

## Comments on the draft recommendation of substances for inclusion in Annex XIV

and

## Call for information (on behalf of the Commission) on the possible socio-economic consequences of the au- thorisation requirement




**Substance name:** Lead

**EC Number:** 231-100-4

**This contribution is sent on behalf of the companies/business associations listed below participants in the RoHS Umbrella Industry Project ("the Umbrella Project"):**

 <p>ANIMA Confindustria Meccanica varia</p> <p>EU Transparency Re- gister ID number: 222607318896-47</p>	 <p>Communications and Information Network Association of Japan (CIAJ)</p>	 <p>European Semiconductor Industry Association</p> <p>EU Transparency Register ID number: 22092908193-23</p>	 <p>European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)</p> <p>EU Transparency Register ID number: 05366537746-69</p>
 <p>GAMBICA - The UK Association for Instrumentation, Control, Automation &amp; Laboratory Technology</p>	 <p>Interconnect Technology Suppliers Association (ITSA)</p>	 <p>IPC International, Inc.</p> <p>EU Transparency Register ID number: 390331424747-18</p>	 <p>Information Technology Industry Council</p> <p>EU Transparency register ID number 061601915428-87</p>

 <p>Japan Analytical Instruments Manufacturers' Association (JAIMA)</p>	 <p>Japan Auto Parts Industries Association (JAPIA)</p>	 <p>Japan Business Council in Europe (JBCE) EU Transparency Register ID number: 68368571120-55</p>	 <p>Japan Business Machine and Information System Industries Association (JBMIA)</p>
 <p>Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA)</p>	 <p>Japan Electrical Manufacturers' Association (JEMA)</p>	 <p>Japan Electronics and Information Technology Industries Association (JEITA)</p>	 <p>Japan Federation of Medical Devices Associations (JFMDA)</p>
 <p>Japan Inspection Instruments Manufacturers' Association (JIMA)</p>	 <p>Japan Medical Imaging and Radiological Systems Industries Association (JIRA)</p>	 <p>Japan Land Engine Manufacturers Association (LEMA)</p>	 <p>Japan Lighting Manufacturers Association (JLMA)</p>
 <p>Japan Measuring Instruments Federation (JMIF)</p>	 <p>MedTech Europe EU Transparency Register ID number: 433743725252-26</p>	 <p>Nippon Electric Control Equipment Industries Association (NECA)</p>	<p>The Test and Measurement Coalition EU Transparency register ID number 31367501249-92</p>
 <p>ZVEI - German Electrical and Electronic Manufacturers' Association EU Transparency Register ID number: 94770746469-09</p>	 <p>The European Federation of Associations of Locks and Builders Hardware Manufacturers (ARGE) EU Transparency Register ID number: 881365536049-72</p>	 <p>The European Steel Association (EUROFER) EU Transparency Register ID number: 93038071152-83</p>	 <p>Wirtschafts Vereinigung Metalle (WVMetalle) EU Transparency Register ID number: 9002547940-17</p>

 <p>European Garden Machinery Industry Federation (EGMF)</p> <p>EU Transparency Register ID number: 82669082072-33</p>	 <p>European Partnership for Energy and the Environment (EPEE)</p> <p>EU Transparency Register ID number: 22276738915-67</p>	 <p>EU Transparency Register ID number: 7721359944-96</p>	
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The Umbrella Project is an unprecedented cross-industry global initiative, currently involving more than 70 partnering industry associations globally, fostering cross-industry dialogue and alignment on possibilities for adaptation of RoHS Exemptions based on scientific and technical progress. Participants in the Umbrella Project have been key contributors to the current Directive, including the continuing Exemptions' technical adaptations, to everyone's benefit.

As lead is the most relevant substance for the named exemptions, participants gained through the years, very high experience regarding technical aspects like the technical practicability of substitution, the availability of substitutes and their safety and the total impacts of substitution. The participants also gained very high knowledge about socio-economic impacts of substitution or the cessation of product lines in case materials for which no substitute exist cannot be used anymore.

### HEALTH AND ENVIRONMENTAL PROPERTIES

**Regarding the health and environmental properties of lead as pure substance and in mixtures or articles we want to express our support to the comments provided by the International Lead Association (ILA).** In addition, as during intended use and correct end of life treatment of electrical and electronic equipment of participants in the Umbrella Project no or nearly no lead is released and no exposure to lead is caused, we will not discuss these properties.

We wish to provide the downstream users perspective on the consequences in case lead would be taken up in annex XIV.

### IMPACT ON THE SUPPLYCHAIN AND COMPETITIVENESS OF THE EU INDUSTRY

The first and most obvious consequence of the inclusion in Annex XIV, would be a disadvantage for EU manufacturers compared to non-EU manufacturers and relevant supply chain risks. In case of non-EU production, no authorisation requirement for the materials applies and the finished articles can be exported to the EU. In contrast the EU manufacturers of the materials will in many cases need an authorisation. This generates additional not negligible costs and severe supply chain risks. We would like to remind that RoHS exemptions are often applied for investment goods with lifetimes of several decades. Accordingly, the supply of the required raw materials has to be ensured during this time. As very correctly the "repaired as produced" principle applies in RoHS these materials are required not only for the production of new equipment but also for spare parts to allow the long lifetimes.

We are also worried by previous experience with another non-niche substance group that was taken up in annex XIV: chromiumVI oxide and its derivatives. As we understand

the process for granting the required authorisations did not work as intended for these substances. The same might happen for lead.

The in-depth assessments of the RoHS exemptions in the last more than ten years showed that the electrical and electronic industry cannot work without several specific leaded materials. In the consumer but even more in the professional area many of the applications have systemic relevance for society. For example, most of the connectors and many capacitors use leaded materials, several automated soldering processes require leaded solders and thousands of specialized applications requiring leaded materials exist, including life-saving medical equipment. Putting additional risks and challenges on the existing supply chain is the opposite of what the electrical and electronic industry needs at the moment.

## **LINKS WITH OTHER EU LEGISLATION AND FURTHER NORMATIVE REQUIREMENTS**

The inclusion of lead in REACH Annex XIV will also result in unintended consequences due to requirements in other legislation that reference REACH Annex XIV.

For instance, the Platform on Sustainable Finance just published its "Annex to the Platform on Sustainable Finance's report with recommendations on technical screening criteria for the four remaining environmental objectives of the EU taxonomy"<sup>1</sup>. For the activity "Manufacture of electrical and electronic equipment", where product specific EU Ecolabel or EU GPP comprehensive criteria do not exist, one requirement besides others would be:

„1. No SVHC in REACH Annex 14 in each article are contained in the product. Authorization to Annex 14 is not allowed. No Substances included in REACH candidate list (within 6 months following the publication the last update of the candidate list in force on 1st January of the reporting year), except if essential use is proven or if use is allowed under RoHS as detailed in criteria n°2 of this section.“

The criteria in n°2 cover either two or three specific RoHS exemptions (page 152 names two, page 156 names 3). We commented on the draft for the technical screening criteria in August 2021. While we still think that not two exemptions should be prioritized, in the 2021 draft the requirement „No Substances included in REACH candidate list“ was not yet contained. This requirement would be very problematic as several applications that support Green Deal goals, as for example the generation of renewable energy, depends on lead and other candidate list substances. So, even when this requirement would not be kept in the final delegated act defining the technical screening criteria the inclusion of lead in REACH Annex XIV can still hinder the investment in the named applications. Also the limitation of the technical screening criteria to a restriction of REACH Annex XIV substances and an exemption for all applications covered by RoHS exemptions would not solve this problem because many of the applications named above are excluded from the scope of RoHS, e.g. a windmill is a large scale fixed installation.

### *Further normative requirements:*

A very high number of company standards exist that proactively restrict the use of substances from REACH Annex XIV. While it is relatively fast possible to change these company standards, we expect also several national or international standards and even other legal requirements to restrict the use of REACH Annex XIV substances. They could not be changed in short time resulting in normative requirements that can technically not be fulfilled.

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<sup>1</sup> [Annex to the Platform on Sustainable Finance's report with recommendations on technical screening criteria for the four remaining environmental objectives of the EU taxonomy | European Commission \(europa.eu\)](https://ec.europa.eu/economy_finance/annex-to-the-platform-on-sustainable-finance-report-with-recommendations-on-technical-screening-criteria-for-the-four-remaining-environmental-objectives-of-the-eu-taxonomy)

**From the above we conclude that it is not recommended to include lead in REACH Annex XIV. The disadvantage for EU-manufacturers is un-avoidable and it is one of the issues under consideration in the scope of the REACH revision. Before proceeding with the inclusion of a widely used and critical substance such as lead, we strongly recommend to the EU Commission and ECHA to first launch an deep and detailed impact assessment and figure out the normative requirements that reference to REACH Annex XIV. This is critical to decide if the benefits from adding lead to REACH Annex XIV would outweigh all the consequent impacts.**

**It might be a better solution to restrict the use of lead in the applications where really a benefit for human health and the environment is achieved via REACH Annex XVII.**

## **ARTICLE 58.2 EXEMPTIONS**

We would like to provide our analysis for the possibility of granting exemptions under REACH article 58.2 for applications covered by RoHS.

As explained above, there are many more applications that are not covered by RoHS.

In its "Draft background document for lead"<sup>2</sup> ECHA comes to the conclusion that "if the Commission were to consider Art 58(2) exemptions possible, uses of lead compounds exempted and subject to regular review under RoHS and ELV legislation may have a stronger case for Art 58(2) exemption than other uses." [<sup>2</sup>, page 6]

We wish to discuss in the following the elements in deciding whether to recommend an exemption of a use of a substance as given by ECHA:

- *There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;*

The exemptions in RoHS Directive 2011/65/EU annexes III and IV have clearly defined scopes. The scopes are as narrow as currently possible and are regularly reviewed. All requirements are clearly defined in the directive.

- *The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;*

RoHS contributes to human health and the environment, see for example recitals (2), (7), (10), (18), articles (1), (5) and (6). As it is not limited to the use of the substance lead in substances and mixtures in the EU, its impact is broader as that of REACH annex XIV.

The reference to lead is clearly defined in RoHS Annex II.

- *The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in*

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<sup>2</sup> <https://echa.europa.eu/documents/10162/1cff5712-6e86-df7f-1e4c-f29559c80dd8>

*the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.*

The RoHS exemptions define an exact threshold that refers in nearly all cases to the "homogenous material" which is a very exact definition, often more stringent than the "article" under REACH. The harmonized standard EN IEC 63000 also defines the required documentation. ROHS also applies to imported articles, therefore removing the uneven playing field and it also covers the waste stage of EEE products.

We would also like to remind that the paper "REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING"<sup>3</sup> explains the possibility "to exempt the uses covered by the RoHS restriction (including its exempted applications) from the authorization process under REACH pursuant to Article 58(2) of REACH on the basis of the arguments described above."

This paper also explains: "While recognizing the preference for RoHS to deal with all aspects of the incorporation of substances in EEE, a case-by-case analysis may conclude that the restriction of a substance under RoHS with exempted applications does not constitute "proper control" for the purposes of Article 58(2) of REACH. In this event it is worth underlining that subjecting the inclusion of a substance to REACH authorization for manufacture of EEE for which an exemption has been granted under RoHS will only apply to EU manufacturers and not to imported EEE manufactured outside the EU. Consequently, there would be an additional burden for EU manufacturers until such time that the exemption under RoHS is terminated."

Considering that the ROHS exemptions are assessed in very detail in a clearly defined process including all stakeholders and even more the disadvantage of the EU manufacturers in case lead is included in REACH Annex XIV as explained above we are sure that it is justified to exempt applications in annexes III and IV of RoHS in case lead would be included in REACH Annex XIV.

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<sup>3</sup> <https://ec.europa.eu/docsroom/documents/5804/attachments/1/translations>