Additional comments on the proposal for Candidate Listing of Lead Metal published in the context of REACH Article 59

We welcome that the format used by ECHA to conduct the public consultation provides the opportunity for submitting comments that go beyond the question of whether a substance has hazardous properties that render it eligible for inclusion in the Candidate List. However, noting that the commenting form states that information on Use, Exposure, Alternatives and Risks will not be taken into account for SVHC identification, we request that such comments are taken into consideration by the ECHA Member State Committee in the context of 'relevancy' and the SVHC Roadmap.

If it had been the intention of the legislator that all CMRs must be included on the Candidate List, there would have been no need for a decision-making process on the inclusion. All CMRs with harmonised classification in Annex VI to CLP could have been automatically included in the Candidate List without the need for deliberations at the ECHA Member State Committee (MSC). That the legislator tasked the ECHA MSC with seeking agreement on the inclusion of harmonised CMRs in the Candidate List clearly shows that there is discretion that can be exercised by MSC and its representatives. Such an exercise of discretion would also be consistent with the fact that there is no obligation for the regulator to propose the Candidate Listing of harmonised CMRs, and that under the SVHC Roadmap authorities aim to identify "relevant" SVHCs. The question of 'relevancy' is also within the scope of the ECHA MSC's considerations for SVHC identification.

Members of the International Lead Association and the Lead REACH Consortium therefore urge the ECHA Member State Committee representatives to use their discretion to oppose the proposal to include lead metal on the Candidate List of substances of very high concern for Authorisation based on the finding that the proposed substance is not of relevance for Candidate Listing.

We do not dispute that lead metal has a harmonised CLP classification as Toxic for Reproduction Category 1A. However, the companies represented in this response to the public consultation on the Swedish Chemicals Agency's proposal question the proportionality and regulatory effectiveness of using the REACH Authorisation process, and therefore Candidate Listing, to further regulate lead metal on the following grounds:

1. Lead use is already highly regulated in the EU

Lead is one of the most highly-regulated substances in the EU, with a significant existing framework of substance-specific legislation intended to address risks to human health and the environment (Annex 1). The existing legislation covers all lifecycle stages of products made using lead metal, including production, use, and end-of-life/waste, and includes lead-specific limits on industrial emissions to air and water, and for lead in food and drinking water. The use of the REACH Authorisation process to further regulate lead metal would therefore be disproportionate to the additional benefit obtained.

In the workplace, lead and inorganic lead compounds are the only substances in the Chemical Agents Directive (98/24/EC) to have EU-wide binding occupational exposure and biological limit values, supplemented by a mandatory requirement for employers to undertake health surveillance. In addition, the Pregnant Workers Directive (92/85/EEC) protects the health and safety of women in the workplace when pregnant or having recently given birth, and women who are breastfeeding. The Directive includes specific provisions intended to ensure that expectant mothers and those breastfeeding are not exposed to lead.

Despite the absence of a recent scientific review of existing EU binding limit values, the lead manufacturing and battery industries already go beyond workplace legislation on lead, by establishing proactively, and progressively reducing, voluntary employee blood lead targets, and requiring continuous improvement – its exposure management performance now far exceeds the current EU binding limit values mandated in the Chemical Agents Directive.

The EU-wide binding occupational exposure limits established by DG Employment have not kept pace with Industry exposure management practices and the developing scientific knowledge about health effects; we agree with the Advisory Committee on Health & Safety at Work recommendation made in 2013 that an urgent scientific review by SCOEL was necessary as a precursor to lowering the binding limit values.

ILA and the Lead REACH Consortium would emphasise that the failing to review the EU binding limit values should be remedied through an update to the existing limit in the Chemical Agents Directive, and not through the introduction of additional burdensome legislative requirements. Industry remains supportive of a review by an appropriate scientific committee as first step to the revision of EU limit values as a priority.

Product use of lead is regulated through a plethora of existing legislation including the Batteries Directive, the End of Life Vehicles Directive (ELV), the Directive on the Restriction of Hazardous Substances (RoHS), the Directive on the safety of toys, the Drinking Water Directive, the Directive on packaging and packaging waste, the Regulation on food contact materials etc (see Annex 1). Where residual risk has been identified that has not been addressed through the existing framework, REACH Annex XVII (restriction) has successfully been applied to such uses, including jewellery (R836/2012), consumer articles that can be mouthed by children (R628/2015) and will be applied to other scenarios such as use of lead shot over wetlands (shot restriction). Moreover, by nature of its current harmonised EU classification as Repr 1A, under Entry 30 of Annex XVII to REACH, supply of lead metal as a substance or in a mixture to the general public is already prohibited.

In the case of EU Directive 2000/53/EC on end-life-vehicles, this legislation restricts the use of several heavy metals, including lead, in vehicles. There are a few exemptions to this restriction where substitution is not possible due to technical reasons. These exemptions are subject to regular reviews according to technical and scientific progress. Recently, lead-based batteries in automotive applications have been granted an extended exemption because of the lack of alternatives for the use of lead in automotive batteries.

This existing EU regulatory framework for lead metal is already delivering against the objective to reduce occupational and general population exposures. Lead is one of the few chemicals used in Europe for which routine biological monitoring (as blood lead) has been undertaken over many years that has demonstrated that existing risk management measures have on the large been successful. Most studies available through periodic National surveys or legislative mandated measurements have demonstrated that blood lead levels in occupationally exposed and the general population has fallen substantially over time with geometric means for children and non-occupationally exposed adults in the most recent surveys now approaching 1µg/dL. It is also relevant to highlight that population blood lead is a function of natural background, historical and current anthropogenic sources. Natural and historical uses (e.g. lead paint) make up a substantial amount of the body burden and it is recognised through E-PRTR submissions that several of the current diffuse emissions sources of lead (e.g. from power stations) would not be addressed through REACH Authorisation.

Considering the existing substance specific legislation addressing risks associated with lead use we conclude that inclusion of lead metal in the REACH Candidate List as a pathway to future Authorisation fails to meet the requirement for proportionality and is not necessary to achieve the

objective of protecting the health of workers and consumers, while it leads to highly disproportionate costs for Industry.

2. Lead metal has essential uses, vital to the EU economy and wellbeing

Information on the uses of the substance

The use of lead metal in the production of lead-based batteries is, by far, the predominant use of lead in the EU, and worldwide. In the EU alone, 84% of the total volume of lead metal is used to produce lead-based batteries, the figure having grown from 64% in 2000. According to figures compiled by the International Lead and Zinc Study Group, automotive and industrial lead-based battery applications accounted for 1,274,000 tonnes of lead metal used in 2015 in the EU. Automotive batteries account for more than half – 53% – of the total EU use volume, and industrial batteries for 31%.

Lead-based batteries are critical to the day-to-day economic and social wellbeing of Europe. They are an essential, reliable and safe enabler of the EU economy, supporting critical infrastructure including power back-up for emergency services, hospitals, computer networks and telecommunications. The lead-based battery is a vital component in each of over 250 million cars on Europe's roads and 1.5 billion cars worldwide, including hybrid and electric vehicles. No other battery technology has comparable performance characteristics for all seasons and cost effectiveness for users worldwide. Lead-based batteries are sealed units with no potential for lead exposure to users or the environment throughout their use. There are no substitutes for the use of lead metal in lead-based batteries, and there are no alternatives for lead-based batteries in the majority of applications.

Lead-based batteries are already highly regulated at EU level through a framework of substance-specific product and waste legislation – including the Batteries and ELV Directives – designed to address risk throughout the product lifecycle and end-of-life stage. 99% of used lead-based batteries are collected at end-of-life and recycled using Best Available Techniques with a high recycling efficiency meaning that the vast majority of lead can be recovered and reused. Most of the recovered metal is used to produce new batteries: today, more than 85% of a new lead-based battery is made from recycled materials. No other battery technology meets these sustainability credentials.

Lead-based battery producers are situated in 14 EU Member States, in an industry employing approximately 20,000 workers; the sector has an annual turnover of €5 billion and has spent more than €845 million on R&D over the last five years. In addition, a highly effective collection and recycling network exists to ensure that lead batteries are handled in a closed loop. Lead-based battery recyclers are present in 15 Member States and recycle over 1,000,000 tonnes of used batteries per year.

Lead metal also has important uses in the production of rolled and extruded products such as architectural lead sheet and in radiation shielding, in sub-marine cable sheathing, in leaded steel, in copper- and other alloys, and in ammunition.

Although most lead metal is used by the battery sector, lead used in the production of metal alloys, in particular copper-based alloys, is a critical but low-volume application (<1% of total EU volumes – see **Figure 1**).

Lead is added as a functional alloy constituent because lead, embedded as tiny globules (e.g. in brass alloys), acts as a lubricant and, most importantly, as a chip breaker, allowing the high-performance machining of semi-products, without continuously damaging the product itself or the production tools. This results in extended tool lifetime, higher productivity and less usage of resources, together with a high-quality surface of the machined material. In addition, lead exhibits corrosion-inhibiting characteristics which minimises the corrosion/metal release of the other alloy constituents.

Alloys have a multitude of end-uses in articles – and complex objects made up of many individual articles; many such uses are already subject to lead-specific requirements that encourage substitution (e.g. through the WEEE, RoHS and ELV Directives) or define specific risk management measures (e.g. for approval for use in drinking water products).

Over the last 20 years, the industry has reduced, to a minimum, the amount of lead needed for a series of copper alloys while still fulfilling downstream customer requirements. During the last years, the copper industry performed intensive research work to replace lead in free cutting brasses. This research work, however, was aimed at the production processes and material properties required in products for drinking water applications where strict lead release limits are required to meet existing EU legislation covering drinking water safety.

It should also be recognised that lead-containing alloys are also subject to a high degree of recycling after the end of service use. Implications of this activity and negative effects of REACH Candidate Listing of lead metal on Circular Economy objectives would also need to be taken into consideration.

Consideration of alternatives indicates the essentiality of lead in performance-critical applications, for example:

Architectural lead sheet: An Analysis of Alternatives (AoA) and Socio-Economic Assessment (SEA) carried out for the European Lead Sheet Industry Association (ELSIA) in 2014 concluded that none of the potential alternatives to lead sheet would be a technically or economically feasible substitute.

Radiation shielding: The key advantage of lead is in applications where radiation must be stopped in a short distance; in those uses, effective substitution would be difficult to achieve. For end-use applications such as in nuclear installations, a replacement for lead sheet would be subject to a stringent, lengthy requalification and approval processes; installation of replacements would involve potential exposure to remove existing lead metal, as well as significant and costly downtime at the facility. Therefore, the socio-economic benefits of continued use of lead in radiation shielding are regarded as outweighing any risk posed.

Cable sheathing: Lead-sheathed cabling plays a vital role in the EU, from social, economic and technical perspectives; there is no mass market alternative available. For extremely high-voltage cables, lead provides a barrier layer that is completely impervious to water. Lead-sheathed cables play a vital role in the decarbonisation of the EU by providing safe, reliable energy transfer from offshore wind farms to energy networks. The design life for sub-marine cables is currently 50 years; cable integrity must remain intact for many decades. The total value to the EU of large projects employing lead-sheathed cables is significant, potentially several trillion Euros per annum. Many alternatives to lead have been investigated, but costly failures in performance of the alternatives has always resulted in a return to lead.

Alternatives to lead in other applications are discussed further in the appended report on the Consortium's assessment of potential Risk Management Options for lead metal.

As noted in the REACH registration dossier, lead metal is also used as an **intermediate** in the production of lead compounds, predominantly lead oxides. This intermediate use was overlooked in the Annex XV dossier submitted by the Swedish Chemicals Agency (Table 6: Uses). According to figures compiled by ILZSG, in 2015, 4% of the total EU lead metal use was as an intermediate in the

production of lead compounds; that volume should be omitted from any prioritisation considerations.

Note that the use of lead oxides and other lead compounds is diminishing in all sectors other than the lead-based battery market, primarily due to market-driven voluntary replacement programmes.

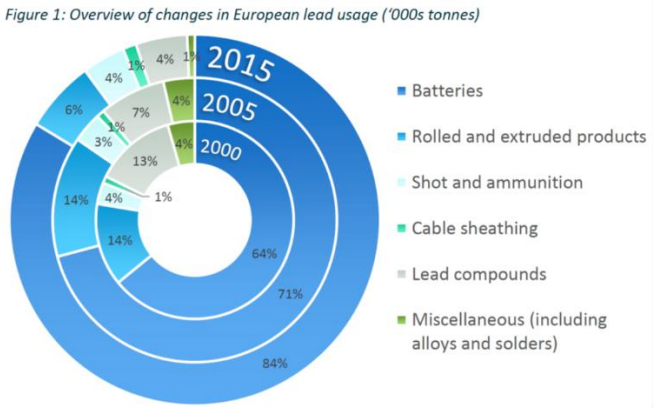

Figure 1 Overview of changes in European lead usage ('000s tonnes). Taken from International Lead and Zinc Study Group report, First Uses of Lead and Zinc in Europe

Professional use of lead

There is only one ECHA-recognised professional use of lead as a substance (in a mixture) – the professional use of lead solder – as reflected in the latest update to the Chemical Safety Report and Lead Registrant dossier. Lead metal is still used in solder alloys in some electrical and electronic components. These uses are already regulated through RoHS and WEEE Regulations and are only permitted where no alternative exists due to technical and safety issues. REACH Candidate Listing of these applications would cause a double regulation with additional requirements prescribed to companies placing articles manufactured with lead containing solders on the EU market. Such double regulation should be avoided as previously explained in the paper "REACH and Directive 2011/65/EU (RoHS) A Common Understanding" of the EU Commission.

Consumer use

There are no supported or legal consumer uses of lead metal as a substance or in a mixture, as this is effectively prohibited under Entry 30 of Annex XVII to REACH. Previously, there was one identified consumer use of lead as a substance/in a mixture – the use of lead solder – which became subject to a REACH Restriction on 1 March 2018 and is denoted as a use advised against in a dossier update to be submitted by the Lead Registrant.

All other consumer uses of lead metal as shown on the ECHA website are in fact article service life 'uses', which were denoted as such in the dossier update submitted by the Lead Registrant in 2016.

3. The REACH Authorisation process does not address risk from imported articles

Recent REACH Restrictions on lead metal [R836/2012 and R628/2015] have highlighted that the majority of the risk resulting from use of articles containing lead can be attributed to imports. The use of the REACH Authorisation process will not lead to improved protection of human health from the placing on the EU market of such articles.

Industry recognises that Candidate Listing would trigger the obligation of supply chain disclosure per Article 33. However, it should be noted that this obligation is based solely on intrinsic hazard, i.e. whether an SVHC is present above 0.1% w/w in the article: it is a mechanism which neither considers, nor addresses, risk.

Article 33 communications for highly complex objects containing lead in alloys would have significant impacts on EU supply chains, particularly SMEs that are already operating in a challenging and highly competitive environment.

Candidate Listing of lead metal in order to drive information disclosure, to assess whether targeted REACH Restrictions may be required, would lack direct effectiveness under the principle aim of REACH and would be disproportionately burdensome for complex supply chains.

The use of lead-containing articles would not be regulated by REACH Authorisation – any risks related to the use-phase of these articles will therefore not be addressed and would require parallel REACH Restriction activity (as has already been the case for use in consumer articles that can be mouthed by children and lead-containing jewellery). In article applications where no alternative to lead exists, the burden of Authorisation for EU manufacturers could well lead to a non-use scenario of increased importation of lead-containing articles from countries outside the EU.

4. Lead is a key enabler of the Circular Economy

Lead metallurgy is a critical infrastructure. The carrier metal properties of lead make it an efficient and effective way to recover a broad range of non-ferrous metals from increasingly complex end-of-life products. Lead enables high-tech recycling in the EU, and provides a critical source of other metals that are sustainability-enabling but have low recycling rates. This is supported by the Supervisory Board of SOCRATES, the European Training Network for the Sustainable, zero-waste valorisation of critical-metal-containing industrial process residues.

The lead-based battery itself is managed through a highly efficient closed-loop recycling process at end-of-life, driven by the economic value of the recycled materials that are re-used to manufacture new batteries.

More detailed information on the essentiality of lead to the recovery of other valuable materials, and the potential impact of REACH Authorisation on primary production of metals such as zinc, is provided in the attached paper, "Lead as a key enabler of the Circular Economy".

5. Conclusions of Industry's shadow Risk Management Option Analysis

The Lead REACH Consortium has conducted its own assessment of potential Risk Management Options that clearly demonstrates that **existing legislation is the most appropriate RMO** to address potential exposure and consequent risk in the use of lead metal in industrial workplaces and to produce articles. The study further concluded that any residual risk related to current use of lead metal not addressed by the existing framework of legislation is better managed through **targeted REACH restrictions** – which would also have the benefit of addressing imported articles containing lead – in combination with **updating the existing workplace binding occupational and biological exposure limits**.

A copy of the RMOA report is appended.

Conclusions

Application of the REACH Authorisation process to regulate existing uses of lead metal fails to meet the requirement for proportionality and would be lacking in regulatory effectiveness. It would undermine the EU's industrial competitiveness, particularly in the case of the European battery manufacturing and metal recovery/recycling sectors, without reducing the risk to human health and the environment.

Further engagement with Industry and proper enforcement/implementation of existing legislation, coupled with targeted REACH Restrictions and an update of the existing lead binding limit values in Occupational Health and Safety Legislation, would be a more effective risk management strategy.

Annex 1: Existing EU Legislation Controlling Lead metal (and compounds)

Annex 2: List of members of the International Lead Association

Annex 3: List of members of the Lead REACH Consortium

Attachments:

- Lead REACH Consortium position statement
- Lead REACH Consortium paper on lead as a key enabler of the circular economy
- Lead REACH Consortium paper on the essentiality of lead-based batteries
- Lead REACH Consortium assessment of potential Risk Management Options for Lead Metal (confidential attachment)

About the Lead REACH Consortium

The Lead REACH Consortium represents more than 90 legal entities involved in the mining, smelting, refining and recycling of lead, the manufacture of lead compounds, and the production of lead-based automotive and industrial batteries.

Managed by the International Lead Association (ILA), the Lead REACH Consortium advocates proportionate regulation which is based on sound science and is supportive of responsible, sustainable production and use of lead and its substances. www.ila-reach.org

About the International Lead Association

ILA is the trusted and authoritative global trade association for the lead industry. Its member companies are at the forefront of lead mining, smelting and recycling and through ILA are working towards a vision of a sustainable global lead industry that is recognised for the positive contribution it makes to society. www.ila-lead.org

Annex 1: Summary of the existing EU Legislation controlling lead metal (and international agreements)

The hazardous properties of lead have been known for many years. Due to these well-documented properties, metallic lead and lead compounds have been extensively regulated at national, Union and global level. This is reflected in the large number of sector specific Union legislative acts which restrict the use of lead and or its compounds in mixtures, articles and consumer products with regard to their risks to human health (incl. occupational) and the environment.

A comprehensive (but non-exhaustive) inventory of existing Union legal requirements related to lead, is listed in the following tables:

Table 1 EU General Legislation controlling lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
Regulation (EC) 1123/2009 on cosmetics products	• List of substances that cosmetic products must not contain (including lead and its compounds)
Directive 98/70/EC on petrol	• Prohibition of leaded gasoline (except aircraft) • Lead content restricted to 0.005 g/l
Directive 1999/45/EC relating to the classification, labelling and packaging of dangerous preparations	• The label on the packaging of paints and varnishes containing lead in quantities exceeding 0.15% (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars: o 'Contains lead. Should not be used on surfaces liable to be chewed or sucked by children'. • In the case of packages, the contents of which are less than 125ml, the particulars may be as follows: o 'Warning! Contains lead'
Council Regulation (EEC) 304/2003 on the export and import of dangerous chemicals (Rotterdam Convention)	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
Directive 2006/66EC on batteries and accumulators and waste batteries and accumulators	• Sets out measures relating to the collection, treatment, recycling and disposal of waste batteries and accumulators containing lead, with specific recycling efficiency targets for lead-acid batteries • Requires Member States to promote research and encourage improvements in the overall environmental performance of batteries and the development of batteries which contain smaller quantities of dangerous

	substances or which contain less polluting substances, in particular as substitutes for mercury, cadmium and lead.
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (to be replaced on 3 Jan 2013 by Directive) Directive 2012/19EC on waste electrical and electronic equipment (WEEE)	• Substances (including lead) restricted in a waste management perspective • Maximum concentration of up to 0.1% by weight in homogeneous material tolerated • Articles concerned: electrical and electronic equipment including IT and telecommunications equipment, household appliances and consumer equipment, lighting equipment, electrical and electronic tools, toys, leisure and sports equipment, medical devices, monitoring and control instruments, and automatic dispensers • Exemptions include lead in cathode ray tubes; certain electrical and electronic components which contain lead in a glass or ceramic; lead in white glasses for optical applications; in certain printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses; bound in crystal glass; • Lead is exempted from certain medical devices and monitoring and control instruments • Sets criteria for the collection, recycling and recovery of such equipment and selective treatment of certain materials and components
Directive 2000/53/EC on end-of-life Vehicles	• Member States shall ensure that materials and components of vehicles put on the market do not contain lead (certain exemptions apply) • Products concerned: passenger vehicles comprising no more than eight seats in addition to the driver's seat, and goods transport vehicles not exceeding 3.5 tons • Maximum concentration of up to 0.1% by weight in homogeneous material tolerated • Exemptions include lead in alloys and in components such as batteries (to be reviewed in 2021), vulcanising agents and stabilisers, certain electrical and electronic components which contain lead in a glass or ceramic matrix (compound), pyrotechnic initiators etc.
Directive 2009/48/EC on the safety of toys	• Total prohibition of certain substances or preparations in toys except those which are essential to their functioning. In this case, they are submitted to a maximum concentration defined for each substance individually • Bioavailability resulting from the use of toys < 0.7µg/day (EN 71-3) • Lead migration limit from toys = 90 mg/kg (EN 71-3) • Lead migration limit = 13.5 mg/kg dry, brittle, powder-like or pliable toy material • Lead migration limit = 3.4mg/kg or sticky toy material

	• Lead migration limit = 160mg/kg scraped-off toy material
Directive 2001/95/EC on General Product Safety	• Only safe products for consumers are placed on the market (conception and/or information) • Information system (RAPEX)
Directive 94/62/EC on packaging and packaging waste as amended by Directive 2004/12/EC	• Requirements on management of packaging and packaging waste effectively eliminated this application of lead by reducing the sum of the amount of lead, cadmium, mercury and hexavalent chromium present in packaging and packaging components to 100 ppm (mg/kg) • Exemption for packaging made of lead crystal glass • Derogation from heavy metal limit for glass packaging and for plastic crates and pallets
Food related EU legislation	
Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs as amended by Directive 2005/31/EC Framework Regulation EC No. 1935/2004 on materials and articles intended to come into contact with food	• Lays down maximum limits for lead transferred by ceramic objects to the foodstuffs with which they enter into contact • Maximum permitted quantity of lead is 0.8mg/dm² for articles which cannot be filled or which can be filled but not deep (25mm), 1.5mg/l for cooking ware and storage vessels which have a capacity of more than 3 litres and 4.0 mg/l for other articles (+50% of these thresholds tolerated)
Commission Regulation 466/2001 on contaminants in foodstuffs Regulation (EC) No 1881/2006 setting maximum levels for certain contaminations in foodstuffs	• Lead level in milk, meat, fish, shellfish, cereals, vegetables, fruits, berries, oils, fats fruit juice and wine must be between 0.02mg/kg by wet weight (cow's milk) and 1.5mg/kg w.w. (mussels) • Sets maximum levels for lead in a number of different foodstuffs. In various food items the maximum level is between 0.02 and 1.5mg/kg
Directive 98/83/EC on quality of water intended for human consumption	• Lead content in water for human consumption must be <25µg/l (until 2014) and <10µg/l thereafter
Directive 88/344/EEC on extraction solvents in foodstuffs	• Residues of solvents used in food industry • Lead content in extraction solvents < 1 mg/kg
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	• Lead content in flavourings < 10mg/kg
Directive 2002/32/EC on undesirable substances in animal feed as regards lead, fluorine and cadmium	• Sets maximum content of lead in different types of feed materials, between 5 and 40 mg Pb/kg

Table 2 List of EU legislative related to lead and its compounds associated with human health protection (non-exhaustive list)

EU Legislation	Legal requirements
Annex XVII of REACH: restriction of the use of certain hazardous substances (entries 16, 17, 28, 30, 63)	• Direct restriction of lead carbonates and lead sulphates in mixtures intended to be used as paints • Restriction of lead and its compounds in jewellery and consumer articles that can be placed in the mouth by children • Restriction on sale to the public of lead metal and mixtures containing lead metal (2017/1510) • Restrictions on use in shot over wetlands and of lead (compounds) use in PVC currently being progressed
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work	• The principal objective is to prevent (personal) exposure to hazardous substances. Where this is not possible, the Directive requires adequate control through engineering and individual protective measures, and in the case of inorganic lead and its compounds, a binding occupational exposure limit value (BOELV) of 0.15 mg/m³ at European level has been set. • The binding biological limit value is 70 µg Pb/dl blood. • The Directive requires medical surveillance to be carried out
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	• Sets out measures to protect pregnant workers and workers who have recently given birth or are breast-feeding, including the requirement to assess exposure to health risks including lead compounds due to their reprotoxic effects. • Lead and lead compounds are only chemical agents included in Annex II covered by Article 6 “Cases in which exposure is prohibited”.
Directive 94/33/EC on the protection of young people at work	• Prohibits the use of certain chemical agents, including lead/lead compounds as a reprotoxic agent, by young workers.

Table 3 List of EU environmental legislation related to lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
Directive 2010/75/EU on industrial emissions (replaced Directive 2008/1/EC on integrated pollution prevention and control (IPPC) and was required to be transposed by Member States by 7 January 2013)	• Categories of activities subject to IED permitting are listed in Annex 1 of the Directive • Relevant activities controlled include primary and secondary production of, and processing of, non-ferrous metals; manufacture of glass and ceramic products; chemical installations for the production of organic (e.g. synthetic rubbers, dyes and pigments) and inorganic (e.g. metal oxides) chemicals, and for the production of explosives

	• Where relevant, emission limit values along with other conditions have to be set in individual plant permits to control the emissions and other impacts to the environment • Best Available Technique Reference (BREF) documents and their BAT conclusions adopted by the Commission provide the reference concerning techniques to control/reduce emissions. Relevant BREFs include the non-ferrous metals BREF that establishes emission level values for lead.
Regulation No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (EPRTR)	• Member States have to report on the emissions of industrial facilities regulated (scope is similar to the IPPC Directive). Reporting covers a wide range of pollutants including lead and its compounds.
Directive 2008/50/EC on ambient air quality and cleaner air for Europe	• A limit value of the lead concentration in ambient air is established for the protection of human health (expressed as an average over a calendar year) of 0.5 µg/m³. Member States shall ensure that, throughout their zones and agglomerations, levels of lead in ambient air do not exceed this limit value.

Table 4 List of International agreements related to lead and its compounds (non-exhaustive list) (EPA, 2014)

Agreement (entry into force)	**Main provisions on lead**
The Convention for the Protection of the Marine Environment of the North-East Atlantic/**OSPAR Convention** (1992)	Lead in the form of tetraethyl and tetramethyl lead is on the OSPAR list of substances of possible concern, aiming to reduce discharges in order to reach near-background concentrations in the North-East Atlantic. Lead and 8 organic lead compounds are on the Priority action list of OSPAR.
Helsinki Commission /HELCOM (2000)	The Helsinki Commission has issued a range of recommendations regarding lead. This includes the reduction of emissions 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.
Barcelona convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (1995)	Lead is listed in Annex II of Annex regarding Harmful or Noxious Substances and Materials for which the disposal in the Protocol Area is subject to special permit.
Bucharest convention on the Protection of the Black Sea Against Pollution (1994)	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.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989)	The Basel convention set out control measures of the movements of hazardous waste incl. waste containing lead between nations, and restricts the transfer of hazardous waste from developed to less developed countries. 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.
Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (rev 2013)	Lead is not directly covered by the 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.

Annex 2: List of members of the International Lead Association

Affinerie de Pont Sainte Maxence
Aurubis AG
Berzelius Metall
BMG Metall und Recycling
Boliden AB
Britannia Refined Metals
BSB Recycling
Campine Recycling
Doe Run
East Penn Manufacturing
EcoBat Italy
EcoGlobal Inc
EnviroWales
Exide Technologies Recycling II, Lda
Exide Technologies SLU
Glencore Canada
Gopher Resource
Hakurnas Lead Works
H J Enthoven & Sons
JCI (Europe)
KCM SA
Kovohute Pribram
Lundin Mining
Metallo Belgium N.V.
MPI Reciklaza
Muldenhutten Recycling und Umwelttechnik GmbH
Recylex
RSR
South32
STCM
Teck Resources Ltd.

Associate members of ILA:

AFEMS
As Batteriretur
Calder Industrial Materials
Cookson Group
Coplosa SA
Enersys
Engitec Technologies SpA
H Folke Sandelin AB
Interstate Batteries
Lead Sheet Association
Penox GmbH
W L Gore and Associates

Annex 3: List of members of the Lead REACH Consortium

5N Plus Belgium SA	Johnson Controls Autobaterie spol (Czech)
Akkumulatorenfabrik Moll GmbH	Johnson Controls Autobatterie GmbH & Co.
Anton Schneider Sohne GmbH	Johnson Controls Recycling GmbH
Asua Products SA	Johnson Controls Sachsen-Batterien GmbH
Aurubis GA	KCM 2000 SA SC
Azor Ambiental SA	KGHM Polska Miedz SA
BAE Batterien GmbH	Kovohute Pribram Nastupnicka a.s
Baerlocher GmbH	Le Plomb Francais Sarl
Banner GmbH	Loxa Sp. Z.o.o.
BASF SE	MECA Lead Recycling SpA
Berzelius Stolberg GmbH	Metal Processors Limited
BMG Metall und Recycling GmbH	Metalblanc
Boliden Bergsoe AB	MetAlliance LLP
Boliden Mineral	Metallo-Chimique NV
BSB Recycling GmbH	Metalurgica de Medina SA
Campine Recycling NV	Midac
Chemson Polymer-Additive AG	Midland Lead Manufacturers Ltd
Colorobbia Italia spa	MPI Reciklaza d.o.o
COPLOSA, Sociedad Anonima	Muldenhutten Recycling und Umwelttechnik GmbH
Eco-Bat SpA	Nederlandse Accumulatoren Produktie
Ecological Scrap Industry SpA	Nizi International SA
Ecometal Ltd	Nyrstar
EnerSys Newport	Penox GmbH
EnerSys SARL	Piombifera Italiana Spa
EnerSys Sp. Zoo	Piomboleghe Srl
EnviroWales	Portovesme Srl
Exide Technologies GmbH (Deutsche Exide)	PPUH Autopart Jacek BAK Sp z o.o
Exide Technologies Lda (SPAT)	RECOBAT
Exide Technologies Recycling II Lda (So-nalur)	SC Rombat SA
Exide Technologies Recycling SL (Oxivolt)	SIA Industria Accumulatori Spa
Exide Technologies SA (Centra)	STCM-APSM
Exide Technologies SA (Tudor)	Sunlight SA
Exide Technologies SAS (CEAC)	TAB dd
Exide Technologies Srl (Exide Italia)	Teck Resources Ltd.
Fenix Metals Sp. z o.o.	Traxys Europe SA
FIAMM SpA	Umicore
Floridienne Chimie SA	Union Derivan SA (Undesa)
Glencore Import BV	Uzimet
Glencore International Import BV	Vippiemme SpA

H J Enthoven Ltd	Weser-Metall GmbH
Hakurnas	Wilhelm Grillo Handelsgesellschaft mbH
Hammond Lead Products	Xstrata Zinc (Britannia Refined Metals Ltd)
Hoppecke Batterien GmbH & Co KG	Yuasa Battery UK Ltd
Huta Cynku “Maisteczko Slaskie”	Zap Sznajder Batterien s.a
IKa Innovative Kunststoffaufbereitung GmbH & Co.KG	
Jenox Akumulatory Sp. z o.o	
Johnson Controls Autobaterias SA (Spain)	**Associate Member**: AFEMS