RESPONSES INTO THE ECHA PUBLIC CONSULTATION FOR TETRALEAD TRIOXIDE SULPHATE

About the ILA

The International Lead Association is a membership body that supports companies involved in the mining, smelting, refining and recycling of lead. The ILA represents the producers of about 3 million tons of lead. As secretariat to the Lead (Pb) REACH Consortium, ILA is acting on behalf of the Lead Registrants for several lead substances including lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate. Please refer to Appendix A for a list of all the Lead (Pb) REACH Consortium members.

General Comments

Detailed comments were already provided in a previous consultation the context of the 6th priority list recommendation and are not repeated here unless not adequately reported in the current draft background document.

We disagree with the total priority setting score of 23 reported in the conclusions and justification in the current draft background document (Section 2.5) based upon the volume in scope of authorization and description of uses. The use of tetralead trioxide sulphate in plastics is scheduled to be phased out at the end of 2015 as a result of a voluntary commitment to replace lead based stabilisers in PVC. As such the additional score of 2 applied to the WDU score of 5 due to "non-negligible release from articles as the integrity and stability of the plastic matrix is difficult to guarantee over time" should not be considered. Therefore we would contend that a total score of 21 be applied to tetralead trioxide sulphate.

We would also like to highlight that there is an error in the reported volumes in sections 2.2 and 2.5. We have highlighted this issue previously but in our opinion the total EU volume for this substance should be 100,000-1,000,000 t/y and not >1,000,000 tpa. We will re-contact registrants to request that they check volumes reported in dossiers.

Comments on Transitional Arrangements

Given that the vast majority of the total use volume of this substance is related to battery manufacturing and supply chains are not complex we consider 24 months to be an appropriate LAD.

Comments on Uses (or categories of uses) Exempted from the Authorisation Requirement

We note in the background document that ECHA proposes not to recommend exemptions for uses of tetralead trioxide sulphate on the basis of Article 58(2) of the REACH regulation (section 3.3.1). In previous submissions we have provided strong arguments that would indicate that Commission does have discretion for granting a REACH Article 58(2) exemption for use of tetralead trioxide sulphate in battery manufacturing (and possibly other uses that are restricted to industrial processing and where is tetralead trioxide sulphate not present in the article placed on the market)

A detailed explanation for this conclusion was provided in the public consultation for the 6th priority list but in summary we believe that the industrial use of tetralead trioxide sulphate (such as the case for the production of lead based batteries) meets ALL requirements of REACH Article 58(2) in that:

- Existing Community legislation already addresses the use categories to be exempted.
- The existing legislation provides binding and enforceable minimum requirements for the control of risks from industrial use of tetralead trioxide sulphate. In having a binding occupational exposure and biological limit for lead, supported by additional measures such as medical surveillance, Council Directive 98/24/EC ensures that harmonized, EU wide standards operate (although Member States can establish more stringent but not less stringent requirements)

This conclusion is further supported by the recent General Court ruling (T-360/13, Vecco and others) in relation to chromium trioxide and REACH Article 58(2).

We do not agree with ECHA's opinion in response to comments provided during the public consultation for the 6th Priority list (doc ECHA/MSC-41/2015/029) and further in the MSC draft opinion on ECHA's sixth draft recommendation that "*given the wealth of EU legislation governing lead and it's compounds the uses with perhaps the strongest case for Art 58(2) exemption are those for which a legislative regime is already in place to push for substitution in a similar manner to the authorization requirement* …." We believe ECHA and the MSC have included the concept of substitution that is an additional element that goes beyond the criteria of Article 58 (2) of REACH which concerns legislation imposing minimum requirements relating to the protection of human health or the environment that ensures *proper control of risks*".

Support for this proposition is provided by observations that the General Court ruling in relation to REACH Article 58(2) arguments made by Vecco and others did not suggest in any way a push for substitution to be relevant for the assessment of Community legislation per Article 58(2) of REACH. Moreover, it is notable that REACH Articles 57 and 58 do not include any reference to the aim for substitution and that Article 55 itself does not push for all SVHCs to be replaced, but only those subject to authorization (ie uses not exempted under Article 58(2)).
In addition the ECHA guidance on preparation of draft Annex XIV entries does not mention any condition for substitution that should be enshrined in a specific Community legislation in order to grant an exemption on the basis of Article 58(2) and no Annex XIV recommendations by ECHA over the last 6 years refer to substitution requirements of existing community legislation in the context of Article 58(2) exemptions.
An evaluation of the only current existing Article 58(2) exemption that concerns phthalates in immediate packaging of medicinal products by Commission Regulation 143/2011 highlights that no assessment regarding substitutes was made in the process and Commission granted the exemption purely on basis that there was "specific Community legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of risks".

We believe that ECHA's opinion in relation to recommendation for substances to be included in the 6th Priority list that "*the case for REACH Article 58(2) of uses not covered by RoHS and ELV is weaker than use in automotive battery use as there does not appear to be a legislative regime in place to push for substitution in a similar manner to authorization requirement*" is a somewhat flawed argument and that consideration of Article 58(2) exemption should be based solely upon whether "*existing specific Community legislation imposing minimum requirement*s relating to the protection of human health or the environment for the use of the substance, the *risk is properly controlled*…"

Notwithstanding the comments made above we are surprised that Section 3.3.1 of the Background Document does not refer to any of the previous discussions and opinions on REACH Article 58(2) exemption that ECHA and MSC made in relation to the 6th Priority List recommendation. It was our

understanding that at least for uses of tetralead trioxide sulphate that are currently exempted under RoHS and/or ELV, ECHA concluded that exemptions from authorisation might be considered. We understand that this conclusion was reached on the basis that ELV and RoHS already push for substitution in a similar manner to authorization requirement. Whilst we question the rationale for citing end of life legislation when the substance tetralead trioxide sulphate is not present in articles that would be subject to this legislative regime (it is fully transformed in the manufacturing process), we do not understand why the "push for substitution of lead" in the Batteries Directive (2006/66/EU) is less similar to the REACH substitution intention than the one provided by ELV. Article 5 of the Batteries Directive requires that "Member States which have manufacturers established on their territory shall promote research and encourage improvements in the overall environmental performance of batteries and accumulators throughout their entire life cycle as well as the development and marketing of batteries and accumulators which contain smaller quantities of dangerous substances or which contain less polluting substances, in particular *as substitutes for mercury, cadmium and lead*." Moreover, the Batteries Directive includes several other provisions aimed at substituting heavy metals (e.g. Article 4-Prohibitions). We therefore contend that if "end of life" or waste legislation is used to highlight an equivalent drive for substitution as REACH authorization then both the Batteries Directive and ELV should be included in such an analysis.

We conclude that an analysis as to whether REACH Article 58(2) may apply should be restricted to the use for which authorization would be required. In the case of battery use, as tetralead trioxide sulphate is not present in the article (automotive or industrial battery) placed on the market the analysis should be restricted to the industrial use in manufacturing of the article. In this case the binding occupational exposure limit set out for lead and lead compounds and other requirements of existing Occupational health legislation (such as compulsory medical surveillance and protection of pregnant and breastfeeding workers through Directive 92/85/EEC) constitutes "existing specific Community legislation imposing minimum requirements relating to the protection of human health" for the toxicological endpoint for which tetralead trioxide sulphate is placed on the Candidate list. Thus ALL requirement necessary to consider REACH Article 58(2) exemption for the use of tetralead trioxide sulphate in battery manufacturing would appear to have been met.
We contend that the wording used by ECHA and MSC in relation to the 6th Priority List opinion that includes a requirement for an existing legislative regime to "push for substitution " in a similar manner to REACH authorization *is an additional element that goes beyond the legal text requirement of Article 58 (2) of REACH*. However, notwithstanding this we believe that the General Court Vecco ruling (T-360/13) supports the observation that for an industrial use the Chemicals Agents Directive (98/24) includes a provision that drives substitution through its hierarchy of controls that requires replacement of dangerous substances by less hazardous ones (Article 6). Moreover, in the case of lead batteries, product legislation in the form of the ELV Directive and Batteries Directive also support the case that a legislative regime already exists that encourages substitution of this technology where this is technically and economically feasible.

We therefore urge ECHA and Members States to consider an opinion that the industrial use of tetralead trioxide sulphate (such as the case in battery manufacturing) be recommended for exemption from the authorization requirement under Article 58(2).

Appendix A

Lead REACH consortium members

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

IKa Innovative Kunststoffaufbereitung GmbH & Co.KG	Xstrata Zinc (Britannia Refined Metals Ltd)
Jenox Akumulatory Sp. z o.o	Yuasa Battery UK Ltd
	Zap Sznajder Batterien s.a
Associate member	Association of European Sporting Ammunition Manufacturers (AFEMS)