil were found (depth 5 cm) A peak level of about 1650 mg Pb/kg was measured (Danish EPA, 2004c).

The Danish quality criterion for earth is based on human health concern is 40 mg Pb/kg (no restriction for use) and the action level is 400 mg Pb/kg (Danish EPA, 2010).

Air

In Denmark the level of lead in ambient air has been followed intensively for several decades.

The figures below show the lead level in rural ambient air as well as the lead levels in Danish towns over the last decades. A great reduction of the lead levels is seen predominantly due to the phasing out of lead from petrol since the late seventies (DMU, 2004). Thus in towns a decline from around 1000 ng/m^3 to 4-5 ng/m^3 have been registered from 1982 to 2011 (Danish Centre for Environment and Energy, 2012a).

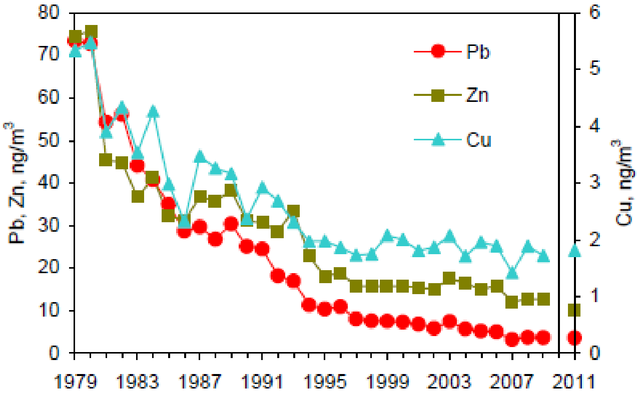


FIGURE 5-2 DEVELOPMENT OF THE CONCENTRATION OF HEAVY METALS IN AIR FROM 1979-2011, RURAL BACKGROUND LEVELS (DANISH CENTRE FOR ENVIRONMENT AND ENERGY 2012B)

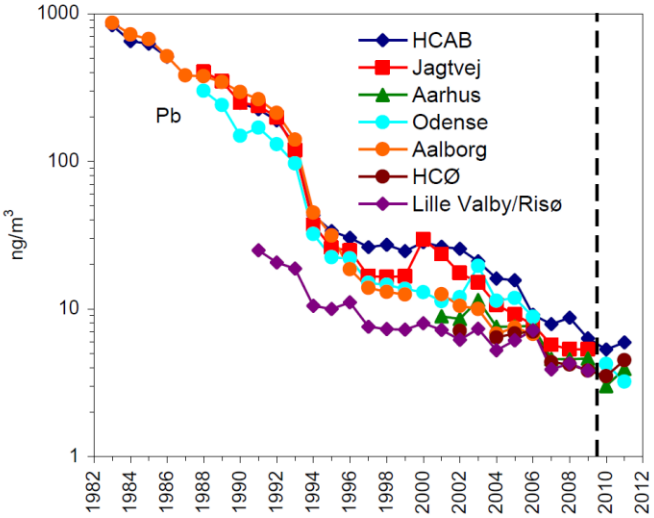


FIGURE 5-3 LEAD CONCENTRATION IN AMBIENT AIR (1982-2011) MEASURED AT VARIOUS LOCATIONS IN DENMARK (DANISH CENTRE FOR ENVIRONMENT AND ENERGY, 2012B)

Water environment

The concentration in the in- and outlet of Danish sewage treatment plants (based on data from 1998-2009) is reported as 13 µg/L and 1.8 µg/L respectively (Danish Nature Agency, 2011).

In Denmark the concentration of lead in marine waters has been reported as 0.01-0.2 µg/L (Kattegat, Skagerrak and The Baltic) (Danish EPA, 1998).

In Danish streams concentrations of 0.2-1.6 µg/L are reported (Danish EPA, 1998).

The concentration of lead in Danish sediments will vary from location to location and is dependent on the degree of pollution in a certain area. Also the age of the sediment is important. Examples which have been reported are by the Danish EPA are presented in Table 5-4 below.

In Danish mussels the lead content was for more than 80% of the samples measured to be below the limit value of 20 µg/kg (Danish Centre for Environment and Energy, 2012b).

TABLE 5-4 REPORTED CONCENTRATIONS (MG/KG DW.)OF LEAD IN DANISH SEDIMENTS (DANISH EPA, 1998)

Location	Lead content mg/kg d.w.
Lakes	<1-170
Marine areas (surface sediment)	2-80
Harbour sediment	1-100
Background concentrations (marine sediment, before 1850)	6-27

5.5 Predicted Environmental Concentration (PEC)

In the risk assessment report prepared by the lead-industry (LDAI, 2008) various scenarios for lead release to the environment were made in connection with local as well as regional scenarios for lead in the environment.

Since there is no detailed information on how to deal with elements, that have a natural background concentration in the environment, such as lead, the “total risk approach” was used in the risk assessment by LDAI (2008). In the “added risk approach”, the "Predicted Environmental Concentration" (PEC) is expressed as Pb added by man, resulting in an “*added* Predicted Environmental Concentration” (PEC_{add}) and “*added* Predicted No Effect Concentration” ($PNEC_{add}$), respectively. The use of the added risk approach (a method that in principle can be used for all naturally occurring compounds) implies that only the anthropogenic amount of a compound, i.e. the amount added to the natural background concentration, is considered to be relevant for the effect assessment of that compound. Thus, a possible contribution of the natural background concentration to toxic effects is ignored. Alternatively, the ‘total risk approach’ was used in which the PEC value include both the Pb background and Pb added by man.

The regional scale assesses the exposure levels due to all releases in a larger region ($PEC_{regional}$) and is therefore also representative for the contribution of the diffuse sources. The estimation of the regional releases is consequently based on gathered emission data and/or most adequate emission factors for each emission source (e.g. industry, public utilities, traffic, households, agriculture and natural sources) and not of Pb in ammunition alone (LDAI, 2008).

The resulting *cumulative emissions* and the corresponding PECs are given in Table 5.5.
Please note that the data presented in Table 5-1 did not take into account the cumulative nor historical emission. Therefore values presented in Table 5-5 below are higher.

The “added” PEC values incorporate anthropogenic Pb inputs only. The” total” PEC values on the other hand incorporate both anthropogenic and natural/pristine ambient Pb background concentrations for the different environmental compartments. It can be seen that especially for the water compartment the anthropogenic contribution is high. $PEC_{add\ regional}$ = 0.18 µg/L, which is half the value of $PEC_{total\ regional}$ =0.36 µg/L, i.e. half of the contribution to lead in surface water is anthropogenic. In contrast the anthropogenic contribution is quite small to the air compartment.

TABLE 5-5 OVERVIEW OF *CUMULATIVE* PB EMISSIONS (100 YEARS) AND ADDED/TOTAL PECS FOR THE REGIONAL AND CONTINENTAL ENVIRONMENT DETERMINED AFTER 100 YEARS EXPOSURE,(BASED ON EU TGD 2003 RISK ASSESSMENT SPREADSHEET MODEL 1.0 CALCULATIONS. (LDAI 2008))

Input continental (anthropogenic): EUtotal – input, regional			
Amount released to air	848 t/y		
Amount released to surface water	2,448 t/y		
Amount released to agricultural soil	23,698 t/y (248 t/y (agricultural use) + 23,450 t/y (lead shot use))		
Amount released to natural soil	0 t/y		
Amount released to industrial soil	297 t/y		
Input regional (anthropogenic):			
Amount released to air	43.7 t/y		
Amount released to surface water	63 t/y (36 t/y (other) + 26 t/y (lead shot use))		
Amount released to agricultural soil	393.5 t/y (27.7 t/y (fertiliser) + 365 t/y (lead shot))		
Amount released to natural soil	0 t/y		
Amount released to industrial soil	10.4 t/y		
PEC values (100 years of exposure)	$PEC_{add\ continental}$	$PEC_{add\ regional}$	$PEC_{total\ regional}$
PEC_{air} (ng/m³)	9.89×10^{-12}	8.86×10^{-11}	13.6
$PEC_{agricultural\ soil}$ (mg/kg dwt)	3.69	5.66	32.68
$PEC_{natural\ soil}$ (mg/kg dwt)	0.15	1.33	28.3
$PEC_{industrial\ soil}$ (mg/kg dwt)	1.19	4.54	31.54
Kp sediment/suspended matter = 295,121 L/kg (median) Kp sediment = 154,882 L/kg (median)			
$PEC_{surface\ water}$ (dissolved fraction) (µg/L)	0.112	0.18	0.36
$PEC_{sediment}$ (mg/kg dwt)	17.34	27.55	55.4

When looking at PEC_{air} it can be seen that the calculated $PEC_{total\ regional}$ is 2-3 times higher (13.6 ng/m³) compared to the monitoring data for Danish towns reported in the previous section (4-5 ng/m³.

The calculated $PEC_{total\ regional}$ (32.68 mg/kg) for soil is in agreement with the monitoring data for agricultural soils reported by LDAI (2008) (29.7 mg/kg soil) however higher than the median background concentration reported for Danish soils (11.3 mg Pb/kg soil) (DMU, 1996).

The calculated $PEC_{surface\ water}$ is in agreement with the values measured in Danish fresh waters. The value is however higher than the lead concentration which was measured in marine waters (Kattegat, Skagerrak and The Baltic).

When comparing the calculated PEC values in Table 5.5 with the sediment data from Danish fresh- and marine waters (Table 5.4) it can be seen that the calculated PEC is within in concentration found in Denmark. However there are also hotspots in Denmark, probably located more closely to larger urban areas, where concentrations are much higher.

5.6 Environmental toxicity

Due to several physico-chemical processes, lead will exist in different chemical forms, some of which are more bioavailable than others. It is thus realised that the bioavailability and thereby also the toxicity of metals in both laboratory tests and in the environment may be affected by several physico-chemical parameters, such as pH, alkalinity and hardness.

Aquatic toxicity
Results on the acute and chronic toxicity of lead to aquatic organisms (algae, crustacean and fish) are available and results from the tests showing the highest toxicity are reported in Table 5-6 and 5-7. Data for freshwater are reported for the pH range of 5.5-8.5. The soluble test compounds used in both the freshwater and saltwater long-term were lead nitrate, lead acetate and lead chloride (LDAI, 2008).

TABLE 5-6 REPORTED TOXICITY TO FRESHWATER ORGANISMS (LDAI, 2008)

Organism	Test water	Exposure time (days)	pH	Hard-ness (mg $CaCo_3$ /L)	DOC (mg/L)	Criterion	Nominal/ measured	NOEC/L(E)C_{10} (µg/L) total risk approach	
								Total	Dissolved
(Alge) *Pseudokirhneriellaa subcapitata*	Artificial	3	6.0	25	2.1	$EC_{10\ growth}$	Measured dissolved Pb	/	30.0
(Alge) *Chlorella kesslerii*	Artificial	2	6.0	25	2.1	$EC_{10\ growth}$	Measured dissolved Pb	/	99.0
(Crustacean) *Hyalella azteca (1.2-1.3 mm)*	Well + deionized water	42	8.4	138	1.1	$NOEC_{growth}$ $NOEC_{survival}$	Measured dissolved	/	6.3 6.3
(Crustacean) *Daphnia magna (<24 hrs)*	Lake	21	8.1	225	NR	$NOEC_{reproduction}$ $NOEC_{survival}$	Measured total Pb	250 750	168.2* 504.6*
Daphnia magna	Artificial	21	NR	44-53	NR	EC_{16}	Measured dissolved		27.0
(Fish) *Ictalurus punctatus (2-3 d)*	Well	60	6.8 -7.3	36	NR	$NOEC_{growth}$	Measured total Pb	75	70.5
(Fish) *Cyprinus carpio (eggs)*	Artificial	7	5.6	35	NR	$EC_{10Survival}$ $EC_{10Abnormalties}$	Assumed total Pb	20.2 48.8	19.1* 46.1*

*: estimated dissolved Pb concentration using the US EPA (1996) conversion factor
NR: Not reported
DOC: Dissolved Organic Carbon

TABLE 5-7 REPORTED TOXICITY TO MARINE ORGANISMS (LDAI, 2008)

Organism	Test water	Salinity	Criterion	Nominal/ measured	NOEC total risk approach
(Alge) *Asterionella japonica*	Natural sea water	/	$EC_{10\ growth}$	Nominal Pb	49.7
(Alge) *Champia parvula* *(male gametophyte)*	Natural sea water	30	$NOEC_{growth}$ $NOEC_{reproduction}$	Measured total Pb	9.1 40.2
(Invertebrate) *Cancer anthonyi* *(embryos)*	Natural sea water	34	$NOEC_{hatching}$ $NOEC_{survival}$	Nominal Pb Nominal Pb	100 10
(Invertebrate) *Ophryotrocha diadema*	Natural sea water	Not reported	$NOEC_{reproduction}$	Nominal Pb	1,000

$PNEC_{aquatic}$
In general the most sensitive endpoint reported as an EC_{50}- or NOEC-value is applied in the calculation of the Predicted No Effect Concentration (PNEC) dividing the selected endpoint with an assessment factor (AF) which takes account for uncertainties such as variations in species sensitivity. Also when a large dataset exist the species sensitivity distributions (SSD) method can be applied (ECHA, 2008). LDAI has applied the later method which is in line with the approach previously agreed by the EU's Technical Committee on New and Existing Compounds (TCNES) for the comparable zinc risk assessment.
Applying an assessment factor of 2 or 3 this to the $HC_{5\text{-}50}$[1] of 8.0 µg/L results in a ***$PNEC_{freshwater}$* value of 4.0 µg/L** (AF=2) or 2.7 µg/L (AF=3) (LDAI, 2008).

Sediment Toxicity

Data on the toxicity of lead towards sediment living organisms are reported and range from a NOEC of 2,093 mg total Pb/kg dry wt (*Hexagenia limbata*) to a NOEC of 573 mg total Pb/kg dry wt for the oligochaete *T. tubifex* (LDAI, 2008).

$PNEC_{sediment}$
There are several approaches reported for the calculation of the PNEC for sediment. Applying an assessment factor of 10 (Assessment Factor approach) on the lowest chronic NOEC value of 573 mg/kg dry weight for freshwater benthic organisms is for the oligochaete *T. tubifex* (endpoint reproduction) results in a $PNEC_{freshwater\ sediment}$ of 57.3 mg/kg dry wt. The assessment factor of 10 is in accordance with the TGD (2003) / Guidance Document R.10 (ECHA, 2008) (LDAI, 2008).

[1] HC5-50: According to ECHAs Guidance Document (R.10.) the concentration corresponding with the point in the SSD profile below which 5% of the species occur (Hazardous Concentration 5% = HC_5) should be derived as an intermediate value in the determination of a PNEC. A 50% confidence interval (c.i.) associated with this concentration should also be derived.
The 50% confidence value of the 5th percentile value is referred to as **HC5-50** (thus PNEC = HC5-50/AF).

Seven EC_{10}/NOEC values for 7 different species are available for lead for the sediment compartment. Therefore, similar to what has been agreed for the nickel and copper risk assessments it was found appropriate to evaluate the benefits of estimating the PNEC for sediment by using the available toxicity sediment toxicity tests and applying the statistical extrapolation methodology.

The 7 dataset encompasses different habitats, feeding strategies and very different endpoints. This may suggest that the lead data set reflects organisms exposed to sediment-bound lead by different exposure pathways representing enough life forms, feeding strategies and taxonomic groups that employment of the SSD approach may be acceptable (LDAI, 2008).

Applying an Assessment Factor (AF) of 3 on lognormal fit derived HC_5 (Hazardous Concentration 5%) would result in a $PNEC_{sediment}$ of 522/3 = 174 mg/kg dry wt. Applying an AF of 3 on lognormal fit derived HC_5 expressed as bioavailable lead would result in a ***$PNEC_{sediment}$* of 244/3 = 81 mg/kg dry wt**.

Toxicity to sewage treatment plants

The lowest observed NOEC value for inhibition of nitrification using activated sludge was 2.79 mg/l dissolved Pb. The lowest observed NOEC value for inhibition of respiration was 1.06 mg/L.

The lowest observed EC_{50} value from tests with the ciliated protozoa *Tetrahymena* was 42 mg/L Pb. The lowest observed EC_{50} value from tests with other ciliated protozoa tested in activated sludge mixed liquor medium is 2.29 mg Pb/L (for ciliate *Vorticella convallaria*). On the other hand, a (visually) derived LC_{10} for the sludge protozoan community in the activated sludge mixed liquor of 1 mg/L dissolved Pb is estimated. Preference was given to this community endpoint because it is more relevant (LDAI, 2008).

$PNEC_{microoranisms}$

Applying an assessment factor of 10 to the LC_{10} for the sludge protozoan community results in a ***$PNEC_{microorganism}$* = 0.1 mg/L** (LDAI, 2008).

Terrestrial toxicity

Toxicity to higher plants

NOEC's selected for the risk assessment range from 65 mg kg^{-1} for *Hordeum vulgare* (oat) to 2207 mg kg^{-1} for *Triticum aestivum* (wheat) (LDAI, 2008).

Toxicity to soil invertebrates

NOEC and EC_{10} values selected for the risk assessment range from 130 mg kg^{-1} for *Dendrobaena rubida* (earthworm) to 2207 mg kg^{-1} for *Folsomia candida* (LDAI, 2008).

Toxicity to soil microflora

There are 18 NOEC or EC_{10} values on functional parameters. The functional parameters comprise C- and N-mineralization. The NOEC's on functional parameters vary from 96 mg Pb kg^{-1} to 4144 mg Pb kg^{-1} (LDAI, 2008).

$PNEC_{soil}$

It was decided not to split the terrestrial toxicity data set in effects assessment for the calculation of the HC_5. An AF=2 to was applied to derive the $PNEC_{soil}$ from the $HC_{5\text{-}50}$ (the 50% confidence value of the 5th percentile value (thus PNEC = 5th percentile value/AF)). ***$PNEC_{soil}$* = 333/2=166 mg Pb kg^{-1}_{dw}** (LDAI, 2008).

Table 5-8 below summarises the calculated Predicted No Effect Concentrations (PNEC) for the environmental compartments

TABLE 5-8 OVERVIEW OF THE SELECTED PNEC VALUES (LDAI, 2008)

	Value	Units	Remark
$PNEC_{freshwater}$	**4.0**	**µg Pb dissolved/L**	Species mean HC_5* (log normal distribution, $EC_{16}/2$ value of 13.5 µg/l for *Daphnia magna* included in the dataset) = 8.0 µg/L; AF**= 2
$PNEC_{sediment}$	**174**	**mg Pb/kg dry wt.**	Species mean HC_5* (log normal distribution)= 522 mg/kg dw; AF**= 3
$PNEC_{sediment\ bioavailable}$	**81.0**	**mg Pb/kg dry wt.**	Species mean HC_5* (log normal distribution) of toxicity data expressed as bioavailable Pb = 244 mg/kg dw; AF**= 3
$PNEC_{micro\text{-}organisms}$	**100**	**µg Pb dissolved/L**	dissolved fraction only; AF**= 10
$PNEC_{soil}$	**166**	**mg Pb/kg dry wt.**	Species mean HC_5* (log normal distribution) = 333 mg/kg dw; AF**= 2

*HC_5: Hazardous Concentration 5% (Concentration of a compound that is hazardous to 5% of the organisms/population tested)

**Assessment Factor (AF)

Assessment of secondary poisoning

Several mammalian and avian toxicity data from laboratory feeding studies are reported these studies are applied in deriving the $PNEC_{oral}$.

According to the TGD methodology the $PNEC_{oral}$ should be calculated from the lowest $NOEC_{oral}$ using an assessment factor. The lowest NOEC's are 150 mg kg^{-1} for mammals and 100 mg kg^{-1} for birds. The assessment factors for the feeding test are based on the TGD (TGD, 2003 /ECHA, 2008)) and are 300 for the 23-day study and 30 for the studies with birds. Lead concentrations in the unspiked diet were reported in only 2 studies (C_b = 1.42 mg $kg^{-1}{}_{fw}$ and 1.1 mg $kg^{-1}{}_{fw}$) but are all well below the nominal added NOEC values. Adding a mean Pb concentration (C_b=1.3 mg $kg^{-1}{}_{fw}$) to the nominal added NOEC values, which results in:

$$\mathbf{PNEC_{oral} = (NOEC + Cb)/AF = (150+1.3)/300 = 0.5\ mg\ kg^{-1}\ food\ (mammals)}$$
$$\mathbf{PNEC_{oral} = (NOEC + Cb)/AF = (100+1.3)/30 = 3.4\ mg\ kg^{-1}\ food\ (birds)}$$

(LDAI, 2008)

5.7 Environmental impact

In the risk characterisation performed by LDAI (2008) the Risk Characterisation Ratio (RCR) was calculated for each exposure scenario as according to the equation: RCR = PEC/PNEC.
The ratios > 1 indicate a potential risk to the environmental compartment, while PEC/PNEC ratios <1, indicate that no risk is anticipated.

Table 5.11 presents the results from a risk assessment for the environmental compartments which is *based modelled concentrations of lead*. The risk ratios for all land uses vary between 0.15 and 0.28, i.e. no risk to the soil compartment is expected.

The predicted Pb concentrations ($PEC_{regional}$ and $PEC_{continetal}$) in surface water and sediment have been calculated for a range of Kp values (10th percentile, median and 90th percentile). All (PEC) values are below the $PNEC_{water}$ of 4 µg /L hence no risk is predicted for the surface water compartment at a continental and regional scale on the basis of modelled data. Performing the risk characterisation using a PNEC of 2.7 µg dissolved Pb/l (AF=3) also results in a no risk situation.

For the sediment compartment, the PECs derived with the median, 10P and 90P Kp values are situated below the $PNEC_{sediment}$ of 174 mg/kg dw. In this table the PEC values are expressed as total and hence are not reflecting the real bioavailable fraction. Taking bioavailablity into account (as shown in section 3.1.4) results in a no regional risk situation (LDAI, 2008).

TABLE 5-9 REGIONAL RISK CHARACTERISATIONS FOR WATER, SEDIMENT AND SOIL *ON THE BASIS OF MODELLED DATA*. THE RISK CHARACTERISATION RATIO = PEC/PNEC. THE PNECTOTAL, FRESHWATER IS 4.0 µG/L. THE PNECTOTAL, FRESHWATER SEDIMENT IS 174 MG/KG_{DW} WITHOUT AVS CORRECTION. THEN PNECFRESHWATER SEDIMENT, BIOAVAILABLE IS 81 MG/KG_{DW}.THE PNEC TOTAL, SOIL VALUE IS 166 MG/KG DW (LDAI, 2008)

		PEC_{add} continental	PEC_{total} continental	RCR	PEC_{add} regional	PEC_{total} regional	RCR
Surface water							
Kp (median) (selected)	µg/L	0.031	0.12	0.03	0.12	0.22	0.06
Kp (10P)	µg/L	0.17	0.26	0.07	0.62	0.71	0.18
Kp (90P)	µg/L	0.0055	0.099	0.02	0.02	0.12	0.03
Sediment							
Kp (median) (selected)	mg/kg dw	4.8	18.8	0.11	19.2	33.2	0.19
Kp (10P)	mg/kg dw	5.6	8.5	0.05	20.0	23.1	0.13
Kp (90P)	mg/kg dw	3.9	65.8	0.38	15.7	81.6	0.47
Soil							
Natural soil	mg/kg dw	1.02	16.0	0.10	9.12	24.1	0.15
Agricultural soil	mg/kg dw	2.2	17.2	0.10	13.9	28.9	0.17
Industrial soil	mg/kg dw	8.18	23.2	0.14	31.2	46.2	0.28

Table 5-9 presents the results from a risk assessment for the environmental compartments which is *based on measured concentrations of lead*. Total ambient Pb concentrations in European surface waters (Belgium, France, Germany, Ireland, the Netherlands, Sweden and UK) typically range between 0.8 µg/L (Sweden) and 8.4 µg/L (Belgium), i.e. risk factors between 0.04 and 0.38 (PNEC= 22.2 µg total Pb/L). Dissolved ambient Pb concentrations in European surface waters (the Netherlands, UK, Germany and France) typically range between 0.28 µg/l (The Netherlands, Rijkswaterstaat database) and 1.1 µg/L (UK, England), i.e. risk factors between 0.07 and 0.28 (PNEC= 4.0 µg dissolved Pb/L). Performing the risk characterisation using a PNEC of 2.7 µg dissolved Pb/L (AF=3) results in a no risk situation; RCRs vary between 0.10 and 0.41. Hence no risk for the aquatic compartment is predicted on the basis of measured data (LDAI, 2008).

TABLE 5-10 REGIONAL RISK CHARACTERISATION FOR SURFACE WATER (FRESHWATER) *ON THE BASIS OF MEASURED DATA*. THE FACTOR RISK = PEC/PNEC. THE PNECTOTAL, WATER IS 22.2 µG TOTAL PB/L (DISSOLVED CONCENTRATIONS IN FRESHWATER ARE ESTIMATED TO BE 18% OF TOTAL PB CONCENTRATION; KP=295,121 L/KG; CSUSP=15 MG/L THE PNECTOTAL, WATER IS 4.0 µG DISSOLVED PB/L (LDAI, 2008)

Country + database	Ambient PEC (90th percentile)		Ambient PEC (90th percentile)	
	µg/L Pb_{total}	Risk factor	µg/L $Pb_{dissolved}$	Risk factor
Belgium (Flanders, 2000-2003)	7.2	0.32	-	-
Belgium (Walloon region, 2000)	8.4	0.38	-	-
Finland (Barentz area, 2000)	-	-	0.43	0.11
France (Seine, 1999-2000)	-	-	0.54	0.14
France (Rhône-Mediterranean area)	3.6	0.16	-	-
Germany (Hessisches Landesamt, 1999-2000)	3.2	0.14	-	-
Germany – Elbe (1995, 2000)	5.2	0.23	0.69	0.17
Germany - Bund/Länder-Arbeitsgemeinschaft Wasser (LAWA)	2.53	0.11	-	-
Ireland (COMMPS dataset, 1996)	2.1	0.09	-	-
The Netherlands (RIZA, 2000)	3.8	0.17	0.28	0.07
Sweden (lakes and rivers, 1999-2001)	1.1	0.05	-	-
Sweden (reference lakes, 2000)	0.8	0.04	-	-
UK, England	4.3	0.19	1.1	0.28
UK, Wales	-	-	1.0	0.25
UK, Scotland	2.3	0.10	0.64	0.16
Median + Range	3.1 0.8-8.4	0.14 0.04-0.38	0.61 0.28 – 1.1	0.15 0.07-0.28

Ambient Pb concentrations in European sediments (Belgium (Flanders), France, the Netherlands, Scotland, Spain and Sweden) typically range between 38.4 mg/kg dw (Scotland) and 233.1 mg/kg dw (The Netherlands, COMMPS). For Sediment $PNEC_{sediment}$ = 174 mg/kg dw. Risk factors are therefore in the range 0.22 and 1.34 (Table 5.13). No risk for the sediment compartment is predicted for Belgium, France, Scotland or Spain. For The Netherlands and Sweden there is a potential risk, however, this conclusion is based on a comparison with lead concentrations expressed on a total basis and does not reflect the real bioavailable fraction (LDAI, 2008).

TABLE 5-11 REGIONAL RISK CHARACTERISATION FOR *FRESHWATER SEDIMENT* ON THE BASIS OF MEASURED DATA. THE RISK CHARACTERISATION RATIO = PEC/PNEC. PNECTOTAL, FRESHWATER SEDIMENT IS 174 MG/KG DW (LDAI, 2008)

Country + database	Ambient Pb PEC (mg/kg dw)	RCR
Belgium – SEDD (Flanders)	107.3	0.62
France - SEDD (Artois-Picardie)	84.9	0.49
France SEDD (Rhône/Mediterranean area)	81.7	0.47
France -general	83.3	0.48
The Netherlands – COMMPS	233.1	1.34
Scotland	38.4	0.22
Spain – COMMPS	78.4	0.45
Sweden	180.7	1.04
Median + range	100.1 38.4-233.1	0.58 0.22-1.34

Risk characterisation based on Danish monitoring data

In Danish streams the highest value is reported to 1.6 µg Pb/L, which is above the general quality criteria for freshwater and marine water of 0.34 µg Pb/L but below the short term criteria of 2.8 µg Pb/L. Compared to $PNEC_{freshwater}$ = 4.0 µg/L, this does not, however, result in a RCR above one. In Danish marine waters the highest concentration of lead was 0.2 µg Pb/L which is below the quality criteria. Applying a $PNEC_{marine}$ = 0.4 µg/L ($PNEC_{freshwater}$ /10) also does not result in an RCR above one.

The highest reported value for Danish sediment was 170 mg/kg dw (sediment from lakes) (Danish EPA, 1998). This value is lower than the concentration of 233.1 mg/kg dw reported for the Netherlands, which was the highest concentration applied by LDAI (2008) and which did not indicate a risk to the sediment compartment and therefore also no risk is anticipated based on the Danish freshwater sediment data.

5.8 Summary and conclusions

Most lead compounds are classified for acute and chronic hazards to the aquatic environment: Aquatic acute 1, H400 (Very toxic to aquatic life (short term E(L)C50 ≤ 1 mg/L)) and Aquatic chronic 1, H410 (Very toxic to aquatic life with long lasting effects (short term E(L)C50 ≤ 1 mg/L and the substance is not ready biodegradable).

In 2008 it was estimated that 2,672,114 kg Pb/year of lead was released into the environment in EU15 and the emissions were rather evenly distributed to air, soil and water.

The greatest single source was industrial air emissions (704,493 kg Pb/year).

For Denmark the emissions in year 2000 were estimated to be distributed as follows:

Air: 5-19 tonnes
Water: 170-600 tonnes
Soil: 480-2,200 tonnes
Landfills; deposits: 1,300-2,300 tonnes

Danish monitoring data have shown a dramatic decline in the lead content in air from around 1000 ng PB/m^3 in towns in 1982 to 4-5 ng/m^3 in 2011. The decline could be explained by the phase out of lead additives in gasoline in the late seventies and forward. The average background level in Danish soil has been measured to be 16 mg/kg for unpolluted soil whereas soil in the cities and polluted areas may reach levels of several hundred mg/kg.

In Danish streams concentrations of 0.2-1.6 µg/L are reported, whereas the concentration of lead in marine waters has been reported as 0.01-0.2 µg/L (Danish EPA, 1998).

In the LDAI (2008) risk assessment report Predicted No Effect Concentrations (PNECs) have been derived for the environmental compartments: water, sediment, soil as well as for sewage treatment plants ($PNEC_{microorganism}$). These values have been compared to modeled- and monitoring data on the environmental concentration of lead.

$PNEC_{water}$ was determined to be 4.0 µg Pb dissolved/L which is more than a factor 10 higher than the Quality criteria of 0.34 µg Pb dissolved/L for fresh and marine waters and also higher than the short term criteria of 2.8 µg Pb dissolved/L for fresh and marine waters. This might reflect that a less conservative approach has been applied in the calculations performed by LDAI (2008). Based on modelled data on the predicted environmental concentration (PEC) and based on monitoring data no risk towards the aquatic compartment was identified.

$PNEC_{sediment}$ was determined to be 81 mg Pb/kg dry wt. and 174 mg Pb/kg dry wt. for bioavailable Pb and total Pb respectively. Compared to modelled PEC values no risk was identified for this compartment i.e. RCR < 1.

In Denmark the limit for lead contained in sludge to be applied on agricultural soils is 120 mg/kg dw (BEK nr. 1650 of 13/12/2006). According to Council Directive 86/278/EEC the limit values are 750-1200 mg/kg dw. Most EU limit values for lead concentration in soils are in the range of 50-300 mg/kg soil dry weight. $PNEC_{soil}$ was determined to be 166 mg Pb/kg dw. Based on the modelled PEC values no risk was identified for this compartment i.e. RCR < 1.

The concentration of lead in the inlet to and outlet from waste water treatment plants in Denmark is reported as 13 µg/L and 1.8 µg/L, respectively. For comparison emission limit values for discharges of waste water from the cleaning of waste gases from incineration of waste is 0.2 mg/L (Directive 2010/75/EU and BEK nr 1451 af 20/12/2012). $PNEC_{microorganism}$ was determined to be 100 µg Pb dissolved/L.

6. Human health

6.1 Human health classification

Lead compounds have a general entry in Annex VI of the CLP regulation were the lead compounds are subject to EU-harmonised classification for several adverse effects due to observations in experimental animals and not at least humans. The classificatons are:

Acute tox 4, H302 (Harmful if swallowed)
Acute tox 4, H332 (Harmful if inhaled).
STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure)
Repr 1A, H360Df (May damage fertility or the unborn child);

Note that the harmonised classification above does not cover metallic lead and that a range of different self-classifications for metallic lead are applied by industry.

The overview of the toxicology below is mainly been extracted from the information in the restriction proposal from the Swedish Chemical Agency (2012c) and from EFSA (2010). The description cannot be taken as an in-depth review on the toxicity on lead but focuses on the most critical effects of lead and lead compounds.

6.1.1 Absorption, distribution and elimination of lead in the body

6.1.1.1 Oral absorption

Orally ingested lead is absorbed differently depending on the time duration between the exposure and the last meal; adults who have just eaten a meal absorb 3-15% of the ingested amount of lead, whereas those who have not eaten for a period of 24 h absorb about 20-70%.

Lead absorption is affected by nutritional calcium and iron status. High levels of calcium and/or iron in the blood stream protect from GI absorption of lead, and a low iron intake and deficient iron status is associated with increased blood lead levels. This information is important to keep in mind since iron deficiency is very common, especially amongst women of child bearing age.

Concerning children, even though data are more limited, an oral absorption rate of 40–50% for lead and its compounds can be determined for non-fasting children from 2 weeks to 8 years of age.

That excessive absorption may occur from oral exposure to metallic lead can be verified from a number of cases of lead poisoning in children who have swallowed or repeatedly mouthed jewellery with high lead content.

The observed symptoms of these cases go from headaches and diarrhoeas to death. One report of a fatal case of lead poisoning describes the death of a 4 year old boy in the USA after he ingested a bracelet charm containing 99 % lead. The initial symptoms of poisoning manifested as vomiting, abdominal pain and fatigue, and the child had a final blood lead level (PbB level) of 180 µg/dL at the time of death.

6.1.1.2 Dermal absorption

The *dermal absorption* of lead trough unbraided (non- irritated) skin has been established as less than 0.1% (ranging from 0.01% to 0.18% in studies), and is considered to be of much less significance than absorption via the respiratory or gastro-intestinal routes.

Lead is a soft metal that can easily "rub off" on to the skin in the case of dermal contact. Even though absorption directly through the skin is considered negligible, the lead can become systemically available through hand-to-mouth behaviour. This route of exposure is feasible for both children and adults that come in contact with lead containing articles, both at home and in the work place. Especially older and thus oxidised lead surfaces can transfer significant quantities (potentially hundreds or thousands of µg's) of lead to the hands via dermal contact. In the workplace, personal habits such as frequent hand-to-mouth activity, smoking, and eating all provide opportunities for lead ingestion. The intensity of exposure resulting from such habits varies as a function of personal hygiene (e.g. hand washing frequency) and the magnitude of direct lead contact and lead contamination (e.g. dust) on surfaces.

6.1.1.3 Inhalational absorption

For the very small particles (up to 0.5 µm), a dissolution occurs in the lungs and the lead will be available for systemic absorption. More than 90% of these very small particles are completely absorbed after deposition in the lower respiratory tract.

Particles between 0.5–10 µm are partially absorbed in the lung; the non-absorbed parts will be transported up to the mouth via the respiratory tract and then swallowed.

Larger particles over 10 µm will mainly be swallowed and then absorbed via the gastrointestinal tract.

6.1.1.4 Distribution in the body

Once it is absorbed, inorganic lead appears to be distributed to both soft tissues (blood, liver, kidney, etc.) and mineralising systems (bones, teeth) in a similar manner regardless of the route of absorption.

The distribution of lead seems to be similar in children and adults, but in adults a larger fraction of lead is stored in skeletal tissue. More than 90% of the total amount of accumulated lead ends up in bone and teeth in adults, while in children, 75% is accumulated in bones.

Lead concentration is related to calcium status; stored lead can therefore be released from bone tissue into the blood stream in situations where a person suffers from calcium deficiency or osteoporosis.

It should be noted that lead is easily transferred to the foetus via the placenta during pregnancy. The foetal/maternal blood lead concentration ratio is approximately 0.9.

6.1.1.5 Elimination, half-life in the body

Of the eliminated lead elimination takes place mostly via urine (>75%), and 15–20% is excreted via bile and faeces.

Lead has a different half-life in different tissue pools. Blood lead and lead in soft tissue is considered the most labile compartment with a half-life of approximately 40 days, while bone lead is very stable with a half-life of several decades.

In lead exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. Lead is eliminated from bone very slowly; the half-life can be 10 to 20 years or more. In this way, lead can lead to an internal exposure long after the external exposure has ended, by redistribution between different tissue pools.

6.1.2 Toxicity to humans

Although lead may cause acute toxicity as described in section 6.1.1.1 most concern is in relation to low level exposure as repetitive low level exposure to lead may result in accumulation in the body and cause developmental or long term effects.

Adverse effects in humans in relation to lead exposure are often described to be associated with the blood lead level (PbB- level) as the lead level in blood is the best reflection of the lead exposure status of the individual.

EFSA (2010) concluded based on data on humans that the most critical effects in relation to small increases in PbB levels were developmental neurotoxicity; effects on blood pressure, and chronic kidney disease.

Cardiovascular effects
Exposure to lead has been associated with a variety of adverse effects on the cardiovascular system in animals and humans. The most studied dose-response relationship is on the effect of lead exposure on blood pressure; more frequently reported for systolic than for diastolic blood pressure. Based on detailed analyses of five human studies EFSA concluded a blood led level of 36 µg Pb/L to be associated to a 1% increase in systolic blood pressure. This blood lead level was then based on modeling converted to a daily lead exposure of 1.50 µg Pb/kg bw d.

Kidney effects
Exposure to lead has been associated with functional renal deficits e.g., changes in proteinuria, glomerular filtration rates or creatinine levels and clearance. From the most recent human data EFSA concluded a blood lead level of 15 µg Pb/L to be associated with a 10% increase of chronic kidney disease in the population. This blood lead level was then based on modeling converted to a daily lead exposure of 0.63 µg Pb/kg bw d.

Developmental effects
Lead exposure may cause neurological adverse effect in adults as well as in children. The most sensitive effect of lead in that respect is its ability to cause IQ deficits in the developing brain. Lead causes IQ deficits in children at *very* low blood lead levels and since no safe blood lead level has been established, lead should be regarded as a non-threshold toxic compound.

The central nervous system is still under development well over a decade after birth; therefore the IQ effects in children should be considered a developmental effect. The association between children´s IQ and blood-lead levels is shown in Figure 6-1 below.

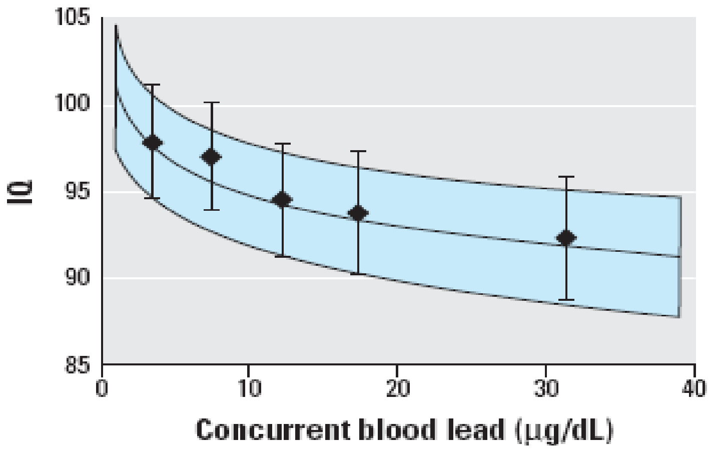


FIGURE 6-1 THE MEAN IQ (95% CONFIDENCE LIMITS) FOR CHILDREN EXPOSED TO LEAD IN THE INTERVALS < 5 µG/DL, 5-10 µG/DL, 10-15 µG/DL, 15-20 µG/DL AND > 20 µG/DL (EFSA 2010)

Based on a detailed analysis of the dose-response association between blood lead levels and IQ levels of children the EFSA concluded a blood lead level of 1.2 µg Pb/dL to be associated with a loss of 1 IQ point. This blood lead level was then based on modelling converted to a daily lead exposure of 0.50 µg Pb/kg bw d.

Currently in Western Europe the typical blood lead level of small children is in the range of 1.5-2 µg Pb/dL, i.e. at the start of the curve shown in Figure 6-1. On the other hand this is the steepest part of the curve and a small reduction in blood lead level would have a greater impact here than in children with higher blood lead levels. Although a decrease in 1 IQ point in an individual child having an average IQ of 100 may not be noted at an individual level the loss of 1 or more IQ points in every person in a population would result in a significant impact on the IQ distribution in the population i.e. the number of people in the population which are on the borderline of mental retardation (at an IQ level of about 70) would increase.

Fertility
Impacts of lead upon reproduction have been evaluated in a large number of animal studies documenting the negative effects of lead upon fertility. The combined animal evidence strongly suggests that lead will have negative impact on sperm production and will cause histopathological changes in testicular tissue. Extrapolation from experimental animal data to humans is generally unnecessary since large amounts of human data are already available.

In humans, alterations in semen quality are the most commonly observed effects in the occupational setting and can be documented with precision. The decrements in semen quality associated with high blood lead levels are expected to have an impact upon the fertility of normal, healthy individuals.

Effects of lead on female reproduction have been observed in numerous animal species. These effects include alterations in sexual maturation, hormone levels, reproductive cycles, impaired development of the fertilised egg as well as decreases in fertility. Historical human data suggest fertility effects in females are probable as well, but fertility effects in women cannot be estimated with precision.

Carcinogenicity
According to IARC (2006), most inorganic lead compounds are classified as “potentially cancer-causing in humans” (Group 2A), based on epidemiologic studies in which cancers of the stomach

and the lungs were noted. Organic lead compounds are not classified as to their cancer-causing ability in humans.

According to the CLP-legislation, lead acetate is classified and listed in annex VI as Carc 2 (H351), because carcinogenic effects have been observed in animal studies. LDAI (2008) proposes to extend this classification to all inorganic lead compounds, since they have a greater bioavailability compared to other lead compounds.

Comments regarding classification
It should be noted that these adverse effects from repeated exposure on the nervous system, on the cardiovascular system and on the kidneys would - as the basis is human evidence - comply with the CLP criteria for classification as STOT RE1;H372 (Causes damage to organs through prolonged or repeated exposure) and not as STOT R2;H372 which is the currently used harmonised classification.

The effects on fertility and the developing brain is accordance with the present harmonized classification as Repr 1A; H360Df (May damage fertility or the unborn child).

With respect to carcinogenicity a harmonized classification as Carc 2, H351 (Suspected of causing cancer) for lead compounds may apply as this also have been prosed by the lead industry (LDAI 2008). Also, this classification has been reported as self-classification to the ECHA classification inventory by several notifiers (see section 2, Table 2-3).

6.2 Derivation of DNELs/DMELs or other measure for dose-response

6.2.1 Tolerable daily intake

In 1995, a TDI value of 3.6 μ g/kg bw/day was established for both children and adults by the WHO. This value was established based on the assumption that an intake of 3–4 μ g Pb/kg bw/day does not affect the Pb levels in blood (PbB) in children or increase the body burden of lead.

In 2003, the WHO (World Health Organization) reported a possible correlation between Pb levels below 10 μ g/dL and a reduction in IQ.

EFSA (European Food Safety Authority) reported in 2010 that no TDI value could be placed upon lead exposure for children due to the fact that no known threshold for the decrease in IQ scores in relation to lead exposure has been found.

6.2.2 Chronic DMEL (Derived Minimal Effect Level)

No exposure threshold has been determined for chronic exposure to lead in regards to neurotoxic effects in children.

As mentioned above and based on most recent data EFSA (2010) concluded that a TDI value could no longer be established for lead exposure as it was not possible to define a lower level of exposure without any adverse effect. Therefore EFSA defined the dose level that corresponded to a 1% response or to a loss of 1 IQ point. This Bench Mark Dose Level 01 or the BMDL01 dose was calculated to an exposure of 0.50 μ g Pb/kg bw/day. So for each time the average daily dose level is increased (or decreased) with 0.50 μ g Pb/kg bw/day in relation to the current background exposure, this is associated with a loss (or gain) of 1 IQ point.

Based on this evaluation The Risk Assessment Committee at ECHA in 2011 established a DMEL value of 0.05 µg Pb/ kg bw/ day by using a margin of exposure (MoE) of 10 in order to establish a dose level that could be considered a dose without any appreciable risk. This DMEL value was used when making conclusion on a restriction proposal on lead in jewellery and is thus was the basis for this EU restriction.

Thus the reference point from which to assess tolerable human exposure level for lead has now shifted from a dose level of 3.6µ g Pb/kg bw/day (WHO in 1986) to a dose level of 0.05 µg Pb/ kg bw/ day (ECHA, 2011a).

Comment
The tolerable dose level established in 2011 *is a factor 70 lower* than the previous used tolerable dose level at 3.6 µ g Pb/kg bw/day. This of course have impact on the risk assessment of lead as human exposure to lead may not have declined at the same magnitude.

6.3 Human exposure

6.3.1 Direct exposure from articles

Consumers' exposure from articles
For consumers the most critical direct exposure to lead is though children´s mouthing of objects containing lead e.g. jewellery. For metallic jewellery a tolerable migration rate of 0.05 µg Pb/g jewellery /h (or 0.05 mg/kg/h) during mouthing was found to correspond to the DMEL value of 0.05 µg/kg bw/d (ECHA, 2011a+b).

In appendix 8 the lead contents in various types of articles from which consumer exposure may occur are given (Swedish Chemical Agency 2012b).

In connection to the Swedish Restriction proposal on lead content in consumer products a series of migration test have been conducted, Table 6-1.

TABLE 6-1 TEST RESULT FROM MIGRATION TESTS WITH ARTICLES (SWEDISH CHEMICAL AGENCY, 2012C)

No	Article	Part of the article sent for testing	Migration Pb (mg/kg)
1	Garden glove	Green plastic dots	22
2	Reflective cat collar	Mixed materials	29
3	Green textile bag	Outer layer	2
4	Spectacle case	Front layer	18
5	Reflective bracelet orange	Inner layer	15
6	Reflective bracelet yellow	Inner layer	70
7	Grey purse	Front layer (silver)	13
8	Orange purse	Front layer (orange)	290*
9	Strap purse in red polymer	Back and front layer	28
10	Purse in red polymer	Front layer (red)	3.2
11	Wallet in red polymer	Front layer (red)	180*
12	Belt coral (lead free reference)	Inner layer (white)	1.3
13	Belt coral	Front layer	130*
14	Belt coral	Back layer	140*
15	Plastic flower	Outer layer	0.27
16	Belt orange	Front layer	270*
17	Belt orange	Back layer	220*

*The limit value in the toy directive is 90mg Pb/kg

It can be seen that for many of these articles the migration exceeds the migration limit of 90mg Pb/kg which is used for regulation toys or the migration rate of 0.05 mg/kg per hour used for jewellery.

Many parameters may affect the migration rate of lead from a product. The lead content is one of these parameters although there may be many other factors that may influence the migration e.g. the water solubility and how strong the lead compound is bound in to the matrix or on the surface.

The following lead content has been found in various articles by the Swedish Chemical Agency (2012c), Table 6-2.

TABLE 6-2 LEAD CONTENT IN ARTICLES (SWEDISH CHEMICAL AGENCY, 2012C)

Article group	Total no of samples	Samples containing lead	Range lead concentration, mg/kg *)	Average lead concentration, mg/kg (%) *)
Clothes	56	7	632-17 200	4 970 (0.5 %)
Accessories	85	18	601-160 000	13 243 (1.3 %)
Stationary	52	7	755 – 24 000	8 754 (0.87 %)
Interior decorations	14	6	731-380 000	45 489 (4.5 %)
Keys	51	34	776-11 900	6 026 (0.6 %)
Wallets, polymer material	26	7	1 202-1 926	1 667 (0.17 %)
Bags and cases	11	3	632-2 386	2 128 (0.21 %)

*Only results above 500 mg/kg are included

The Swedish Chemical Agency (2012) in their proposal for restriction on lead in consumer products uses a migration rate of 0.7 µg/cm²/h from lead articles, which are mouthed by children. This value was concluded by the Risk Assessment Committee at ECHA when they evaluated data on lead migration from jewellery and was the basis for the calculation of a limit value of 500 mg Pb/kg (or 0.05%) in jewellery and which now has been implemented in EU.

Using this migration rate and a surface area of 10 cm² of the article that is mouthed the following exposure of children in various age groups mouthing articles with various lead content could be calculated, Table 6-3.

TABLE 6-3 ESTIMATED LEAD EXPOSURE (MG/KG BW/DAY) IN YOUNG CHILDREN ASSOCIATED WITH MOUTHING ARTICLES (SWEDISH CHEMICAL AGENCY, 2012C)

Age Weight Average/ Max mouthing time	Lead content (%)	Lead exposure (µg/kg bw/day)	
		Realistic case	Reasonable worst case
6-12 months, 9.2 kg bw, 20 min./ 80 min.	0.05	0.01	0.06
	0.1	0.026	0.1
	1	0.26	1
	3	0.8	3.1
	6	1.5	6.2
12-24 months, 11.4 kg bw 20 min./65 min.	0.05	0.01	0.04
	0.1	0.02	0.07
	1	0.2	0.7
	3	0.6	2
	6	1.2	4
24-36 months, 13.8 kg be 15 min./180 min.	0.05	0.008	0.08
	0.1	0.015	0.15
	1	0.15	1.5
	3	0.4	4.6
	6	0.8	9

The exposure was calculated by using the following formula:
Lead exposure (µg/kg bw/day) = (Surface (cm2) × mouthing time (h) × migration rate (µg/h/cm2/% lead) / body weight (kg)

It can be seen that for all mouthing scenarios of articles with a lead content at 1% and above the DMEL value of 0.05 ug Pb/kg bw/d is exceeded in the realistic case scenarios while for the worst case scenarios also articles with a content for 0.05% exceeds the DMEL value.

6.3.2 Ammunition

Recent Danish data found increased blood lead levels in shooters regularly shooting at a shooting facility. 60% of the shooters exceeded a blood lead level of 10 µg Pb/dL and 30% exceeded a level of 20 µg Pb/dL (corresponding to the Danish occupational limit value). The blood lead levels in a reference group were all below 3.4 µg Pb/dL (Grandahl *et al.* 2012).

6.3.3 Indirect exposure of the population

The general population is predominantly exposed by lead from indirect exposure i.e. especially from food and drinking water.

6.3.3.1 Air

The lead content in ambient air in Europe and in Denmark has declined dramatically within the last 30 years due to the ban of leaded gasoline. This can be seen from Figure 5-1, section 5.4, where levels around 1000 ng Pb/m^3 were measured in 1982 in high spot urban areas compared to levels of 4-5 ng Pb/m^3 measured in 2011 (Danish Centre for Environment and Energy, 2012).

Thus exposure from these low levels may be considered nearly insignificant. E.g. a 2 year-old child (13 kg bw) inhaling 10 m^3 per day would be exposed to 0.004 µg Pb/kg bw/d.

6.3.3.2 Soil

In Denmark the background concentration of lead in agricultural soil and unpolluted areas is generally in range of 4-20 mg Pb/kg with a median level of 11 mg Pb/kg soil. In polluted urban areas, e.g. typical lead concentrations may be around 200 mg/kg with peak levels up to above 1650 mg Pb/kg.

These values may be compared to the Danish soil quality criteria for unrestricted use of the soil/ area which is at 40 mg Pb/kg. A level of 400 mg Pb/kg has been set as an action level. The level in-between is a so called information level for slightly polluted sites Danish EPA (2010).

A well-documented correlation exists between lead level in soil and blood lead level in children. Mielke *et al.* (2007) found a strong curvilinear correlation between blood lead levels of more the 55.000 children coupled with soil measurements (more than 5400 samples). Thus based on this correlation an increase in lead level in soil from 40 mg Pb/kg to 400 mg/kg would result in an increase in the blood lead level of approx. 23 µg Pb/L.

A 2 year-old child ingesting 100 mg soil per day will at a soil concentration corresponding to the soil quality criteria of 40 mg/ kg be exposed to 0.3 µg Pb/ kg bw/d. This exposure is 6 times above the DMEL value concluded by the Risk Assessment Committee at ECHA.

6.3.3.3 Indoor dust

LDAI (2008) has compiled a series of dust measurement with regard to lead content. Here Swedish data from 2000 indicate a median lead level in dust of 100 mg Pb/ kg dust from day care centers and 135 mg Pb/kg dust from private homes. Especially in private homes the range of the measurements was very wide (39-2,700 mg Pb/kg dust).

Using an ingesting rate of house dust of 60 mg/day for 1-6 year-old child (US-EPA exposure hand book 2009) with a content of 135 mgPb/kg in the dust would result in a lead exposure of 0.6 µg Pb/kg bw/d for a child weighing 13 kg. This exposure is 12 times above the DMEL value of 0.05 µg/kg bw/d concluded by the Risk Assessment Committee at ECHA.

6.3.3.4 Drinking water

Lead content in water

Drinking water may be a significant source to the lead exposure of the population. In EU, the limit value for drinking water is set at 10 µg/L.

Lead may occur in groundwater however lead may also be released from the distribution system and from the installations in –house in buildings. In Denmark the limit value for lead in drinking water is thus allocated to various stages of the water:

Quality criteria for groundwater under polluted sites: 1 µg Pb/L (Danish EPA 2010)

Quality criteria for drinking water in the public distribution system: 5 µg Pb/L when entering households and 10 µg Pb/L at the tap (The Danish Ministery of Environment 2011).
In a recent Danish EPA report the limit value of 10 ug Pb/L in drinking water was reevaluated. Based on health concerns it was concluded that the level of inorganic lead in drinking water should be as low as possible. However, no specific alternative value was proposed (Danish EPA, 2012).

In general levels of lead content in the groundwater in Denmark are low. In Danish groundwater samples taken in the period 1993-2006, lead was found in 406 of 663 (61%) abstraction wells and occurred in concentrations over the drinking water standard (5 µg Pb/L, value at the entrance to the property) in 10 samples (2%). The average concentration was 0.6 µg Pb/L and the maximal concentration measured was 35 µg Pb/L. In 2010, lead occurred in concentrations over the drinking water standard (5 µgPb/L value at the entrance to the property) in four of 238 samples from Danish groundwater (GEUS, 2011).

However, lead may still be released by the currently used water pipes made of different kind of alloys. The Danish EPA in 2001 made a detailed survey analyzing the water in various experimental rig systems composed of different commercial available pipes and fittings. Especially alloys made of brass resulted in migration of lead into the water and after 12 hours of stagnation of the water in the pipes/ fittings the limit value for drinking water at 10 µg Pb/L was exceeded (Danish EPA 2001b).

In a screening survey of metal release at consumers' kitchen taps, the release of lead was measured in 51 domestic drinking water installations on Zealand (primarily in the vicinity of Copenhagen), Denmark (FORCE Technology, 2008). Water samples were taken in three different ways: A fully flushed sample (A-sample), and two four-hour stagnation samples of 200 ml (B-sample) or 800 ml (C-sample). The three samples were taken in order to represent water from mains, first part of installation (mixer taps, connecting pipe, stop valve) and remaining part of installation (pipes, manifolds, water meter, valves). The concentration of lead was low in the A-samples, and generally increased in the B- and C-samples with average concentrations of 7.3 µg/l in the B-samples and 2.8 µg/l in the C-samples. The maximum concentration of 110 µg/l was found in a B-sample (Danish EPA, 2012).

When flushing the tap and pipes for 5 minutes the drinking water in 33 out of 51 samples contained less than 0.5 µg Pb/L (FORCE, 2008).

Other data (from a 2003 survey) from the National Food Institute, Technological University of Denmark (DTU Food) indicate an average lead level in tap water of 0.87 µg Pb/L (DTU Food, 2013b).

In 2011 a severe case of lead pollution was disclosed in the city of Tønder in Denmark where the lead content in drinking water was measured to levels up to 570 µg/L because old lead pipes were still a part of the distribution system in the town (Tønder Kommune, 2013).

In a recent Swedish survey it was shown that water from 24 of 60 commercial available taps exceeded the limit value of 10µg/L with the highest value at 350 µg/L (Politiken, 2011).

An approval scheme for construction products in contact with drinking water has existed in Denmark since the 1970'ies. This scheme, which has recently been modified, i.e. requires that taps are tested for release of lead before being placed on the market.

Lead exposure from drinking water
The Danish Food Institute has estimated an average lead content in tap drinking water at 0.9 µg Pb/L.

Assuming a 2 year-old child weighing 13 kg would drink 1L water per day this would result in a daily exposure of 0.07 µg Pb/kg bw/d, or just above the DMEL value of 0.05 µg Pb/kg bw/d used by RAC.

At an exposure level corresponding to the current limit value of 10 µg Pb/L the exposure would be 0.77 µg Pb/kg bw/d, or 15 times above the DMEL value.

However, to minimise exposure from drinking water it is in general recommended by the authorities that the tap and fittings are well flushed before intake of drinking water so that intake of stagnant water with high levels of contaminants is avoided.

6.3.3.5 Food

EU

EFSA (2012) has made an update of the dietary lead exposure to the European population. The exposure estimates was based on more than 144,000 analytical results on lead content in food items coupled with food consumption data of the various age groups in the population.

Food is concluded to be the major source of exposure to lead in all age groups, although for children ingestion of soil and dust also can be an important contributor.

TABLE 6-4 LOWER (LB), MIDDLE (MB) AND UPPER (UB) BOUND MEAN AND 95TH PERCENTILE (P95) LEAD DIETARY EXPOSURE IN µG/KG B.W. PER DAY FOR EACH AGE GROUPS AND AS A MEAN AND 95TH PERCENTILE AVERAGE LIFETIME EXPOSURE CALCULATED BY WEIGHTING THE CONTRIBUTION OF EACH AGE GROUP ACCORDING TO THE NUMBER OF YEARS COVERED (DIFFERENT RANGE OF COUNTRIES COVERED IN THE RESPECTIVE AGE GROUP)

Age group	N	Mean				P95		
		LB	MB	UB		LB	MB	UB
Infants	876	0.73	0.91	1.09		1.39	1.80	2.22
Toddlers	1,597	1.10	1.32	1.54		1.95	2.28	2.56
Other children	8,468	0.87	1.03	1.18		1.46	1.68	1.92
Adolescents	6,329	0.46	0.55	0.63		0.84	0.97	1.11
Adults	30,788	0.43	0.50	0.57		0.74	0.85	0.97
Elderly	4,056	0.42	0.48	0.55		0.72	0.82	0.92
Very elderly	1,614	0.40	0.47	0.53		0.71	0.79	0.89
Adjusted average	**53,728**	**0.58**	**0.68**	**0.78**		**1.02**	**1.17**	**1.33**

For setting the exposure values in perspective EFSA (2010) determined a bench mark dose level (BMDL01) value of 0.50 µg/kg bw per day for developmental neurotoxicity in young children (i.e. a dose level corresponding to 1% decrease in IQ, i.e. a loss of 1 IQ point).

For infants, consumption via: drinking water; milk and dairy products; infant food, and grain products accounted for 69% of the total lead exposure from food.

For toddlers, consumption via: milk and dairy products; grain products; drinking water, and vegetables accounted for 55% of the total lead exposure from food.

For adults, grain products, non-alcoholic beverages, alcoholic beverages, and vegetables accounted for 49% of the total lead exposure from food.

With respect to lead content in food an overall decrease of 23% was estimated from 2003 to 2010, see Figure 6-2 below:

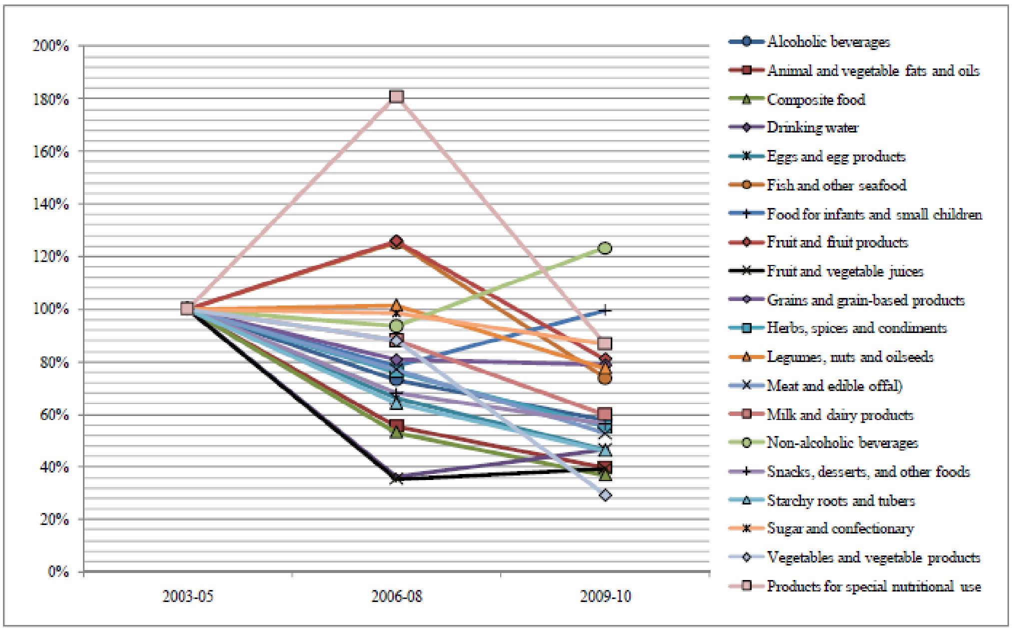


FIGURE 6-2 LEAD LEVELS IN TWENTY BROAD FOOD CATEGORIES BETWEEN 2003 AND 2010 (EFSA 2012)

EFSA (2012) in the conclusion stated:
More than half of the individual food samples tested had levels of lead at less than detection or quantification limits, while individual quantified values ranged from a low of 0.001 µg/kg for a regular boar sample to a high of 232,000 µg/kg for a wild boar meat sample.

The mean lead level in 82 out of 734 specific food categories exceeded 100 µg/kg including dietetic products, seaweed, mineral supplements, wild boar meat, thyme, boletus, ginger and iodised salt.

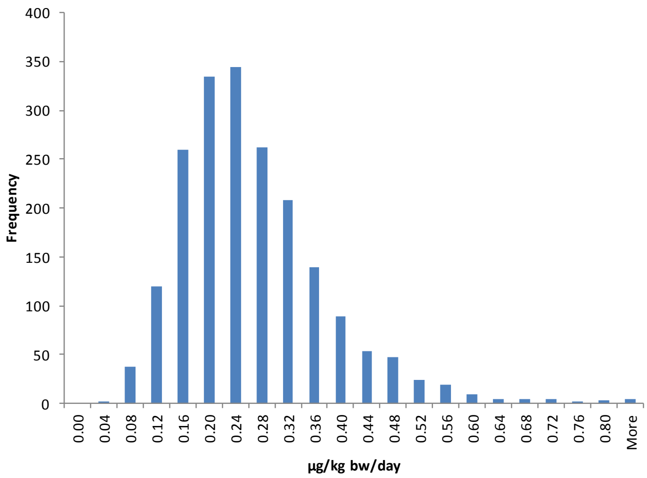
-Using detailed individual food consumption data, middle bound mean and 95th percentile lifetime dietary lead exposure for the European population was estimated at 0.68 and 1.17 µg/kg bw per day, respectively. It was highest in toddlers and lowest in the very elderly population group. Individual dietary survey results varied between a daily minimum lower bound mean of 0.28 µg/kg bw for adolescents to a maximum upper bound mean of 1.77 µg/kg bw for toddlers and a minimum lower bound 95th percentile of 0.49 µg/kg bw for adolescents and the elderly and a maximum upper bound 95th percentile of 3.27 µg/kg bw for toddlers reflecting different dietary habits and survey methodologies.

Food consumed in larger quantities had the greatest impact on lead dietary exposure and this was true for the broad food categories of grains and grain products (16.1%), milk and dairy products (10.4 %), non-alcoholic beverages (10.2) and vegetables and vegetable products (8.4%). At a more detailed level tap water (6.0%), wheat bread and rolls (3.7%), regular beer (3.0%), pastries and cakes (2.8%), iodised salt (2.4%) and potatoes most commonly consumed boiled (2.2%) were important contributors to exposure.

Dietary lead exposure was found to be about a third lower than previously estimated with mean levels for the four older age groups not exceeding the BMDL01 and BMDL10 of 1.50 and 0.63 µg/kg bw per day established for cardiovascular and nephrotoxicity effects in adults. However, mean exposure for the three children age groups exceeded the BMDL01 of 0.50 µg/kg bw per day for developmental neurotoxicity in young children.

Denmark

In a recent report from DTU Food analyses of various contaminants in food (including lead) have been made in a great variety of food items in the period of 2004-2011. Results from the chemical analysis were then combined with data on the consumption of the food items and the daily exposures for the various contaminants were calculated for both adults and children (DTU Food, 2013a).



		µg/kg bw/day
Mean		0.25
sd		0.11
N		1974
Percentile	1	0.069
	5	0.102
	25	0.17
(median)	50	0.23
	75	0.30
	95	0.46
	99	0.62
Minimum		0.03
Maximum		1.05

FIGURE 6-3 DISTRIBUTION OF LEAD EXPOSURE IN µG/KG BW/DAY IN THE DANISH POPULATION (4-75 YEARS) (DTU FOOD, 2013A)

The estimated mean exposure of 15 µg/day (0.25 µg/kg bw/day) is lower compared to the previously reported mean exposure of Danish adults at 19 µg/day for the time period 1998-2003, corresponding to an overall decrease of 21%.

Figure 6-5 shows the contribution to the exposure of lead from different food groups. Beverages are the food group with the largest contribution to lead exposure comprising 46.6 % of the total exposure. Fruits and fruit products (17.6 %), sugar, honey and sugar confectionary (11.6 %), vegetables (9.1%) and cereals (8.4 %) are other food groups with significant contributions, whereas other food groups only provide low contributions to the overall dietary exposure of lead.

In relation to the contribution from the various beverages, data from earlier surveys indicated that 40% stems from coffee, 11% from tea, 10% from tap water and 6% from white wine. With respect to the contribution from tap water an average content of 0.87 µg Pb/L had been measured (DTU Food 2013b).

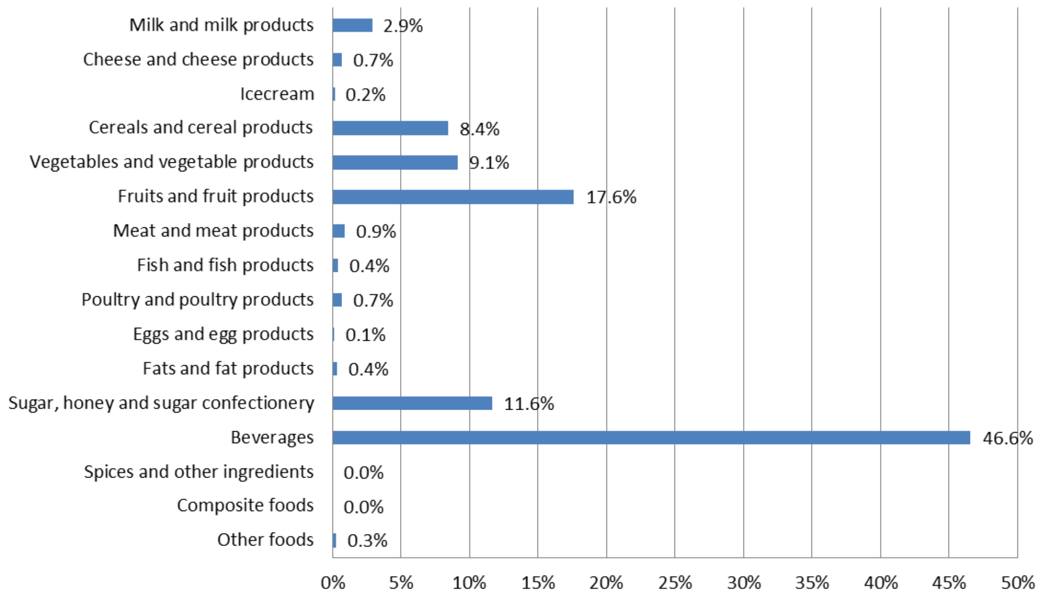


FIGURE 6-4 EXPOSURE OF LEAD FROM MAIN FOOD GROUPS IN THE DANISH POPULATION (4-75 YEARS) (DTU FOOD, 2013A)

For children (4-14 years) the mean and 95th percentile exposure was estimated at 0.30 and 0.56 µg/kg bw/day), respectively. The values are at the same level as the exposure estimated for French children at 0.27 µg/kg bw/day (mean) and 0.57 µg/kg bw/day (95th percentile) by ANSES in 2012, but lower than the estimates in the recent EFSA evaluation 2012 on dietary exposure to lead in the European population, where a mean exposure to Danish children at 1.07 µg/kg bw/day was reported. The exposure is near the $BMDL_{01}$ (0.5 µg/kg bw/day) for developmental neurotoxicity so the margin of exposure (MOE) is close to 1. It is therefore desirable that children decrease the exposure of lead.

Thus the lead exposure from food should be about 10 times lower in order to reach the DMEL level of 0.05 µg/kg bw/day concluded by the Risk Assessment Committee at ECHA.

For adults (15-74 years) the mean and 95th percentile exposure was estimated at 0.23 and 0.41 µg/kg bw/day), respectively. The values are at the same level as estimated for French adults at 0.20 µg/kg bw/day (mean) and 0.35 µg/kg bw/day (95th percentile) (ANSES, 2012a), but lower than the estimates in the EFSA evaluation, where the mean exposure for Danish adults was reported at 0.58 µg/kg bw/day (LB-UB) (EFSA, 2012b). As for children the MOE is also low for adults (DTU Food, 2013a).

6.4 Occupational exposure

6.4.1 Occupations and air borne exposure levels

A potential for occupation exposure to lead and lead compounds occur in a variety of working environments.
The Danish Working Environment Authority in their guidance on metallic lead and lead compounds lists the following occupations where lead exposure may occur (DWEA, 2002):

- Primary and secondary casting of lead and zinc
- Manufacture of lead compounds
- Manufacture and use of lead containing paint, enamels, kit and dyes.
- Manufacture and renovation of accumulators

- Manufacture of metallic lead items or lead alloys
- Ceramic industry and potteries
- Plastic industry using lead additives
- Printing
- Demolition work, abrasion, burning, cutting with cutting torch of items/ surfaces with lead containing paint, demotion of plants e.g. foundry furnaces
- Car industry and repair
- Foundries
- Industrial painting

Furthermore, according to LDAI (2008) occupational exposure to lead may occur e.g. in the scrap industry, in welding, in soldering, in waste combustion, in bronze casting, in the iron industry, in lead sheet production and in the production of lead crystal glass.

Some examples of measured occupational exposure levels are given below (LDAI, 2008):

Production of crystal glass:	0.034 mg Pb/m^3 (median personal exposure)
Production of batteries:	0.063 mg Pb/m^3 (median personal exposure)
Production of ceramic ware:	0.033-0.040 Pb/m^3 (median personal exposure)
Demolition work:	in the range of 0.001-0.054 Pb/m^3 depending of the task (geometric mean of personal exposure data)

It is not possible to say whether these figures are representative for Denmark as no specific Danish measurements have been found.

6.4.2 Individual lead exposure to workers

Although the airborne exposure level may give some guidance regarding exposure the best measure for the occupational exposure is obtained by measurement of the blood lead level of the workers as this measure represent the total exposure status of the individual i.e. the sum of exposure from inhalational, oral and dermal exposure.

The typical average blood lead values for a variety of occupations have been determined by LDAI (2008):

Bronze and brass foundry:	27 µg Pb/dL
Stained glass workshops:	10 µg Pb/dL
Incineration plants:	28 µg Pb/dL
Welding fumes:	8 µg Pb/dL
Enameling:	10 µg Pb/dL
Soldering of electronic circuits boards:	16 µg Pb/dL
Tyre fitters:	5 µg Pb/dL
Construction workers:	14 µg Pb/dL
Iron workers:	24 µg Pb/dL
Engine reconditioning	9 µg Pb/dL
Carpenters	8 µg Pb/dL

These figures may be compared to the general background blood lead levels in the adult population in e.g. UK and Sweden of about 2-5 µg Pb/dL (LDAI, 2008).

No systematic data on blood lead levels in Danish workers are available. Experiences from an occupational clinic indicate typical blood lead levels in the range of 2-25 µg Pb/dL and high blood lead levels in the range of 50-60 µg Pb/dL in workers occupationally exposed to lead. Especially, occupations with cleaning/ abrasion of window frames may result in the very high blood lead levels (Occupational Clinic of Bispebjerg Hospital, 2013).

Occupational work in waste management is considered a further source for lead exposure in Denmark e.g. in relation to handling of waste of lead batteries and lighting (DWEA, 2013).

6.4.3 Occupational measures

As described in section 2 EU and national Danish occupational regulation has been implemented in order to protect the workers from exposure to lead.

In EU a binding occupational exposure limit value of 0.15 mg Pb/m^3 for inorganic lead and its compounds and a binding biological limit value of 70µg Pb/dL blood have been set according to Council Directive 98/24/EC, 7 April 1998.

In 2002 SCOEL (the scientific Committee on Occupation Exposure Limits) recommended a reduction of these figures to 0.10 mg Pb/m^3 and 30 µg Pb/dL blood (SCOEL, 2002).

In Denmark an occupational exposure limit value of 0.050 mg Pb/m^3 and a biological limit value of 20 µg Pb/dL blood has been set (DWEA, 2002). Measurement of the blood lead level of workers is obligatory for workers occupied in work where lead exposure occurs. According to the Danish worker regulation the work should be organized and measures should be taken to minimize the exposure in the working environment as much as possible even in exposure situations that already comply with the occupational exposure limit value.

Annex 1 to the Executive Order no 292 of 26 April 2001 on Work with Substances and Materials (chemical agents) stipulates the requirements for work with metallic lead and its ionic compounds. Detailed guidance on this is given in the Danish Occupation Guidance on metallic lead and lead compounds with respect to how to monitor the content of lead in the air and how to follow the blood lead levels of the workers. Further, guidance is given on health surveillance of works on protective equipment and specific groups of employees. Thus, young people below the age of 18 years are not allowed to work in occupational environment with lead exposure. Also pregnant women should not work in areas with risk for lead exposure. Further, recommendations are given with regard to hygiene, cleaning etc. (DWEA, 2002).

In relation to handling of waste the classification limits for lead and lead compounds for the categorization as hazardous waste is an important instrument for applying adequate risk management measures for the working environment and for protecting the workers.

The Danish Asbestos Association has recently published a very detailed guidance in connection with lead abatement work in the construction industry. This guidance covers the duties of the employer, specific training and instruction of the workers, requirements for protective equipment, measurement in the occupational environment, how to limit in dust formation, requirements for dusty working operations, storage and handling of waste containing lead, sampling and analyses, specific organization of the work, etc. (Danish Asbestos Association, 2012).

6.5 Bio-monitoring data

General population

The levels of lead in blood are a highly reliable biological marker of recent exposure to lead.

WHO/ENHIS (2009) has compiled data on the mean blood lead levels in children of various age groups in a number of European countries between 1991 and 2008 as shown in Figure 6-6.

The phasing out of lead from petrol, first in Western Europe and later in central and eastern Europe, has resulted in a significant fall in blood lead levels in children over the last two decades. Industrial emissions are still important local sources of lead exposure in some countries. Since lead was phased out from petrol, other sources of exposure to lead that had previously been ignored have become increasingly significant. It is still necessary to further re-duce the levels of lead in the blood because there is no known safe level in children (WHO/ENHIS, 2009).

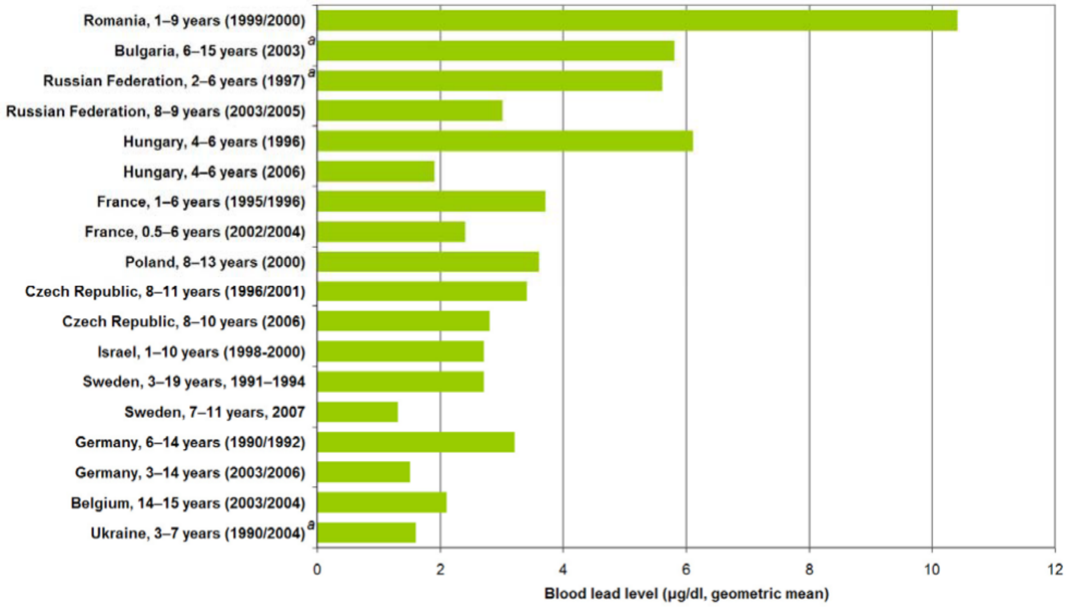


FIGURE 6-5 MEAN BLOOD LEAD LEVELS OF CHILDREN MEASURED IN AREAS WITHOUT SIGNIFICANT LOCAL SOURCES OF LEAD EXPOSURE IN SELECTED EUROPEAN COUNTRIES, 1991–2006 (WHO/ENHIS, 2009)

It is seen from figure 6-5 that the mean blood levels measured in children in various European countries exceed the BMDL01 value of 1.2 µg/dL determined by EFSA for developmental neurotoxicity in young children (i.e. a change 1.2 µg/dl in blood lead level is associated with a change of 1 IQ point). It is, however, also evident that the blood lead levels are decreasing over time as indicated by the data from Hungary, France, Czech Republic, Sweden and Germany.

In the Swedish restriction proposal on lead in consumer products it is indicated that typical blood lead levels in children today in Western Europe are in the range of 1.5-2 µg Pb/dL (Swedish Chemical Agency, 2012c).

This decreasing trend in blood lead levels in children has been observed to be especially associated to the phase out of the use of lead additives in gasoline as illustrated by the Swedish data below, see figure 6-6 (EEA, 2005).

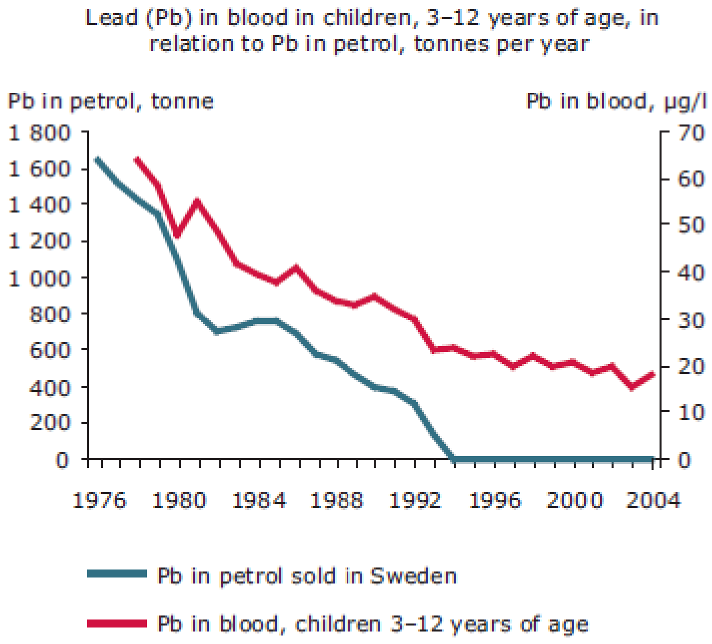


FIGURE 6-6 LEAD USED IN PETROL AND BLOOD LEAD LEVELS IN SWEDISH CHILDREN (EEA, 2005)

The LDAI (2008) risk assessment report made a very detailed evaluation of European data on blood lead levels from the 1970-ies an up till 2005. Based on this it was concluded that the average blood lead levels for adults in western and north European countries in general have decreased to levels in the range of 2-5 µg Pb/dL blood.

Few Danish data are available, but data from a reference population in Funen from 1994 indicated a mean blood lead level of 3.5 µg Pb/dL blood for 209 adults in the age of 20-89 years (LDAI, 2008).

Workers
See section 6.4.2., where blood lead levels are given for different types of occupations.

6.6 Human health impact

6.6.1 General population

Human health impact assessments have been made recently for children exposed from 1) lead in consumer products and articles, 2) children exposed to lead in jewellery and 3) the impact on children's IQ in France based on biomonitoring data in France. These impact assessments use the new non-threshold approach for risk assessment on lead, where each source of lead exposure is counting and anticipated to have an impact on IQ proportional to the exposure level.

Health impact of the lead content in consumer product
Based on the exposure scenarios in Table 6-3 and the EFSA (2010) associations between lead exposure, blood lead levels and IQ loss the estimations of IQ loss as shown in Table 6-5 was made in relation to mouthing of articles with various specific lead contents (Swedish Chemical Agency, 2012c).

TABLE 6-5 ESTIMATED IQ REDUCTION (POINTS) IN YOUNG CHILDREN ASSOCIATED WITH A REALISTIC EXPOSURE CASE FOR MOUTHING ARTICLES (SWEDISH CHEMICAL AGENCY, 2012C)

Age, Weight, Mouthing	Lead content (%)	Lead exposure (µg/kg bw/day)	Increase of blood Pb level (µg/l)	IQ reduction (points)
6-12 months 7-4 kg 20 min.	0.05	0.01	0.24	0.02
	0.1	0.026	0.62	0.05
	1	0.26	6.17	**0.5**
12-24 months 11.4 kg 20 min.	0.05	0.01	0.24	0.02
	0.1	0.02	0.48	0.04
	1	0.2	4.8	**0.4**
24-36 months 13.8 kg 15 min.	0.05	0.008	0.19	0.016
	0.1	0.015	0.36	0.03
	1	0.15	3.6	**0.3**

The bold numbers in the table show the estimated lead exposure values that exceed an IQ reduction of 0.1 points

The above table shows that for children 6-36 months of age, 0.1 points of IQ reduction occurs at a lead content of 1 %, for a realistic mouthing exposure (15-20 min). The IQ reduction at a lead content of 1 is higher than 0.1 points and therefore is seen as a risk. These calculations are in agreement with the calculated tolerable lead content of 0.2% for a realistic mouthing exposure.

TABLE 6-6 ESTIMATED IQ REDUCTION (POINTS) IN YOUNG CHILDREN ASSOCIATED WITH A REASONABLE WORST CASE EXPOSURE CASE FOR MOUTHING ARTICLES (SWEDISH CHEMICAL AGENCY, 2012C)

Age, Weight	Lead content (%)	Lead exposure (µg/kg bw/day)	Increase of blood Pb level (µg/l)	IQ reduction (points)
6-12 months 9.2 kg 80 min	0.05	0.06	1.44	**0.12**
	0.1	0.1	2.4	**0.2**
	1	1	24	**2**
12-24 months 11.4 kg 65 min	0.05	0.04	0.96	0.08
	0.1	0.07	1.68	**0.14**
	1	0.7	16.8	**1.4**
24-36 months 13.8 kg 180 min	0.05	0.08	1,92	**0.16**
	0.1	0.15	3.6	**0.3**
	1	1.5	33.8	**2.8**

The bold numbers in the table show the estimated lead exposure values that exceed an IQ reduction of 0.1 points

Table 6-5 shows that for the reasonable worst case exposure, the loss in IQ score will exceed 0.1 IQ units when the lead concentration roughly exceeds 0.05%. This implies that a 0.05% lead content might be a suitable threshold for worst case exposure conditions, as higher concentrations of lead will lead to concern. This is in accordance with the calculated tolerable lead content of 0.03%–0.08%.

As a central estimate The Swedish Chemical Agency estimated that the restriction on lead in consumer product would cost 184 million Euro per year. In contrast, the loss of IQ due to lead exposure is associated with substantial socio-economic costs. As it is generally estimated that a 1 point decrease in IQ leads to a decrease in lifetime productivity of approximately 1% the cost of 184 million Euros will thus be counterbalanced if 23,000 IQ points are gained based on the proposed restrictions of lead. The total IQ loss associated with children's mouthing of lead containing articles in EU was estimated to approximately 208,000 IQ points. Thus, the socio-economic benefits obtained by adopting the restriction proposal for consumer articles will thus exceed the estimated compliance costs for industry by several magnitudes (Swedish Chemical Agency, 2012c).

Health impact of the lead content in jewellery

The above made health impact was based on the method used in background documentation for the restriction on lead in jewellery elaborated by the Risk Assessment Committee at ECHA (ECHA, 2011b).

The impact on IQ from mouthing of jewellery was assessed from the following Table 6-6.

TABLE 6 - 7 THE IMPACT OF LEAD EXPOSURE ON THE IQ FROM MOUTHING JEWELLERY OF DIFFERENT LEAD CONCENTRATIONS FOR 1 HR PER DAY (ECHA, 2011B)

Lead content in jewellery	Lead exposure	Increase of blood lead level	IQ reduction
(%)	(µg/kg bw/day)	(µg/l)	(points)
0.05	0.035	0.84	0.07
0.1	0.07	1.68	0.14
1	0.7	16.8	1.4
3	2.1	46	3.8
6	4.2	83	6.9
10	7	125	8.7
25	17.5	234	10.3
50	35	354	12

The table shows that a continuous daily 1 hr mouthing of jewellery that contains 0.05% lead leads to an IQ reduction below an acceptable exposure level of 0.05 µg/kg bw/day that according to the Risk Assessment Committee at ECHA was considered "sufficiently low to ensure no appreciable risk".

Mouthing times less than one hour per day or frequencies less than every day have a correspondently lower impact on the IQ. For example, mouthing a metallic piece of jewellery containing 0.1% lead once a week for 1 hr results in an IQ impact of 0.02, which is about five-fold below the level of no appreciable risk.

The Socioeconomic Assessment Committee, SEAC estimated the restriction on lead in jewellery would cost 4.6 million Euros per year.
SEAC further considered that a change of 1 IQ point in average would affect the life-time earning of a person with 10,000 Euro. Thus the cost of the restriction could be out- weighted by the gain of a total of 460 IQ or 6.2 grammes of lead which would be less mouthed and ingested. Such an exposure would occur if every 6-36 months old child in Europe would mouth a piece of jewellery in an average time of 32 seconds a year.

Health impact of lead in ammunition

Recent data indicate that 30% of shooters (adults) may have a blood lead level exceeding 20 µg Pb/dL.

The impact of these values can be put in perspective by comparing with the recent EFSA (2010) evaluation that developed the following Bench Mark Dose Levels, BMDLs for haematological effects and adverse kidney effects that were considered the most susceptible end-points with respect to lead exposure to adults:

> Haematological effects: BMDL01= 3.6 µg Pb/dL (i.e. exposure resulting in an increase in the blood lead level of 3.6 µg Pb/dL in the workers corresponds to 1% increase in systolic blood pressure).
>
> Effects on the kidneys: BMDL10= 1.5 µg Pb/dL (i.e. exposure resulting in an increase in the blood lead level of 1.5 µg Pb/dL in the workers corresponds to a 10% increase in the prevalence of chronic kidney disease).

Thus, shooters may be in increased risk for haematological effects and chronic kidney disease.

Health impact on current blood lead level in children
Pichery et al. (2011) evaluated the health impact and the socioeconomic consequences of the current blood lead level in 1-6 year-old French children. In Table 6-7 below it is indicated how many IQ points is lost in the fraction of children with blood lead levels above 15 µg Pb/L which is considered as a hypothetical or pragmatic threshold, although it is stated that no specific threshold can be identified. The allocation of children in the various ranges of blood-lead levels were based on data from screening programs in France with measurement of the n blood- lead levels.

Based on this a total a loss of 3.1 million IQ points were estimated to be lost among these 4.7 million children and applying socioeconomic models of the economic consequences, this IQ loss was estimated to result in a socioeconomic cost of nearly 54 billion Euros of which 22.3 billion Euros was associated to loss of life-time earning, see Table 6-8.

TABLE 6-8 IQ POINT LOSSES WITHIN BLOOD-PB CONCENTRATION RANGES AND SOCIOECONOMIC IMPACTS

Blood-lead concentrations range (µg/L)	IQ point loss assumptions [a.b.c]	Number of children	Number of IQ point losses	Total costs (€billion)[e]	Lost life time earnings with a discount factor w30 (€billion)
B-PB < 15	0	2,348,091	0	0	0
15 ≤ B-Pb < 24	1	1,648,975	1,648,975	28.6	11.8
24 ≤ B-Pb < 100	4.9 (1+3.9)	693,783	1,421,769	24.7	10.2
B-Pb ≤ 100	6.8 (1+3.9+1.9)	5,333	36,265	0.6	0.3
TOTAL		4,696,182	3,107,009	53.9	22.3

No such estimates have been made so far for Denmark as bio-monitoring of blood lead levels in the population are lacking. For a rough estimate of the impact in Denmark a scaling could be made according to the sizes of the population in France and Denmark. As France has a population of 63.5 million people and Denmark a population of 5.6 million people the figures could be scaled down by a factor of 5.6 / 65.5 or 0.09. Thus among the 0.42 million Danish 1-6 year old children the lead levels would contribute to an IQ loss of 279,000 IQ points corresponding to a total socioeconomic cost of 4.85 billion Euros, of which the loss in earning was estimated to be 2.01 billion Euros.

This of course is a snap-shot picture of today for the 1-6 year children and the future consequences. The impact on population basis can be considered to be much higher as the older generations grew up with much higher blood-lead levels.

Impact assessment of other quantifiable exposures
With respect to the quantified indirect exposures through air, soil, drinking water and food the following rough impact assessment can be made:
Air
From air an average exposure level of 0.004 µg Pb/kg bw/d was estimated for a 2-year-old child. As 0.5 µg Pb/kg bw/d correspond to a loss of 1 IQ point the exposure from air correspond to less than 0.01 IQ points which may be considered as insignificant.

Drinking water
Assuming an average level of 0.9 µg Pb/L a child of 2 year weighing 13 kg that ingest 1L of drinking water would be exposed to 0.07 µg Pb/kg bw. At the level of the limit value of 10 µg Pb/L the child would be exposed to 0.77 µg Pb/kg bw/d.

In terms of effects on the central nervous system these exposures would correspond to a loss of 0.14 1 IQ point and 1.5 IQ point, respectively.

Soil
From urban soil at a level comparable to the limit value of 40 mg Pb/kg soil a daily exposure of a 2-year-old child has been estimated to 0.3 µg/kg bw/day. Thus the average child in Denmark is affected by this lead exposure to a degree that corresponds to a loss of 0.6 IQ point.

Indoor dust
No current data on the lead content of indoor dust in Denmark has been found. Based on Swedish data from 2000 a child was estimated to be exposed to 0.6 µg/kg bw/day. As 0.5 µg Pb/kg bw/d correspond to a loss of 1 IQ point the exposure from indoor dust may result in a loss of 1.2 IQ points.

Food
The average exposure to children has been estimated to 0.30 µg/kg bw/day. Thus the average child in Denmark is affected by this lead exposure to a degree that corresponds to 0.6 IQ point. At the 95 percentile exposure level of 0.56 µg/kg bw/day this exposure corresponds to a loss of 1.1 IQ point.

Discussion
It can be concluded that all exposures except exposure from ambient air contribute with an amount of lead that is considered to have slight impact of the IQ of the children. However, all exposures are based on estimated exposure levels and intakes and furthermore there may be some double counting as e.g. the lead exposure from food to a great extent pertains to beverages and thus adding the exposure from drinking water may lead to some double counting. Further the average exposure from dust is rather uncertain as exact average values for the lead content in dust is missing.

To get a more precise health impact assessment from the total lead exposure of children, updated biomonitoring data would be needed.

6.6.2 Workers
The LDAI (2008) risk assessment report defined a blood lead level of 40 µg/dL as a NOAEL in relation to neurotoxic effects for male and female workers, and thus based their risk characterisation of the various occupational exposure scenarios on this value.

SCOEL (2002) indicated that subtle effects in workers have been registered at 40µg/dL and stated that no definite NOAEL for lead can be concluded. SCOEL therefore recommend minimization ofoccupational exposure and set a biological limit value of 30 µg Pb/dL.

In Denmark, a more strict value for occupational exposure has been set as currently the biological limit value is at 20 µg Pb/dL.
The impact of these values can be put in perspective by comparing with the recent EFSA (2010) evaluation that developed the following Bench Mark Dose Levels, BMDLs for haematological effects and adverse kidney effects that were considered the most susceptible end-points with respect to lead exposure to adults:

Haematological effects: BMDL01= 3.6 µg Pb/dL (i.e. exposure resulting in an increase in the blood lead level of 3.6 µg Pb/dL in the workers corresponds to 1% increase in systolic blood pressure)

Effects on the kidneys: BMDL10= 1.5 µg Pb/dL (i.e. exposure resulting in an increase in the blood lead level of 1.5 µg Pb/dL in the workers corresponds to an 10% increase in the prevalence of chronic kidney disease).

This emphasises the strict measures that apply when working with lead and lead compounds as even occupational exposure to lead below the acceptable level may contribute to adverse effects.

6.7 Summary and conclusions

Human health hazards
Lead that enters into the human body either by oral, dermal or inhalational exposure progressively accumulates in the human body tissues. Lead in blood and soft tissue have a half-life of approximately 40 days in the tissue, whereas the concentration of lead accumulated in bone is much more stable with a half-life of several decades. Stored lead in bones may be liberated to other body compartments in persons with low calcium status e.g. in lactating mothers or people suffering from osteoporosis.

The most critical effects of lead (i.e. effects that occur at the lowest exposure levels) are the neurodevelopmental effects which causes impaired brain function in children, the haematological effects (increased blood pressure), and the adverse effects on the kidneys in adults.

No lower threshold for the adverse effects of lead has been identified. Thus, in a recent evaluation made by EFSA (the European Food Safety Authority) no-effect-levels and acceptable levels could not be identified, so instead so-called bench mark dose levels for the critical effects were derived. For neurodevelopmental effect the lowest benchmark dose (BMDL01) of 0.50 µg Pb/kg bw/day was derived, i.e. the dose that is considered to affects a child with an IQ loss of 1 point.

In relation to the EU restriction on lead in jewellery the maximum acceptable exposure to lead from jewellery for children was concluded to be 0.05 µg Pb/kg bw/day (i.e. ten times lower than the BMDL01 level and this was considered to be equivalent to a loss in IQ in children of 0.1 point). This tolerable dose level established in 2011 *is a factor 70 lower* than the previous tolerable dose level at 3.6 µg Pb/kg bw/day. This of course have impact on the risk assessment of lead as human exposure to lead may not have declined at the same magnitude.

Human exposure
The general population is primarily exposed to lead through food, although lead levels in food have decreased, also in the last decade. Thus EFSA, based on surveillance data has concluded that from 2003 to 2010 an overall decrease of lead in food items in EU was 23%.

Recent data from DTU Food in Denmark estimated mean lead exposure levels for Danish adults and children to 0.25 µg Pb/kg bw/day and 0.30 µg Pb/kg bw/day, respectively. These figures that were based on food analyses in the period 2004-2011 were approximately 21% lower compared to the exposure calculated from food analyses in the period 1998-2003. Beverages, sugar and

confectionary, cereals, vegetable and fruit, all together accounted for more than 90% of the lead exposure from food.
Also exposure to lead from drinking water may contribute significantly to the lead exposure especially if release of lead from taps, pipes and fitting occur because of the use of lead containing alloys or lack of quality control of the installations. For children, lead exposure from ingestion of soil and dust particles may further be an important source for lead exposure.

A recent Swedish restriction proposal focusing on lead in consumer products provide data that show that lead migration from articles may occur, especially when mouthed by children. This further contributes to the overall lead exposure and in order to control the exposure down to a level of 0.05 Pb/kg bw/day a maximum lead content of 500 mg/kg in the articles has been proposed.

For adults sport shooters have been shown to have highly increased blood lead levels due to the diffuse exposure from the lead content in the ammunition.

Due to the high number and rather diffuse sources of lead exposures it is very difficult to perform a valid estimate of the total lead exposure of the population, as this may vary a lot due to different preferences in food choice and the control and use of various products and metallic parts containing lead. Furthermore, the exposure through drinking water, soil and dust may also vary a lot.

Human Health impact assessment
Only few health impact assessments have been made regarding the current lead exposure and its consequences to human health when using EFSA´s recent risk estimates for lead exposure:

In the current Swedish restriction proposal of maximum lead content of 0.05% for all types of consumer products that due to their size may be mouthed by children it was estimated that compared to the present situation with the existing lead levels in these types of consumer products there would be a gain of 208,000 IQ points 6-36 months among old children in EU due to the reduced lead exposure. This gain was estimated to be 8.7 times higher than the gain in IQ in connection with the implementation of the recent ban on lead in jewellery.

Lead exposure of shooters from the use of ammunition causes increased blood lead levels that may contribute to increased risk for adverse hematological and kidney effects.

A French study has assessed the impact of the current blood lead levels of French children. When looking only at the fraction (50%) of French children with a blood lead level exceeding 1.5 µg Pb/dL it was estimated that these higher blood lead levels were associated with an overall IQ loss of 3.1 million IQ points among the French children. In socioeconomic terms this was estimated to a cost of 54 billion Euros. Scaled to the size of the Danish population this calculation would imply an overall IQ loss of 279,000 points among Danish 1-6 year old children and a socioeconomic cost of 4.85 billion Euros.

Although the blood lead level of children in Western Europe has decreased to a level of 1.5-2 µg PB/dL blood this is still to be considered to be within an effect level and thus, every small additional lead exposure will contribute further to the adverse effects. Thus, further limitations of the lead exposure would still have beneficial effects even though substantial benefits already have been obtained due to the gradual and continuous decrease in the lead exposure (and the blood lead levels) over the last decades.

7. Information on alternatives

Great efforts have been made - both from the authorities and from the industry - in order to replace lead and lead compounds with alternative substances and materials. This section will briefly describe the availability of alternatives for lead and lead compounds for some of the most significant uses.

7.1 Identification of possible alternatives

7.1.1 Batteries

Recently, the Substitution Support Portal has published an assessment on alternatives to lead and its inorganic compounds (http://www.subsport.eu/wp-content/uploads/data/lead.pdf).

The Subsport assessment states that a substitution of the use of lead in batteries is difficult. This is mainly because some alternatives would pose a high risk to the environment or human health, which is the case for nickel and cadmium. However, several alternatives are mentioned and alternative battery technologies are still emerging.

TABLE 7-1 ALTERNATIVE TECHNOLOGIES TO LEAD BATTERIES, OBTAINED FROM THE SUBSPORT ASSESSMENT

Alternative technologies to lead batteries	Description
NICKEL/IRON	FOR TRACTION APPLICATION
NICKEL/CADMIUM	STATIONARY BATTERIES
ZINC-AIR	ELECTRIC CARS
LITHIUM CELL	ELECTRIC CARS
SODIUM-SULPHUR	FOR ELECTRICITY STORAGE FOR GRID SUPPORT, ELECTRIC VEHICLES
LITHIUM-POLYMER	SOLAR PLANES, ELECTRIC CARS, MOBILE PHONES

7.1.2 Lead sheet

A survey performed in 2001 for the Danish EPA on the possible alternatives to lead sheets in construction building come to the conclusion that many alternatives exist, and that substitution of lead sheets is technically feasible, even in situations such as window and chimney flashing, where a certain flexibility is typically required; several products, such as soft zinc sheets, prefabricated form fittings, butyl rubber flashing with aluminum reinforcement exist. The results of the Danish report is not presented in tables as it is considered covered by the outcome of the more recent Subsport report, as presented in Table 7.2. The Danish report, however, points to the fact that care should be taken when considering the best alternatives. Some of the alternatives, for example copper and zinc, are very toxic to aquatic life, and the use of these alternatives in roofing might result in adverse effects of roof runoff water. In addition, recycling of metals used in combination with polymers is often difficult (Danish EPA, 2001).

TABLE 7-2 ALTERNATIVES TO LEAD SHEETS, OBTAINED FROM THE SUBSPORT ASSESSMENT

Alternative to lead sheets	Description
COPPER	KICK PANELS FOR THE FRONT DOOR AT HOME OR OFFICE; BACKSPLASHES BEHIND AN OVEN OR STOVE; A UNIQUE SURFACE FOR TABLE TOP OR BAR; MOUNTING
ZINC	GREAT FOR COUNTERTOPS, BACK-FORMS, RANGE-HOODS, ROOFING, FLASHING, ARTISTIC PROJECTS, MOUNTING
IRON	APPLICATIONS IN INDUSTRIAL AND RESIDENTIAL SECTORS; ROOFING SHEETS
TITANIUM-ZINC	ROOFING, FAÇADES, RAIN GUTTERS, PIPES, FITTINGS, WIND AND OTHER LININGS, WINDOW SILLS, ROOF DECORATION
SHALE SCHIEFER	STAIRS, WINDOW SILLS, TILES COVER PLATES, FLOOR PLATES, WALL PLATES
THATCH	BUILDING MATERIAL MADE FROM RENEWABLE RESOURCES; ROOF COVERING
CONCRETE	ROOF COVERING, CONSTRUCTION INDUSTRY
PVC, PLASTICS, SYNTETIC RUBBER	CHEMICAL PROCESSING TANKS, VALVES, FITTINGS AND PIPING SYSTEMS, PVC SHEETS, RODS AND TUBES, MOUNTING, SANITARY EQUIPMENT
ALUMINIUM	MOUNTING
BITUMEN	MOUNTING
GAMMABLOK® (PLASTIC MATERIAL)	RADIATION SHIELDING (OTHER ALTERNATIVES BASED ON BARIUMSULPHATE CONTAINING PLASTERBOARD EXISTS)(SAFEBOARD,2013)
TIN	SHIELDING PROTECTIVE CLOTHING
TIN + BISMUTH	SHIELDING PROTECTIVE CLOTHING
TUNGSTEN IMPREGNATED SILICONE PIECES (SILFLEX)	SHEETS, TAPES, BLANKETS, PIECE OF SHIELDING, SHIELDING A PIPE, PLATFORM SHIELDING, CUSTOM APPLICATIONS

7.1.3 X-ray protection

In protection against radiation, lead is used for enclosing the radioactive source. Lead is highly efficient in absorbing radioactivity. In constructions other metals and concrete can be used as alternatives, but require higher amounts of materials for the same protection level (Swedish Chemical Agency, 2007). X-ray protection shields, based on barium sulphate have recently been developed and marketed (Safeboard, 2013). For certain uses, e.g. protective aprons for x-ray facilities, lead is difficult to substitute (Swedish Chemical Agency, 2007).

7.1.4 Keels

Where metallic lead is used in situations where the density of lead is important (ship keels, weight belts etc.), alternatives are other metals, such as iron, steel, zinc and bismuth, but also probably concrete (Swedish Chemicals Agency, 2007, 2012c).

7.1.5 Fishing tools

In a project financed by the Danish EPA possible alternatives to lead in the fishing industry was investigated, and concluded that zinc and iron were the most technically and economically feasible alternatives (Danish EPA,2005). However, another project concluded that for some purposes, sink-lines and seine-ropes, no alternative to lead could be developed (Danish EPA, 2007). A draw-back for the alternatives to lead is that they tend to corrode faster, and in addition equipment, for example fishing equipment, will be more difficult to handle due the lower density, thereby higher volumes needed (Swedish Chemicals Agency, 2007). Traditionally lead was used in sinks and splitshots used in sports fishing. The uses have practically been phased out and replaced with zinc, tin and wolfram (Swedish Chemicals Agency, 2007). In Denmark a new lead free sink-line was introduced to the marked in 2013. Work is still on-going in order to further develop/improve the lead free alternatives to sink-lines.

7.1.6 Weights for balancing wheels

Lead weights for wheel balancing are still allowed for cars with seats for more than 8 persons and vehicles for transporting goods over 3.75 tonnes. For this use it is technically feasible to develop a lead free alternative (Danish EPA, 2006a).

7.1.7 Ammunition

With respect to the use of lead in ammunition, it is technically possible to reduce the use of lead. Lead free alternatives exist for riffle ammunition in standard calibers, but for sports shooting alternatives seem to be less developed (Danish EPA, 2006a). The alternative metals are primarily copper and steel. However, some guns do not tolerate the toughness of copper and steel, and in these cases, the alternatives are wolfram and bismuth. Additionally copper and steel can affect the quality of wood, and the presence of copper and steel in wood might present a risk for forestry during wood cutting. Steel and copper ammunition are therefore usually not allowed in areas with forestry (Naturvårdsverket, 2006).

An additional use of lead in ammunition is the use of lead as percussion primer in the form of lead-2,4,6-trinitroresorcinolate (lead styphnate) in detonator caps in cartridges, as well as other detonators. This lead compound is used to control and contain the explosion. Alternatives are identified, but it is not yet known to what extend lead styphnate is replaced, which potentially leads to widespread dispersion of lead around shooting grounds and areas with hunting activities (Danish EPA, 2006a).

7.1.8 Alloys

In alloys, the lead present is often unintentional and the substitute is therefore another quality of the alloy. However, lead is used for making brass more smooth and workable. According to the Swedish Chemical Agency (2007), the most used alloys in articles is brass; and bronze or steel are mentioned as possible alternatives, but substitution of lead with bismuth or silicon in lead free brass qualities are also mentioned as possible alternatives.

7.1.9 Pigments

Most uses of lead pigments have been phased out, although some pigments are still in use as indicated from the data from the Danish Product Registry, section 3.4 and 3.5 . Lead pigments are used for paints in restoration of historical buildings and for traffic paint. Lead based pigments are available in basic colours, white, red and yellow. Several hundred alternative pigments exist in the colours where lead were previously used, and an environmental risk assessment of the pigments reveal that in general all the alternative pigment have less severe environmental hazard properties (Swedish Chemicals Agency 2012c).

TABLE 7-3 ALTERNATIVES TO LEAD PIGMENTS, OBTAINED FROM THE SUBSPORT ASSESSMENT

Alternative to lead pigment	Description
IRON OXIDE	PIGMENT
TITANIUM DIOXIDE	FOOD COLORING AND IN TOOTHPASTE, SUNSCREEN
ZINC	TO LIGHTEN MIXTURES SUBTLY WHILE MAINTAINING TRANSPARENCY, IN WATERCOLORS
ZINC PHOSPHATE	PIGMENT
ZIRCONIUM	PIGMENT
STRONTIUM	PIGMENT
CALCIUM	PIGMENT
ALUMINIUM	PIGMENT

7.1.10 Jewellery, ornamental

Lead has been widely used for casting/extrusion of metals used for jewellery and ornamentals, such as door knobs etc., which leads to a relatively high consumer exposure. Several alternatives have been identified as indicated in Table 7.4.

TABLE 7-4 ALTERNATIVES TO LEAD IN JEWELLERY, OBTAINED FROM THE SUBSPORT ASSESSMENT

Alternative to lead	Description
COPPER	STAND-ALONE BRACELETS, NECKLACES AND OTHER
BRONZE	BRACELETS, ANKLES, AND EARRINGS, AND BEADED NECKLACES, FASHION SMALLER ITEMS LIKE BROOCHES AND PINS
BRASS (COPPER/ZINC)	BED FRAMES, DOORKNOBS, ELEGANT FINISHES FOR PICTURE FRAMES, BRASS CHARMS AND STAMPINGS FOR BRACELETS, NECKLACES, RINGS, AND BODY JEWELLERY
ALPACA	MADE OF COPPER ALLOYED WITH NICKEL, ZINC, AND TIN; FASHION JEWELLERY
TITANIUM	JEWELLERY, ORNAMENTAL
PEWTER	JEWELLERY, ORNAMENTAL
SURGICAL STAINLESS STEEL	AN ALLOY OF STEEL, CHROMIUM, MOLYBDENUM, AND SOMETIMES NICKEL; BODY JEWELLERY
PMC (PRECIOUS METAL CLAY)	MADE BY ADDING FINELY GROUND SILVER OR GOLD TO CLAY, SHAPING IT AND FIRING IT IN A KILN

7.1.11 Heat stabilisers in PVC and Elastomers

PVC stabilisers are mixtures including metal oxides or metal salts. In the evaluation of the statutory order regarding lead (Danish EPA, 2006a), it was suggested to revoke the exemption on the use of lead in heat stabilisers. As there is little or no recycling of PVC containing lead, fortunately many commercially available alternatives exist. According to the Swedish Chemicals Agency (2012), calcium-zinc stabilising systems are the most common substitute to lead stabilisers. The sale of calcium and calcium/zinc stabilisers has been increasing over the last years, and further growth is expected to phase out lead-based systems (Swedish Chemicals Agency, 2012c).

TABLE 7-5 ALTERNATIVES TO LEAD HEAT STABILISERS FOR PVC, OBTAINED FROM THE SUBSPORT ASSESSMENT

Alternative to lead	Description
CALCIUM-ZINC	STABILISER USED FOR PVC WIRE AND CABLE, SLUSH TOYS, FILMS, HOSES AND OTHER PVC PRODUCTS WITH DIFFERENT PROFILES
BARIUM-ZINC	STABILISER USED IN FLEXIBLE FOILS (E.G.; FOR MEMBRANES, STATIONARY AND AUTOMOTIVE APPLICATIONS) FLOORING, WALL COVERING, FLEXIBLE TUBING AND FOOTWEAR
MAGNESIUM-ZINC	STABILISER
MAGNESIUM ALUMINIUM HYDROXIDE CARBONATE HYDRATE	STABILISER
MAGNESIUM-ZINC ALUMINIUM HYDROXIDE CARBONATE	STABILISER
TIN/ ORGANIC TIN COMPOUNDS	STABILISER

7.1.12 Other uses

Alternatives to lead in solder are combinations of copper, silver, antimony, bismuth and zinc, usually in combination with tin. The most common solder is a combination of tin, silver and copper (Swedish Chemicals Agency, 2007). Products, or use area where alternatives are still lacking
Lead is still used as a stabiliser in high flexibility cables, such as in elevators and other machines where high flexibility is needed, as no alternative currently exists (Danish EPA, 2006a). The same evaluation points to three areas where lead can still not be replaced;

- Superconductors
- Igniters for ammunition
- Lead paint for restoration of historical buildings

Lead has been used in electrical cables for moisture protection. In soil cables aluminum laminate is replacing lead, but for sea cables no alternative is identified (Swedish Chemicals Agency, 2007). The highest quality of crystal glass can contain up to 30% lead. The production and use of crystal glass in craft have decreased, and alternatives to lead are barium and zinc in medium quality crystal, but for the highest quality crystal no alternative exists (Swedish Chemicals Agency, 2007).

7.2 Historical and future trends

Following the implementation of the legal actions described in chapter 2, considerable effort has been made in substitution of lead and lead compounds. Previously the construction sector was a significant consumer of lead, such as lead sheets for roofing and flashing. This use has been almost eliminated, except in historical buildings.

On a national level many projects regarding substitution of lead have been initiated by the Danish EPA in connection with and after the implementation of the national ban on lead.
Substitution efforts on lead and lead compounds are still ongoing, and a driver for continuing the efforts would not at least be the increased awareness of the adverse effects of lead to humans, even at extremely low exposure levels.

7.3 Summary and conclusions

Substitution of lead in batteries is difficult, primarily because some alternatives would pose a high risk to the environment or human health. However, several alternatives exist and alternative battery technologies are still emerging. Previously the construction sector was a significant consumer of lead, such as lead sheets for roofing and flashing. In Denmark this use has been almost eliminated, except in historical buildings. Several alternatives to lead sheets are available on the market.

The fishing industry was previously also an important consumer of lead for weights and sinks. These have to a great extend been replaced by iron and zinc. For sink-lines work is still ongoing in order to further improve existing lead free alternatives. In the sports fishing industry lead has been almost completely replaced by zinc, tin and wolfram.

Lead is gradually replaced as a heat stabiliser in PVC and elastomers, primarily with calcium-zinc systems. Lead is used for moisture protection in cables, where it is replaced in ground cables, but no useful alternative have been identified for sea cables.

In ammunition lead is replaced primarily by steel, copper, wolfram and bismuth, the latter two when the gun does not tolerate the toughness of steel and copper. Lead in the form of lead styphnate is still used in gunpowder and other explosives for containing the explosion. Alternatives are known and developed, but to what extend lead styphnate is replaced, is unclear. Lead compounds were traditionally used in several different pigments. This use is to a great extent replaced by hundreds of different alternatives.

Conclusively many of the traditional high volume uses of lead have been phased out more or less completely. However, several uses are still not possible to phase out, and this is primarily the use in batteries, but also other uses such as in alloys and high flexibility cables.

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Appendix 1
Lead compounds registered under REACH (June 2013)

EC/ List No.	CAS No.	Name	Tonnage band
201-075-4	78-00-2	tetraethyllead	1,000 - 10,000 tonnes per annum
206-104-4	301-04-2	lead di(acetate)	1 - 10 tonnes per annum
208-908-0	546-67-8	lead tetraacetate	10 - 100 tonnes per annum
215-174-5	1309-60-0	lead dioxide	100 - 1,000 tonnes per annum
215-235-6	1314-41-6	orange lead	10,000 - 100,000 tonnes per annum
215-267-0	1317-36-8	lead monoxide	100,000 - 1,000,000 tonnes per annum
215-290-6	1319-46-6	trilead bis(carbonate) dihydroxide	10 - 100 tonnes per annum
215-693-7	1344-37-2	lead sulfochromate yellow	1,000 - 10,000 tonnes per annum
231-100-4	7439-92-1	lead	1,000,000 - 10,000,000 tonnes per annum
231-845-5	7758-95-4	lead dichloride	1 - 10 tonnes per annum
232-382-1	8012-00-8	pyrochlore, antimony lead yellow	10 - 100 tonnes per annum
233-245-9	10099-74-8	lead dinitrate	10 - 100 tonnes per annum
234-363-3	11120-22-2	Silicic acid, lead salt	100 - 1,000 tonnes per annum
234-853-7	12036-76-9	lead oxide sulfate	100 - 1,000 tonnes per annum
235-038-9	12060-00-3	lead titanium trioxide	10 - 100 tonnes per annum
235-067-7	12065-90-6	pentalead tetraoxide sulphate	100,000 - 1,000,000 tonnes per annum
235-252-2	12141-20-7	trilead dioxide phosphonate	100,000 - 1,000,000 tonnes per annum
235-380-9	12202-17-4	tetralead trioxide sulphate	1,000,000 - 10,000,000 tonnes per annum
235-702-8	12578-12-0	dioxobis(stearato)trilead	100,000 - 1,000,000 tonnes per annum
235-727-4		Lead titanium zirconium oxide	100 - 1,000 tonnes per annum
235-727-4		Lead titanium zirconium oxide	100 - 1,000 tonnes per annum
235-727-4	12626-81-2	Lead titanium zirconium oxide	100 - 1,000 tonnes per annum
235-759-9	12656-85-8	lead chromate molybdate sulfate red	1,000 - 10,000 tonnes per annum
236-542-1	13424-46-9	lead diazide	10 - 100 tonnes per annum
237-486-0	13814-96-5	lead bis(tetrafluoroborate)	10 - 100 tonnes per annum
239-290-0	15245-44-0	lead 2,4,6-trinitro-m-phenylene dioxide	10 - 100 tonnes per annum
244-073-9	20837-86-9	lead cyanamidate	1 - 10 tonnes per annum
244-073-9	20837-86-9	lead cyanamidate	10 - 100 tonnes per annum
244-073-9	20837-86-9	lead cyanamidate	1 - 10 tonnes per annum
257-175-3	51404-69-4	Acetic acid, lead salt, basic	10 - 100 tonnes per annum
263-467-1	62229-08-7	Sulfurous acid, lead salt, dibasic	100 - 1,000 tonnes per annum
272-271-5	68784-75-8	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped	10 - 100 tonnes per annum
273-688-5	69011-06-9	[phthalato(2-)]dioxotrilead	100 - 1,000 tonnes per annum
292-966-7	91031-62-8	Fatty acids, C16-18, lead salts	10,000 - 100,000 tonnes per annum
297-907-9	93763-87-2	Slags, lead-zinc smelting	100,000 - 1,000,000 tonnes per annum
614-455-3	68411-07-4	copper lead resorcylate salicylate complex	1 - 10 tonnes per annum

A total of 35 compounds containing lead are registered with the indicated tonnage levels as given above. Further 30 lead containing compounds are registered as intermediate substances.

Appendix 2
Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in chapter 3. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 3.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvring as to the form and means of implementation. However, there are great differences in the space for manoeuvring between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market; the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).

- The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive, even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabel criteria for specific product groups.

- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulates to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation[2] and the CLP Regulation[3] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration

All manufacturers and importers of chemical substances > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation

A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation

Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction

If the authorities assess that that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling

The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in

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[2] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[3] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.

2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 2 to the main report.

Ongoing activities - pipeline
In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)
The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV
Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:
It has to be identified as a SVHC leading to inclusion in the candidate list[4]

1. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
2. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions
When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.
-

This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intensions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions
- for the three types of Annex XV dossiers.

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[4] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

International agreements

OSPAR Convention

OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- guidelines or guidance setting out the way that any programme or measure should be implemented
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention

The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:
- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower
The EU eco-labelling Regulation lays out the general rules and conditions for the EU eco-label, the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan
The Nordic Swan is cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Eco-labelling Board consists of members from each national Eco-labelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Eco-labelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Eco-labelling Denmark’s website (according to Statutory Order no. 447 of 23/04/2010).

Blue Angel (Blauer Engel)

The Blue Angel is a national German eco-label. More information can be found on: http://www.blauer-engel.de/en.

Appendix 3
Lead substances on the candidate list

30 LEAD SUBSTANCES ON THE CANDIDATE LIST (LAST UPDATED: 19/12/2012) FROM THE ECHA WEB-SITE

Substance name	EC Number	CAS Number
Pyrochlore, antimony lead yellow	232-382-1	8012-00-8
Silicic acid, lead salt	234-363-3	11120-22-2
Lead titanium zirconium oxide	235-727-4	12626-81-2
Lead monoxide (lead oxide)	215-267-0	1317-36-8
Lead bis(tetrafluoroborate)	237-486-0	13814-96-5
Lead dinitrate	233-245-9	10099-74-8
Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]*	272-271-5	68784-75-8
Trilead bis(carbonate)dihydroxide	215-290-6	1319-46-6
Lead oxide sulfate	234-853-7	12036-76-9
Lead titanium trioxide	235-038-9	12060-00-3
Tetralead trioxide sulphate	235-380-9	12202-17-4
Acetic acid, lead salt, basic	257-175-3	51404-69-4
[Phthalato(2-)]dioxotrilead	273-688-5	69011-06-9
Tetraethyllead	201-075-4	78-00-2
Pentalead tetraoxide sulphate	235-067-7	12065-90-6
Dioxobis(stearato)trilead	235-702-8	12578-12-0

Trilead dioxide phosphonate	235-252-2	12141-20-7
Fatty acids, C16-18, lead salts	292-966-7	91031-62-8
Orange lead (lead tetroxide)	215-235-6	1314-41-6
Sulfurous acid, lead salt, dibasic	263-467-1	62229-08-7
Lead cyanamidate	244-073-9	20837-86-9
Lead(II) bis(methanesulfonate)	401-750-5	17570-76-2
Lead diazide, Lead azide	236-542-1	13424-46-9
Lead dipicrate	229-335-2	6477-64-1
Lead styphnate	239-290-0	15245-44-0
Trilead diarsenate	222-979-5	3687-31-8
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	235-759-9	12656-85-8
Lead chromate	231-846-0	7758-97-6
Lead hydrogen arsenate	232-064-2	7784-40-9

Appendix 4

Below are Annex 1 and Annex 2 with derogations in the Danish statutory order on lead covering derogations and specific rules in relation to the general ban on lead.

From: Bekendtgørelse EK nr. 856 af 05/09/2009 Bekendtgørelse om forbud mod import og salg af produkter, der indeholder bly.

Bilag 1: Liste over produktkategorier, der indeholder kemiske for-bindelser af bly, hvor import og salg - uanset forbuddet i § 6, stk. 1 - er tilladt indtil de anførte tidspunkter

Produktkategorier		Tilladt indtil
1.	Højfleksible kabler til maskindele, herunder elevatorkabler	indtil videre
2.	Superledere	indtil videre
3.	Tændsats til ammunition og boltpistoler	indtil videre
4.	Blymønje til restaurering af historiske genstande	indtil videre
5.	Udladningslamper	indtil videre
6.	Maling til specielle formål: – korrosionsbeskyttelsesmaling med under 250 ppm bly – antibegroningsmaling med under 1250 ppm bly	 indtil videre indtil videre
7.	Glas til specielle formål: – lyskilder – optik – strålingsbeskyttelse – krystalglas – silikatglas til sandblæsning	indtil videre
8.	Glasurer på tændrør til udendørs anvendelse	indtil videre
9.	Glasur på tegl, mursten og klinker	indtil videre
10.	Elektroniske komponenter	indtil videre
11.	Produkter til forskning, udvikling og laboratorieanvendelse	indtil videre

Bilag 2:Liste over produktkategorier, der indeholder metallisk bly, hvor import og salg - i henhold til § 7, stk. 1 - er forbudt fra de anførte tidspunkter

Produktkategorier		Forbudt fra
1.	Produkter til hobbyformål	1. marts 2001
2.	Fyrfadslys og andre lys	1. marts 2001
3.	Gardinvægte	1. marts 2001
4.	Produkter til dekorative formål, herunder smykker	1. marts 2001
5.	Sikkerhedsplomber	1. marts 2001
6.	Produkter til tagdækning af bygninger	1. marts 2001
7.	Produkter til inddækning på bygninger	1. december 2002
8.	Produkter til reparation af samt om- og tilbygning på huse, med undtagelse af fredede og bevaringsværdige bygninger samt kirkebygninger af kulturhistorisk betydning	1. november 2007
9.	Fiskeredskaber til erhvervsfiskeri: – Import af synk – Import af synkeliner og vodtove – Salg af synk – Salg af synkeliner og vodtove	 1. december 2007 1. december 2011 1. juni 2008 1. juni 2012
10.	Fiskeredskaber til lystfiskeri	1. december 2002
11.	Loddelegeringer til VVS- og blikkenslagerformål, undtagen til lodning af zinkplader	1. december 2002
12.	Kappe til elektriske jordkabler < 100 kV AC, med undtagelse af søkabler i vand og på land Kappe til elektriske jordkabler < 150 kV DC, med undtagelse af søkabler i vand og på land	1. november 2007 1. november 2007
13.	Bly i hjulvægte til motordrevne køretøjer undtagen biler, der er indrettet til befordring af højst 9 personer, føreren iberegnet (personbiler) og biler, der er indrettet til godsbefordring, og som har en tilladt totalvægt på ikke over 3500 kg (varebiler)	1. november 2009

Appendix 5

Import, export and production of lead in connection with metallic raw materials in Denmark 2000 (from Danish EPA, 2004)

Halvfabrikata	Blyindhold %	Produktion Tons Pb/år	Import Tons Pb/år	Eksport Tons Pb/år	Forsyning Tons Pb/år
Bly og blylegeringer					
Blymalm	5-95	-	0,78-15	-	1-15
Uraffineret bly	95	-	450	0,38	450
Raffineret bly	99	440	1.400	1.700	140
Bly-antimon legeringer	91-97	-	1.400	180-190	1.220-1.210
Andre blylegeringer	91-97	-	6-6,4	230-250	-224--244
Stænger, profiler og tråd	99	220	270	23	467
Bånd og folie (<0,2 mm)	99	-	26	-	26
Plader og bånd (>0,2 mm)	99	-	3.300	97	3.203
Rør og rørfittings	95	-	-	0,67	-1
Fladvalset jern/ulegeret stål, beslag eller overtrukket med bly, yderligere forarbejdet	0-1	-	-	0-5	0--5
Andre varer af bly	85-95	-	750-830	910-1.000	-160--170
Tinlegeringer					
Tinlegering, ubearbejdet	10-20	...	1,1-2,1	0,31-0,62	1
Stænger, profiler og tråd	40-60	...	140-220	15-22	125-198
Andre varer af tin	35-40	1,1-1,2	30-34	1,3-1,5	30-34
Kobberlegeringer					
Stænger af kobber-zink legeringer	2-3	-	560-840	18-26	542-814
Rør af kobberlegeringer (andre end messing, nysølv og cupronikkel)	3-7	-	7-16	1,1-2,5	6-14
I alt (afrundet)	**-**	**660**	**8.300-8.800**	**3.200-3.300**	**5.800-6.200**

Appendix 6

Pigment compounds containing lead as registered under REACH or already restricted REACH (from Swedish Chemicals Agency, 2013)

EC No.	CAS No.	Name	Structural formula	Synonyms / Other information
215-235-6	1314-41-6	Orange lead	Pb_3O_4	Lead tetroxide
215-267-0	1317-36-8	Lead monoxide	PbO	Pigment Red 105 Red lead Litharge Also used as stabiliser
232-382-1	8012-00-8	Pyrochlore, antimony lead yellow	---	C.I. 77588 Pigment yellow 41
233-245-9	10099-74-8	Lead dinitrate	$Pb(NO_3)_2$	
215-693-7	1344-37-2	Lead sulfochromate yellow	$PbCrO_4+PbSO_4$	C.I. 77600 C.I. 77603
231-846-0	7758-97-6	Lead chromate	PbCrO4	Pigment yellow 34 SVHC
235-759-9	12656-85-8	Lead chromate molybdate red	$PbCrO_4 \times nPbMoO_4 \times mPbSO_4$ ‘× $AL(OH)_3$	C.I. 77605 C.I. Pigment Red 104
209-943-4	598-63-0	Lead carbonate	$PbCO_3$	Annex XVII:16

Stabilisers containing lead as registered under REACH (from Swedish Chemicals Agency, 2013)

EC Number	CAS Number	Name	Structural formula	Other information
215-267-0	1317-36-8	lead monoxide	PbO	Also used as pigment
234-853-7	12036-76-9	lead oxide sulfate	Pb_2SO_5	
235-067-7	12065-90-6	pentalead tetraoxide sulphate	Pb_5SO_8	
235-252-2	12141-20-7	trilead dioxide phosphonate	Pb_3HPO_5	
235-380-9	12202-17-4	tetralead trioxide sulphate	Pb_4SO_7	
235-702-8	12578-12-0	dioxobis(stearato)trilead	$C_{36}H_{70}O_6Pb_3$	
263-467-1	62229-08-7	Sulfurous acid, lead salt, Dibasic	$PbSO_3$	
273-688-5	69011-06-9	[phthalato(2-)]dioxotrilead	$Pb_3C_8H_4O_6$	
292-966-7	91031-62-8	Fatty acids, C16-18, lead salts	N/A	

Appendix 7

Sources for lead in municipal waste in Denmark 2000 (Danish EPA, 2004)

Kilde	Tilførsel Tons Pb/år	% af total	Til forbrænding Tons Pb/år	Til deponi Tons Pb/år
Lyskilder	12-18	1,6	12-18	-
Dekorationsgenstade mm af bly-tin	0,1-1	0,06	0,1-1	-
Billedrør	10-40	2,6	5-20	5-20
Anden elektronik (lodninger)	15-30	2,4	15-30	-
Kabelkapper	2-20	1,2	2-20	-
Inddækningsbly	10-100	6	10-100	-
Akkumulatorer	<10	0,5	<10	-
Fiskeredskaber	210-420	33	42-86	170-340
Restprodukter fra hjemmestøbning	0,2-2,1	0,1	0,2-2,1	-
Ammunition	5-11	0,8	5-11	-
Legetøj og blyfolie fra dekorationer	0,6-7	0,4	0,6-7	-
Gardiner og forhæng	3-5	0,4	3-5	-
Kobberlegeringer	3-17	1	3-15	0,2-2
Blyfolie til røntgenfilm	0,5-5	0,3	0,5-5	-
Andre varer med metallisk bly	2-10	0,6	2-10	-
Blykrystalglas og andet glas	97-270	19	97-270	-
Keramiske produkter	40-150	10	20-75	20-75
Pigment i maling og plast	56-170	12	56-170	-
Stabilisatorer i PVC	26-86	6	18-60	8-26
Rør og rørfittings	1-5	0,3	1-5	-
Affald fra cementfremstilling og følgestof i beton	12-18	1,6	-	12-18
Følgestof i andre varer	0,5-5	0,3	0,5-5	-
Støbning o.a. bearbejdning af legeringer	0,2-2	0,1	-	0,2-2
Støbning af bly	-	0	-	-
I alt (afrundet)	**510-1.400**	**100**	**290-930**	**220-480**

Appendix 8

Human health effects and exposure

Lead content in various articles from which consumer exposure may occur (Swedish Chemical Agency 2012b)

Table 1. Materials containing lead or its compounds which are used in articles intended for consumer use

Use of lead or lead compound	Substance	Examples of consumer articles with indicated exposure routes	Reported concentrations	Indications for alternatives	Other information
Stabiliser in PVC	The five most important commercial lead stabilisers are: - Tribasic lead sulphate - Dibasic lead stearate - Dibasic lead phthalate - Dibasic lead phosphite - Lead stearate	Rain wear (M) * Printed t-shirts (M) ** *Shoes* *Scooter handles* Practical joke devices (M) *Garden hoses*	1,5% 0,05-0,58% Up to 0,22% 0,9% 0,5%	*Alternative stabilizers* Calcium/zinc compounds Barium/zinc Organostannic compounds Potassium/zinc *Another type of polymer/plastic material*	Organostannic compounds are restricted under Reach Annex XVII, entry 20, with a derogation for use in PVC until 1 January 2015.
Additives in other plastic materials	*/**	* Printed t-shirts (M) ** *Shoes*	0,05-0,58% Up to 0,22%		
Additives in synthetic rubber	*/**	** *Shoes*	Up to 0,22%		-
Metal, lead based	Metallic lead	Candle wicks (I) Cast alloys (I), New year's molybdomancy (I) *Interior details* Fishing sinkers (M, S) Weights: *pet equipment,* *diving weighting systems,* *built-in weights in curtains,* *cosmetic dispensers* (NS), etc.	25-85% 87% 65-75%	Thicker cotton thread, zinc, tin Other tin based metal alloys Other metals, e.g. tin or iron based alloys Alloys of zinc and iron/steel, tungsten, tin and bismuth Iron/steel, cast iron with plastic coating, for some uses the article works without weights	In the case of fishing sinkers, the environmental hazards should pose a greater risk than health hazards. Waste

Use of lead or lead compound	Substance	Examples of consumer articles with indicated exposure routes	Reported concentrations	Indications for alternatives	Other information
Brass alloys	Metallic lead	In metal parts for clothing accessories (M, S), bags, purses and wallets (M) Padlocks	0,2-1,2% 4%	Other lead-free alloys Alternatives vary with use and may be plastic, tin, aluminium, stainless steel, iron, precious metals, etc.	Swallowing of clothing accessories can be expected for buttons and rivets.
Other Metals	Metallic lead	Se above Practical joke devices (M) *Vessels like buckets, water cans, canisters (for petrol)* Magnets (S)	 0,6-1,6% 0,03-4%	Other lead-free alloys Alternatives vary with use and may be plastic, tin, aluminium, stainless steel, iron, precious metals, etc.	
Paints	Pigments	Painted parts on clothing accessories like buttons,(M) Sunglasses (M)		Several alternatives are available, e.g. organic pigments, tin-zinc-titanate, and bismuth vanadate. Choice of alternative depends on cost, colour, weather resistance etc.	
Coloured polymers	In paints Colouring of PVC and other polymers	Pigments in textile prints (M) * Printed t-shirts (M) ** *Shoes*	*/**	See above	

* / ** There is currently no information available on the function of lead in textile prints and shoes. It could be used as stabiliser in PVC, pigment in PVC or in other matrices or materials.

Survey of Trisodium nitrilotriacetate
This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The report defines the substance and present information on the use and occurrence of lead and lead compounds internationally and in Denmark, information on existing regulation, on environmental and health effects, on monitoring and exposure, on waste management and on alternatives to the substance.

Lead is classified as toxic to reproduction due to severe effects on fertility and on the brain development in the unborn and developing child. Lead is furthermore classified as toxic after repeated exposure and toxic for the aquatic environment.

Kortlægning af bly og blyforbindelser
Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Rapporten definerer stoffernet og indeholder blandt andet en beskrivelse af brugen og forekomsten af bly og blyforbindelser internationalt og i Danmark, om eksisterende regulering, en beskrivelse af miljø- og sundhedseffekter af stoffet, af moniteringsdata, af affaldsbehandling samt alternativer til stofferne.

Bly er klassificeret som reproduktionstoksisk med alvorlige effekter på forplantningsevnen samt på hjernens udvikling hos børn. Bly er endvidere giftigt ved længere tids udsættelse og giftigt for vandmiljøet.

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