Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

Lead

EC Number: 231-100-4
CAS Number: 7439-92-1

CLH-O-0000001412-86-260/F

Adopted

30 November 2018

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: lead
EC number: 231-100-4
CAS number: 7439-92-1
Dossier submitter: Denmark

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Belgium	European Copper Institute	Industry or trade association	1
Comment received				
The European Copper Institute welcomes the opportunity to provide its comments on the proposal for harmonized classification of lead as hazardous to the aquatic environment, authored by the Danish competent authority. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20171030_ECI comments on Pb ENV classification FINAL.pdf				
Dossier Submitter's Response				
See response to comment number 10				
RAC's response				
Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of the RAC mandate. For more details see response to comment number 19.				

Date	Country	Organisation	Type of Organisation	Comment number
26.10.2017	Germany		MemberState	2
Comment received				
The German CA supports the proposal to classify lead as aquatic acute 1 and aquatic chronic 1. And we also agree not to make any distinction in particle size for the environmental classification. Consequently both entries for lead should be amended accordingly. The exposure to lead by ingestion of spent ammunition, definably larger than 1 mm, poses				

hazard especially to wildlife (e.g. Watson et al. 2009; Haig et al. 2014, Green and Pain 2015)and is one of the main concern for the current restriction proposal of lead shot. Poisoning of scavengers such as the European White-tailed Sea Eagles (Haliaeetus albicilla) occurs from the ingestion of lead bullet fragments in discarded gut piles and fatally shot-and-lost animals (Krone et al. 2009; Helander et al. 2009; Nadjafzadeh et al. 2013).

It is also not reasonable to conclude that portioning to organic matter is similar to degradation as done in the registration dossiers. This view is short sighted - the sink i.e. lead bound to organic matter can become a source of lead again.

Furthermore, we noticed that more than 20 impurities are listed in table 7. Most of them in concentration ranges of 0-10 or 15 % (w/w). No typical concentration is provided. It seems to be likely that most of the impurities are present in concentrations much lower that 10 % (w/w), since metallic lead is a mono-constituent substance having a concentration of ≥ 80 % (w/w). If this is the case, the concentration range should be narrowed and a typical concentration given. Alternatively all impurities could be removed in accordance with CA/54/2017 document.

References:

GREEN RE, PAIN DJ (2015). Risks of health effects to humans in the UK from ammunition-derived lead. In: Delahay RJ, Spray CJ (eds). Proceedings of the Oxford Lead Symposium. Lead ammunition: understanding and minimising the risks to human and environmental health. Edward Grey Institute, The University of Oxford. pp 27-43.

HAIG SM, D'ELIA J, EAGLES-SMITH C, FAIR JM, GERVAIS J, HERRING G, RIVERS JW, SCHULZ JH (2014). The persistent problem of lead poisoning in birds from ammunition and fishing tackle. The Condor 116(3), 408-428. DOI:10.1650/CONDOR-14-36.1.

HELANDER B, AXELSSON J, BORG H, HOLM K, BIGNERT A (2009). Ingestion of lead from ammunition and lead concentrations in white-tailed sea eagles (Haliaeetus albicilla) in Sweden. Science of the Total Environment 407(21), 5555-5563.

KRONE O, KENNTNER N, TRINOGGA A, NADJAFZADEH M, SCHOLZ F, SULAWA J, TOTSCHEK K, SCHUCK-WERSIG P, ZIESCHANK R (2009). Lead poisoning in whitetailed sea eagles: causes and approaches to solutions in Germany. In: Watson RT, Fuller M, Pokras M, Hunt WG (eds). Ingestion of lead from spent ammunition: implications for wildlife and humans. The Peregrine Fund,Boise, Idaho, USA. pp 289-301.

WATSON RT, FULLER M, POKRAS M, HUNT W (eds) (2009). Proceedings of the conference ingestion of lead from spent ammunition: implications for wildlife and humans. The Peregrine Fund, Boise, ID, USA. https://www.peregrinefund.org/subsites/conference-lead/2008PbConf_Proceedings.htm

Dossier Submitter's Response

Thank you for your comments and support. With respect to the content of impurities reported we generally agree in the comments. The section on impurities has been taken from the human health dossier.

RAC's response

Thank you very much for your comments and support, the impurities issue is noted.

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2017	Austria	AMAG	Company-Manufacturer	3

Comment received

Highlights of the attached document:
I. Lead Content of secondary aluminium, scrap, dross and waste (see attachment) and the consequences (Seveso III directive, hazardous waste,...)
II. No diffentiation between powder form and massive form of lead and the comsequences
III. Impact on the European Aluminium industry
IV. Consequences of the classification in General
V. Lead in different EU directives

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 1710_Comment Pb to ECHA.docx

Dossier Submitter's Response

I.+ III. + IV. +V.
Socio-economic aspects are not included in the CLP, and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

II.
See response to point 4. in comment 9.

RAC's response

Thank you very much for your comments and suggestions, the socio-economic questions (I, III, IV, and V) are not in the scope of the RAC mandate.

Powder and massive form of lead (II)

The powder and "massive" forms do not exhibit different crystal structures or differences in important chemical/physical properties (*e.g.* the powder being explosive) and it is not unlikely that "massive" forms can produce powder-like particles. A brick or piece of lead could under "reasonably expected use" *e.g.* be melted; an example is casting of bullets and fishing weights at home. The metal can also be ground into smaller pieces or polished. Also there are, on the market, lead films with a thickness of only 25 µm, while the powder particles have a diameter around 75 µm. Such films are particularly used in connection with x-ray films and are employed in great amounts in industrial equipment and also by dentists, and can easily be worn into small fragments with a relative surface area greater than that of the powder particles, especially when disposed of. In fact, one mg of the film would have a greater surface area than one mg of the powder, and a T/Dp test with the film would produce greater concentrations of Pb in solution than the powder would.

Thus, there is no clear distinction between the "massive" form and the powder, and it is probable that "massive" lead will lead to lead particles in "powder" size which can enter the environment *e.g.* as dust or through industrial and other discharge to surface water directly or via sewage treatment plants.

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Austria	Wirtschaftskammer Österreich	Industry or trade association	4

Comment received

see document attached.

And a general remark to this form:
I was not able to clearly indicate "Type of organisation/institution:". There is no option for "public bodies". WKÖ is a public body and cannot be described by any of the options. The selected option "regional or local authority" was only the closest, but is not correct.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_189_StN CLH Blei.pdf

Dossier Submitter's Response

Wirtschaftkammer Österreich (WÖ) does not agree to one entry for the massive form and the powder.
They write: "Die Argumentation Dänemarks ist aus unserer Sicht nicht haltbar. Die Erfahrungen der Metallbranche zeigen, dass Blei derart genutzt wird, dass bei bestimmungsgemäßer Verwendung von Blei in massiver Form erwartungsgemäß keine pulverartigen Partikel erzeugt werden"

We would like to stress that there is no clear destinction between the massive form and the powder because there are, on the market, lead films with a thickness of only 25 µm, while the powder particles have a diameter around 75 µm. Thus 1 mg of such a film will have a greater surface area than 1 mg of powder.
See also response to comment 19.

WÖ writes:
"Weiters hält sich Dänemark bei der Ableitung des M-Faktors nicht an die geltende Leitlinie zur Anwendung der CLP-Kriterien. [siehe Seite 37 des Dossiers:
„In the current CLP guidance document the M-factor is set by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic) with a loading of 1 mg/L by the ERV. In our opinion this is a wrong methodology… "… the right thing to do would be to set the M-factor directly in relation to the ERV as for all other kinds of substances."
Diese Vorgehensweise ist strikt abzulehnen. Die CLP Leitlinie wurde nach jahrelanger Arbeit unter Einbeziehung aller EU-Mitgliedstaaten erstellt. Es ist nicht statthaft, dass sich ein einzelner Mitgliedstaat über dieses Ergebnis hinwegsetzt und einseitig abweichende Regeln aufstellt."

The cited section has been taken out of ist context, in as much as the dossier further down in fact takes account of the current guidance, and concludes that regardless of what you refer to the result will actually be the same.

We would also like to stress that the current CLP-guidance on setting M-factors for metals is not in accordance with the GHS (globally harmonized system for classification), which the CLP is supposed to implement.

WÖ writes:
"Dänemark hat bei der Ableitung von ERV (ecotoxicity reference value) und für die Einstufung Nicht-Standard Arten herangezogen."

Yes we also included information on non-standard species. We should like to refer to CLP, Annex I, section 4.1.1.2.2: "Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006.**"**

WÖ writes:
"Dänemark hat Test-Daten für einen an Daten reichen Stoff (Blei) statistisch nicht korrekt angewendet."

What do they mean by this?

WÖ writes:
"Dänemark hat es verabsäumt, ERVs abhängig von pH-Wert abzuleiten, wie dies für schwer lösliche Metalle angemessen wäre."

We should like to refer to the dossier, section 5.5:
"If data are available for both dissolution and toxicity at different pH levels the corresponding toxicity values and dissolution values at different pHs may be compared. In the current case the powder has only been tested in a full T/Dp test at pH 6.
Further, if we look at the two most sensitive species, *Lymnaea stagnalis* and *Ceriodaphnia dubia*, then *L. stagnalis* has been tested only in the pH interval from 7.1 to 8.6, and there is no indication of a correlation between pH and toxicity. In fact the correlation (Spearman rank) is $r_s = 0.000$ (but there are only 4 values covering the same life stage, effect type and test duration).
With *C. dubia* there are 39 EC_{10} or NOEC values for reproduction from 7 days tests, and the pH span is from 6.05 to 8.5. However there is a much stronger relationship between DOC and toxicity than between pH and toxicity. Without taking DOC and hardness into account the correlation between pH and EC_{10} or NOEC is $r_s = 0.237$, $P > 0.1$ (two-tailed), while for the relationship between DOC and EC_{10} or NOEC the correlation is $r_s = 0.335$, $P < 0.05$, without taking pH and hardness into account.
Thus, a comparison between the toxicity at different pH levels with the T/Dp test results at the same levels is not possible and as well not recommendable."

WÖ writes:
"Dänemark hat pH-relevante T/Dp-Daten inkorrekt angewendet"

What do they mean by this?

WÖ presents a number of socio-economic arguments.
However socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

RAC's response

Thank you very much for your comments and suggestions.
For more details see response to comments number 3 and 19.

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Belgium	The European Steel Association (EUROFER)	Industry or trade association	5
Comment received				
The European Steel Association (EUROFER) supports the submitted Eurometaux generic comments and the notion that the objective of classification should be to recognise the properties of metal alloys such as steel, as some of our material streams are not lead-free.				
Dossier Submitter's Response				
See response to comment 13				
RAC's response				
Thank you very much for your comments and suggestions. For more details see response to comment number 13.				

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	United Kingdom	International Lead Association; Lead REACH Consortium	Industry or trade association	6
Comment received				

A detailed set of comments and supporting information have been included as attachments to this submission.

Many years of scientific discussion initiated at the Commission Working Group on the Classification and Labelling of Dangerous Substances and continued after the enactment of the Classification, Labelling and Packaging Regulation has resulted in the development of an Annex to the Guidance on the Application of the CLP Criteria (ECHA, 2017) that describes classification strategies for metals and metal compounds.

The Danish harmonised classification proposal neglects or incorrectly interprets this guidance and the precedent established with other metals, including zinc and nickel metal, and more recently the approach taken in the CLH Annex XV dossier for some copper forms.

This Danish proposal is atypical in the following areas;
• non-differential classification of powder and massive forms of a metal;
• use of non-standard species for ERV (Ecotoxicity Reference Value) derivation and classification;
• inappropriate statistical treatment of test data for a data-rich substance;
• failure to derive pH dependent ERVs that are appropriate for a sparingly soluble metal
• incorrect application of pH related T/Dp data
• inappropriate selection of M-factors.

Whilst we agree with classification of lead metal powder as Aquatic Acute and Chronic 1 (M-factor 10), the approach taken by Denmark "that there is no distinction between massive and the powder" results in an extremely precautionary harmonised classification proposal for lead metal in massive (>1mm) form that is not warranted.

This proposal is not supported by knowledge of the reasonably foreseeable handling and use of lead in massive form. Moreover, it fails to use the available scientific evidence on transformation/dissolution (T/Dp) on lead in massive form presented in the REACH Registration dossier to apply the classification strategy available as Annex IV in the

Guidance on the Application of the CLP Criteria (ECHA, 2017).

We appreciate that there are ongoing discussions concerning the application of rapid removal of metals from the aquatic environment (through application of the TICKET Unit World Model) for classification and labelling purposes. Considering the lack of scientific consensus, as noted in the CLP guidance (section IV.3), we agree not to apply this concept at this time. However, we would like to note that the CLP classification conclusion presented in the REACH joint registration dossier for lead in massive form is not changed by this decision, i.e., it should NOT be classified as hazardous to the aquatic environment as proposed in the Danish Annex XV dossier.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ILA, PbRC - public attachments - contains 3 files.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Final_Report_Pb_massive_pH8_20_10_2017.pdf

Dossier Submitter's Response

See response to comment number 19

RAC's response

Thank you very much for your comments and suggestions. For more details see response to comment number 19.

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Germany	WirtschaftsVereinigung Metalle (WVMetalle)	Industry or trade association	7

Comment received

A broad variety of Members of WVMetalle are producers of lead metal and abroad variety of lead containing alloys. The mixture rules foresee that mixtures - be it in the form of a powder or a massive alloy - containing as low amounts of lead as > 0.025% will obtain Aquatic Chronic 3 classification. Mixtures containing > 0.25% lead will obtain Aquatic Chronic 2 classification. As downstream legislation often rely directly on this classification the consequences are extremely relevant for our industry. For example the SEVESO directive and transport regulations are triggering additional requirements which are increasing administrative burdens, costs and measures which are not justified by the intrinsic properties of lead metal, especially when it comes to massive alloy parts.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-10-30_WVMetalle commenting on Pb env classification.pdf

Dossier Submitter's Response

Socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

It is possible to directly test alloys, including T/D, to get a more precise estimation of the hazards.

RAC's response

Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of the RAC mandate.
It is possible that lead alloys shouldn't be classified. They can be tested according to the T/Dp protocol. Furthermore, alloys need not be labelled if they do not pose a risk to human health or the environment.

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	Austria	Austrian Non-Ferrous Metals Association	Industry or trade association	8

Comment received

Die harmonisierte Einstufung von Blei in massiver Form hat weitreichende Konsequenzen. Sie betrifft nicht nur die Bleibranche als solche, sondern reicht viel weiter und trifft auch andere Metallbranchen, weshalb wir den Vorschlag als sehr kritisch sehen.

Metalllegierungen (dies sind Gemische) sind ebenso für die Umweltgefahr entsprechend einzustufen, wenn die Konzentration von Blei in der Legierung die vorgeschriebenen Grenzwerte übersteigt (≥0.025% für die Einstufung als aquatisch chronisch 3 und ≥0,25% für die Einstufung als aquatisch chronisch 2 – siehe Annex 1 der CLP-VO, Tabelle 4.1.2). Die Einstufung würde insbesondere Legierungen aus Aluminium oder Kupfer betreffen, aber auch andere Metalle.

Die Einstufung würde vor allem Recyclingunternehmen negativ treffen. Ein großer Teil der Metalle in Österreich und der EU wird auf Schrottbasis („Sekundärmetallproduktion") erzeugt. Der Anteil von Blei in Metallschrotten variiert; in den meisten Fällen enthalten aber z.B. Aluminiumschrotte mehr als 0.025% Blei, sodass sich daran die Einstufung als aquatisch chronisch 3 knüpfen würde.

Schrottverfügbarkeit ist eine Grundbedingung für das Funktionieren der Recyclingwirtschaft. Wenn künftig weniger Schrott verfügbar sind, weil mit Blei verunreinigte Schrotte nicht mehr eingesetzt werden, kann es zu Verknappungen des Einsatzmaterials kommen und damit zu einer Gefährdung der Produktion und Verteuerung der Kosten.

Negative Konsequenzen ergeben sich insbesondere aufgrund des Zusammenspiels von Chemikalien- und Abfallrecht:
• Die Neueinstufung wirkt sich aufgrund des Anhang III der Abfallrahmenrahmen-richtlinie auch auf Abfälle aus (vgl. HP-Kriterien). Dadurch sind derartige Abfälle und solche, welche Blei oberhalb der erlaubten Limits enthalten, als gefährlicher Abfall zu deklarieren.
• Dies wirkt sich negativ auf den Beschaffungsprozess von Recyclingunternehmen (insbesondere grenzüberschreitende Abfallverbringung) und auf die Behandlungsanlagen aus (Behandlung gefährlicher Abfälle; IPPC; Anlagengenehmigung, usw.).
• Weiters sind durch die Behandlung von gefährlichen Abfällen bestehende Genehmigungen nach der Gewerbeordnung nicht mehr ausreichend und es müssen die Anlagen nach dem strengeren Abfallwirtschaftsgesetzt neu genehmigt werden oder auch die strengen Vorgaben der Seveso III-Richtlinie eingehalten werden.
• Voraussichtlich hat diese Einstufung auch negative Auswirkungen auf das Erreichen des Abfallendes (vgl. Verordnung (EU) Nr. 715/2013), was demnach nicht mehr erreichbar sein könnte.
• Insgesamt ist zu befürchten, dass Produkte, deren Vormaterial als „umweltgefährdend" eingestuft wurde, vom Markt nicht nachgefragt und daher in Europa nicht mehr erzeugt werden. Importe von Billigerzeugnissen aus dem EU-Ausland, welche dort unter mitunter fragwürdigen Bedingungen hergestellt wurden, könnten die Folge sein.

Der Vorschlag steht somit nicht im Einklang mit dem EU-Ziel einer funktionierenden Kreislaufwirtschaft. Ein Zielkonflikt besteht aber auch zu dem Energieeffizienzziel der EU: denn bei der Herstellung von Metallen auf Recyclingbasis (Sekundärproduktion) bis zu 95% Energie im Vergleich zur Primärherstellung eingespart werden kann. Ebenso werden dabei im gleichem Ausmaß auch CO2-Emissionen im Falle der Sekundärmetallgewinnung (im

Vergleich zur Primärherstellung) eingespart.

Letztlich führt eine Behinderung der Recyclingwirtschaft auch zu einer Schwächung der Wettbewerbsfähigkeit in Europa.

Unsere Forderungen

Hinsichtlich der vorgeschlagenen harmonisierten Einstufung von Blei-Metall für die Umweltgefahr fordern wir:
• von einer harmonisierten Einstufung von Blei in massiver Form für die Umweltgefahr abzusehen und
• die harmonisierte Einstufung auf Blei in Pulverform als Aquatisch Akut und Chronisch 1 (M-Faktor 10) zu beschränken.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 171027 harmonisierte Umwelt_Einstufung von Blei Metall.pdf

Dossier Submitter's Response

Socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

See also response to comment number 4.

RAC's response

Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of RAC mandate.
For more details see response to comment number 4.

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	Belgium	European Aluminium	Industry or trade association	9

Comment received

1.About European Aluminium

European Aluminium, founded in 1981, is the association that represents the whole value chain of the aluminium industry in Europe.
We actively engage with decision-makers and the wider stakeholder community to promote the outstanding properties of aluminium, secure growth and optimise the contribution our metal can make to meeting Europe's sustainability challenges.
Through environmental and technical expertise, economic and statistical analysis, scientific research, education and sharing of best practices, public affairs and communication activities, European Aluminium promotes the use of aluminium as a permanent material that is part of the solution to achieving sustainable goals, while maintaining and improving the image of the industry, of the material and of its applications among their stakeholders.

2.Context

European Aluminium and its members would like to outline the impacts in the European aluminium industry of the proposal for a harmonized environmental classification and labelling of lead metal (CAS Number 231-100-4, EC Number 7439-92-1), submitted by the Danish Environmental Protection Agency on the 16th of February 2017, based on Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). According to this proposal, lead will be classified as:

- Aquatic acute 1; H400: very toxic to aquatic life with an M-factor of 10.
- Aquatic chronic 1; H410: very toxic to aquatic life with long lasting effects with an M-factor of 10.

3.Implications for the aluminium industry

Alloys are considered to be mixtures for the purposes of CLP Regulation. The classification of mixtures for long-term hazards, based on the summation of the concentrations of classified components, is summarised in Table 4.1.2 of Annex I to CLP Regulation. Applying the formulas set in this table, the classification of lead as aquatic chronic 1 with an M-factor of 10 will trigger the environmental classification of aluminium alloys containing lead as follows:

- Aluminium alloys containing lead in a concentration ≥ 0.025% shall be classified as aquatic chronic 3.
- Aluminium alloys containing lead in a concentration ≥ 0.25% shall be classified as aquatic chronic 2.

The classification of aluminium alloys as aquatic chronic 2 would trigger further consequences:

3.1. Aquatic chronic 2 substances and mixtures are covered by Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III Directive):

3.1.1.Annex I to Seveso III Directive sets out the qualifying quantities of dangerous substances for the application of lower-tier and upper-tier requirements. For the particular case of aquatic chronic 2 substances or mixtures these quantities are 200 and 500 tons, respectively.

3.1.2.Therefore an establishment where 200 tons of aluminium alloys containing lead in a concentration at or above 0.25% (hence classified as aquatic chronic 2) are present will be in the scope of Seveso III Directive.

3.2. At the end of their lifetime, products made of aluminium alloys containing lead in a concentration at or above 0.25% will become hazardous waste:

3.2.1. Council Regulation (EU) No 2017/997 lays down conditions to classify a waste as hazardous by HP14 "ecotoxic". According to this Regulation, waste which contains lead in a concentration at or above 0.25% shall be classified as hazardous.

3.2.2. Out of the scope of the End of Waste Regulation:

3.2.2.1. Council Regulation (EU) No 333/2011 establishing criteria determining when certain types of scrap metal cease to be waste (End of Waste Regulation) is applicable, among others, to aluminium scrap that does not display any of the hazardous properties listed in Annex III to Directive 2008/98/EC.

3.2.2.2. Therefore, aluminium scrap containing lead at or above 0.25% will be out of the scope of the End of Waste Regulation.

4. Technical aspects

4.1. No distinction between massive and powder form

The proposal does not provide for a distinction in the classification of the massive form and the powder form of lead. Both forms are classified with an M-factor of 10.

The proposal presumes that the massive form could lead to particles in the powder range. However, the experience in the aluminium industry shows that the melting process of scrap and the manufacturing of recycled aluminium alloys does not produce particles.

The final product, the aluminium ingot, will not produce particles due to handling.

Therefore it is not probable that massive forms of aluminium alloys containing lead can produce powder-like particles under reasonably expected use.

4.2. Biological availability

Article 12 of CLP Regulation states that, for the purposes of classification, it shall be taken into account if conclusive scientific experimental data show that the substance or mixture is biologically available.
The solubility of a substance increases with decreasing particle size; however, the proposal does not take into account the different biological availability of the metal form.

Alloys represent a specific case of materials which require more information as they show disparate intrinsic properties compared to their individual metal constituents. A number of metallurgical factors can affect metal release, such as crystal structure, inclusion in a matrix, density… in addition to physical form and shape.

Bio-elution refers to the in vitro extraction methods used to measure the degree to which a substance or metal ion is released into artificial biological fluids.

European Aluminium has performed some in vitro tests in order to measure and evaluate the degree to which lead ion is released from aluminium alloys.
The tests were performed using massive lead as the reference substance and aluminium alloys containing lead in different concentrations.

These tests have demonstrated that the migration of lead ions from aluminium alloys is much lower than the migration of lead ions from massive lead metal.

It can be concluded that the migration of lead ions is reduced when the lead is contained in a metallic matrix. Therefore, the biological availability of lead from aluminium alloys is very limited.

5.Current situation of the European aluminium industry

Europe is a world leader in aluminium recycling, providing products to automotive, building, packaging, aerospace and engineering solutions sectors.
Today, more than 90% of recycled aluminium alloys produced in the EU contain lead above 0.025%. Therefore, these alloys will be classified as aquatic chronic 3.

In addition, in some EU regions more than 80% of recycled aluminium alloys contain lead in the range of 0.25% – 0.40%. Therefore, these alloys will be classified as aquatic chronic 2 and will be subject to the provisions explained above.

Lead cannot be economically separated from aluminium alloys or removed during the scrap processing or secondary refining due to the high reactivity of aluminium compared to that of lead.

In order to produce secondary aluminium with a lead content below 0.025%, recyclers would need to dilute the scrap with high purity aluminium or with primary metal. This would increase the cost of production and companies would lose profitability. The cost estimated is 200 – 300 €uro/ton (it can differ depending on the facility).

The aluminium recycling industry is essential for the European economy because allows the recycling of end of life aluminium scrap in order to produce new materials with energy savings up to 95% compared to the production of primary aluminium. The emission of greenhouse gases are reduced in the same amount.

Recycling aluminium contributes to the decarbonisation of Europe and to the achievement of resource efficiency goals. This makes the aluminium recycling industry a key contributor for a true circular economy in the EU.

6.Consequences of the proposed classification

The proposed classification will have a severe impact on the recycling businesses operating in Europe. The main consequences of the proposed classification of lead for the aluminium recycling sector are:

- Decrease in market demand for recycled aluminium. The products classified as aquatic chronic will have more difficulties to be absorbed by the market and will suffer from higher and unbearable production costs. This will jeopardise the entire aluminium recycling industry. It would be expected that the European recycled aluminium industry lost orders and, as a consequence, became less competitive.

- Increase in imports. It is expected that articles containing parts made on aluminium lead alloys above the listed concentration limits will be imported from outside the EU borders; this is, the manufacturing processes of finished goods will move to areas outside EU and then export the products back to the EU.

- Dependency on imported primary aluminium. As stated above, companies would need to dilute aluminium scrap with high purity aluminium or with primary aluminium in order to reduce the concentration of lead in their products. As European smelters are already running at full capacity, this will lead to need of import aluminium from non-EU regions.

- Increase in export of scrap. It is foreseeable that the aluminium scrap containing lead at or above 0.025% will be exported outside Europe's borders. This will hinder the aluminium sector's efforts to increase scrap availability and limit scrap leakage.

- Increase in landfilling in the EU. The additional costs implied to scrap treatment can lead to landfilling. This would generate a loss of an essential resource as an "energy bank" for the sector and for Europe as a whole and will not bring any net benefit to the EU environment.

- Companies granted environmental permits for end of waste criteria cannot process hazardous waste. The change of classification from non-hazardous to hazardous waste will impact the current environmental permits of the plants treating aluminium scrap according to the end of waste criteria. It would not be possible to apply the end of waste criteria, which is widely applied in the Italian market, and consequently it will be necessary to apply for an authorization for the recycling of hazardous waste.

- Higher operational costs. Higher transport cost, specific storage area and more complex

shipment permit.

- Higher administrative costs. Applying for an authorization to treat hazardous waste is usually more complex and expensive than the procedure to treat non-hazardous waste.

- Higher costs for labelling and packaging. The final product will need to be labelled and packaged according to the new classification.

It can be concluded that the proposed classification:

- will have a serious impact on the recycling businesses operating in the EU and therefore in the circular economy roadmap
- will not bring any net benefit to the environment
- will hamper other EU key goals, especially in the fields of: resource efficiency, recycling targets, financial and administrative burden on Small and Medium Enterprises (SMEs), competitiveness and employment.

7. Provisions on lead in other EU directives

The following EU directives set limits for the concentration of lead in aluminium alloys:

7.1. Directive 2000/53/EC on end of life vehicles.
- Objective. This Directive lays down measures which aim, as a first priority, at the prevention of waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of life vehicles and their components so as to reduce the disposal of waste, as well as at the improvement in the environmental performance of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-of life vehicles.
- Exemption 2(c): Aluminium with a lead content up to 0.4% by weight.

7.2. Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive).
- Objective. This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.
- Exemption 6(b): Lead as an alloying element in aluminium containing up to 0.4% lead by weight.

The common purpose of these EU directives (end of life vehicles and RoHS) is to ensure a high level of protection of human health and the environment.

These directives set limits for the concentration of lead in aluminium alloys containing lead. As seen, this limits exceed the value of 0.025% which will trigger the aquatic chronic 2 classification of aluminium alloys containing lead.

8. Further provisions on lead

8.1. Directive 94/62/EC on packaging and packaging waste.
- Objective. This Directive aims to harmonize national measures concerning the management of packaging and packaging waste in order, on the one hand, to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade

and distortion and restriction of competition within the Community.
- The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium shall not exceed 0.01%.
- This provision is applied in aluminium "can to can" recycling. It is possible to keep such low level of lead due to the scrap coming from one source: cans which are re-melted into cans again. This cannot be achieved in case of other scrap sources as they contain more than 0.025%.

8.2. CEN harmonized standards:
- EN 601:2004 (Chemical composition of castings for use in contact with foodstuff)
- EN 602:2004 (Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuff)
- Lead content in aluminium alloys used for food contact materials: 0.05%

9. Conclusions

The European aluminium industry has demonstrated its strong and voluntary commitment to delivering best in class performance in terms of environmental sustainability and protection of human health and safety.

The aluminium recycling industry is an important industry in Europe, which contributes to the decarbonisation of Europe and to the achievement of resource efficiency goals.

The proposal for a harmonised environmental classification of lead metal would lead to a further loss of competitiveness of the European aluminium industry in a context already characterized by an uneven global playing field, shortage of raw materials, increasing dependency from third-countries imports, plant closures and job loss.

For these reasons, European Aluminium and its members call for a careful consideration of the proposal for harmonised classification and labelling of lead in the massive form as aquatic acute 1 and aquatic chronic 1.

European Aluminium remains at ECHA's disposal to further assess the implications of such a measure on the aluminium recycling industry.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LEAD - proposal for environmental classification.pdf

Dossier Submitter's Response

3.+5.+6.+7.+8.
Socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

4.
See response to comments from the International Lead Association (Comment number 19).

It might well be that Al-alloys shouldn't be classified. That can be tested with T/D testing. Further, according to Article 23 and Annex I, section 1.3.4 alloys need not be labelled if they do not pose a risk to human health or the environment.

Bioelution is not relevant for the assessment of environmental hazard as this concept addresses human health, and the concept of bioelution has not gained regulatory acceptance at this stage. There is, so far, no concensus concerning the methodology and no standardised test methods to

assess bioelution for bioavailability assessment.
RAC's response
Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of the RAC mandate. 4. For more details see response to comment number 3. It is possible that lead alloys shouldn't be classified. They can be tested according to the T/Dp protocol. Furthermore, alloys need not be labelled if they do not pose a risk to human health or the environment. (Guidance on the Application of the CLP Criteria Version 5.0,2017, Annex IV, section IV.5.6.1).

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Belgium	European Copper Institute	Industry or trade association	10
Comment received				
For the technical aspects of the classification proposal, we refer to the comments by the International Lead Association and by Eurometaux. Specifically, we would like to reinforce the need for correctly applying the CLP regulation and its guidance to derive the environmental hazard classification. This includes a distinction between powder and massive forms, correctly derived ecotoxicity reference values, considerations on data-rich substances, and the use of transformation-dissolution data. Additionally, we note that "rapid degradation" is a concept embedded in the CLP regulation, but guidance is currently lacking on how to apply it to inorganic substances. This hampers a correct assessment according to the provisions of the CLP regulation. The proposed classifications for lead metal will have serious and direct implications for the European copper industry. The mixture rules dictate that mixtures (powder or massive forms) containing trace amounts of lead (above 0.025%) will obtain Aquatic Chronic 3 classification. Mixtures containing more than 0.25% lead will obtain Aquatic Chronic 2 classification, which has far-reaching consequences, including the SEVESO directive and transport legislation. In the EU, there is an annual demand of approximately 1.3 million tonnes for copper in the form of alloys (data 2016). This market is being threatened by the present proposal. In "lead-free copper alloys", lead is present as an impurity at concentrations between 0.02 and 1%. The impurity level is, for each alloy family, the result of years of industry investigation and development to reuse and recycle valuable raw materials. For several other applications, lead is added up to 3.5% for functional reasons. A preliminary analysis highlights the following areas where direct impacts can be expected: 1. The sites of many copper semi-fabricators will fall under the SEVESO Directive. This will directly lead to increased administrative burdens and safety measures, including e.g. additional monitoring of process and storage facilities, additional storage capacity, and containment infrastructure. 2. Serious increases in transportation costs of lead-containing mixtures, such as copper alloys, are foreseen. Mixtures containing > 0.25% lead (even in massive form) will obtain "Dangerous good - Class 9" status under UN transport regulations. This triggers additional requirements, including training of every person involved in transport, appointment of safety advisors, safety precautions when loading or unloading, reduced choice of shipping				

companies, and increased insurance fees. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20171030_ECI comments on Pb ENV classification FINAL.pdf
Dossier Submitter's Response
See response to comments from the International Lead Association (Comment number 19). **Socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.**
RAC's response
For more detail please see response to comment number 19.

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Belgium	The European Steel Association (EUROFER)	Industry or trade association	11
Comment received				
Please refer to Eurometaux comments for a detailed response.				
Dossier Submitter's Response				
See response to comment 13				
RAC's response				
Thank you very much for your comments and suggestions, for more details see response to comment number 13.				

Date	Country	Organisation	Type of Organisation	Comment number
26.10.2017	Germany		MemberState	12
Comment received				
The German CA supports the proposal.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for your support.				

Date	Country	Organisation	Type of Organisation	Comment number
25.10.2017	Belgium	Eurometaux	Industry or trade association	13
Comment received				
Eurometaux's comments on the CLH proposal for Pb metal (EC number: 231-100-4; CAS n° 7439-92-1) Eurometaux usually refrains from reacting to substance-specific public consultations in respect to REACH or CLP. However, in the context of the proposal submitted by Denmark for a harmonised environmental classification of lead metal, Eurometaux would like to raise some concerns related to conceptual aspects and the application of the metals CLP guidance. Indeed, several elements in the proposal appear to be neither in line with the				

specific metals' environmental classification guidance (CLP Annex IV), nor with practices used for other data rich metals classified in the past following the CLP guidance. These aspects are therefore highly relevant to the broader metal and inorganic sectors, hence Eurometaux's comments supported by its members.
The comments and suggestions reported hereunder are all of a conceptual nature covering:
1) Generic classification concepts for metals;
2) Guidance and practices for data rich metals;
3) Specific classification rulings for metals, and
4) Conclusions.

1. Generic classification concept for metals
Massives versus powders:
Both the GHS and CLP foresee specific ruling and guidance for metals and metal compounds. An important deviation to the generic ruling for organic substances is that the legal text foresees separate classification entries for massive and powder forms. This provision was introduced based on the concept that the release/surface is a physical constant for metals and therefore an intrinsic property, as is the toxicity of the soluble ion. For the time being the number of entries was limited to two: the massive (default of 1 mm) and the powder form (relevant finest powder form on the market).
However, the possibility to use two entries was conditional to:
- Both forms being produced in a different way (i.e. that the powder is not produced by milling the massive form)
- Normal handling and use of the massive form not resulting in relevant amounts of fine particles
- The dissolution kinetics of the two forms differing to such an extent that they result in a different environmental classification category or M factor for each form.
This approach has been successfully applied in the past for metals such as nickel, zinc and, more recently, some metallic copper forms.
Under REACH, the burden of proof is with the registrant who has to demonstrate that the data set fulfils these three criteria.
We noted from the registration file on lead metal that all three conditions are fulfilled given:
- Lead sheet and ingots are produced in a separate way to the powder forms (no milling involved)
- Lead is a very malleable material (like zinc), which means that the sheets are cut in slabs and the ingots are melted. Therefore they do not generate fine particles in relevant amounts. This is a concept that has been debated and accepted in the past for other metals
- The dossier contains Transformation Dissolution (TD) data for both forms including clearly distinctive dissolution kinetics. While "full TD tests" (e.g. 28-day test results) (OECD 29) were not available in the Registration file; the tests that were provided already show a clear and decisive difference.
The standard release per surface means that larger forms (e.g. massives) would release significantly less than smaller forms (e.g. powders), which was the driver for the UN and the EU to distinguish the two entries if the conditions as listed here above, are fulfilled. The Dossier Submitter uses this reasoning ("the two forms are not different physically or chemically, apart from the particle size and the fact that the solubility of a substance increasing with decreasing particle size"), to reject the concept of the two entries. This is clearly contrary to the agreement reached at the time, which resulted in specific GHS and CLP legal texts and therefore constitutes in principle a breach of the legal provisions applicable to the metals environmental classification assessment.
Quantitative evidence for these conclusions is available in the registration dossier and complemented by a technical submission by the lead sector under this Public Consultation.
The metal sector cannot accept that the Dossier Submitter rejects the legal right of the registrant to have two entries, based upon "an assumption" that the use of the massive

form generates fine particles without providing any evidence base for this and the reasoning that no full Transformation Dissolution test is available. This proposal is in our view not in line with the law and in clear contradiction with previous metal reviews as quoted above while the evidence base in the registration file is comparable.

2. Guidance and practices for data rich metals
Substances with extensive data sets have a principle benefit that they reduce some of the uncertainty created by smaller or minimal data sets. The environmental data set for lead is very extensive, providing evidence for all three trophic levels, for more than hundreds of acute and chronic ecotoxicity data points, covering a wide range of species and abiotic conditions. This abundance of evidence also has a drawback, as it has a higher chance to include outlier evidence, substances tested in non-relevant abiotic culture/test water conditions and endemic or specific, more sensitive, species. More than two decades of practice with data sets for data rich metals has therefore resulted in specific ruling/practices to ensure the quality of the assessment and a level playing field with substances with more limited data sets. These rulings include, amongst others, the focus on standard test species for CLP, statistical treatment in case of multiple data on a same species and endpoint, and normalisation for bioavailability.
Standard versus non-standard species
Both the GHS and CLP allow the use of non-standard test species. This provision was foreseen to ensure a minimal data set covering the three trophic levels used for environmental hazard classification: primary producers, invertebrates and fish. Building on the GHS, CLP as well as REACH, however, include specific species that act as representative species, and that are also those that are recommended to comply with the REACH minimal information requirements when (new) data needs to be developed. The basic concept of the classification system aims at comparing substances on an equal and standardised basis. This approach therefore inherently requires a level-playing field to ensure data rich substances are not more severely classified only because they have more data and the database includes endemic as well as non-standard species which are sometimes more sensitive.
While such evidence is most useful for risk assessment purposes, this clearly goes beyond the aim of hazard classification: comparing all substances in an equal way. In previous metal cases, standard species have been used for the classification assessment of data rich metals, so as to ensure a level playing field. Non-standard data would only be relevant in case of an incomplete data set for any trophic level required by CLP.
While standard and non-standard species can be used for Risk Assessment (derivation of the PNEC), Eurometaux insists, independently of the outcome, that the hazard classification is conducted on standard species, provided they cover all required trophic levels with multiple data sets, which is absolutely the case for lead.

Freshwater versus saltwater data sets
Due to their natural occurrence, all metal ions including lead are homeostatically controlled by organisms. Toxicity is expressed when the boundaries of the homeostatic control are reached. These control mechanisms are often different for organisms living in freshwater compared to saltwater or brackish water. The classification ruling was developed for freshwater organisms with the option to expand to saltwater or brackish organisms, in case the data set would have otherwise been insufficient. Anyway data rich substances have complete and abundant data sets for standard aquatic organisms for all three levels.
The data submitter used all data from standard and non-standard fresh and saltwater species.
In line with the original aims of the classification system to compare substances on an equal basis and independent of the outcome, Eurometaux requests RAC to focus on freshwater data sets originated from studies conducted with standard methods and species when available.

Data treatment
Data rich substances often have multiple data sets for a given species and endpoint, thereby considerably reducing the uncertainty. Moreover, test conditions for the same standard test will always vary somewhat (different culture medium and conditions, different genetic clones, different abiotic conditions of the test waters…) resulting in some variety or variability in the toxicity expression. It is therefore recommended in the guidance that geometric means are derived for data sets of four or more values for a given species and endpoint. It is understood that the mean will take care of the variability caused by the factors raised above, thereby making the overall assessment more robust while ensuring a level playing field with data poor substances.
This approach has been followed in all data rich metal environmental dossiers so far. Nevertheless the Dossier Submitter deviates from this approach, indicating that none of these tests are conducted under equal conditions. The approach applied by the Dossier Submitter therefore uses an additional safety factor solely based on the data richness. This is a factor that is not applied on smaller data sets.
Eurometaux consequently urges RAC to maintain the data treatment approach as agreed and applied in all previous metal data rich cases and to not penalise data richness, ensuring a level playing field.

3. Specific classification rulings for metals
Loading for the TDp (OECD 29) screening test
The Dossier Submitter refers to a loading of 100 mg/L for the 24-hour screening test as an important criterion to decide whether the substance should be classified as the soluble ion, or differently. However, the 100 mg/L refers to the GHS Acute Category 3 level which is not implemented in the EU (neither is Acute Category 2). The EU system has only implemented the Acute 1 category at a 100 x lower dose meaning that the screening test should also be conducted at that level. The metals sector raised this anomaly several times during the drafting of the CLP and its guidance. It was always stated that this was a minor issue to be included in future updates but was never implemented. Moreover the screening test is ONLY applicable to metal compounds and not to metals. Both the GHS and the CLP systems are clear and identical on this point. The role of the 24-hour screening test for metals is therefore limited to defining the relevant pH for the full test, as well as the filtering efficiency; in essence defining the test conditions for the full TD tests.
Eurometaux insists that the classification being decided in accordance with the assessment scheme for metals in the CLP, any reference to the role and relevance or the TD screening test for the assessment of a metal such as lead is eliminated and that this evidence is only used to define the test conditions for the full 7 or 28-day test.

Applying the metals classification scheme correctly
The transformation dissolution results at 7 and/or 28 days should be used to assess the relevance of the classification category and potential M factor, not the 24-hour test at 100 mg/L as presently used. The screening test is wrongly applied in the lead metal Annex XV dossier to justify a classification equal to the soluble ion (see above), while a distinctive assessment of the hazard classification for lead metal powder and massive is lacking. According to the guidance, such an assessment should normally include for the massive and powder form (separately), the following steps:
o Define the pH conditions that maximise dissolution (pH 6, 7 or 8) and optimise the filtration
o Split the ecotoxicity data set in a data set by pH band, or even better, normalise the complete standard species data set with a BLM to the pH with maximal dissolution
o Conduct a 7-day TDp test at the pH with maximal dissolution and compare it with the selected acute data set at that pH or the normalised acute data set
o Conduct a 28-day TDp test or calculate the result from the 7-day test, and compare it

with the selected chronic ecotoxicity data set at that pH or the normalised acute data set This approach as described in the GHS, CLP and the CLP guidance has not been followed by the Dossier Submitter. It has been noted though that the TD data set in the registration file is incomplete, but the registrant has recently performed TDp tests to complete it. Eurometaux would request to have the metals assessment approach as included in the CLP guidance in section IV.2.2 and Annex X to the GHS correctly and fully implemented.

Rapid Degradation
While both the GHS as well as CLP foresee explicitly that Rapid Degradation (assessed as rapid removal) can be demonstrated for metals, Member States have not progressed with the guidance needed to allow this assessment to be applied. Industry developed a model, called the Unit World Model, validated with extensive field evidence that allows the assessment of rapid removal from the water column, a condition that would, as for organics, prevent exposure resulting in the expression of toxicity. At a workshop at ECHA in 2012, the concept was felt too much risk oriented and questions and research needs were defined. Industry followed up with the submission of an elaborated research and data package in 2013. In parallel, industry, in consultation with SETAC and the regulatory community, developed an extension of the Transformation Dissolution protocol allowing to assess the rapid removal properties of metal ions. However, Member States and ECHA did not progress with the development of the guidance, whilst now the Dossier Submitter argues that due to the lack of such guidance the concept cannot be assessed nor applied. Eurometaux would like to remind ECHA and the Member States that this legal requirement allowing the registrant to demonstrate rapid removal is still an open question, leaving an unfair situation compared to the organic sector. Eurometaux would therefore welcome reopening this technical debate on guidance development.
Eurometaux would more than welcome that the scientific debate on the Rapid Removal could be restarted and is committed to positively contribute to the discussion.

4. Conclusions:
The Danish classification proposal for lead metal includes significant shortcomings compared to the GHS and CLP texts and the CLP guidance. The Dossier Submitter provides a unilateral "interpretation" that is not in line with how assessments have been done for other metals such as nickel (Denmark) and specific copper forms (France) and others.
The approach applied by the Dossier Submitter:
- relates more to how metal compounds and not the metal form should be assessed;
- makes unproven assumptions in respect to the uses, which are contrary to the evidence provided in the registration dossier and the additional information submitted by the registrant during the Public Consultation;
- does not consider two separate entries (massive and powder) as a relevant option, despite distinctive dissolution rates in the TDp and fulfilling the criteria for such a split;
- applies the metal classification strategy in a wrong way and does not properly reflect the previously agreed ruling for data rich substances.
Eurometaux is therefore of the opinion that these methodological and conceptual shortcomings are of such an extent that they impact the hazard classification category or M factor for the substance and they also deny a fair assessment for lead compared to other metals previously assessed. Moreover, the different assessment and application of the classification ruling compared to CLP and its guidance, as well as with previous metals' experience, creates confusion and uncertainty that need resolution.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments of Eurometaux on the proposal for harmonised Classification of Pb metal.docx

Dossier Submitter's Response
1. **The driver for distinguishing between massive metal and powder was that certain metals in fine powder form have special physical-chemical properties that warrant special classification, i.e. they are flammable or even explosive.** **That smaller particles of the substance are more soluble than greater particles is in itself not an argument for splitting in two entries. To do so so the powder and "massive" must be different in other aspects.** **Splitting the classification in two entries should as far as possible be avoided because of, among other things, the question of which entry to relate to when classifying mixtures. The default is that the metal should be classified according to results obtained with the smallest particle size on the market.** **The CLP guidance Annex IV, section IV.5.5 states:** **"There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (e.g. different crystallographic structure) and/or it has been produced by a special process and is not generally generated from the massive metal, classification of the massive can be based on testing of a more representative particle size or surface area, …"** **Concerning the production of lead power, one method is dispersal of melted lead, which is quite analogous to milling.** **Further, thin lead films with a thickness of only 25 µm are on the market, and 1 mg of such a film will have a surface area greater than or equal to 1 mg of the powder that was tested.** **(http://www.selfgrowth.com/articles/lead-powder-manufacture-and-use** **http://www.gravitaindia.com/products/lead-powder/** **https://books.google.dk/books?id=JBmPhh19k7AC&pg=PA120&lpg=PA120&dq=lead+powder+production&source=bl&ots=AndqlHZqLu&sig=pGe_pRgwekP61TiD66GGPTZNi90&hl=da&sa=X&ved=0ahUKEwi824Gwo__YAhUEbFAKHVeXD-wQ6AEIcTAN#v=onepage&q=lead%20powder%20production&f=false)** **See also response to comment 19.** **2.** **CLP, Annex I, section 4.1.1.2.2 states: "Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006."** **Neither the legal text nor the guidance mentions anything about deviation from this when dealing with data-rich substances.** **Freshwater/saltrwater:** **Saltwater data are not just included "in case the data set would have otherwise been insufficient"** **The CLP, Annex I, section 4.1.1.2.2 and the CLP guidance, section 4.1.3.1.2. state: "In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent." And nowhere is it said that you should use the freshwater data only when the data set is large.** **Data treatment**

"*It is understood that the mean will take care of the variability caused by the factors raised above, ….*". No, the CLP guidance section 4.1.3.2.4.3. states: "In estimating a mean value, it is not advisable to combine tests of different species within a taxonomic group or in different life stages or tested under different conditions or duration." Different levels of DOC, hardness, pH etc. are clearly "different conditions".

We have not applied any safety factors.

3.
The 24h sreening test with a loading of 100 mg/l does not relate to Acute 3. The idea behind the screening test is to distinguish between soluble and sparingly soluble compounds.

It is clearly stated in the dossier that the screening test normally is used only for metal *compounds*. The screening test had nevertheless been performed with the powder, while no full T/D had been performed at a loading of 1 mg/l or lower. You can only use the data that are available, and that is what was done in this case. The screening test data were not used directly, only as an indication.

We agree with the classification scheme that EUROMETAUX outlines except that it should have been applied to the powder. The extra T/D performed with the massive form does not change the conclutions of the dossier.

Concerning the rapid removal question, suffice it to say that the T/D testing fully accounts for rapid transformation of soluble forms to insoluble forms. If the transformation is sufficiently rapid then the dissolved fraction will not reach the level of the ERV, which will lead to "no classification".

Binding to particles and subsequent sedimentation and binding in sediment is risk assessment. It is not accepted in the assessment of hazards in neither organics nor metals. It may further be noted that the reasonable (and highly realistic-) worst case scenario is that there is no sedimentation and no sediment (fast running rivers).

RAC's response

1. RAC does not support to split classification of lead to two forms. Firstly lead powder is not structurally a different material, with different crystallographic structure. The reason for distinguishing between massive metal and powder was that certain metals in fine powder form have special physical-chemical properties that warrant special classification, i.e. they are flammable or even explosive. That smaller particles of the substance are more soluble than greater particles is in itself not an argument for splitting in two entries. To do so the powder and "massive" must be different in other aspects.
Splitting the classification in two entries should as far as possible be avoided because of, among other things, the question of which entry to relate to when classifying mixtures. The default is that the metal should be classified according to results obtained with the smallest particle size on the market.
It should be also noted that there is no clear destinction between the massive form and the powder because there are, on the market, lead films with a thickness of only 25 µm, while the powder particles have a diameter around 75 µm. Thus 1 mg of such a film will have a greater surface area than 1 mg of powder.

2. RAC agrees with dossier submitter's response. RAC believes that, in principle, it is preferable to base classification decisions on data from standard test guideline studies, since these methods have been ring-tested and approved for use for regulatory purposes. However, where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006. In general, both

freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent. 3. RAC agrees with dossier submitter's response. Unfortunately, for the powder form of lead we have only screening 24h test with loading of 100 mg/L. For classification purpose the loading 1, 0.1 and 0.01 in the T/Dp test should be carried out. So, we have to use all possible data for our evaluation and in the case of missing information, the extrapolation from existing data was carried out.

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	France		MemberState	14
Comment received				
FR agrees with classification proposal				
Dossier Submitter's Response				
Thank you for the support				
RAC's response				
Thank you very much for your support.				

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Austria	Wirtschaftskammer Österreich	Regional or local authority	15
Comment received				
see document attached. ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_189_StN CLH Blei.pdf				
Dossier Submitter's Response				
See response to comment 4				
RAC's response				
Thank you very much for your comments and suggestions, for more details see response to comment number 4.				

Date	Country	Organisation	Type of Organisation	Comment number
27.09.2017	Italy	<confidential>	Company-Manufacturer	16
Comment received				
NONE FOR NOW				
Dossier Submitter's Response				
Comment noted				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
27.09.2017	Italy	<confidential>	Please select organisation type..	17
Comment received				
NONE FOR NOW				

Dossier Submitter's Response
Comment noted
RAC's response
Noted

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	United Kingdom		MemberState	18

Comment received

1. Although we are inclined to agree with arguments presented by the DS in relation to the setting of M-factors and the lack of sufficient evidence of rapid removal and environmental transformation of lead (as an equivalent to 'rapid degradation') - we think the issue of whether the bioconcentration potential of lead meets CLP criteria could be discussed further.

The only parameter routinely used under CLP is the BCF not the BAF, and this is usually taken from studies on fish rather than invertebrates or other aquatic life. The mean and median wet weight BCFs for all organisms quoted from the VRAR, 2008 are 728 and 424 L/kg, with a wide range of 5 - 8000 L/kg. However, for fish alone, the CLH Report indicates BCF values which are typically lower than the CLP trigger value of 500 L/Kg.

2. Although it appears to be the case from the CLH conclusion and the source documents, e.g. VRAR, 2008, can it please be clarified that the acute and chronic endpoints reported in Table 23 (at least the key ones used for classification) are based on mean measured test concentrations, or supported nominals, relating to dissolved lead.

Can it also please be clarified that the acute and chronic endpoints for algae (at least the key ones in relation to classification) are based on growth rate.

3 We note the arguments presented by the DS on why 'massive' and powder forms of lead should not be treated differently with respect to their aquatic classification. We will not express an opinion on this at present - but given previous discussions on this highlighted in, e.g. the ECB Technical Meeting minutes appended to the CLH Report, we are highlighting this now for further consideration at the RAC itself please. Our main wish is that there should be consistency in approach for all metals and between human health and environmental classifications, taking in to consideration where particle size really is shown to make a difference in terms of classification.

Related to this, nano-scale forms of lead (i.e. lead nanoparticles and nanopowders) are currently being manufactured - but does the DS also propose these would not be distinguished in the lead classification? Current indications under GHS are that nano forms of metals should be differentiated in harmonised classifications - but at what scales are size effects actually no longer relevant? We think this issue of different classifications for different sized forms of metals (& potentially also non-metals?) warrants further generic discussion at RAC.

Dossier Submitter's Response

1.
It should be borne in mind that there is an inverse relationship between the concentration of Pb in the water and the concentration factor, and therefore the relevant value would be the BCF or BAF at environmentally relevant concentrations. It is reasonable to operate with concentrations close to the PNEC as "environmentally relevant".

We do feel it is relevant to look also at other organisms than fish, i.e. "seafood".

2.
Yes, mean measured values, and yes, growth rate data were used for algae.

3.
As we recall it, the driver for distinguishing between massive metal and powder was that certain metals in fine powder form have special physical-chemical properties that warrant special classification, i.e. they are flammable or even explosive.
That smaller particles of the substance are more soluble than greater particles is in itself not an argument for splitting in two entries. To do so so the powder and "massive" must be different in other aspects.
Splitting the classification in two entries should as far as possible be avoided because of, among other things, the question of which entry to relate to when classifying mixtures with the summation method. The default is that the metal should be classified according to results obtained with the smallest particle size on the market.
The CLP guidance Annex IV, section IV.5.5 states:

"There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (e.g. different crystallographic structure) and/or it has been produced by a special process and is not generally generated from the massive metal, classification of the massive can be based on testing of a more representative particle size or surface area, …"

Nano-particles should probably have their own entry, but we have not addressed this issue, and nano-forms have not been considered.

RAC's response

Thank you very much for your comments and suggestions. RAC agrees with the dossier submitter's responses.
The issue regarding the nano-particles was taken into account.

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	United Kingdom	International Lead Association; Lead REACH Consortium	Industry or trade association	19

Comment received

1. Assessment of Massive and Powder Metal

The Danish CLH proposal fails to properly account for the impact of surface area by neglecting to use T/Dp (dissolution data) available on lead in massive form.

The concept and importance of surface area is recognised in ANNEX IV of the ECHA Guidance on the application of CLP criteria (ECHA, 2017): "Surface area is a crucial parameter in that any variation in surface area tested may cause a significant change in the levels of metals ions released in a given time-window. Thus, particle size or surface area is fixed for the purposes of the transformation test, allowing the comparative classifications to be based solely on the loading level."

A detailed report is included as an attachment that describes the special process undertaken to produce lead metal powder that are distinct from the process used for manufacturing massive lead. It also describes the forms of lead metal placed on the market; Lead metal as a "substance" is only placed on the market in three forms; large ingots, shot and powder.

Products produced from lead metal (e.g. sheet, plate, gunshot, wool, extruded or cast products) are all defined as "articles" under CLP and as such are not subject to classification and labelling requirements.

The attached report also demonstrates that because of the physico-chemical properties of lead (e.g. soft and malleable) and the reasonably expected use of lead in massive form (that does not involve polishing or grinding) production of small particle powders from massive lead is improbable.

Conclusively for lead metal, the data generated for a metal powder are not considered as suitable for classification of the massive forms and hence it is wholly appropriate in this case to assess the impacts of surface area on release of the Pb-ion by using dissolution test data on massive lead samples in the strategy for deriving an environmental classification as recommended in ANNEX IV of the ECHA-Guidance on the application of CLP criteria (ECHA, 2017). By omitting the use of the appropriate T/Dp data the Danish CLH proposal adopts a highly precautionary CLH strategy for lead massive by comparing environmental reference values for the soluble Pb ion with metal powder dissolution characteristics. This strategy is discriminatory and not in line with precedent established for other metals.

2. Use of non-standard species to derive the chronic ERV and classification

In our opinion, an environmental classification should only be based on relevant toxicity data that are generated from the recommended standardized testing procedures, using specified standard test species that represent either algae, invertebrates (crustaceans) or fish. Any deviation from these principles (use of other species/taxonomic group, exposure period or testing guideline) would compromise the basic principle of classification that all substances within the same hazard category share a common hazard profile.

The snail Lymnaea stagnalis does not belong to any of the three taxonomic groups (algae, crustacean, fish) recognised in the CLP guidance for classification purposes and in reference to OECD methods (CLP guidance, Section 1.2).

Moreover, the CLP guidance calls for using standardized test methods (preferable according to section 4.1.1.2.2 of the CLP regulation) or non-standard methods if only internationally validated and accepted, for generating toxicity data for classification purposes (CLP guidance Section 1.2). The study used in the CLH proposal for the snail (Lymnaea stagnalis) does not fulfil these criteria as there is no standard testing guidance available for this species. It should therefore not be used for deriving ERVs.

The Danish CLP proposal also relies on use of data from C. dubia to derive a chronic ERV. Whilst the C. dubia is a crustacean, and therefore one of the three standard taxonomic groups suitable for classification, the exposure period of 7 days widely used in the USA and applied in the CLH proposal is not in line with the OECD methods 202(2) and 211 (14- or 21-day Daphnia reproduction) that is specified in the CLP Regulation. As a result, the EU Joint Research Centre (JRC) has rejected the use of C. dubia for chronic ERV derivation and stated that "a 7-days reproduction study cannot be considered as valid for classification purposes" (JRC, 2015).

Daphnia magna is the standard test species for almost every substance when considering acute/chronic toxicity to crustaceans under CLP; when available, data for this species should always take preference over data that are generated with other crustaceans to eliminate the impact of inter-species variability on the hazard profile (and classification of a substance within a specific hazard category).

The Danish CLH dossier relies on use of data from these two-non-standard species (L. stagnalis and C. dubia) to select the proposed chronic ERV (1.7 µg/L) while many other standard species and corresponding high-quality data points were not given proper weight in making the decision. This strategy is discriminatory, not in line with precedent established for other metals, and contributes to the derivation of the precautionary chronic environmental classification for lead massive proposed in the Annex XV dossier.

3. Statistical treatment of test data

The dossier submitter has used the two lowest values (EC50 of 20.5 µg /L for the algal species Pseudokirchneriella subcapitata and EC10 of 1.7 µg/L for Ceriodaphnia dubia and Lymnaea stagnalis) from the entire lead toxicity databases that include both freshwater and saltwater species for respectively the acute and chronic ERVs. Given the data-rich nature of the Pb aquatic toxicity database it is more appropriate to take a different approach that reflects the data-rich nature of the database and that is in line with the CLP metals guidance.

The ECHA guidance on the application of CLP criteria (ECHA, 2017) deals with the subject of deriving a geometric mean as follows: "When larger data sets (four or more values) are available for the same species, the geometric mean of toxicity values may be used as the representative toxicity value for that species. In estimating a mean value, it is not advisable to combine tests of different species within a taxonomic group or in different life stages or tested under different conditions or duration. This implies that for substances, where four or more ecotoxicity data on the same species and endpoint are available, the data should be grouped, and the geometric mean used as a representative toxicity value for that species."

The Pb aquatic toxicity database includes more than 45 freshwater and marine water species with close to 350 individual high quality EC50/NOEC/EC10 values for only freshwater species (fish, invertebrates, higher plants and algae). Yet, the CLH dossier for Pb has used the lowest value instead of the geometric mean approach.

The Danish CLH dossier does not follow the ECHA guidance in selecting geometric mean of toxicity values when large data sets are available. By selecting the two lowest values available in the data set the dossier is discriminatory, not in line with recent precedent established for other metals, and contributes to the derivation of the precautionary chronic environmental classification for lead massive proposed in the Annex XV dossier.

4. Derivation of pH-dependent Environmental Reference Values and Classification

The ECHA CLP metals guidance states that where an extensive toxicity/dissolution dataset is available, a split of the acute and chronic ecotoxicity reference values can be performed according to their pH used during T/Dp test. This means that toxicity data (ERV) and transformation data should always be compared at the same pH.

In the Danish proposal no pH-specific ERVs were determined and the lowest toxicity data point from a non-standard species were selected to represent the acute and chronic ERV for comparison with the highest dissolution measured at pH 6.0. This is clearly very precautionary as it adopts the "worst-case" for all parameters.

The original self-classification proposal for lead in massive form submitted in the joint REACH registration dossier also took a precautionary approach by comparing the highest toxicity ERV derived at pH 8 with the highest dissolution observed at pH 6 from the massive lead sample. This was necessary as no T/Dp data was available for the massive at pH 8 (which was the pH expressing the highest toxicity). This has since been rectified and the

new test report on transformation and dissolution kinetics of massive Pb at pH 8 (CIMM, 2017) is submitted as a confidential attachment with these comments. This now allows a direct comparison of toxicity and dissolution/transformation at equivalent pH as recommended in the CLP guidance and is used to derive the conclusion that lead in massive form should not be classified as hazardous to the aquatic environment.

5. Inappropriate use of screening T/Dp test data for acute classification of lead massive

The Danish CLH proposal for lead massive acute aquatic toxicity compares predicted dissolution from a 75µm powder sample extrapolated from a 24hr T/Dp screening test with a single pH ERV that represents the highest toxicity observed. The rationale for taking this approach is the assumption that it is inappropriate to consider a separate classification for massive lead samples and the lack of 7 day T/Dp test data on powder (it should be highlighted that a full 7 day transformation/dissolution test was not conducted on the powder as it failed the screening test and thus was considered to be readily soluble thus allowing a direct comparison with the acute ERV- this is clearly not appropriate for lead in massive form given the dissolution kinetics observed).
By ignoring the extensive 7 day T/Dp data available on lead massive that clearly demonstrates that the dissolved metal ion concentration at 1mg/L loading does not exceed any acute ERV the submitting member state has not followed the classification strategy outlined in ANNEX IV of the ECHA-Guidance on the application of CLP criteria (ECHA, 2017); had they done so the data supports not classifying lead massive as acute hazard category 1 (see p3 and the CLP scheme for acute classification in the Annex 1 of this document)-in fact the correct use of this classification strategy would highlight that lead in massive form does not warrant any CLP classification for aquatic toxicity endpoints due to the slow rate of solubilisation of the toxic Pb ion from metal in this form.

The approach taken by Denmark does not follow the ECHA guidance nor does it follow precedent established for other metals, including zinc and nickel metal and more recently some forms of copper. As such it is discriminatory, as the acute environmental classification proposed for lead massive can only be derived by adopting this atypical strategy and by ignoring the comprehensive T/Dp data derived on lead in massive form.

6. Derivation of M-Factors

Although we do not believe this to be so relevant as the data we provided support no classification for lead in massive form we would like to highlight that Denmark have incorrectly assigned M-Factors based upon the strategy they have proposed.
Notwithstanding the arguments we have presented in the comments above it is clear that the Danish CA does not agree with the current approach to establishing the M-Factor presented in the existing CLP metals guidance (see page 37, paragraph 7 of the Danish proposal). This we need to challenge as the metals CLP guidance was developed over a number of years with the involvement of Member States. It is therefore not appropriate that a Member State uses a CLH proposal to challenge the guidance and ignores precedent established for other metals.

The CLP Guidance document states that "the M-factor is set by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic) at a loading of 1 mg/L (acute) or 0.1 mg/L (chronic) by the respective ERV." This approach does NOT justify an M-factor for massive lead. However, this is a fact that is challenged and the approach is ignored in the M-factors proposed in the Danish dossier.

ECHA note – An attachment was submitted with the comment above. Refer to public

attachment ILA, PbRC - public attachments - contains 3 files.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Final_Report_Pb_massive_pH8_20_10_2017.pdf

Dossier Submitter's Response

1.
We do not agree that lead film should be regarded as an article.
Lead film is used for protection against radiation, and it is the chemical/physical properties, and thus the radiation absorbing properties, of the substance that enables this use. Sheets are produced in all sorts of thicknesses depending on the degree and nature of radiation that should be protected against.

1 mg of sheet with a thickness of 25 µm will have a greater relative surface area than 1 mg of powder with particles with a diameter of 75 µm.

See also response to comments 14 and 18.

2.
CLP, Annex I, section 4.1.1.2.2 states: "Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006." Thus the tests species and the tests do not need to be standard, and information on species like *Lymnaea* sp. can certainly be used, and results from such non-standard tests should as well be considered,

Concerning the *C. dubia* 7-day test:
The test is a chronic test as three broods are produced within the test duration, which compares to three broods in a *Daphnia magna* 28 days test. The CLP guidance Annex I, section I.2 states "Chronic testing involves an exposure that covers a significant period of time when compared to the organism´s life cycle. The term can signify periods from days to a year, or more depending on the reproductive cycle of the aquatic organism."
C.dubia 7-day test is further mentiond in Example C in section IV.7.3 in Annex IV of the CLP guidance.
It is further widely used also in hazard assessment in risk assessments and in setting water quality standards under the Water Framework Directive. It is not only used in EU but also internationally (e.g. in the USA).

Thus the technical guidance on risk assessment under REACH, chapter 7b, section 7.8.4.1 specifically mentions the *C. dubia* 7-day test, and *C. dubia* 7-day chronic EC_{10} and NOEC values are fully accepted for hazard assessment in EU risk assessment reports (RAR), including nickel-RAR and zinc-RAR, where the data have been thoroughly evaluated and validated by member state experts, and where also SCHER has accepted the data. *C.dubia* data from such tests were as well used in the voluntary risk assessments (VRAR) performed by industry for lead and copper.

Also in the evaluation of copper compounds in RAC *C. dubia* data were accepted.
We never heard of the JRC report conclusion on this topic before, probably because this was not the scope of the report, and because it is in a footnote and not in the main text. We absolutely do not agree that *C. dubia* 7-day test cannot be used in hazard assessment.

3.
The use of geometric means was considered in every case, but as is stated in the dossier, geometric means have not been employed because the tests were performed under very varying conitions concerning pH, DOC, hardness etc.

4.
As the toxicity values for e.g. *C. dubia*, apart from pH, represent greatly varied conditions of hardness and DOC, and as there is a very weak, if any, correlation between the toxicity and pH for e.g. *C. dubia*, mean values cannot be employed, and the toxicity cannot be related to pH bands.

5.
We do not agree to a differentiation of the environmental hazard classification between the two existing entries for lead ("massive" and powder). The powder is often produced by dispersal of melted lead, which

is quite analogous to milling, and there is therefore no clear destinction between the "massive" and the powder.
The proposal covers massive lead as well as lead powder and the existing two entries for lead metal in Annex VI should thus both be updated accordingly. See also comments under 1.

6.
It is true that we question the methodology for setting M-factors given in the guidance, but we none the less also applied the CLP guidance methodology, and the conclution was the same regardless of which methodology was employed.

We would also like to stress, that the methodology given in the CLP guidance is not in accordance with the GHS, which the CLP is supposed to implement.

RAC's response

Thank you very much for your comments and suggestions, RAC agrees with the DS's responses to questions 1-5.
6. The Dossier submitter used another way for setting of the M-factors, which is different from the guidance method. RAC does not agree with the DS and prefers to stay with the method presented in the existing CLP metals guidance (section IV.5.4).

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2017	Germany	WirtschaftsVereinigung Metalle (WVMetalle)	Industry or trade association	20

Comment received

Lead is a very malleable material and by no means brittle or porous. That is the reason why e.g. lead sheets are used as roofing material where it is easily adopted to rough edges and corners. Lead massive materials therefore do not generate abrasives or fine particles. Looking for the re-lease per surface clearly shows that larger forms release significantly less than smaller forms (e.g. powders), which was finally the reason for the EU to distinguish the two entries. In addition Transformation Dissolution (TD) data for both forms are available and documented within the registration file including clearly distinctive dissolution kinetics. We therefore cannot understand why this concept is rejected within the classification dossier and we urge RAC to follow the specific CLP legal texts applicable to the metals environmental classification assessment and stick to already existing distinction between powder and massive forms

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-10-30_WVMetalle commenting on Pb env classification.pdf

Dossier Submitter's Response

See responses to comments 13 and 19

RAC's response

Thank you very much for your comments and suggestions for more details see responses to comments number 3 and 13.

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2017	Austria	AMAG	Company-Manufacturer	21

Comment received

Highlights of the attached document:
I. Lead Content of secondary aluminium, scrap, dross and waste (see attachment) and the

consequences (Seveso III directive, hazardous waste,...)
II. No diffentiation between powder form and massive form of lead and the comsequences
III. Impact on the European Aluminium industry
IV. Consequences of the classification in General
V. Lead in different EU directives

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 1710_Comment Pb to ECHA.docx

Dossier Submitter's Response

I.+ III. + IV. +V.
Socio-economic aspects are not included in the CLP, and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

II.
See response to point 4. in comment 9.

RAC's response

Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of the RAC mandate.

II. It is possible that lead alloys shouldn't be classified. They can be tested according to the T/Dp protocol. Furthermore, alloys need not be labelled if they do not pose a risk to human health or the environment. (Guidance on the Application of the CLP Criteria Version 5.0,2017, Annex IV, section IV.5.6.1).

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	Austria	Austrian Non-Ferrous Metals Association	Industry or trade association	22

Comment received

Unsere Argumente richten sich gegen die harmonisierte Einstufung von Blei in massiver Form für die Umweltgefahr, nicht jedoch gegen die harmonisierte Einstufung von Blei in Pulverform als Aquatisch Akut und Chronisch 1 (M-Faktor 10).

Dänemark lehnt die Unterscheidung in Blei in massiver Forum und Blei in Pulverform, wie sie im gemeinsamen Registrierungsdossier vorgenommen wird, ab. Die Argumentation Dänemarks ist aus unserer Sicht nicht haltbar. Denn die Erfahrungen der Metallbranche zeigen, dass Blei derart genutzt wird, dass bei bestimmungsgemäßer Verwendung von Blei in massiver Form erwartungsgemäß keine pulverartigen Partikel erzeugt werden. Dies gilt für den Schmelzvorgang an sich und auch für die Herstellung von Metalllegierungen, die Blei enthalten.

Weiters hält sich Dänemark bei der Ableitung des M-Faktors nicht an die geltende Leitlinie zur Anwendung der CLP-Kriterien. [siehe Seite 37 des Dossiers: „In the current CLP guidance document the M-factor is set by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic) with a loading of 1 mg/L by the ERV. In our opinion this is a wrong methodology… "… the right thing to do would be to set the M-factor directly in relation to the ERV as for all other kinds of substances."] Diese Vorgehensweise ist strikt abzulehnen. Die CLP Leitlinie wurde nach jahrelanger Arbeit unter Einbeziehung aller EU-Mitgliedstaaten erstellt. Es ist nicht statthaft, dass sich ein einzelner Mitgliedstaat über dieses Ergebnis hinwegsetzt und einseitig abweichende Regeln aufstellt.

Aus wissenschaftlicher Sicht sind noch folgende Punkte zu beanstanden:

• Dänemark hat bei der Ableitung von ERV (ecotoxicity reference value) und für die Einstufung Nicht-Standard Arten herangezogen.

• Dänemark hat Test-Daten für einen an Daten reichen Stoff (Blei) statistisch nicht korrekt angewendet.

• Dänemark hat es verabsäumt, ERVs abhängig von pH-Wert abzuleiten, wie dies für schwer lösliche Metalle angemessen wäre.

• Dänemark hat pH-relevante T/Dp-Daten inkorrekt angewendet.

Dazu verweisen wir ausdrücklich auf die umfassende Argumentation der International Lead Association und Eurometaux.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 171027 harmonisierte Umwelt_Einstufung von Blei Metall.pdf

Dossier Submitter's Response

Wirtschaftkammer Österreich (WÖ) does not agree to one entry for the massive form and the powder. They write: "Die Argumentation Dänemarks ist aus unserer Sicht nicht haltbar. Die Erfahrungen der Metallbranche zeigen, dass Blei derart genutzt wird, dass bei bestimmungsgemäßer Verwendung von Blei in massiver Form erwartungsgemäß keine pulverartigen Partikel erzeugt werden"

We should like to stress that there is no clear destinction between the massive form and the powder because there are, on the market, lead films with a thickness of only 25 µm, while the powder particles have a diameter around 75 µm. Thus 1 mg of such a film will have a greater surface area than 1 mg of powder.

WÖ writes:
"Weiters hält sich Dänemark bei der Ableitung des M-Faktors nicht an die geltende Leitlinie zur Anwendung der CLP-Kriterien. [siehe Seite 37 des Dossiers:
„In the current CLP guidance document the M-factor is set by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic) with a loading of 1 mg/L by the ERV. In our opinion this is a wrong methodology… "… the right thing to do would be to set the M-factor directly in relation to the ERV as for all other kinds of substances."
Diese Vorgehensweise ist strikt abzulehnen. Die CLP Leitlinie wurde nach jahrelanger Arbeit unter Einbeziehung aller EU-Mitgliedstaaten erstellt. Es ist nicht statthaft, dass sich ein einzelner Mitgliedstaat über dieses Ergebnis hinwegsetzt und einseitig abweichende Regeln aufstellt."

The cited section has been taken out of ist context, in as much as the dossier further down in fact takes account of the current guidance, and concludes that regardless of what you refer to the result will actually be the same.

We would also like to stress that the current CLP-guidansce on setting M-factors for metals is not in accordance with the GHS (globally harmonized system for classification), which the CLP is supposed to implement.

WÖ writes:
"Dänemark hat bei der Ableitung von ERV (ecotoxicity reference value) und für die Einstufung

Nicht-Standard Arten herangezogen."

Yes we also included information on non-standard species. We should like to refer to CLP, Annex I, section 4.1.1.2.2: "Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006.**"**

WÖ writes:
"Dänemark hat Test-Daten für einen an Daten reichen Stoff (Blei) statistisch nicht korrekt angewendet."

What do they mean by this?

WÖ writes:
"Dänemark hat es verabsäumt, ERVs abhängig von pH-Wert abzuleiten, wie dies für schwer lösliche Metalle angemessen wäre."

We should like to refer to the dossier, section 5.5:
"If data are available for both dissolution and toxicity at different pH levels the corresponding toxicity values and dissolution values at different pHs may be compared. In the current case the powder has only been tested in a full T/Dp test at pH 6.
Further, if we look at the two most sensitive species, *Lymnaea stagnalis* and *Ceriodaphnia dubia*, then *L. stagnalis* has been tested only in the pH interval from 7.1 to 8.6, and there is no indication of a correlation between pH and toxicity. In fact the correlation (Spearman rank) is $r_s = 0.000$ (but there are only 4 values covering the same life stage, effect type and test duration).
With *C. dubia* there are 39 EC_{10} or NOEC values for reproduction from 7 days tests, and the pHspan is from 6.05 to 8.5. However there is a much stronger relationship between DOC and toxicity than between pH and toxicity. Without taking DOC and hardness into account the correlation between pH and EC_{10} or NOEC is $r_s = 0.237$, $P > 0.1$ (two-tailed), while for the relationship between DOC and EC_{10} or NOEC the correlation is $r_s = 0.335$, $P < 0.05$, without taking pH and hardness into account.
Thus, a comparison between the toxicity at different pH levels with the T/Dp test results at the same levels is not possible and as well not recommendable."

WÖ writes:
"Dänemark hat pH-relevante T/Dp-Daten inkorrekt angewendet"

What do they mean by this?

WÖ presents a number of socio-economic arguments.
However socio-economic aspects are not included in the CLP and SEAC does not consider hazard classifications. In hazard classification socio-economic aspects are not relevant. A substance will not become more or less toxic because of socio-economic interests.

RAC's response

Thank you very much for your comments and suggestions. RAC agrees with the DS's responses.

Date	Country	Organisation	Type of Organisation	Comment number
27.10.2017	Belgium	European Aluminium	Industry or trade association	23

Comment received

The proposal does not provide for a distinction in the classification of the massive form and the powder form of lead. Both forms are classified with an M-factor of 10.

The proposal presumes that the massive form could lead to particles in the powder range. However, the experience in the aluminium industry shows that the melting process of scrap and the manufacturing of recycled aluminium alloys does not produce particles.

The final product, the aluminium ingot, will not produce particles due to handling. Therefore it is not probable that massive forms of aluminium alloys containing lead can produce powder-like particles under reasonably expected use.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment LEAD - proposal for environmental classification.pdf

Dossier Submitter's Response

One of the ways lead powder is produced is by dispersal of melted lead, which is quite analogous to milling
We would further like to stress that there is no clear destinction between the massive form of lead and the powder because there are, on the market, lead films with a thickness of only 25 µm, while the powder particles have a diameter around 75 µm. Thus 1 mg of such a film will have a greater surface area than 1 mg of powder.

It might well be that Al-alloys shouldn't be classified. That can be tested with T/D testing.
See also response to comment 9.

RAC's response

Thank you very much for your comments and suggestions, the socio-economic questions are not in the scope of the RAC mandate.

Aluminium alloys
It is possible that aluminium alloys shouldn't be classified. They can be tested according to the T/Dp protocol. Further, alloys need not be labelled if they do not pose a risk to human health or the environment. (Guidance on the Application of the CLP Criteria Version 5.0,2017, Annex IV, section IV.5.6.1).

No distinction between massive and powder form
For more details see response to comment number 3.

PUBLIC ATTACHMENTS
1. su_189_StN CLH Blei.pdf [Please refer to comment No. 4, 15]
2. 2017-10-30_WVMetalle commenting on Pb env classification.pdf [Please refer to comment No. 7, 20]
3. 20171030_ECI comments on Pb ENV classification FINAL.pdf [Please refer to comment No. 1, 10]
4. ILA, PbRC - public attachments - contains 3 files.zip [Please refer to comment No. 6, 19]
5. 171027 harmonisierte Umwelt_Einstufung von Blei Metall.pdf [Please refer to comment No. 8, 22]
6. LEAD - proposal for environmental classification.pdf [Please refer to comment No. 9, 23]
7. Comments of Eurometaux on the proposal for harmonised Classification of Pb metal.docx [Please refer to comment No. 13]
8. 1710_Comment Pb to ECHA.docx [Please refer to comment No. 3, 21]

CONFIDENTIAL ATTACHMENTS
1. Final_Report_Pb_massive_pH8_20_10_2017.pdf [Please refer to comment No. 6, 19]