Paris, 28 April 2022

NON-CONFIDENTIAL COMMENTS ON ECHA'S DRAFT ANNEX XIV RECOMMENDATION FOR LEAD METAL

Space Sector Contribution to the ECHA Public Consultation on its draft 11th recommendation for inclusion in the Authorisation List

PREFACE

This is the joint contribution of the European Space Industry, represented by ASD-EUROSPACE – with the support of European and national space agencies, and the European Defence Agency as observer – to the ECHA Public Consultation on its draft 11th recommendation for inclusion in the Authorisation List in relation to lead (metal), EC# 231-100-4, CAS# 7439-92-1 (hereafter also "the Substance", "Lead" or "Pb").

It has been prepared in the frame of the Lead (metal) REACH Space Task Force (LTF)[1], which comprises the following

Industrial members:

AIRBUS DEFENCE AND SPACE – ARIANEGROUP – ESR TECHNOLOGY – JENA-OPTRONIK – RUAG SPACE (from 1.5.2022: BEYOND GRAVITY) – SODERN – TESAT SPACECOM – THALES ALENIA SPACE – TNO

Space agencies:

EUROPEAN SPACE AGENCY (ESA) – CENTRE NATIONAL D'ETUDES SPATIALES (CNES) – GERMAN AEROSPACE CENTER (DLR)

and the EUROPEAN DEFENCE AGENCY (EDA) as an observer.

ASD-EUROSPACE is acting as the LTF Secretariat and REACHLAW as consultant.

This contribution complements our comments to the parallel ECHA call for information (on behalf of the Commission) on the possible socio-economic consequences of the authorisation

[1]The LTF was initiated by the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB) in response to the Candidate List proposal for lead in 2018. The ESCC MPTB is a partnership between the European Space Agency (ESA), national space agencies, and space industry represented by ASD-EUROSPACE; it is chaired at present by ESA.

requirement. We also wish to refer to and express our support for the comments made by the International Lead Association (ILA) / Lead REACH Consortium (PbRC) to the same consultation; the LTF has contributed to it as a participant of the cross-sector "Lead Authorisation Task Force".

Please note that the information below has also been inserted in the dedicated ECHA consultation webform (Section III) for each section, with the exception of footnotes and the section on "additional information" which constitutes additional input.

PRIORITISATION RESULTS AND GENERAL ISSUES

We would like to make the following comments on the prioritisation results and general issues:

REACH Art. 58(3)2 stresses that the prioritisation based on the three criteria (incl. wide dispersive use and volumes) shall (only) apply ***"normally"***. In our view there are a number of reasons that warrant an exception from this rule with regard to lead metal:[2]

First of all, this ECHA initiative for such an important substance comes in the midst of the Commission's activities and critical stakeholder consultation activities for an impact assessment to prepare a proposal for a **revision of the REACH Regulation** by the end of 2022, including a **substantial Reform of the Authorisation and Restriction processes** (one of the options even being the removal of the authorisation title from REACH!) and the development of an Essential Use Concept to better protect uses without alternatives that are necessary for health, safety or are critical for the functioning of society.

Further to the REACH revision, a substantial **review of the RoHS Directive 2011/65/EU** is currently carried out by the Commission. A public consultation is on-going until 2 June 2022. RoHS includes lead as an important substance. The review also addresses the interface with REACH as one of its central elements.

In such situation of pertinent legal revision (REACH, RoHS) we seriously question the timeliness of this Annex XIV (draft) recommendation for lead metal.

As an EU agency ECHA should also take into account the Commission's policy priorities for a substance. The **Commission's Action Plan under the Chemicals Strategy for Sustainability** of 14 October 2020 (which is also the basis for the REACH revision) explicitly foresees the **implementation of the Chemical Agents Directive** by proposing lowering existing occupational limit values as the **tool of choice** to strengthen the protection

[2] As rightly pointed out by ECHA (see link, p4), the consideration of further aspects and criteria for priority setting than the points mentioned in REACH Art. 58(3) is not excluded.

of workers.[3] By intending to recommend lead for authorisation in parallel / addition, ECHA does not take due account of the Commission's strategy as reflected in the Action Plan.

Furthermore, it appears more like a "box-ticking exercise" by ECHA, knowing that there are many substances which have already been recommended for Annex XIV but where the Commission has postponed the inclusion, often with regard to other regulatory management options (such as restrictions, OELs). This applies in particular to the four lead compounds previously recommended by ECHA (2016).[4] In the latter case – as even stated by ECHA in its prioritisation assessment of 2 February 2022[5] – the European Commission in its previous amendment of Annex XIV (Commission Regulation (EU) 2020/171) **postponed the decision on the inclusion of four lead compounds**. Reference was made to the Chemical Agents and Industrial Emissions Directives covering lead and its compounds and to the revision of the binding occupational and biological limit values. In our view ECHA should take into account such conclusion by the Commission when making its Annex XIV recommendation, but with a **deprioritising effect**. Therefore, the ECHA recommendation for lead appears premature.

Also, in the latter regard it is not clear to us why substances with a higher priority score such as MCCP (score of 42 as compared to 28 for lead) and 1,4-dioxane (score of 32) have not been recommended by ECHA with regard to on-going work related to REACH restriction, but the same has not been considered for lead. This amounts to an **unequal treatment of similar cases** and an **undesired interference between different regulatory actions**, which according to ECHA's own general approach for prioritisation of SVHCs should be avoided.[6]

Additionally with regard to 1,4 dioxane, we do not understand the ECHA conclusion that *"an OEL is not expected to have a major impact on the prioritisation"*. According to the Commission this very fact justifies even a postponement of the Annex XIV inclusion (see above).

In addition, lead is the first element (metal) ever intended to be proposed for REACH authorisation. Also, there is no precedent for an authorisation requirement to apply to **alloys as "special mixtures"** according to REACH and CLP Regulations. There is a need for ECHA to clarify first how alloys should be treated before taking any initiative to include the substance contained in Annex XIV.

> REACH Annex I "General provisions for assessing substances and preparing chemical safety reports" sets out in Section 0.11. *"When assessing the risk of the use of one or more substances incorporated into a special mixture (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account."*

[3] See action #25 at https://ec.europa.eu/environment/system/files/2021-11/Table_implementation_CSS_actions.pdf.

[4] Orange lead, lead monoxide, pentalead tetraoxide sulphate, tetralead trioxide sulphate.

[5] https://echa.europa.eu/documents/10162/ad8e4db7-d1bb-ab21-68e5-cb4603b6e5ac.

[6] See p10 at https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf.

> Similarly, according to the **Guidance on the Application of the CLP Criteria** *"metal alloys, or alloy manufacturing products, are not simple mixtures of metals or metal components, since the alloy clearly has distinctive properties compared to a classical mixture of its component metals"* (IV.5.6.1 Classification of alloys and complex metal containing materials).

Further to this, REACH Art. 58(3)3 sets out that "[t]*he number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for."* We refer to the contribution by ILA / PbRC and our estimate below, which indicates an excessive number of expected AfAs not only for the Space Sector, but also at the broader industrial scale. Clearly, this informed estimate should be taken into account already at the point of deciding on an ECHA Annex XIV recommendation. No recommendation for lead should be made in such case.

As far as the background document[7] (p3&9/10) mentions the use of lead in articles above 10 t/y, we would like to note that uses of articles are not in scope of authorisation. Companies in the Space Sector have been working with lead and have managed related risks for decades. Risks are well known and considered as negligible. They are already reduced by the fact that operators use mainly finished or semi-finished products. Further information is included in our comments to the Commission on the same consultation (answers to question 6 and 7). Therefore, we question the related increase of the priority score with regard to article uses (presently +2).

TRANSITIONAL ARRANGEMENTS

Based on our comments above on prioritisation results and general issues we believe that lead should not be recommended for Annex XIV inclusion. Therefore, the following comments on the proposed Latest Application Dates (LAD) and Sunset Dates are only made as a precaution:

ECHA proposes the standard LAD slots of 18, 21 and 24 months from the date of inclusion in Annex XIV and 18 months after the LAD as a sunset date.

As far as the Space Sector is concerned, the supply chains are very complex and it will be challenging to define a viable strategy for applications for authorisation (AfAs) covering all operators, including many SMEs.

For *soldering*, which would require the majority of AfAs for our sector, **the entire complex EU space systems supply chain would be impacted**, including the primary metal producer, the solder paste supplier, manufacturer of each independent element (component, printed circuit, alloy, cable), distributor and assembler of all these parts (internally or with a subcontractor). Space companies as assemblers are located at the end of the long supply chain; they are also downstream users of solder paste, especially for PCBs. They are found on

[7] https://echa.europa.eu/documents/10162/1cff5712-6e86-df7f-1e4c-f29559c80dd8.

most satellites; industry buys them and sometimes solders on them. All European PCB manufacturers as well as satellite motherboard manufacturers are concerned. Hence, upstream operators (e.g. the solder paste producer, PCB manufacturers) would also have to apply for their own uses, because these cannot be covered by Downstream Users.

Based on information from ESA and Eurospace, the total number of AfAs required only in the European Space Sector and only for lead-based soldering activities (including subcontractors) could go up to 200 or more AfAs.

This estimate does not even include uses subject to authorisation by upstream operators outside the European Space Sector (e.g. soldering by PCB manufacturers, solder paste formulation) and other than soldering uses. Hence, the total number of AfAs may be even higher (see further details in the response to question 29 of our response to COM, ref. MPTB-ES-PO-0099).

It is expected that all or at least the vast majority of the mentioned sites/soldering processes will require an AfA for continued operations as there will be no alternative in place at the expected Sunset Date.

The challenges of upstream authorisation for Cr(VI) would thus be exacerbated for lead, which has a higher diversity of uses and soldering activities are very site specific.

In addition to soldering, AfAs may be needed (*not exhaustive*) for other uses of lead for space applications, such as *Pb coating for lubrication*, *other alloys used as "mixtures"* and containing lead above the relevant limit, lead in *adhesives* or as *addition in chemical-nickel electrolyte*, unless alternatives are implemented successfully before a sunset date. Also here, space companies would be reliant on upstream operators, including downstream users who process raw materials (still) qualifying as mixtures.

Given the uncertainties encountered with upstream AfAs in the chromates case on the one hand and the multiple use steps in the supply chain leading to the production of lead-containing articles and complex objects on the other hand we expect that a **"hybrid" AfA strategy** will be needed, including

- ***Individual* DU AfAs** by many companies in the Space Sector to cover their own uses; and
- **AfAs further *upstream*, e.g. by formulators** of solder paste or (other) producers of raw materials qualifying as "mixtures" and containing lead as a component

Sector-level cooperation to prepare core dossier elements for an AfA (e.g. AoA, SEA) and collaborate with upstream actors (e.g. formulator) would need to be considered too.

In summary, the latest possible LAD (24 months or later) would need to be chosen for lead.

USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

Based on our comments above on prioritisation results and general issues we believe that lead should not be recommended for Annex XIV inclusion. Therefore, the following comments on uses (or categories of uses) that should be exempted, including reasons for that, are only made as a precaution:

Even though not an exemption, but rather an exclusion from the scope of authorisation, we would like to note for ***alloys*** (e.g. parts made of Lead-containing copper, brass or aluminium) that they are typically procured in a machined state by space companies and will therefore often be (semi-/finished) "articles" as defined in REACH (e.g. brass or round rods and plates). In those cases, the authorisation requirement would be limited to upstream operators who process raw materials qualifying as "mixtures". However, uncertainties remain due to the subjective nature of some of the indicative questions in the ECHA Guidance on requirements for substances in articles. This could imply a possible need for an AfA to be on the safe side, unless the article status in a specific case is sufficiently backed by the competent authorities. This, in turn, would result in the possible need for multiple AfAs in the same alloy supply chain with dependency on upstream authorisation. We therefore require the support from ECHA to clarify borderline cases.

Furthermore, with regard to adding exemptions according to **REACH Art. 58(2)**, the Commission's paper *"REACH and Directive 2011/65/EU (RoHS) A Common Understanding" (2014)"*[8] has clarified that the possibility is also open to exempt the uses of substances covered by the RoHS restriction (such as Lead) - including its exempted applications - from REACH authorisation pursuant to Article 58(2) of REACH. Electrical and Electronic Equipment (EEE) designed to be sent into space is excluded from the scope of RoHS without a defined time limit (**RoHS Art. 2(4)(b)**). In our view, requiring AfAs for the solder use would undermine this exclusion and favour imported EEE (which could still contain lead without the need for an authorisation).

ADDITIONAL INFORMATION

We make reference to our comments to the parallel ECHA call for information (on behalf of the Commission) on the possible socio-economic consequences of the authorisation requirement. In our view Annex XIV inclusion of lead is not the right regulatory option to address the concerns for human health from its use(s). Besides, the ECHA recommendation is untimely, given the various ongoing initiatives relevant for lead and the possible authorisation requirements (CSS REACH Revision, RoHS Review, OEL revision, on-going restriction activities)

Therefore, the ECHA draft recommendation for lead should be withdrawn.

[8] Available at https://ec.europa.eu/growth/sectors/chemicals/reach/special-cases_en.

Kind regards,

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