Consolidated non-confidential submission into ECHA public consultation on draft 11th recommendation for Authorisation

Text submitted into ECHA webform

The organisations represented in this response – listed in Annex 1 – do not support the inclusion of lead metal in REACH Annex XIV. It would be disproportionate and an inefficient risk management measure.

In 2020, a typical year for lead production and use, approximately 1.65 million tonnes of lead metal was manufactured in the EU, 73% coming from recycling of end-of-life products, and approximately 1.62 million tonnes of lead metal was used in the EU (Footnote 1 – see Annex 5 (attached) for list of footnotes).

Use of lead metal in the production of lead-based automotive and industrial batteries is the main application: industrial use in EU battery production currently accounts for 86-90% of the use by volume (Footnote 2). Other smaller-volume industrial uses are listed in Annex 2 to this response.

Professional uses of lead are limited to specific applications, e.g. reparative uses of lead solder in plumbing.

The organisations represented by this response do not support the consumer use of lead as a substance or in a mixture, not least considering the Restrictions imposed by REACH Annex XVII, Entry 30.

Regarding prioritisation scoring: According to the ECHA document, "Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) PRIORITISATION APPROACH" ((Footnote 3; Page 4), the primary basis of prioritisation are the REACH Article 58(3) criteria. Article 58(3) requires taking the mentioned three criteria 'normally' into account, but there is no provision how this should be done in practice. Moreover, the consideration of further aspects and criteria is not excluded. Hence, Article 58(3) leaves the discretion to consider other relevant information (i) to the ECHA Member State Committee (MSC) when preparing its opinion on the draft recommendation and (ii) to ECHA when finalising its recommendation.

Prioritisation should be used correctly and effectively, to ensure regulatory action is focused on the right substance at the right time. Prioritisation scoring of lead metal based crudely on the Article 58(3) criteria alone does not adequately consider the effectiveness of existing legislation already implemented by the EU to address risk (e.g. restrictions in the ELV and RoHS Directives etc), nor the anticipated impact of on-going regulatory actions (e.g. REACH Restrictions on lead in ammunition and fishing tackle, Battery Regulation proposal, updated binding workplace limits etc).

One of the three main (i.e. Article 58 (3)) criteria for prioritisation is EU use volume in scope of REACH Authorisation. This simplistic approach prejudices high-density materials, particularly metals such as lead, as 'volume' is quantified in tonnes per year.

The vast majority (at least 95% (Footnote 2)) of lead metal used in the EU is in applications which result in the incorporation of the metal into an article. Use of lead metal in the EU to produce articles would be in scope of REACH Authorisation but import of the same articles produced outside the EU would not be in scope. Therefore, the competitiveness of EU article producers in a global marketplace would be adversely affected by Authorisation Listing.

Other uses, representing less than 5% of the annual use volume, include: use as an intermediate in lead compound manufacture (exempt from REACH Authorisation), use of lead metal in galvanising, use of molten lead as a heat transfer agent, use as a lubricant/tribological agent, and use of lead metal in chemical analysis (fire assay; use in Scientific Research and Development (i.e. less than 1 tpy) is exempt from REACH Authorisation).

The presence alone of SVHCs in a process or in an article does not automatically confer a risk to human health or the environment. 86-90% (Footnote 2) of lead used in the EU each year is used to make lead-based batteries. These products are almost exclusively supplied ready for use as sealed articles: during article service life they do not have the potential for end-user exposure nor do they release lead to the environment. In other articles made using lead or lead alloys, the lead-containing parts are usually enclosed inside a complex object, encapsulated in e.g. plastic, or are painted. Therefore from a proportionality perspective it is not appropriate to use the total volume of lead used in the EU for all uses in scope of REACH Authorisation as a surrogate for potential exposure. This approach lacks any assessment of actual exposure/emissions and hence risk and therefore fails a test of proportionality.

To ensure a greater degree of proportionality, priority scoring should be applied only to the volume of lead used in the EU where existing legislation is not adequate to address any risk. If this approach were to be adopted, lead metal would attract a significantly lower score: there are no consumer uses, and industrial and professional uses are already regulated by workplace health, safety and environmental legislation including an EU binding OEL and BLV, and the majority of end-use applications are already covered by product-specific and end-of-life legislation as discussed in this response and listed in joint ILA-Lead REACH Consortium Position Paper (Footnote 4).

ECHA's lack of consideration of on-going regulatory risk management activities for lead is inconsistent with its approach for other substances in the draft 11th recommendation: As noted in the PRIORITISATION APPROACH document (Page 4), "on-going regulatory risk management activities can be considered when deciding on which substances to include in a specific recommendation, in order to avoid undesired interference between different regulatory actions". According to "ECHA's general responses on issues commonly raised in consultations on draft recommendations" (Footnote 5), prioritisation is a comparative exercise supporting the conclusion on which substances to recommend first, i.e. the priority scores need to be considered in relation to each other and should not be seen in isolation.

Referring to the ECHA "Results of the prioritisation" document (Footnote 6); on-going work related to REACH Restriction and/or POP identification was the ONLY reason cited by ECHA as to why it considered it appropriate to postpone the recommendation of MCCP and 1,4-dioxane – substances which were scored more highly by ECHA than lead metal in this round of prioritisation.

We question why ECHA did not apply the same rationale in the case of lead metal, especially considering that there is a much broader range of lead-specific legislative measures in progress and/or under review. As with MCCP and 1,4-dioxane, there is already an ongoing REACH Restriction proposal, i.e. for lead in ammunition and fishing tackle, and moreover there are additional relevant regulatory actions also in progress that are also designed to manage risks related to lead exposures, including:

-The review of the existing EU binding limit values (OEL and BLV) for lead and lead compounds,

-The Battery Regulation proposal which is currently under scrutiny by Council and the European Parliament, that includes as Article 6 a requirement for restrictions of certain hazardous substances present batteries when they are placed on the market, or during their subsequent life cycle stages, including the waste phase,

-The ELV and RoHS Directives which are under review by the European Commission.

Regarding proportionality and effectiveness: Lead metal is already extensively regulated by lead-specific legislation in the EU, as highlighted in Annex 1 of the joint ILA-Lead REACH Consortium Position Paper (Footnote 4). We therefore question what benefit ECHA believes a recommendation for inclusion in REACH Annex XIV would deliver. Our position is that subjecting lead metal to REACH Authorisation will not deliver any significant reduction in exposure or emissions. Moreover, we doubt whether REACH Authorisation Listing would lead to a faster phase-out of lead than foreseen in existing regulations. Inclusion of lead metal in REACH Annex XIV would lack regulatory coherence, creating many cases of double regulation resulting in inefficient use of resources from both Regulators and EU Industry. Requiring companies to apply for REACH Authorisation for the same uses of lead metal under two different legislative mechanisms (ELV Directive 2000/53/EC and REACH Authorisation / RoHS Directive 2011/65/EU and REACH Authorisation) would mean duplicating work in the ECHA Committees which is already carried out by the consultants appointed by the European Commission in respect of the RoHS/ELV exemption reviews. The exemption reviews and REACH Authorisation applications would in general also take place in parallel, potentially with overlapping yet misaligned timelines.

We note from the PRIORITISATION APPROACH document (Footnote 3) that the Authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. However, the existing legislative framework for lead already aims at substitution in automotive batteries and other applications in scope of the EU ELV Directive – uses which cover more than 55% (Footnote 2) of the current EU volume. Substitution is mandated by ELV where there is a feasible alternative; exemptions are granted only where there is no technically feasible alternative and are time-limited, reviewed regularly and at a greater frequency than normally envisaged under REACH Authorisation, to re-assess feasibility of potential alternatives. As such, battery and other automotive uses exempted by ELV are already being subject to more stringent substitution pressure based on technical feasibility alone.

Moreover, it is expected that all battery use of hazardous substances will in future also be assessed for risks through application of Article 6 of the proposed EU Battery Regulation.

In addition to automotive and other battery applications, use of lead in a broad range of electronics and electrical equipment (EEE) is already restricted, except where permitted under time-limited exemption by the RoHS Directive, an application which has been estimated to account for 0.5-1% (Footnote 7) of the annual EU use of lead metal.

Collectively at least 87% (Footnotes 2, 8) of the total lead volume used in EU is used in the industrial production of complex objects which are already under pressure for substitution via existing legislation that is at least equivalent to that which could be achieved by REACH Authorisation. The ongoing REACH Restriction proposal on ammunition use will add approximately 4% to the total volume of lead that will be under substitution pressure from existing regulation, meaning that less than 9% of the total volume of lead metal used in the EU would ultimately be covered by REACH Authorisation alone in the context of specific regulatory pressure for substitution – notwithstanding the more general requirements of Directive 2004/37/EC in respect of the obligation for employers to reduce the use of reprotoxic substances at the place of work, in particular by replacing them, in so far as is technically possible.

We therefore question the proportionality of an Annex XIV recommendation for lead metal, and therefore its effectiveness.

We take this opportunity to remind ECHA of the European Commission's common understanding paper, "REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING" (Footnote 9) – in particular the comments in respect of substances already in Annex II to RoHS being proposed for inclusion in Annex XIV (pp5-6): "it should be noted that decisions taken under Article 5 of RoHS to include materials in Annexes III and IV (exempt applications) must take into account the practicability, reliability or socioeconomic impact of substitution. Moreover, the exemptions are time limited and will only be renewed after submission of the information listed in Annex V to RoHS, including updated details of the practicability and reliability of substitution, an analysis of possible alternatives and a timetable for action to develop /apply possible alternatives. All of these requirements may be seen as mirroring the substitution objective of the REACH Authorisation procedure". Similar arguments can be applied to applications covered by ELV Annex II exemptions, however the pressure for substitution is even stronger. As with RoHS, substitution is mandated by ELV where there is a feasible alternative; however under ELV time-limited exemptions are granted only where there is no technically feasible alternative. ELV exemptions are reviewed regularly to re-confirm feasibility of potential alternatives, but no socio-economic factors are considered – which means the pressure for substitution is more stringent under ELV compared to REACH Authorisation.

Regarding other, more effective regulatory actions:

Regarding environmental emissions; the current IED provisions and the related NFM BREF process have been a major step forward for the reduction and elimination of pollutants. Recent E-PRTR (Footnote 10) data indicates that across the EU-27 there was an 88% reduction in emissions of lead to air and an 80% reduction in lead emissions to water between 2007-2020. However, the same data highlight that the majority of current lead emissions in the EU now result from activities which are NOT in scope of REACH Authorisation for lead metal.

A recent Pb emission inventory study (Footnote 11) using E-PRTR data, facility emission data from EU lead battery producers and recyclers, and other information sources, concluded that 65% of yearly lead emissions to air in the EU come from thermal power stations, pig iron & steel production, and waste management – activities which are not in scope of REACH Authorisation for lead metal (as they do not use lead metal) and which are all regulated by the IED.

From a proportionality perspective, despite the lead battery value chain, for example, using 86-90% (Footnote 2) of the total EU tonnage of lead per year, the study (Footnote 11) estimated that this value chain contributes just 2.2% of the total Pb emissions to air and 0.02% total Pb emissions to water.

Using data obtained from facilities producing and recycling lead batteries across the EU, another recent study (Footnote 12) concluded that emissions from this value chain have a minimal impact on general population blood lead levels at regional level: "The predicted contribution of Pb in human blood arising from emissions from lead battery manufacturing and recycling for the regional scale was 0.15 µg Pb/L for children (1-3 years) and 0.06 µg Pb/l for adults. This value is about 1% of total Pb blood levels, according to available recent monitoring data for children less than 7 years across Europe".

The Pb emission inventory study (Footnote 11) also confirmed that use of lead-containing ammunition is the major source of lead emissions to water (87%) and soil (98+%). As articles, the use of lead-containing ammunition cannot be subject to REACH Authorisation – and in any case a REACH Restriction has already been proposed and is currently being considered by ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).

The Pb emission inventory study (Footnote 11) then compared anthropogenic emissions with emissions via natural processes, concluding that:

-emissions to water via natural processes are 8 times higher than the total from anthropogenic sources (16,140 vs 2,007 tonnes per year),

-emissions to soil via natural processes are 1.7 times higher than the total from anthropogenic sources once ammunition (for which a REACH Restriction is currently under consideration by the ECHA Committees) is excluded (723 vs 434 tonnes per year).

-strengthening the IED and the E-PRTR Regulation, and delivering the ongoing REACH Restriction proposal on lead in ammunition and fishing tackle, will be more effective at reducing lead emissions to air, water and soil than REACH Authorisation Listing of lead metal.

Regarding worker exposure; the most appropriate and effective way, on an EU-wide basis, to address worker exposure is to strengthen and implement revised occupational and biological exposure limits. The biological limit value (and the OEL) applies not just to workers using lead metal but also to those who might be incidentally exposed to lead in the course of their work, e.g., in demolition, in shipbuilding, repair and breaking, in the scrap industry, in installation and maintenance of lead-containing articles, and more. Therefore, from a regulatory effectiveness perspective the ongoing review of the existing EU binding biological and occupational limit values is key to reducing worker exposure on an EU-wide basis in all workplaces where employees may be exposed to lead in the course of their professional activities and will cover a much wider population that would be in scope of REACH Authorisation.

The companies represented in this response are committed to adopting best practice and continuous improvement in the management of occupational lead exposures. Most EU companies that manufacture lead metal, including those who recycle lead-based batteries, or produce lead batteries, are enrolled in long-standing voluntary exposure management programmes such as that administered by the International Lead Association (ILA) and EUROBAT (the European Association for Automotive and Industrial Battery Manufacturers). Enrolment in these Workplace Blood Lead Reduction Programmes is a condition of membership of the Trade Associations. The current blood lead target, established in 2017, is for no employee to have a blood lead level exceeding 20 µg Pb/dL blood. This target value is less than one-third of the existing EU binding biological limit value of 70 µg Pb/dL blood specified in the Chemical Agents Directive (now transposed to Directive 2004/37/EC). The ILA Voluntary Blood Lead Reduction Programme has resulted in significant reductions in lead exposures in employees working in lead metal manufacturing facilities. At the beginning of the ILA programme in 2013, nearly 2000 workers – i.e. 25% of all workers across ILA member companies – had a blood lead value exceeding 20 µg Pb/dL blood. By the end of 2020, less than 10% of workers in ILA member companies had blood lead levels exceeding the Industry voluntary target of 20 µg Pb/dL blood (Footnote 13).

Regarding other appropriate risk management options: Where unacceptable risk resulting from lead exposures has been identified, the EU has already adopted legislative measures to protect human health, including via the environment, and this work continues e.g. in regards the ongoing discussions on the proposed REACH Restriction for lead in ammunition and fishing tackle. Present regulatory restrictions on lead metal in articles include use in childcare articles and items which could be mouthed by children, toys, drinking water and food contact materials, jewellery, cosmetics, electronic and electrical equipment, household appliances, clothing, textiles and footwear, lead in copper, aluminium and steel alloys, passenger vehicles, and lead shot over wetlands, together with a general restriction under Annex XVII Entry 30 on the supply of lead metal as a substance or in a mixture to the general public. Moreover, the recent Commission Battery Regulation proposal also includes a provision for restricting substances where there is a risk identified during a battery's life cycle (covering 86-90% (Footnote 2) of the current volume of lead metal in scope of REACH Authorisation). These measures already encourage substitution, especially where technical and socio-economically viable alternatives exist.

In the case of lead, many of the potential alternative technologies use substances which have similar intrinsic hazards concerns (CMR), as seen in the battery industry. Such substitutions do not automatically bring an overall added-value for human health and the environment when the substance is already used safely. Alternative risk management options are, from this perspective, better suited for the task than REACH Authorisation Listing.

Should the existing lead-specific measures be deemed insufficiently effective, they should be strengthened within the existing regulatory framework, including non-REACH product-specific legislation, and properly enforced to ensure both cohesion of the internal market and competitiveness with non-EU actors.

If residual unacceptable risks remain about which ECHA, Member States or the European Commission are concerned, instead of a broad-sweep approach of recommending lead metal for inclusion in the REACH Authorisation List, additional targeted REACH Restrictions could be used. This would be more effective and proportionate – and moreover could also apply to imported articles, whereas REACH Authorisation itself would only impact EU production.

Regarding impact on the circular economy and end-of-life considerations objectives: A recommendation to include lead metal in REACH Annex XIV disregards the essential role it plays in the EU's ability to deliver policy objectives including Europe's Industrial Strategy, the European Green Deal, and the EU's Circular Economy Action Plan.

Lead plays an essential role in the European circular economy of other metals. The carrier metal properties of lead make it an efficient and effective enabler of high-tech recycling in the EU. The EU's non-ferrous metals recyclers can recover over 20 metals from post-consumer and industrial waste streams, including scrap, catalytic converters, e-waste, and other increasingly complex products at end-of-life (Footnote 14). In this way, lead is a key enabler in maintaining the value of materials and resources for as long as possible by returning them into the product cycle at end-of-life, helping to minimise waste.

As shown by the 'metal wheel' in the UNEP (2013) report (Footnote 15), the lead value chain is inextricably linked to the production of other valuable and critical raw materials – metals such as zinc, copper, tin, bismuth, indium, gold, silver, and platinum group metals – many of which contribute to future breakthrough technologies for a more sustainable economy. As the EU's ETN Socrates project has also highlighted (Footnote 16), lead has a fundamental role in delivering the circular economy and in urban mining, enabling the recovery and recycling of other critical metals and materials from electronics waste and other complex products: "lead metallurgy is fundamental if the EU wants to retain its leading position in the global circular economy".

With a quarter of the world's recycled metals already generated in Europe (Footnote 17), lead's unique metallurgy helps ensure the EU's continued global leadership role in the circular economy: the loss of lead metallurgy due to Authorisation Listing would remove a central process for Europe's multi-metallic recycling industry, making it less efficient and less competitive.

The closed loop circular economy of the EU lead battery value chains provides the raw materials needed locally to make new energy storage products, thereby limiting the potential for environmental exposure by keeping lead metal in the value chain and out of Europe's waste stream, indefinitely. Nearly all lead batteries that are available for collection are recycled in the EU by a comprehensive infrastructure of highly regulated facilities (Footnote 18). Every year, more than 100 million used lead batteries are kept out of the EU's waste stream by a value chain embracing circular economy principles and operating in a fully closed loop (Footnote 19). But without EU demand for lead, the 1.2+ million tonnes (Footnote 20) of lead being recycled every year in the EU would instead need to be discarded, somehow, as hazardous waste, or exported to non-EU countries to be used, mainly, for their own battery production. A significant reduction in lead demand driven by REACH Authorisation would also impact the EU economy: currently, approximately €2 billion worth of lead from recycled sources is used per year for EU lead battery production (Footnote 18).

2. Transitional arrangements

It is noted from Industry experience in other sectors, with other substances included in Annex XIV previously, that the feasibility of upstream Applications for Authorisation is often limited. Downstream users may also prefer, from a strategic business perspective, to make their own application instead of relying on the Application for Authorisation submitted by an upstream supplier.

How the industries using lead metal would coordinate Applications for Authorisation, in the event that it were included in REACH Annex XIV, has not yet been determined. However, it is envisaged that, in general, users – not lead metal manufacturers/importers – would submit Applications for Authorisation. In a recent survey (Footnote 21) carried out by ILA, just 14 out of 273 respondents indicated that they would expect EU suppliers to apply for upstream Authorisations for their downstream uses.

The breadth of industrial uses, particularly in the context of IU6 (Use of lead metal in the production of a range of lead articles), would result in thousands of Applications for Authorisation, if lead metal were included in REACH Annex XIV without exemption. The proportion of SME applicants across all industries applying for Authorisation would also be significant. In the battery value chain alone, a recent study by EBP (Footnote 22) concluded that almost 40% of companies in the European lead battery value chain are SMEs.

Per the ECHA document, "Setting Latest Application Dates - Practical implementation document for the Annex XIV entries approach" (Footnote 23), the high number of industrial sites using lead metal in the EU directly impacts the complexity of the EU supply chain and warrants a longer Latest Application Date.

The number of Applications for Authorisation would be increased considerably where users only applied for their own uses, not those of their downstream customers: for example, an alloy producer would apply for Authorisation to use lead metal in the formulation of alloys; each of his customers using those alloys to produce articles would apply for Authorisation to make the different (types of) article for different end-use applications.

During H1 2022, ILA carried out a survey of downstream users of lead. 273 responses were received from organisations representing a total of more than 27,000 legal entities, including 25 responses from EU associations representing in total more than 16,600 entities, and 219 responses from EU companies representing more than 4,850 entities in total. Respondents were asked to indicate the number of uses per legal entity that would require Authorisation, and the number of entities represented by the response. To estimate a reasonable worst-case number of AfA, a number of assumptions were made (Footnote 21).

Of the 273 responses received, 92 responses indicated that the 4,490-plus legal entities represented would apply for Authorisation.

Considering that not all entities represented in the survey responses would end up in applying for Authorisation, and analyses of activities may reveal some applications which would also not be in scope of Authorisation (e.g. uses of articles, intermediate uses, etc), a reasonable estimate of the number of AfA might be based on 50% of the entities represented applying for Authorisation, and half the number of uses initially considered relevant. In which case the survey responses suggest there could be between 1,200 and 8,000 AfA submitted for Pb metal. (For a more detailed assessment of the survey responses, please refer to Annex 3 to this response, submitted confidentially.)

Even if only half of the applications currently foreseen were realised, it could still result in more than 1,000 Applications for Authorisation for which RAC and SEAC opinions would be required, for which ECHA would need to provide secretariat services, and for which Commission decisions and REACH Committee votes would be required.

Adequate time and resources for the scientific committees and decision-makers to consider thoroughly each of those applications in full, and in consultation with relevant experts in the field, is essential in order to avoid regrettable substitution. Regrettable substitution is not only the substitution of a substance or a technology by an alternative which may pose similar or worse risks, but also the substitution by alternatives which are unsustainable from an energy consumption, sourcing, or resource efficiency standpoint, and those which shift or transfer the risk elsewhere. Adequate consideration is therefore especially important in regard to technical performance, hazard properties and exposure potential, and viability of any proposed alternatives – including from a resource demand vs supply perspective and considering the relative ability to supply sustainably, locally and from secondary sources – as well as any indirect consequences.

Per Article 58 (3), the number of substances included in Annex XIV and the transitional arrangements (i.e. the dates specified under Article 58 (1)) must both take into account ECHA's "capacity to handle applications in the time provided for". The extremely high number of Applications for Authorisation anticipated for lead metal is unprecedented – the substance with the highest number of applicants and highest number of uses so far being Chromium trioxide, with its 148 RAC and SEAC Opinions and 98 Commission decisions (Footnote 24). The processing of lead metal Applications for Authorisation would require significantly more resources at ECHA and its Committees, at the Commission, and of Member States. From an Industry perspective, a Latest Application Date of at least 30 months before the sunset date should be recommended, if ECHA decides to continue with a recommendation to include lead metal in Annex XIV; however ECHA should consider its own capacity and resourcing, and that of its committees of Member State representatives, for the anticipated number of AfA and define an appropriate transitional period.

3. Uses exempted from the authorisation requirement

The organisations represented in this response do not support the inclusion of lead metal in REACH Annex XIV as it would be a disproportionate and an inefficient risk management measure.

However, if ECHA were to make such a recommendation, we believe there are many uses that meet the criteria for exemption under REACH Article 58(2) in that:

-Existing "lead specific" Community legislation already addresses uses or categories of use to be exempted from the Authorisation requirement, and

-The existing legislation provides binding and enforceable minimum requirements relating to the protection of human health or the environment for the use of the substance, such that risks from the industrial use of lead are properly controlled.

As a minimum, exemption should be granted for all industrial activities in which exposure to lead is already managed adequately through the extensive existing lead-specific framework of EU legislation, and where there is already pressure for substitution as discussed in previous sections, including especially those applications covered by the RoHS and ELV Directives.

Annex 4 to this response lists key uses of lead metal currently exempted from restriction under the ELV and RoHS Directives.

We believe that other non-vehicular battery applications (e.g. motive and industrial batteries) in scope of the proposed Battery Regulation may in future also see pressure for substitution at least equivalent to REACH Authorisation through application of Article 6 and hence these will also be candidates for application of REACH 58(2) exemption from Authorisation.

Moreover, any use that is restricted to the industrial or professional workplace, with no potential for consumer exposure, that is already covered by existing lead-specific community occupational, health and safety legislation (currently being revised and improved) is also a candidate for a REACH Article 58(2) exemption. Examples include inter alia the use of lead in satellites and space vehicles, in renewable energy technologies such as PV panels and solar cells, as a chemical reagent, for recovery of other metals during recycling, in the production of inert lead anodes for electrowinning, electrogalvanising and chrome plating, as a tribological agent in the aerospace industry, in chemical vessels and pipework and for hazardous chemical transportation. Existing workplace legislation provides binding and enforceable requirements for the control of risks from industrial use of lead in the workplace. In having a binding occupational exposure and biological limit for lead and lead compounds, supported by additional measures such as medical surveillance, Council Directive 98/24/EC ensures that harmonised EU wide standards operate that constitute minimum requirements relating to the protection of health. The General Court Vecco ruling (T-360/13) supports the observation that for an industrial use the Chemicals Agents Directive (98/24/EC) includes a provision that drives substitution through its hierarchy of controls that requires replacement of dangerous substances by less hazardous ones (Article 6). Binding workplace exposure limits for lead and compounds are now regulated under Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work: the requirement for substitution of lead through the hierarchy of controls is now strengthened and clearly meets the criteria required to grant a REACH Article 58(2) exemption from Authorisation.

International Lead Association

Lead REACH Consortium

Annex 1: Lists of ILA and Lead REACH Consortium members

ILA members: https://ila-lead.org/new-members/

Full Members

APSM

Aurubis AG

Berzelius Metall

BMG Metall & Recycling

Boliden AB

BSB Recycling

Campine Recycling

Clarios (Europe)

The Doe Run Company

East Penn Manufacturing

Ecobat

Envirowales

Exide Technologies Recycling II, Lda

Exide Technologies SLU

Glencore

Gopher Resource

Gravita (Jaipur, India)

Gravita (Chittoor, India)

Hakurnas Lead Works Ltd

Hecla Mining

Jiangsu New Chunxing Resource Recycling Co., Ltd.

KCM SA

KGHM

Korea Zinc

Kovohute Pribram

Lundin Mining

Metallo Belgium N.V.

Moura

MPI Reciklaza

MR Umwelttechnik GmbH

Orzel Bialy

RSR North America

South32

STCM

Systems Sunlight

Teck

Terrapure Environmental

Associate Members

Association of European Manufacturers of Sporting Ammunition (AFEMS)

Batteriretur

Boab Metals Limited

Calder Industrial Materials

Coplosa SA

EnerSys

Engitec Technologies SpA

H. Folke Sandelin AB

Interstate Batteries

Midland Lead

PENOX GmbH

Traxys

W L Gore and Associates

Lead REACH Consortium members: https://ila-reach.org/the-consortium/members/

Full Members

5N Plus

Akdeniz Chemson

Akkumulatorenfabrik Moll GmbH

Anton Schneider Sohne GmbH

Asua Products SA

Aurubis AG

Aurubis Beerse nv

Azor Ambiental SA

BAE Batterien GmbH

Baerlocher GmbH

Banner GmbH

BASF SE

BMG Metall und Recycling GmbH

Boliden Bergsoe AB

Boliden Mineral

Britannia Refined Metals

Campine Recycling NV

Clarios Ceska Lipa spol. S.r.o

Clarios Iberia P&D S.L.

Clarios Recycling GmbH

Clarios VARTA Hannover GmbH

Clarios Zwickau GmbH & Co KG

Colorobbia Italia spa

COPLOSA, Sociedad Anonima

Derichebourg España SAU

ECOBAT Resources Braubach GmbH

ECOBAT Resources Estrées Saint Denis

ECOBAT Resources Freiberg GmbH

ECOBAT Resources Stolberg GmbH

ECOBAT srl

Ecometal Ltd

EnerSys Newport

EnerSys SARL

EnerSys Sp. zoo

EnviroWales

Exide Technologies GmbH (Deutsche Exide)

Exide Technologies Lda (SPAT)

Exide Technologies Recycling SL (Oxivolt)

Exide Technologies Recycling II Lda (Sonalur)

Exide Technologies SA (Centra)

Exide Technologies SA (Tudor)

Exide Technologies SAS (CEAC)

Exide Technologies Srl (Exide Italia)

Fenix Metals Sp. z o.o.

FIAMM Energy Technology S.p.A

Glencore Import BV

Glencore International Import BV

GS Yuasa Battery Manufacturing UK Ltd

Hammond Lead Products

Hakurnas

H J Enthoven Ltd

Hoppecke Batterien GmbH & Co KG

Huta Cynku “Miasteczko Slaskie”

IKA Innovative Kunstofoffaufbereitung GmbH

Jenox Akumulatory Sp. z o.o.

KCM 2000 SA

KGHM Polska Miedz SA

Kovohute Pribram Nastupnicka a.s

Metalblanc

Metal Processors Limited

International Lead Association

Lead REACH Consortium

Metalurgica de Medina SA

Midac S.p.A.

ML Operations Ltd

Monbat Recycling EAD

MPI Reciklaza d.o.o

NEW MECA S.r.l.

Nordenham Metall GmbH

Penox GmbH

Piombifera Italiana S.p.a.

Piomboleghe Srl

Portovesme Srl

PPUH Autopart Jacek BAK Sp z o.o

SC Rombat SA

SIA Industria Accumulatori Spa in liquidation

S.I.A.P. Sp. z.o.o

STCM-APSM

Systems Sunlight SA

TAB dd

Teck Resources Ltd

Traxys Europe SA

Umicore

Uzimet

Vellonton Ltd

Vipiemme SpA

Wilhelm Grillo Handelsgesellschaft mbH

Zap Sznajder Batterien s.a

ZM Silesia SA – Grupa Impexmetal

Associate Members

Association of European Manufacturers of Sporting Ammunition (AFEMS)

Annex 2: List of key uses of lead metal in the EU

Use of lead metal in the production of lead-based automotive and industrial batteries is the main application: EU battery production currently accounts for 86-90% of the use by volume.

Other smaller-volume industrial uses of lead metal include (in no particular order):

- Use as an alloying element in free-machining brasses, bronzes, steel, and aluminium alloys, including in the automotive sector under ELV Annex II exemptions and in sectors regulated by the RoHS Directive (2011/65/EU)
- Use in solder, e.g., in the case of electrical and electronic equipment, as permitted under exemption in the RoHS Directive
- Use in the production of inert lead anodes, articles which are used in for electrowinning and electrogalvanising processes, and in every chrome plating facility
- Use in sheathing of electric cables, e.g. for high-voltage export cables connecting renewable energy farms to the electricity grid
- Use as a chemical reagent in scientific research and development, including in fire assay for precious metals analysis
- Use in the production of radiation shielding, e.g. for medical, dental, veterinary, and non-destructive testing facilities, in nuclear medicine and in security applications
- Use of molten lead in closed systems, as a heat transfer agent e.g. in the nuclear industry
- Use as an industrial lubricant, e.g. in aerospace applications
- Lining of tanks/vessels/pipework in the chemical industry, e.g. for phosphoric acids, bromides
- Use as a chemical intermediate to make lead compounds, including in the battery production process
- Use in the production of architectural lead sheet, e.g. for weatherproofing, soundproofing and in earthquake protection
- Use in the production of ballast
- Use in the production of various cast and extruded articles such as weights and counterweights
- Use in the production of lead wool, primarily used as caulking to seal joints between lead and steel fittings in industrial settings, and also in specialist gas sensors
- Use in other galvanising processes such as hot-dip galvanising
- For steel wire patenting
- Use in the production of ammunition for hunting and sports shooting
- Lead also acts as (extraction) medium in recycling and precious metal metallurgical processes.

Professional uses of lead are limited to specific applications, e.g. reparative uses of lead solder in plumbing.

ILA and the Pb REACH Consortium and their members do not support the consumer use of lead as a substance or in a mixture, not least considering the REACH Restrictions imposed by Annex XVII, Entry 30.

Annex 3: Analysis of responses received in ILA AfA survey of downstream users

Executive summary

Between 15 February and 19 April 2022, ILA, as secretariat to the Lead REACH Consortium, carried out a survey to assess the number of Applications for Authorisation (AfA) that would be submitted if lead metal were included in REACH Annex XIV.

The online survey was distributed to downstream users via a Pb Metal Advocacy and Communications Taskforce ("Pb MACTF"), and to Lead REACH Consortium and Eurometaux members; a link was also posted on the Pb REACH Consortium's website[1].

273 responses were received directly by ILA, from organisations representing a total of more than 27,000 legal entities. Those responses included 25 from EU associations representing collectively more than 16,600 entities, and 219 responses from EU companies representing more than 4,850 entities.

Analysis of the responses received by ILA, and making an assumption of AfA submissions from just 50% of the entities indicating they would apply, and for half the number of uses initially considered relevant, indicates the potential **for between 1,200 and 8,000 Applications for Authorisation for lead metal**.

Analysis and discussion

Types of respondent

During the survey period, 15 February to 19 April 2022, 273 responses were received from organisations representing a total of more than 27,000 legal entities. Those responses comprised:

- 25 from EU associations collectively representing more than 16,600 entities,
- 219 from EU companies representing more than 4,850 entities,
- 29 from other organisations, collectively representing approximately 5,600 legal entities, such as EU lead metal manufacturing facilities, EU recycling federations, non-EU companies, a non-EU industry association representing suppliers of complex objects to EU and non-EU markets, and an EU museum.

Figure 1 presents the relative proportions of responses by type of respondent, and the number of entities represented by those responses.

As shown in **Figure 1**, 80% of the 273 responses were received from EU-based companies using lead metal as a substance, in an alloy, in an article, and/or in combinations of those options. However, by type of respondent, representation of the majority – 61% – of entities came from the 9% of responses provided by EU associations representing users of lead metal.

[1] https://ila-reach.org/

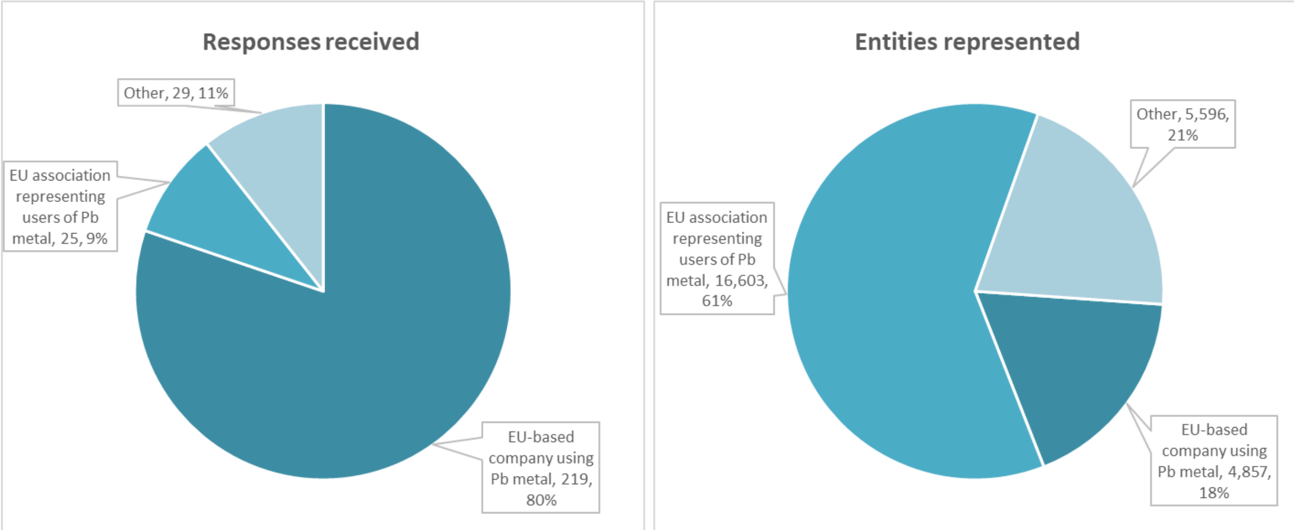


Figure 1 Types of respondent and number of entities represented

Indicative uses / market sectors

Figure 2 shows the sectors/applications indicated by respondents as relevant to them, either as suppliers to that sector and/or as actors within the sector. The blue bars indicate the number of responses which indicated that sector; the number of entities represented by those responses are shown by the red bars.

Note that the number of responses per sector/application, and similarly for the number of entities represented, is not additive, as multiple selections were possible and indeed made in many responses. Please also note the logarithmic scale on the horizontal axis.

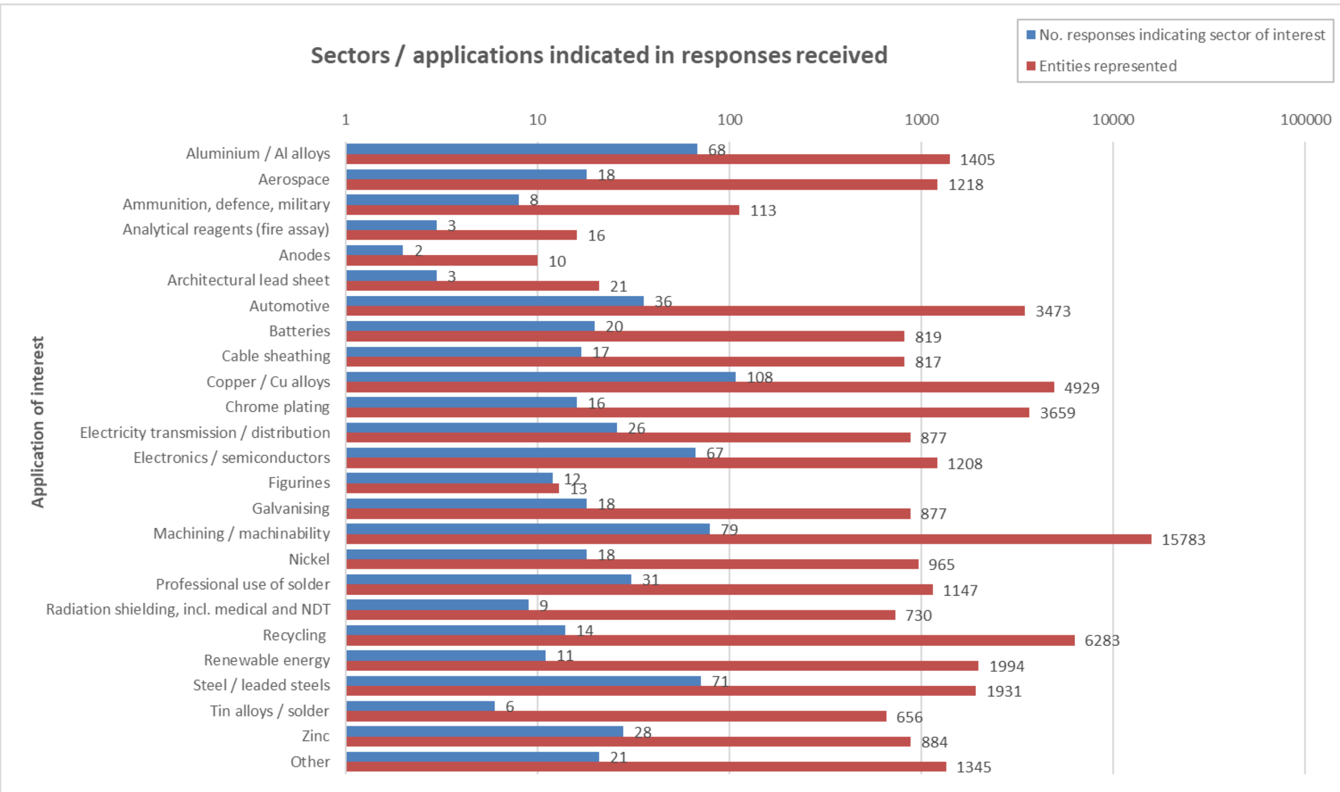


Figure 2 Sectors/applications indicated as relevant to the respondent

Forms of use of lead metal

12 of the 273 responses (representing at least 49 legal entities) indicated use of lead metal **as a substance**.

98 responses (representing at least 4,321 legal entities) indicated use of lead metal **in an alloy**.

73 responses (representing at least 3,979 legal entities) indicated use of alloys containing Pb **at concentrations in scope of REACH Authorisation**.

107 responses (representing over 16,750 legal entities) **cited use of lead metal in/as an article**, mainly in machining/mechanical engineering sectors and as anodes or as radiation shielding, with 24 of those responses (over 12,750 legal entities) citing use in/as articles exclusively.

In approximately **40% of cases**, respondents indicated the **use of lead metal in multiple forms** from the three options provided in the survey (as a substance, in an alloy, in/as an article). In the case of complex object assembly, as an example, producers may use lead-containing articles (components/sub-assemblies) as well as using lead as a substance/mixture (e.g. for soldering).

Availability of alternatives and substitution

67 out of the 273 responses received stated that **substitution was not possible** – **52 on technical grounds**, and 15 on economic grounds.

Of the responses indicating the potential for substitution, 73% indicated it would not be possible before 2028, and moreover the respondents could not state by when it would be possible.

Non-use scenarios

More than 40 responses (representing over 140 legal entities) indicated that they would **cease Pb-using processes in the EU**; some responses indicated that production of Pb-containing products would be relocated to non-EU locations, including those owned within corporate groups, where economically feasible.

36 responses (approximately 1,370 legal entities represented) indicated that they would **continue to look for alternatives**; where substitution to lead-free alternatives were not possible, companies would attempt to reduce the lead content below the threshold for Authorisation, or otherwise cease EU use.

14 responses (560 represented legal entities) indicated that, as downstream users, they would **urge or expect EU suppliers to apply for upstream Authorisations** for their downstream uses.

Although not specifically asked about prices, 38 responses indicated that their **prices would have to be increased due to higher costs** related to the use of alternatives and/or to cover the costs associated with applying for Authorisation.

Applications for Authorisation

Respondents were asked to indicate the number of uses (1, 2, 3-5, 6-10, more than 10) per legal entity that would require Authorisation and the number of entities they represented. To estimate a reasonable worst-case number of AfA, the following assumptions have been made:

-Where the number of entities represented has been quoted as “at least”, “more than”, or a range, the lowest value given in the response has been used; in the case of “many”, 5 entities was assumed,

-Where the number of uses was indicated as a range, the lowest number has been used,
-Each entity represented is assumed to apply for the (lowest) number of uses indicated in the response,
-Responses indicating use in alloys containing less than 0.3% w/w Pb, i.e. the Authorisation threshold for Pb-containing mixtures in massive form, have been excluded from the calculations.

With these assumptions in mind, of the 273 responses received by ILA;

- **92 responses indicated that the 4,490-plus legal entities they represent would apply for Authorisation**,
- 66 responses said they were not sure at this point in time,
- 41 responses indicated that the represented (10,690) legal entities at the time considered that they would not apply for Authorisation – however 28 of those responses (representing 10,150 legal entities) indicated they had at least one use which would require Authorisation.

Of the 92 'yes – would apply for authorisation' responses received by ILA, one might take a conservative approach and exclude any and all responses indicating use in/as articles. 55 responses, representing approximately 400 entities would remain, responses indicating that the entities use lead metal only as a substance and/or in alloys and that they would apply for authorisation. If all the entities represented in the 55 responses stating 'yes – would apply for authorisation' which indicated only substance/alloy use were to apply for Authorisation, the results of the survey indicate that **1,639 AfA could be submitted**.

However, this approach neglects ALL respondents who indicated use of lead both in a form subject to Authorisation (e.g. SnPb alloys used for soldering) as well as in/as articles (e.g. a mechanical part or an electronic component). One such respondent, a sector organisation representing approximately 400 additional entities, indicated that **80-85 applications for Authorisation should be expected from within that sector for soldering alone** – just one of the 20 or so uses in their industry – and that there could be **as many as 200 or more AfA for that one use in their sector**. Additional uses within the sector would also require AfA, and upstream suppliers to the sector would also need to apply for Authorisation.

If one were to include all 92 responses, but using that sector's own estimate of 200 AfA for that one use instead of multiplying the number of their entities with the number of uses per entity, the results of the survey suggest **a (reasonable) worst-case of more than 30,000 AfA**.

Clearly, not all entities represented would end up in applying for Authorisation, and analyses of activities may reveal some applications which would also not be in scope of Authorisation (e.g. uses of articles, intermediate uses, etc). However, the ILA survey was not exhaustive: there will be other stakeholders who would need to apply for Authorisation but who did not respond to the survey.

A more reasonable estimate of the number of AfA might be based on **50% of the entities represented applying for Authorisation**, and **half the number of uses initially considered relevant**. In which case the survey responses suggest:

- there **could be in the region of 1,200 AfA considering just the 55 substance/alloy use 'yes' responses**, whereas
- **considering all 92 'yes' responses**, where respondents indicated article and substance/mixture use, **would suggest in the region of 8,000 AfA.**

Annex 4: Key uses of lead metal currently exempted from restriction under the ELV and RoHS Directives

-List of key uses of lead metal currently exempted from restriction under the **ELV Directive**:

- Annex II 2(c)(i) Aluminium alloys for machining purposes with a lead content up to 0.4 % by weight
- Annex II 3 Copper alloys containing up to 4 % lead by weight
- Annex II 5(b)(i) Lead in batteries used in 12 V applications not included in entry 5(a) and entry 5(b)(ii)
- Annex II 5(b)(ii) Lead in batteries in high voltage systems that are used only for propulsion in M1 and N1 vehicles
- 8(a) - Lead in solder used in electronic circuit board applications
- 8(b) - Lead in solders in electrical applications other than soldering on electronic circuit boards or on glass
- (c) - Lead in finishes on terminals of electrolyte aluminium capacitors
- 8(d) - Lead used in soldering on glass in mass airflow sensors
- 8(e) - Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
- 8(f) - Lead in compliant pin connector systems
- 8(g) - Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages
- 8(h) - Lead in solder to attach heat spreaders to the heat sink in power semiconductor assemblies
- 8(i) - Lead in solders in electrical glazing applications on glass except for soldering in laminated glazing
- 8(j) - Lead in solders for soldering on laminated glazing

-List of key uses of lead metal currently exempted from restriction under **Annex III of the RoHS Directive**:

For Categories 1-7, and 10:

- Annex III 6(a)-I Lead as an alloying element in steel for machining purposes containing up to 0.35 % lead by weight and in batch hot dip galvanised steel components containing up to 0.2 % lead by weight, for categories 1-7 and 10
- Annex III 6(b)-I Lead as an alloying element in aluminium containing up to 0.4 % lead by weight, provided it stems from lead-bearing aluminium scrap recycling
- Annex III 6(b)-II Lead as an alloying element in aluminium for machining purposes with a lead content up to 0.4 % by weight
- Annex III 6(c) Copper alloy containing up to 4 % lead by weight
- Annex III 7(a) Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
- Annex III 15(a) Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of certain listed criteria applies
- Annex III 24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors,

For Categories 8 and 9 other than in vitro and industrial:

- Annex III 6(a) Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35 % lead by weight
- Annex III 6(b) Lead as an alloying element in aluminium containing up to 0.4 % lead by weight
- Annex III 6(c) Copper alloy containing up to 4 % lead by weight
- Annex III 7(a) Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
- Annex III 15(a) Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages
- Annex III 24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors,

For Categories 8 in vitro and 9 industrial:

- Annex III 6(a) Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight
- Annex III 6(b) Lead as an alloying element in aluminium containing up to 0.4 % lead by weight
- Annex III 6(c) Copper alloy containing up to 4 % lead by weight
- Annex III 7(a) Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
- Annex III 7(b) Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications
- Annex III 9(b) Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications
- Annex III 15 Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages
- Annex III 24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors
- Annex III 31 Lead in soldering materials in mercury free flat fluorescent lamps (which, e.g. are used for liquid crystal displays, design or industrial lighting)
- Annex III 33 Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers
- Annex III 37 Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body
- Annex III 41 Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines

For Category 11:

- Annex III 6(a) Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35 % lead by weight

- Annex III 6(b) Lead as an alloying element in aluminium containing up to 0.4 % lead by weight
- Annex III 6(c) Copper alloy containing up to 4 % lead by weight
- Annex III 7(a) Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)
- Annex III 7(b) Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications
- Annex III 9(b) Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications
- Annex III 15 Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages
- Annex III 24 Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors
- Annex III 31 Lead in soldering materials in mercury free flat fluorescent lamps (which, e.g. are used for liquid crystal displays, design or industrial lighting)
- Annex III 33 Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers
- Annex III 37 Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body
- Annex III 42 Lead in bearings and bushes of diesel or gaseous fuel powered internal combustion engines applied in non-road professional use equipment: —with engine total displacement ≥ 15 litres; or —with engine total displacement < 15 litres and the engine is designed to operate in applications where the time between signal to start and full load is required to be less than 10 seconds; or regular maintenance is typically performed in a harsh and dirty outdoor environment, such as mining, construction, and agriculture applications
- Annex III 44 Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council, installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users.

-Key uses of lead metal currently exempted from restriction under **Annex IV of the RoHS Directive**:

For Categories 8 and 9 other than in vitro and industrial:

- Annex IV 1 Lead in detectors for ionising radiation
- Annex IV 2 Lead bearings in Xray tubes
- Annex IV 3 Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate
- Annex IV 5 Lead in shielding for ionising radiation
- Annex IV 1a Lead in ion selective electrodes including glass of pH electrodes
- Annex IV 1b Lead anodes in electrochemical oxygen sensors
- Annex IV 1c Lead in infra-red light detectors
- Annex IV 11 Lead in alloys as a superconductor and thermal conductor in MRI
- Annex IV 12 Lead in metallic bonds to superconducting materials in MRI and SQUID detectors
- Annex IV 13 Lead in counterweights

- Annex IV 15 Lead in solders for bonding to ultrasonic transducers
- Annex IV 17 Lead in solders for portable emergency defibrillators
- Annex IV 18 Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm
- Annex IV 26 Lead in listed applications such as solders on circuit boards, and for connecting components, wires, cables, etc that are used durably at a temperature below – 20 °C under normal operating and storage conditions; lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C
- Annex IV 27 Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy
- Annex IV 29 Lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments
- Annex IV 31a Lead in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer
- Annex IV 37 Lead in platinized platinum electrodes used for conductivity measurements where at least one of the listed conditions applies
- Annex IV 39 Lead in micro-channel plates (MCPs) used in equipment where at least one of the listed properties is present,

For Category 8:

- Annex IV 1 Lead in detectors for ionising radiation
- Annex IV 2 Lead bearings in Xray tubes
- Annex IV 3 Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate
- Annex IV 5 Lead in shielding for ionising radiation
- Annex IV 6 Lead in Xray test objects
- Annex IV 1a Lead in ion selective electrodes including glass of pH electrodes
- Annex IV 1b Lead anodes in electrochemical oxygen sensors
- Annex IV 1c Lead in infra-red light detectors
- Annex IV 10 Lead in atomic absorption spectroscopy lamps
- Annex IV 11 Lead in alloys as a superconductor and thermal conductor in MRI
- Annex IV 13 Lead in counterweights
- Annex IV 15 Lead in solders for bonding to ultrasonic transducers
- Annex IV 17 Lead in solders for portable emergency defibrillators

- Annex IV 18 Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm
- Annex IV 27 Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy
- Annex IV 31a Lead in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer
- Annex IV 37 Lead in platinized platinum electrodes used for conductivity measurements where at least one of the listed conditions applies
- Annex IV 39 Lead in micro-channel plates (MCPs) used in equipment where at least one of the listed properties is present,

For Category 9:

- Annex IV 1 Lead in detectors for ionising radiation
- Annex IV 2 Lead bearings in Xray tubes
- Annex IV 3 Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate
- Annex IV 5 Lead in shielding for ionising radiation
- Annex IV 6 Lead in Xray test objects
- Annex IV 1a Lead in ion selective electrodes including glass of pH electrodes
- Annex IV 1b Lead anodes in electrochemical oxygen sensors
- Annex IV 1c Lead in infra-red light detectors
- Annex IV 10 Lead in atomic absorption spectroscopy lamps
- Annex IV 11 Lead in alloys as a superconductor and thermal conductor in MRI
- Annex IV 12 Lead in metallic bonds to superconducting materials in MRI and SQUID detectors
- Annex IV 13 Lead in counterweights
- Annex IV 15 Lead in solders for bonding to ultrasonic transducers
- Annex IV 17 Lead in solders for portable emergency defibrillators
- Annex IV 18 Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm
- Annex IV 26 Lead in listed applications such as solders on circuit boards, and for connecting components, wires, cables, etc that are used durably at a temperature below – 20 °C under normal operating and storage conditions; lead in solders of electrical connections to temperature measurement sensors in devices which are designed to be used periodically at temperatures below – 150 °C
- Annex IV 27 Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in (a) magnetic fields within the sphere of 1 m radius around the isocentre of

the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy

- Annex IV 31a Lead in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer
- Annex IV 37 Lead in platinized platinum electrodes used for conductivity measurements where at least one of the listed conditions applies
- Annex IV 39 Lead in micro-channel plates (MCPs) used in equipment where at least one of the listed properties is present.

Annex 5: List of references in main response

1. Data for 2020 not published but submitted by ILZSG in 2021 into a Eurometaux-commissioned study regarding metals and inorganic resources necessary for the Green Deal; the resulting *Metals and Clean Energy* report by KU Leuven was launched on 25 April 2022
2. "First Uses of Lead Metal in the EU", ILA (2021), attached to submission (NB volumes subsequently updated April 2022 based on clarified market data)
3. https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/ (last checked 21 April 2022)
4. https://ila-reach.org/wp-content/uploads/2022/02/Position-paper-Pb-metal-Authorisation-final_web.pdf (last checked 21 April 2022)
5. https://echa.europa.eu/documents/10162/17232/recom_general_responses_doc_en.pdf/ (last checked 21 April 2022)
6. https://echa.europa.eu/documents/10162/ad8e4db7-d1bb-ab21-68e5-cb4603b6e5ac (last checked 21 April 2022)
7. "Main first uses of lead and zinc in Europe", report by Oakdene Hollins report for the International Lead and Zinc Study Group, 2017
8. Mainly: batteries, other uses in vehicles in scope of ELV, uses in electronics/electrical goods in scope of RoHS
9. https://ec.europa.eu/docsroom/documents/5804/attachments/1/translations/en/renditions/pdf (last checked 21 April 2022)
10. https://industry.eea.europa.eu/analyse/pollutant (last checked 27 April 2022)
11. Pb EMISSION INVENTORY FOR THE ENVIRONMENT, Final report prepared for the Lead REACH Consortium, 22nd October 2021, Arche Consulting Ltd (not published) – *submitted as a confidential attachment*
12. De Brouwere, K., Verdonck, F., Geerts, L. et al. Assessment of human exposure to environmental sources of lead arising from the lead battery manufacturing and recycling sector in Europe: demonstration of a tiered approach in a case study. J Expo Sci Environ Epidemiol (2021). https://doi.org/10.1038/s41370-021-00395-5 (last checked 22 April 2022)
13. https://ila-lead.org/ila-member-companies-continue-to-deliver-reductions-in-employee-lead-exposures/ (last checked 27 April 2022)
14. https://leadmatters.org/circular-economy/ / https://www.umicore.com/en/about/recycling/
15. https://wedocs.unep.org/handle/20.500.11822/8423
16. https://etn-socrates.eu/socrates-press-release-on-the-importance-of-lead-metallurgy/ (last checked 21 April 2022)
17. https://www.eurometaux.eu/media/2005/full-report-8-56-17.pdf (last checked 21 April 2022)
18. https://chargethefuture.org (last checked 27 April 2022)
19. https://chargethefuture.org/#:~:text=on%20Europe's%20roads.-,SUSTAINABLE (last checked 21 April 2022)
20. Data for 2020 as submitted by ILZSG in 2021 to ongoing EM Green Deal Resources study (not published)
21. Analysis of responses received in ILA AfA estimation survey, ILA, April 2022 – *submitted as Annex 3, a confidential attachment*

22. Economic Contribution of the European Lead Battery Industry, EBP, 2021, https://ila-lead.org/wp-content/uploads/2022/02/Economic-Impact-of-European-Lead-Batteries_FINAL_02_24_22.pdf (last checked 22 April 2022)
23. https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf/ (last checked 21 April 2022)
24. https://echa.europa.eu/received-applications (last checked 16 March 2022)

Annex 6: First uses of Lead Metal

First Uses of Lead Metal in the EU

Background

To help RAC with the Article 77 (3)(c) request for classification and labelling of lead for aquatic hazards, the European Chemicals Agency RAC Committee has requested additional information on the first uses of lead metal in the EU. At the RAC-57 WG meeting that took place on 27th-28th April 2021, Industry reported that approximately 84% of the total volume of lead metal is used by the EU battery manufacturing industry to manufacture automotive and industrial lead batteries. The rolling of lead ingots to produce lead sheet represented in 2017 approximately 3% of the total volume. RAC therefore requested further information on the "unaccounted" 13% of total volume to better ascertain whether the reasonable handling and use of lead metal in massive form for these applications could result in the production of amounts of lead particles <1mm.

Information on First Use of Lead Metal in the EU

The latest figures available to the International Lead Association relate to production and use of lead metal in 2018. In this year approximately 1,500,000 tonnes of refined lead metal were produced (and used). This compares to a total global refined lead use of nearly 12,000,000 tonnes. In Europe, approximately 80% of the refined lead metal production is from recycled lead containing materials (mainly end-of life batteries).

As lead battery use dominates the sector there has been little effort made recently to undertake a mass balance to identify trivial uses. However, the International Lead Zinc Study Group (ILZSG), set up by the United Nations in 1959 to ensure transparency in the markets for lead and zinc worldwide, commissioned a Study by Oakdene Hollins in 2017 to identify the first uses of lead metal in the EU during the period 2005-2015. It concluded that uses of lead metal in all applications, except battery manufacturing, had reduced significantly over the ten-year period and by 2015 the approximate relative contributions of the known uses were as described in figure 1.

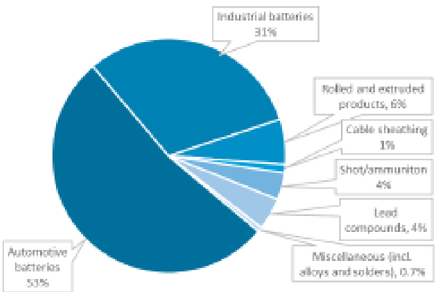
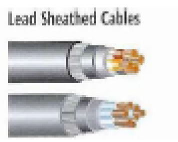


Figure 1: reported first uses of lead metal in the EU in 2015

International Lead Association

Use		Notes	Tonnes (ILZSG 2015 estimate)	Tonnes (ILA 2021 estimate)	Production
Automotive batteries			809,000	809,000	Lead metal used to manufacture battery plates/grids, posts (casting), and compounds used for paste
Industrial batteries			460,000	460,000	Lead metal used to manufacture battery plates/grids , posts (casting) and compounds used for paste
Rolled and extruded products		Lead sheet accounts for most of the lead used in this category with other uses including wires, tubes, weights foils, wools and specialist scientific equipment, representing approx. 5%	95,000	50,000 (there has been a rapid decline in the main application of lead sheet for use in buildings due to market substitution)	Produced by a rolling, casting or extruding process from lead ingots
Shot and ammunition		The hardness of lead shot is controlled through adding variable amounts of other metals including tin and antimony, forming alloys.	57,000	57,000	Lead shots produced by melting lead ingots and passing down a shot towers where lead solidifies into spheres >1mm.
Cable sheathing			18,000	20,000	Lead ingots extruded to produce coverings for undersea cables

Use		Notes	Tonnes (ILZSG 2015 estimate)	Tonnes (ILA 2021 estimate)	Production
Lead compound manufacture			68,000	20,000 (there has been a rapid decline in use of lead compounds due to substitution and restrictions in lead-based stabilisers that were the main market	Starting point is 99.985 % purity lead metal in ingots that will be melted in an agitated reactor and oxidised in an air atmosphere to form lead oxides. Lead oxides then undergo further chemical reactions to form other lead-based chemicals.
Alloys (including solders)		The principal use of lead as an alloying metal is in solders. This has significantly declined due to legislative controls.	10,000	5,000	Lead shot is used for alloying additions to brass, aluminium and other alloys. Lead is used to improve machinability, allowing higher cutting speeds and longer tool life. Potential to form particles of alloy (not lead) in machine shops finishing articles manufactured with the alloy

According to ILA's estimates, lead battery manufacturing in the EU is now expected to represent approx. 90% of the EU use of lead metal given significant declines in other markets such as architectural lead sheet, lead stabilizer and solder use due to combination of market substitution and regulation.
Apart from the cutting of lead sheet products and machining of articles made from alloys containing lead, that will both produce swarf's, we cannot identify any other uses of lead metal that would directly result in the production of lead particles <1mm.

International Lead Association, May-2021