



Danish Ministry
of the Environment
Environmental
Protection Agency

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

Lead and lead compounds

EC No 231-100-4

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Member State: Denmark

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Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The Danish EPA has conducted a survey of all substances listed on the Danish List of Unwanted Substances (LOUS). Access to the surveys carried out so far can be found at the following link:

http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/

The survey carried out for lead and lead compounds provides an overview of the use and the environmental and human health aspects of the substance. The results of the survey have – in addition to current risk management initiatives for specific applications of lead – been used as the main background information for this RMO.

Lead and lead compounds are highly toxic and 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 and lead compounds are also classified as toxic following prolonged and repeated exposure due to adverse effects on several organs. Furthermore, lead and lead compounds are hazardous to the aquatic environment with both acute and long-term effects. It is noted that metallic lead is at present not covered by the harmonized classification for lead and lead compounds. A proposal for a harmonized classification of metallic lead as Repr. 1A was adopted by the Risk Assessment Committee (RAC) in 2013 and is expected to be included in CLP Annex VI in the near future.

The most critical effects of lead are the neurodevelopmental effects which cause impaired brain function in children. An associated loss of IQ has been demonstrated in children exposed to even low levels of lead. Critical effects in adults are haematological effects (increased blood pressure) and adverse effects on the kidneys.

In a recent evaluation made by the European Food Safety Authority (EFSA) in 2010 it was concluded that no-effect-levels and acceptable levels could not be identified. Instead, so-called bench mark dose levels for the critical effects were derived. Thus, no safe level of lead exposure can be identified and previous risk assessments and regulatory measures, which were based on previously established safe levels of exposure, thus need to be reconsidered in the light of this new evidence.

Lead and lead compounds are used in a great variety of applications across different sectors. Lead is furthermore present as a constituent or impurity in many different alloys. The use of lead is widespread and dispersive, and any reduction in the human and environmental exposure to lead is considered beneficial.

Existing legal requirements under EU legislation

Lead have for many years been regulated both in EU and at a global level. Thus, lead and lead compounds may be considered as some of the most extensively regulated compounds in the world. For a thorough review of existing legislation for lead reference is made to the survey rapport for lead and lead compounds ([Danish EPA 2014](#)). In brief, restrictions or total bans have been implemented in a range of applications and sectors in EU, i.e. in paints, cosmetics, toys, packaging, jewelry, ceramics, electronic equipment, vehicles, petrol, fertilizers, feed, food, drinking water, etc. In relation to human exposure, the most effective measure for reduction of human blood lead levels was the phase out of lead from petrol in the 1970'ies.

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. It is, however, noted that SCOEL (the scientific Committee on Occupation Exposure Limits) in 2002 recommended a further reduction of the existing occupational exposure limit and biological limit value for the concentration of lead in the blood of workers. Specific measures are also taken for protecting young workers and pregnant women towards lead exposure at the work place under current EU legislation.

International agreements

Lead is regulated or addressed under different international agreements and conventions which are summarized in brief below:

Tetraethyl and tetramethyl lead is on the OSPAR list of substance of possible concern, 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.

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).

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restrictions	
Other EU-wide measures	X
National initiatives	X
No need for regulatory follow-up action	

The main contributions to the exposure of children and the general population to lead are considered to be via drinking water and food. More data may be needed regarding the actual concentrations of lead in drinking water in various member states to evaluate whether actual exposure levels are close to (or exceed) the present limit value for drinking water. With regard to the lead exposure via food, the monitoring conducted by

EFSA show that the exposure to lead via food is gradually decreasing (confirmed by recent Danish monitoring data). The studies of lead exposure via food furthermore indicate that beverages account for the major part of the intake of lead via food. This relates in part to the exposure via drinking water, but also contributions from e.g. coffee machines and possibly other materials in contact with beverages/food could be important sources of lead exposure. Continued monitoring will be needed to show whether the tendency of declining lead intake with food will continue or whether further risk management measures should be considered.

1. Possible risk management measures regarding lead exposure via drinking water and food should preferably be addressed under the relevant sector specific legislations, i.e.
 - Council Directive 98/83/EC (quality of drinking water)
 - Regulation on materials and articles intended to come into contact with food (EC No. 1935/2004) (migration of lead from metals and alloys)
 - Construction Products Regulation (305/2011/EU) (lead in drinking water installations)
 - Directive 98/24/EC (OEL's for workers)
2. Within the scope of REACH it is suggested that an Annex XV dossier concerning identification of metallic lead as an SVHC substance should be prepared.
3. At a national level the authorities could provide information to citizens about the possible risks of lead contamination in drinking water and give advice on relevant measures to reduce the lead intake via drinking water (flushing of the taps to eliminate stagnant water with high levels of lead). This is especially relevant in areas that still have underground lead pipes and in buildings with old plumbing systems. Such advice is already provided by WHO and different member states.

Finally, a concern has been identified regarding exposure of small children via ingestion of soil and dust. More data on actual concentrations of lead in soil and dust are, however, needed to refine the exposure assessment and confirm this potential risk. It is noted that if the Swedish restriction proposal for lead in consumer articles is adopted, a decrease in the content of lead in dust in households and institutions would be anticipated in the future due to the decreased availability of lead containing articles on the market once the restriction enters into force.