EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

Proposed Lead metal harmonized classification highlights problems with existing regulatory approach in deriving SCL for metals classified as toxic to reproduction

Introduction

This paper represents the collective views of European Metal Associations, Commodities and Companies (represented by their associations and commodities) listed in the Annex who have significant scientific and socio-economic concern related to the derivation of a Specific Concentration Limit assigned for reproductive toxicity assigned to lead metal during RAC-27.

Today, while lead compounds are classified in CLP Annex VI, as Reproductive toxicity 1A, there is no harmonized classification for lead metal. A proposal for a harmonized classification for lead metal as Reproductive toxicity 1A has been included in the 7th ATP proposal of Commission[1] (see table below). This proposal is accompanied by a Specific Concentration Limit (SCL) for developmental effects, of 0.03%. The classification proposal does not make any distinction between massive (>1mm) and powder forms.

Table 3.1 (CLP criteria):	*Table 3.2 (DSD criteria):*
Reproductive toxicity 1A, H360DF	Reproductive toxicity Category 1; R60-61
May damage fertility or the unborn child	May impair fertility, may cause harm to the unborn child
Specific concentration limit: H360D: C > 0.03%	Specific concentration limit: R61; C > 0.03%
Lactation, H362 - May cause harm to breast-fed children	R64 - May cause harm to breast-fed babies

Industry has, for many years, applied a self-classification of Reproductive toxicity 1A for lead powders based upon the long recognised effects on foetal development and fertility on the lead ion and the relatively high bioavailability of lead in powder form. While the lead REACH registration dossier confirmed this self-classification for powders, the dossier proposed no classification for massive forms of lead, based upon evidence that the bio-availability of lead metal in massive form is significantly lower than that for powders. As methodology for deriving SCL for the reproductive toxicity had not been developed when REACH dossiers were submitted in 2010-, neither lead compounds nor metal powder had a SCL and a generic limit of 0.3% was applied to allow assessment and classification of mixtures.

Industry concerns

Industry now accepts the RAC opinion that, if hazard classification is based on intrinsic properties of the substance and does not take into account potential for exposure, then all forms of lead metal meet the criteria of Reproductive toxicity 1A. However we have significant concerns about the derivation of a specific concentration limit of 0.03% that utilised recently developed guidance that has not been validated for

[1] Follow-up to the 13th Meeting of Competent Authorities for REACH and CLP (CARACAL) 26 – 27 – 28 November 2013, February 12 2014

applicability to metals, or special mixtures containing metals such as alloys, that are placed on the market as solid materials rather than liquids or fine powders.

This SCL proposal will also have a fundamentally negative effect on key EU industrial policy areas, such as access to raw materials, resource and energy efficiency, waste management and the recycling of end-of-life products. The non-ferrous metals industry, under the umbrella of Eurometaux, has submitted detailed information to the Commission about the significant socio-economic consequences of the proposed SCL. The selected SCL value is in the range of impurity levels for several primary and secondary metals and even in the upper range of naturally occurring background levels in the EU. The concerns further expressed below cover scientific, legal and impact assessment grounds:

a) Scientific concerns

The SCL value: RAC considered the intrinsic properties of metallic lead, met criteria for classification as Reprotoxic 1A and applied an SCL of 0.03% (developmental toxicity) based on human evidence of small IQ reductions in young children that is apparent at lead blood concentrations of 10µg/dL. Industry notes that the CLP 2013 guidance for deriving SCLs for reproductive toxicants has not been tested or validated for applicability to elemental metals or for mixtures that are placed on the market in solid form such as metallic alloys. The SCL proposed by RAC is so low that many naturally occurring materials that contain trace amounts of lead, including EU soils[2], would contain greater than the 0.03% cut off value for reproductive toxicity described by the SCL.

Specifically for lead, the SCL value is based on the core assumption that a LOEL effect at 10 µg Pb/dL blood, for subtle development effects observed as IQ changes in children, can be compared to the 4 mg/kg/day cut off for high potency based on animal studies. The extrapolation from subtle effects in humans to an oral ED10 or LOEL from experimental animal data is questioned and may lead to an overestimation of the potential for development toxicity, especially when considering that this is applied to a scenario of a solid metallic alloy containing trace amounts of lead.

Member States are invited to consider revising the methodology for assigning SCL for metals or other naturally occurring substances to ensure it is relevant and non-discriminatory.

Powders versus Massive: The classification proposal does not make a distinction between the hazard classification of the powder and the massive metal form. Such a distinction has been used several times, under the Dangerous Substance Directive assessment scheme, based on the principle that *the release per surface area of a material is a physical constant,* and consequently an intrinsic property of that material. So far however RAC did not recognize this.

The limited evidence currently available for lead metal, demonstrates a significant difference in release rate/bio-accessibility between the soluble, powder and massive forms. This evidence, provided by an animal study (Barltrop and Meek), as well as from in vitro bio-elution tests (see evidence summarized in enclosure), illustrates that differences in bioavailability, related to different physical forms, need to be taken into account. Moreover, bio-accessibility evidence was provided to RAC by the European Copper Institute during deliberations to consider risks of lead in consumer articles that illustrated that release of lead from metal alloys is relatively low. This data was used by RAC in the lead restriction case to develop an opinion that the level of lead in brass did not represent a risk to childhood development below 0.5%. Both these factors illustrate that the derivation of a SCL of 0.03% for lead in massive form when applied to solid metal mixtures such as alloys is overtly precautionary and not scientifically justified.

[2] GEMAS (2013) identified a natural background level for Lead in EU soils in the range of 1.6 – 1309 mg/kg (). A size of EU soil as large of the surface of Belgium would naturally exceed the 300 ppm level corresponding with the SCL

Member States are requested to address the arguments for separate SCL entries for powder and massive forms of lead metal and how SCL should be used in the case of solid metal mixtures.

b) Inconsistency of legislation between the SCL and other EU legislations

The proposed SCL risks providing a very confusing message- to the market, given its inconsistency with other hazard/risk based standards for lead content e.g. up to 4% in RoHS and 0.1% in the ELV directive; lead-free standard alloys contain up to 0.8% lead as impurity. As described above, based on the same hazard data set and concerns for effects on childhood IQ, RAC agreed a lead limit of 0.5% in copper alloys in the context of a Restriction for consumer articles. This decision was based on the evaluation of lead bio-elution data from metallic alloys (brasses) (see lead in consumer articles restriction case). The fact that brasses are, in general, representative of the more soluble alloys supports the view that the derived SCL of 0.03% for lead massive and in application for solid metal mixtures is over precautionary.

Member States are requested to consider how an SCL of 0.03% for classification fits with other EU legislation targeted at reducing risk of lead.

c) Impacts on industry are severe and disproportionate

The socio-economic impact of the SCL is very extensive and impacts the competitiveness of the metal industry, including other branches of the EU industry than Lead manufacturing and use. It will affect broader EU industrial policy areas such as access to raw materials, resource and energy efficiency, waste management and the recycling of end-of-life products, and the industries involved, notably the SME's. Illustrative examples include:

- 90% of the aluminium and 80% of the copper scrap, collected in the EU for recycling, has a lead metal concentration >0.03%. In order to manufacture metals and alloys from recycled materials and still meet the requirements of key end-use sectors (automotive, aeronautics, electronics, construction, …) to use substances which are not classified as a CMR, additional refining or dilution the secondary with primary production are required. Significant increases in CO_2 emissions and costs would result. The latter are estimated to be 200-300 €/T for aluminium and around 700-1,200 €/T for copper (loss of scrap value plus re-smelting costs). Such burdens would reduce the economic benefits of recycling in the EU, leading to increased exports of valuable secondary raw materials and higher costs to import more primary materials (either directly, or as semi-fabricated goods or articles).
- The innovative, but highly competitive EU battery market uses >80% of the lead produced in the EU and achieves recycling rates of over 90%. Besides the lead metal, all other battery materials are recycled including the acid, the silver content and the polypropylene casings. A 0.03% SCL would result in these other materials also being reclassified as repro 1A, due to traces of lead. This would create a major competitiveness gap making primary production more desirable and economically more competitive than recycling.
- A series of other comparative examples exist covering ferrous scrap recycling, galvanized sludge recycling and the use of residues in building material applications (e.g. final slags with CEN standard). They all have in common that the volumes and economic impact are enormous with recycling losing its economic advantage over primary production, which in turn will result in export of recyclables and increase in energy consumption and CO_2 emissions, loss of natural resources used in e.g. road or building applications to landfills…

In the longer term, substances that are classified as toxic to reproduction 1A are candidates for listing as Substances of Vey High Concern (SVHC) and consequently, potential candidates for authorization. Such

authorization for recycled metals would be detrimental to the EU recycling industry and its downstream users that use these classified substances, within an already very competitive global environment.

The proposal for ***a SCL of 0.03% combined with the absence of recognition of the need for a separate entry for the massive form leads therefore to highly disproportionate consequences*** for the EU industry, consumer market and in particular many EU environmental policies (climate, resources efficiency, …).

Member States are requested to consider the socio-economic impacts of adoption of a SCL of 0.03% for lead metal and in particular unintended impacts on incentives to recycle recovered metals.

Conclusion and recommendations

- **Industry accepts the RAC opinion that, due to consideration of reasonably expected use, lead metal in all forms meets the CLP criteria for hazard classification as a reproductive toxicant Category 1A.**
- **Industry however remains concerned about the scientific robustness and validity of the guidance developed for derivation of SCL for reproductive toxicants to metals. We suggest that further debate and scientific validation is required to confirm how the guidance should be applied to situations when a classified metallic substance (in this case lead) is present in special mixtures such as alloys.**
- **Inappropriate classification of other metals and metal alloys based upon a low SCL for lead has potentially significant socio-economic impacts**
- **We believe that the derivation of SCLs for metals should take into account both bioavailability/bio-elution testing and the appropriateness of different values for different forms (massive and powders). The SLC expresses a potency which for inorganics is -to a great extent- determined by its release/surface. Such an approach would parallel that of the Transformation Dissolution protocol used for environmental hazard assessments.**

Conclusively industry invites the Member States to:

- **Reconsider the inclusion of the proposed SCL for metallic lead in the 7th ATP**
- **Recognize the need to develop further guidance on derivation of SCL for massive forms of metals and special mixtures and how the SCL should be used in classification of metallic alloys**

Reference:

GEMAS: Reimann, C., Birke, M., Demetriades, A., Filzmoser, P. & O'Connor, P. (Editors), 2014. Chemistry of Europe's agricultural soils – Part A: Methodology and interpretation of the GEMAS data set. Geologisches Jahrbuch (Reihe B), Schweizerbarth, Hannover, 528 pp. /Reimann, C., Birke, M., Demetriades, A., Filzmoser, P. & O'Connor, P. (Editors), 2014. Chemistry of Europe's agricultural soils – Part B: General background information and further analysis of the GEMAS data set. Geologisches Jahrbuch (Reihe B), Schweizerbarth, Hannover, 352 pp.


EUROMETAUX
EUROPEAN ASSOCIATION OF METALS


IMOA
INTERNATIONAL MOLYBDENUM ASSOCIATION
THE VOICE OF THE MOLYBDENUM INDUSTRY


ECOBAT
TECHNOLOGIES


zinc
...essential for life


european
aluminium association


WKO
FACHVERBAND BERGBAU-STAHL


WKO
FACHVERBAND NE-METALL


EUROFER
The European Steel Association


WVM
WirtschaftsVereinigung Metalle


epmf


Cu
European
Copper Institute
Copper Alliance


AGORIA
no future without technology


ila
International
Lead Association
EUROPE


EDG
EUROPEAN
DOMESTIC
GLASS


fritconsortium


i2a
International
Antimony Association


EUROBAT


euromines
TRAXYS
EUROPE