01/07/2015

# Comments and references to responses on ECHA's Draft 6th Recommendation for Lead monoxide (lead oxide) (EC number: 215-267-0)

**PUBLIC VERSION**

***The present document compiles the comments received during the public consultation on the draft 6th recommendation for inclusion of substances in Annex XIV of REACH for Lead monoxide (EC number: 235-267-0). The public consultation took place between 1 September and 1 December 2014. Some of the comments submitted contained additional attachment(s), accessible at http://echa.europa.eu/documents/10162/13640/6th_rec_comref_attachments_lead_monoxide_en.zip. Those comments are indicated accordingly in the table below.***

***For each of the comments there is also a reference to specific section(s) of a document containing the responses to comments ("Response document", available at http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_response_doc_lead_substances_en.pdf). The responses in the Response document are arranged by thematic block and level of information (see more detailed explanations at the beginning of that document).***

## CONTENT



## I - General comments on the recommendation to include the substance in Annex XIV

| Number / Date | Submitted by (name, submitter type, country) | Comment | Reference to responses |
|---|---|---|---|
| 2519<br>2014/10/30 | Company,<br>United Kingdom | None | **A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate** |

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| | | | **A.2.15. Inclusion of lead monoxide and orange lead in the authorisation list impacts companies using substances resulting from the use of these substances as intermediates**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>5. Availability of suitable alternatives |
| | | 2519_Suitable alternatives to lead monoxide.docx | |
| 2542<br>2014/11/17 | Berzelius Metall GmbH,<br>Company,<br>Germany | We support the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium | See responses referred to in comment #2602 in this section. |
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| 2563<br>2014/11/20 | DALIC SAS,<br>Company,<br>France | Dear Sirs,<br><br>We are a SME of less than 20 people working in the field of surfaces treatment without immersion.<br>These localized applications or selective applications are a necessary process in all surface treatment sectors.<br>They can be required at production stage when only a limited area of a new component requires a treatment. So the immersion of the whole component is avoided, the quantity of needed solution and rinsing water are very small and limited to the treated area.<br>They can be required also in production if a defect is detected in a layer deposited for example by immersion or in case of over-machining, and thus the scrapping of the part is avoided.<br>They can be required as well at maintenance stage during the service life of a component for a repair purpose.<br><br>Our activities involving lead oxide concern industry only, mainly Printing, Oil & Gas, Marine, Aerospace and Automotive industries. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>7. Burden for industry and potential competitive disadvantage<br><br>**A.2.24. Raising the need to use a certain substance in past model parts and/or in low volumes** |

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| | | Main points of our comments:<br>☐ We are using 5 kg per year maximum of this substance.<br>☐ It permits to manufacture less than 250 L per year of solutions for plating that is very useful to protect parts against fretting corrosion or locally restore a surface with same appearance.<br>☐ Plating concerns repair of very costly parts.<br>☐ In our workshops, the use of lead oxide is performed under controlled conditions during manufacture of these solutions (general ventilation, local exhaust, protective mask with A2B2P3 cartridge, gloves, facial screen).<br>☐ Finding an alternative would be complex as few litres are used for several technically different applications and would require time for each of them.<br>☐ We are already very affected by REACH regulation with the application for Authorisation of chromium trioxide, by the CLP regulation, with the modification of the labelling of all our electrolytes by 1 June 2015, very involved in the search for less dangerous alternatives for CMR (priority: CrVI) and also in several working groups.<br>☐ A new application for Authorisation for a small company like ours, using such small quantity of lead oxide acid would be too much time and money consuming.<br><br>We hope to have been convincing and thank you for your attention,<br>Yours sincerely, | |
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| 2570<br>2014/11/21 | Germany,<br>Member State | We still have doubts about the proportionality and the regulatory effectiveness of inclusion of further lead substances into Annex XIV. Lead substances are already highly regulated in various legislative acts (e.g. Battery Directive (2006/66/EG), End of Life Vehicle Directive (2000/53/EC), RoHS Directive (2011/65/EU)). Further regulation of lead compounds by listing them in Annex XIV should be reflected in the light of climate protection efforts in Germany: promotion of batteries for storing renewable | **A.2.16. Ask ECHA to assess/ Question the regulatory effectiveness of inclusion of lead substances in AXIV and stresses the high workload for authorities related to these substances at AfA stage** |

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| | | energy.<br>A high number of authorisation applications for the lead compounds can be expected due to the high volumes and the use spectrum of the substances. Authorisation could therefore lead to a high workload for these highly regulated substances. Regarding this we request ECHA to further analyse the benefits of prioritising these already highly regulated lead substances for Annex XIV inclusion at the current stage. Based on the results of this analysis the best way forward for should be discussed. | |
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| 2597<br>2014/11/24 | Allgemeine Unfallversicherungsanstalt, National Authority, Austria | WE Support the inclusion of lead oxide in Annex XIV. Lead Ions demonstrate carcinogenic properties due to the DFG MAK-commission. | Thank you for your comment. |
| | | 2597_Pb.docx | |
| 2602<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe, Industry or trade association,<br>United Kingdom | The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. | **A.2.2. Ask ECHA to reconsider the priority scoring for lead monoxide / Lower WDU score proposed**<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>2. ECHA's proposal for sunset dates<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) |
| | | 2602_ECHA public consultation instructions lead | |

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| | | monoxide_241114.pdf | |
| 2603<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe,<br>Industry or trade association,<br>United Kingdom | The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. | See responses referred to in comment #2602 in this section. |
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| 2625<br>2014/11/25 | EUROBAT,<br>Industry or trade association,<br>Belgium | The Lead REACH Consortium has submitted comments in response to this section and EUROBAT supports their response. | **A.2.8. Claim the use in the production of batteries as intermediate**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>See also responses referred to in comment #2602 in this section. |
| | | 2625_EUROBAT and Lead REACH consortium - Exemption Request document - final_251114.pdf | |
| 2635<br>2014/11/25 | Inorganic Pigments Consortium,<br>Industry or trade association,<br>Spain | The Inorganic Pigments Consortium would like to express its support to the comments provided by the International Lead Association on behalf of the Pb REACH Consortium to the Public Consultation for substance lead monoxide (EC 215-267-0). | **A.2.11. Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>See also responses referred to in comment #2602 in this section. |
| | | 2635_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf | |
| 2636<br>2014/11/2 | Frit Consortium,<br>Industry or trade | The Frit Consortium would like to express its support to the comments provided by the International Lead Association on | **A.2.10. Claim the use in the** |

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| 5 | association,<br>Spain | behalf of the Pb REACH Consortium to the Public Consultation for substance lead monoxide (EC 215-267-0). | **manufacture of frits as intermediate**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>See responses referred to in comment #2602 in this section. |
| | | 2636_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf | |
| 2637<br>2014/11/25 | Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC), Industry or trade association,<br>Spain | The "Asociacion Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC)" would like to express its support to the comments provided by the Frit Consortium and the Inorganic Pigments Consortium for substance lead monoxide | See responses referred to in comments #2636 (Frit consortium) and #2635 (Inorganic Pigments Consortium). |
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| 2651<br>2014/11/25 | CeramTec GmbH,<br>Company,<br>Germany | CeramTec does not recommend the inclusion of PbO into Annex XIV | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>1. Potential other regulatory actions<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage<br><br>**A.2.16. Ask ECHA to assess/ Question the regulatory effectiveness of inclusion of lead substances in AXIV** |

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| | | | **C.2.1. Requests for Article 58(2) exemptions**<br><br>**A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br><br>See also responses referred to in comment #2602 in this section. |
| | | 2651_20141118_AUTH PC SEA Q FINAL_20140717_ceramTec.zip | |
| 2657<br>2014/11/25 | Company,<br>United Kingdom | no comment | - |
| | | | |
| 2669<br>2014/11/26 | Robert-Bosch-GmbH,<br>Company,<br>Germany | see attached documents | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage<br><br>You might also consider the following response:<br><br>**A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br><br>**A.2.15. Inclusion of lead monoxide** |

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| | | | **and orange lead in the authorisation list impacts companies using substances resulting from the use of these substances as intermediates**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |
| | | 2669_Bosch-Papers.zip | |
| 2702<br>2014/11/27 | European Special Glass Association, European Domestic Glass Association and International Crystal Federation,<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments to this section and EDG, ESGA and ICF support their response | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>See responses referred to in comment #2602 in this section. |
| | | 2702_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx | |
| 2720<br>2014/11/27 | Company,<br>United Kingdom | Roxel (UK Rocket Motors) Limited, has noted with interest the call be ECHA, 1st September - 30th November 2014, for comments on proposals to include a number of lead based substances, including lead monoxide, in Annex XIV of the REACH Regulation as substances of very high concern (SVHC) which would require authorisation for use.<br>A number of these substances, including lead monoxide, have critical uses/applications in the manufacture of rocket motors. Roxel asks that, if they are included in Annex XIV, they may be | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**C.2.1. Requests for Article 58(2)** |

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| | | exempted from the necessity for authorisation for use in the manufacture of rocket motors. A request for exemption is based on the grounds that one of the primary uses of this product by Roxel is in the manufacture of propellants and related materials and usage is circa 500kg per year.<br>Within the documentation accompanying the request for information about lead monoxide, it is noted that:<br>"Draft background document for Lead Monoxide - 1 September 2014.<br>Document developed in the context of ECHA's 6th Recommendation for the inclusion of substances in Annex XIV.<br>2.2 Volume used in the scope of authorisation.<br>The amount of lead monoxide manufactured and/or imported into the EU is according to registration data above 100 000t/y.<br>Some uses appear not to be in the scope of authorisation, such as in the manufacture of PVC stabilisers, certain pigments, explosives and technical ceramics and use as laboratory reagent and in chemical analysis." | **exemptions** |
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| 2722<br>2014/11/27 | Company, Germany | The Pb REACH Consortium has submitted comments in response to this section and Exide Technologies supports their response. | See responses referred to in comment #2602 in this section. |
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| 2727<br>2014/11/27 | Company, Germany | | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**C.2.2 Exemption request based on proportionality principle with other uses listed as outside the scope of authorisation in the background document**<br><br>**A.2.24. Raising the need to use a certain substance in past model** |

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| | | | **parts and/or in low volumes** |
| | | 2727_Public consultation_20141127.docx | |
| 2729<br>2014/11/27 | WirtschaftsVereinigung Metalle,<br>Industry or trade association,<br>Germany | WirtschaftsVereinigung Metalle (WVM), the German Non-Ferrous Metals' Association, represents the German non ferrous (NF) metals industry towards politics and economy.<br><br>We support our members in regulatory, occupational health & safety affairs in order to maintain and establish measures at a very high level. Today, WVM has 660 member companies, including producers and users of lead compounds.<br><br>In principle, we appreciate the involvement of stakeholders in the process of including substances in Annex XIV of REACH and would like to take the opportunity to bring our argumentation forward during this phase of internet consultation.<br><br>We want to express the companies' awareness of their duties in safe handling hazardous substances and in establishing appropriate risk management measures. Industry also takes full responsibility to fulfil their obligations under the relevant Community and national legislation.<br><br>Furthermore we support the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium. | See responses referred to in comment #2602 in this section. |
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| 2731<br>2014/11/27 | Wirtschaftsverband der deutschen Kautschukindustrie e. V. (wdk),<br>Industry or trade association,<br>Germany | REACh Public Consultation<br>wdk Statement on<br>Lead Oxide Prioritisation<br><br>Association<br>wdk is the German trade association representing about 85% of national rubber manufacturing industry. Member companies | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks |

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| | | employ 75.000 workers and the aggregated turnover (2013) is at 12 billion Euros. This is roughly 25% of European rubber industry, the biggest share at EU level.<br>Sector<br>With the exception of tyre producers the rubber sector is SME structured. For further information please consult http://www.wdk.de/en/index.html or contact our office.<br>General Status<br>Lead monoxide (PbO) EC Number: 215-267-0, CAS Number: 1317-36-8 is used in rubber industry for very specific and limited applications. The substance has the function of<br>- a binding agent in some defined rubber to metal bonding and anti-corrosion,<br>- making specific rubber articles resistant to aggressive chemicals and swelling,<br>- of protecting against X-ray radiation.<br>To ensure required special physical and chemical properties for some rubber articles PbO has to be used in very small quantities in the preparation of the corresponding rubber compounds.<br>Lead oxide in rubber industry is not a wide spread and dispersive use. The substance is handled under industrial conditions in strict conformity with industrial hygiene requirements.<br>After the first production step, mixing the rubber compound, PbO is entirely bound in the polymer matrix and physically not available in terms of exposition. The articles are produced under controlled and safe industrial conditions. Furthermore PbO containing articles are solely designed for and used in industrial applications.<br><br>Substance Volume<br>For the rubber manufacturing sector lead oxide is a low volume raw material with consumption at about 600t/y. In comparison to total production of rubber articles PbO contribution to material input is less than 0.04%. With the exception of x-ray protecting articles lead oxide content in the specific articles is below 0.1%.<br><br>Physical Appearance | 5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage |

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| | | The raw material is supplied in powder form or batched with a polymer. To a limited extent PbO as powder is still used but the regular physical appearance on the market is to bind the material in a polymeric master batch.<br><br>Exposition<br>- workers, duration<br>The number of workers potentially exposed to lead oxide is limited to five production sites in Germany. Therein only workers might get in contact who are working in the mixing department, the preparatory production step for manufacturing rubber articles. Less than 200 workers are involved.<br>During a shift PbO is not permanently used. As a function of the rubber compound composition and the handling of rubber raw materials in closed systems possible exposition is to a certain extent limited to ½ minute/shift.<br><br>- RMM<br>Full body protection (incl. chemical resistant gloves, goggles) is a compulsory standard. Further safety measures as ventilation of the workplace, separation and enclosure of the workplace, wet floor cleaning are in place.<br>Air quality inspections show a total dust load of <1mg/m³.<br>Because of lead oxide falls below threshold limit, respectively below detection limit, bio-monitoring is executed. Results from ten years experiences clearly show no evidence of lead in the blood of workers.<br><br>Rubber Characteristic<br>After the mixing process of which is the first step in rubber processing lead oxide is bound in the polymer matrix as all other rubber compound constituents as well. Due to this matrix effect lead oxide is not available for the exposition of workers to the substance.<br><br>Articles concerned<br>All articles are designed and used in industrial applications. | |

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| | | Major product groups:<br>- Steelcable reinforced conveyor belts,<br>- chemical resistant linings, membranes, sealings,<br>- roller linings (chemical resistant, swelling resistant),<br>- x-ray protectors (medical devices, body scanner)<br><br>Customers<br>Finished articles are shipped to industrial customers predominantly at national level but also worldwide. Major sectors are mining industry, mechanical engineering industry, textile producers, printing industry, manufacturers of medical devices, chemical industry, steel industry, foil production.<br><br>Alternative Substances<br>No alternative substance could be identified up to now. Potential alternative substances as 'epoxy groups', magnesium oxide, aluminum hydrocalcite, had been tested intensively but all failed as unsuitable to achieve the required physical and chemical properties of the rubber articles.<br><br>Limitation of Substitution<br>Only for conveyor belts it might be possible to replace PbO in the function as a rubber to metal bonding and anti-corrosion agent in a long term perspective. Investigations are under way.<br><br>Consequences of lead monoxide ban<br>The related articles would no longer be produced in Europe. The production, workplaces and know how will drain to outside EU countries. Due to economics of scale parallel not PbO consuming rubber manufacturing will probably also leave the EU. The articles are essential for keeping the customers' production plants running. Therefor the articles will be imported from third countries using lead monoxide under conditions different from approved and effective RMM standards already in place in Europe.<br>A ban of lead monoxide will obviously end up in a loss of safe workplaces, a drain of technical expertise and a displacement of | |

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| | | R&D capacities to third countries. | |
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| 2745<br>2014/11/27 | ELOA (a Cefic industry sector group),<br>Industry or trade association,<br>Belgium | ELOA (European Lead Oxide Association, an industry sector group associated to Cefic) supports the comments submitted in this section by the International Lead Association Europe(ILA) on behalf of the Pb REACH Consortium.<br>See also the ELOA specific comments attached, file < ELOA-PbO-comments-to ECHA PC_20141125b.pdf> | **A.2.8. Claim the use in the production of batteries as intermediate**<br>**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br>**A.2.10. Claim the use in the manufacture of frits as intermediate**<br>**A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br>**A.2.13. Claim the use of lead monoxide in the manufacture of stabilisers for PVC processing as intermediate**<br>**C.1.1. General principles for exemptions under Art. 58(2)**<br>**C.2.1. Requests for Article 58(2) exemptions**<br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br>**B.1.2. Aspects not considered by ECHA when proposing latest** |

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| | | | **application dates/sunset dates:**<br>1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users)<br><br>See responses referred to in comment #2602 in this section. |
| | | 2745_ELOA-PbO-comments-to ECHA PC_20141125b.pdf | |
| 2753<br>2014/11/28 | Preciosa Ornela, a.s.,<br>Company,<br>Czech Republic | Nenahraditelnost PbO ve sklářském průmyslu.<br>Použití ve skle jako meziprodukt.<br>Popis chemie olovnatého skla | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use |
| | | 2753_OLOVO.zip | |
| 2758<br>2014/11/28 | Europacable,<br>Industry or trade association,<br>United Kingdom | Lead monoxide is an additive in rubber compounds for cables insulation and sheating and accessories as stabilizer. Current usage is limited to specific applications for which no alternative is available due to specifications for electrical performance in wet conditions. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>3. Use specific scrutiny foreseen at application stage<br>5. Availability of suitable alternatives |

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| 2760<br>2014/11/28 | Association of the Glass and Ceramic industry of Czech Republic,<br>Industry or trade association,<br>Czech Republic | The use of PbO Lead monoxide and Pb3O4 Lead tetroxide is in line with the definition of intermediates (in the meaning of Article 3(15) REACH ) and is exempted from authorization.<br><br>For details see attached files | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>1. Potential other regulatory actions<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage<br><br>See also responses referred to in comment #2602 in this section. |
| | | 2760_Comments of Association of the Glass and Ceramic Industry of the Czech Republic.zip | |
| 2762<br>2014/11/28 | Europacable,<br>Industry or trade association, | Lead monoxide is an additive in rubber compounds for cables insulation and sheating and accessories as stabilizer. Current usage is limited to specific applications for which no alternative | See responses referred to in comment #2758 in this section. |

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| | United Kingdom | is available due to specifications for electrical performance in wet conditions. | |
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| 2777<br>2014/11/28 | European Tyre & Rubber Manufacturers' Association (ETRMA),<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments in response to this section and ETRMA supports it. | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>See also responses referred to in comment #2602 in this section. |
| | | 2777_20141128 Lead oxides - ETRMA response to ECHA consult.pdf | |
| 2780<br>2014/11/28 | Aurubis AG,<br>Company,<br>Germany | Aurubis is the leading integrated copper group and the world's largest copper recycler. We produce some 1 million t of copper cathodes each year and from them a variety of copper products. Production expertise is our strength and the driving force of our success.<br>Aurubis has about 6,500 employees, production sites in Europe and the USA and an extensive service and sales system for copper products in Europe, Asia and North America.<br>Thanks to our wide range of services, we rank among the global leaders in our industry. Our core business is the production of marketable copper cathodes from copper concentrates, copper scrap and recycling raw materials. These are processed within the Group into continuous cast wire rod, shapes, rolled products and strip as well as specialty wire made of copper and copper alloys. Precious metals and a number of other products, such as sulfuric acid and iron silicate, round off our product portfolio.<br>Customers of Aurubis include companies in the copper semis industry, the electrical engineering, electronics and chemical industries as well as suppliers of the renewable energies, construction and automotive sectors.<br>Aurubis is oriented to growth and to increasing corporate value: the main focuses of our strategy are on expanding our leading market position as an integrated copper producer, utilizing | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>7. Burden for industry and potential competitive disadvantage<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |

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| | | growth opportunities and practicing a responsible attitude when dealing with people, resources and the environment.<br>Aurubis shares are part of the Prime Standard Segment of the Deutsche Börse and are listed in the MDAX and the Global Challenges Index (GCX).<br><br>Summary:<br>Aurubis is using lead monoxide as processing aid for the analysis of precious metal content of secondary and complex materials. Regarding our application lead monoxide is only used by industrial users. Exposure assessments have been carried out as well as monitoring campaigns to assess the risk of the substance to workers, which shows that a risk can be reasonably excluded. Also the risk for the environment is adequately controlled due to waste water collection as well as treatment and off gas cleaning systems.<br><br>The substance is not part of a finished article which may be used by consumer and the use in our application is essential as there is no alternative available.<br>For the analytical use, contracting non EU laboratories or the relocation of the analytical department would result in higher costs for products/services.<br><br>Due to the argumentation described above and in the information attached a listing of the substance would lead to negative effects on cost and price competitiveness as well on the global competitive position of EU companies without a benefit for human health or environment protection.<br><br>We strongly recommend not to include lead monoxide on Annex XIV or to exclude the described uses from authorisation.<br><br>In order to allow a complete view on all aspects and consequences of such a listing for our industry, please find attached our input based on the list of questions proposed by | |

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| | | commission to the socio-economic public consultation.<br><br>*Confidential attachment removed* | |
| 2782<br>2014/11/28 | WKÖ,<br>Other contributor,<br>Austria | See PDF attached. | **A.2.16. Ask ECHA to assess/ Question the regulatory effectiveness of inclusion of lead substances in AXIV**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>4. Control of risks<br>5. Availability of suitable alternatives<br><br>**A.2.8. Claim the use in the production of batteries as intermediate**<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>**A.2.2. Ask ECHA to reconsider the priority scoring for lead monoxide / Lower WDU score proposed because of the professional use limited to the use as laboratory reagent under** |

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| | | | **strictly controlled conditions and because exposure during article service-life is claimed to be negligible.** |
| | | 2782_su_86_WKÖ Bleiverbindungen.pdf | |
| 2819<br>2014/11/28 | Norway,<br>Member State | In general, the Norwegian REACH CA supports measures that will reduce the use and emission of lead and lead compounds. We do also support grouping of lead substances to avoid substitution with substances with similar properties within the same use categories. We consider the prioritisation criteria to be fulfilled and support that lead monoxide is prioritised for inclusion in Annex XIV. | Thank you for your comment. |
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| 2859<br>2014/11/28 | Individual,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and HOPPECKE supports this response. | See responses referred to in comment #2602 in this section. |
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| 2860<br>2014/11/28 | Robert Bosch GmbH,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section,ZVEI and Bosch supports their response. | **C.2.1. Requests for Article 58(2) exemptions**<br>See also responses referred to in comment #2602 in this section. |
| | | 2860_exemption argument for the industrial use of Piezo ceramics.docx | |
| 2869<br>2014/11/28 | Regional or local authority,<br>United Kingdom | Lead (and its compounds) is a Priority Substance under the Water Framework Directive. Member States need to demonstrate decreasing concentrations in the water environment (beyond natural background levels). Some of the uses identified in the background document may result in releases to waste water. In Scotland the main point source of (bioavailable) lead for the water environment seems to be from municipal waste water treatment plants; anthropogenic diffuse sources will also play a role in environmental water concentrations. The major uses of lead monoxide (in battery production) is not likely to result in | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban |

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| | | high releases to the water environment. Use as a stabiliser in PVC may, but this use is being voluntarily phased out. | |
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| 2883<br>2014/11/28 | Company,<br>Italy | 1) General comments on the recommendation to include the substance in Annex XIV<br>General context<br>Semiconductor manufacturing uses highly sophisticated technologies and relies on a complex global supply chain in the world. Manufacturing takes place in a highly controlled environment, ensuring minimization of product contamination risks and employees' exposure control.<br><br>Glass frits description<br>Glass frits paste is a mixture of an extremely finely grinded glass, with an inert filler material, together with a binding resin and solvent. These components mixed together form a glass frits paste.<br>Lead monoxide and Diboron trioxide are among the constituents of the formulation of a Low-Temperature (Low-T) melting glass (i.e. the glass component in the glass frits paste). Lead monoxide lowers the melting Temperature of the glass, rendering the glass compatible with the Aluminium metal in the device. Diboron trioxide gives the glass properties of chemical and mechanical resistance.<br>Based on the chemical reactions for production of glass and frits, Lead monoxide and Diboron trioxide are used specifically in order to be transformed into another substance (i.e. the glass or frits), rather than being added to other substances to modify their properties. Therefore, the use is in line with the definition of intermediates and exempt from authorization.<br>www.glassallianceeurope.eu<br>During the glass "melting" process, the different raw materials react chemically to produce the substance glass, which is an amorphous network of elements bonded together with oxygen ions between cations. For practical reasons, the elemental analyses of glass are expressed in the form of their oxides, but this must not be confused with a mixture of the different oxides. | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**A.2.10. Claim the use in the manufacture of frits as intermediate**<br><br>**A.2.15. Inclusion of lead monoxide and orange lead in the authorisation list impacts companies using substances resulting from the use of these substances as intermediates**<br><br>**A.1.3. Prioritisation: Wide-dispersiveness of uses:**<br>1. Scope of the assessment of wide-dispersiveness of uses<br>2. Assignment of WDU score based on use types and their associated volumes<br>3. Refinement of WDU score based on article service-life<br><br>**A.2.2. Ask ECHA to reconsider the priority scoring for lead monoxide / Lower WDU score proposed**<br><br>**C.2.1. Requests for Article 58(2)** |

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| | | In conclusion, the substance glass does not contain any raw material used as starting materials and particularly does not contain any Lead monoxide or Diboron trioxide.<br>Glass frits used in Semiconductor Manufacturing Industry may be described, however, in terms of Lead monoxide (CAS 1317-36-8). In the Draft background document for Lead monoxide, while the use of technical glass frits is mentioned, a formal position is not taken. Therefore a response to the current consultation is submitted (Draft background document for Lead monoxide - ECHA 01/09/2014).<br>In conclusion, due to the above described "melting" process, the SVHC Lead monoxide is not present in the glass as such and lead is chemically bonded in the glass amorphous structure. For this reason, it is believed that the use of frits in the specific application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization.<br><br>Conditions of use<br>Glass frits are used in semiconductor manufacturing, with the scope of hermetically sealing microelectronic devices.<br>Low Temperature (Low-T) Lead monoxide based glass frits are used in wafer-to-wafer bonding process of MEMS (Micro Electro Mechanical Systems) devices. MEMS devices, such as accelerometers or gyroscopes, are well-known components of smartphones, tablets and several games consoles.<br><br>In the table below, a simplified MEMS process flow is presented, with wafer-to-wafer bonding. All processes are performed in clean room environment and in controlled equipment.<br><br>Process step Description Image<br>Make<br>Sensor wafer Where actual Sensor device is built.<br>Make<br>Cap wafer Role: protect Sensor device from environment;<br>Glass Frits application via Screen Printing | **exemptions**<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |

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| | | Bond<br>Sensor wafer<br>with<br>Cap wafer Bonding Technology: Glass Frit<br><br>Dice & Assemble In package with electronics driver chip (ASIC)<br><br><br>In terms of processing, glass frits paste is screen printed on the wafer, transformed into melted glass at high temperature and used to bond 2 wafers together.<br>Process step Description Image<br>Screen Printing<br>Glass Frits Paste<br>Pattern transfer<br>Firing<br>Thermal treatment in batch oven<br>Transform Glass Frits Paste<br>(Binder + solvent + Glass powder)<br>--> Glass<br>Bonding Thermal Treatment on Bonder Equipment<br>"Soften" Glass --> squeeze wafers together<br>Dice & Assemble In package with electronics driver chip (ASIC)<br><br>The used screens are cleaned in dedicated closed circuit screen cleaner equipment. The solvent used for cleaning the screens is filtered and re-circulated. The spent solvent is collected separately in a dedicated solvent drain, and sent for incineration. The glass frit contaminated filters are collected separately and sent for incineration. All operations take place under local exhaust ventilation and ensuring appropriate solvent containment.<br>The whole process takes place in a controlled environment applying strict risk management measures, ensuring controlled release to the environment and minimizing employees' exposure.<br>Chemical Industrial hygiene monitoring performed regularly in | |

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| | | the working areas ensured all Pb results below 0.007 mg/m3 while applicable TLV is 0.15 mg/m3.<br>Exhausts are installed in all relevant area and air emissions are regularly monitored ensuring all results for Pb <0.001 mg/m3.<br>Controlled discharge to water is expected being plant waste water regularly monitored ensuring all results for Pb < 0.01 mg/l, while applicable emission limit value is 0.3 mg/l.<br>Bio-monitoring for Lead is conducted yearly on a sample of potentially exposed employees, all essays performed (17 checks/year) are < 70 µg/dL Binding Biological Limit Value (EU Directive 98/24/EC, Annex II, Binding Biological Limit Values and Health Surveillance Measuresand) average is 6 µg/dL.<br><br>Glass frits are used for a total quantity of 450 Kg/year in one site, equivalent to a theoretical consumption of 270 Kg/year of Lead monoxide and to the 0.00027 % of the total quantity of Lead monoxide in the authorization scope (Draft background document for Lead monoxide - ECHA 01/09/2014).<br>This quantity is relevant to the production of 500 Million unit/y electronics components. Each electronic component may contain about 0.1 mg Lead in a concentration up to 0.5 %, depending on the component dimensions and weight.<br>Here below picture of MEMS plastic packages with thickness of less than 1.0 mm ranging from 7x5 mm2 , 5x5 mm2 , 3x5 mm2 , 4x4 mm2 ,3x3 mm2<br><br>Glass frits are imported into Europe and, due to low quantity used, are not registered for the specific use in the semiconductor industry.<br><br>Use descriptor<br><br>The here below table reports the relevant descriptor as per Appendix R.12.1 to R.12.6 of the ECHA Guidance on Use Descriptor System (R12) and based on the ECHA-10-R-005-EN publication EXPOSURE SCENARIOS FOR THE SEMICONDUCTOR | |

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| | | INDUSTRY EXAMPLES – August 2010<br><br>Sector of use (SU) SU 3 Industrial manufacturing<br>SU 16 Manufacturing of computer, electronic and optical product, electrical equipment<br>Chemical product category (PC) PC1 Adhesives, sealants<br>Process category (PROC) PROC 2 Use in closed, continuous process with occasional controlled exposure (e.g. sampling) - Industrial setting; (1)<br>Article category (AC) AC2 Electric and electronic articles included (2)<br>Environmental release category ERC5 Industrial use resulting in inclusion into or onto a matrix (2)<br><br>(1) Some process could take place not only in continuous process but also in batch operations with occasional control exposure, only<br>(2) Article category and Environmental release category are relate to glass frits<br><br>Non applicability of the wide dispersive criteria<br><br>With reference to the Draft background document for Lead monoxide - ECHA 01/09/2014 - there is a further clarification need: the total quantity of glass frits paste used in one industrial site is only 450 Kg/y. The number of potentially exposed employees is very limited (40 employees), therefore the use of frits in the specific application of MEMS manufacturing in the semiconductor industry cannot be considered to contribute to the wide dispersive use criteria for prioritization.<br>There is no release to the environment from the article (semiconductor device) since the Lead monoxide, as already explained, is not present in the glass as such and Lead is chemically bonded in the glass amorphous structure. Moreover the semiconductor device is assembled into a matrix resin, to produce the semiconductor component, finally used in the electric or electronic equipment. Waste of electric and electronic | |

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| | | components are managed according to the WEEE Directive, therefore there is no consumers exposure. | |
| | | 2883_LEAD_OX_autho_template_prop20141128.pdf | |
| 2895<br>2014/11/30 | Individual,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports their response. | See responses referred to in comment #2602 in this section. |
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| 2896<br>2014/11/30 | Johnson Controls Autobatterie GmbH & Co. KGaA,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports their response. | See responses referred to in comment #2602 in this section. |
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| 2900<br>2014/11/30 | Johnson Controls Autobaterie spol. s r.o.,<br>Company,<br>Czech Republic | The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Autobaterie spol. s r.o. based in Ceská Lípa, Czech Republic, supports their response. | See responses referred to in comment #2602 in this section. |
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| 2907<br>2014/11/30 | Johnson Controls Autobaterías, S.A,<br>Company,<br>Spain | The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Autobaterías, S.A based in Madrid, which operates two battery production sites in Burgos and Guardamar del Segura (Alicante), Spain, supports their response. | See responses referred to in comment #2602 in this section. |
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| 2912<br>2014/11/30 | Johnson Controls Sachsen-Batterien GmbH & Co. KG,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Sachsen-Batterien GmbH & Co. KG based in Zwickau, Germany, supports their response. | See responses referred to in comment #2602 in this section. |
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| 2916<br>2014/11/30 | Japan Business Council in Europe ( JBCE ),<br>Industry or trade association,<br>Belgium | To request double regulation between REACH and RoHS.<br>Please see an attached file. | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |
| | | 2916_JBCE response for REACH authorization_REACH vs RoHS.pdf | |
| 2920 | Johnson Controls | The Pb REACH Consortium has submitted comments in response | See responses referred to in comment |

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| 2014/11/30 | Recycling GmbH, Company, Germany | to this section and Johnson Controls Recycling GmbH based in Buchholz, Germany, supports their response. | #2602 in this section. |
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| 2938<br>2014/11/30 | DLAC Dienstleistungsagentur chemie GmbH, Company, Germany | CMR substances are evaluated in a binary manner, by classification of compounds as carcinogenic, mutagenic or toxic to reproduction, i.e. DNA damaging in vitro or in vivo, or non-genotoxic. This method of hazard identification is based on the assumption that DNA alterations and their subsequent manifestation as mutations occur with a linear dose-response even at low doses. This classification system is based on the argument that even a single molecule, interacting with DNA, could result in damage and mutation (one-hit model). However, it has been recognized that this linear assessment might not be appropriate for all chemical classes. Evidence against the linear hypothesis was first generated for aneugens1 and leading researchers to question the reliability of the general assumption of dose-response linearity at low doses for numerous CMR substances with diverse modes of action (MoA). Recently, a review was published compiling the existance of thresholds for several genotoxic substances.2<br>Such a threshold for reporductive toxicity of lead oxides should be also taken into account. The registration dossier of lead monoxide inlcudes information on toxicity for reproduction of lead monoxide. Furthermore for lead oxides an occupational exposure limit is given. Recent studies show that keeping the workplace exposure below the occupational exposure limit is not result in hazardous effects on reproduction.<br>Theses studies show the dose-dependent presents and absence of effects on the reproduction reflecting, the existance of a threshold for lead monoxide. such a threshold as well as the strength of CMR properties should be additonally considered in the process of authorisation for lead monoxide. Restictions for lead monoxide has been improved by several legislations and occupational exposure limits at a level below toxicity to reproduction, so that the need for authorisation of this substance is questionable, expecially due to the need of lead in several new technologies. | **A.2.16. Ask ECHA to assess/ Question the regulatory effectiveness of inclusion of lead substances in AXIV** |

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| | | (1) A. Elhajouji, P. Van Hummelen and M. Kirsch-Volders Indications for a threshold of chemically-induced aneuploidy in vitro in human lymphocytes, Environmental and Molecular Mutagenesis 26 (1995) 292-304.<br><br>(2) M. Guérarda, M. Baum, A. Bitsch, G. Eisenbrand, A. Elhajouji, B. Epe, M. Habermeyer, B. Kaina, H.J. Martus, S. Pfuhler, C. Schmitz, A. Sutter, A.D. Thomas, C. Ziemann and R. Froetschl Assessment of mechanism driving non-linear dose–response relationships in genotoxicity testing, Mutation Research (2014) in press. | |
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| 2940<br>2014/11/30 | Association of European Airlines,<br>Industry or trade association,<br>Belgium | This comment is handed in by the European Association of Airlines (AEA) as a common concern shared by all 30 AEA members: the European Aviation industry, the airlines who are responsible for an airworthy fleet, and maintain the aircraft according to their EASA and FAA license. These comments also concern independent MRO (maintenance, repair and overhaul) services in Europe. Both airlines and independent MRO companies guarantee a whole raft of requirements ranging from safeguarding air safety, properly managing aircraft operation, and minimizing costs.<br>The statement is made in close cooperation with several AEA members and with ASD (Aerospace and Defence Industries Association of Europe), the national trade organization who present the Original Equipment Manufacturers (OEMs) a.o. in Europe, and the AIA (Aerospace Industries Association) who present the OEMs outside Europe (US). Therefore the following statement refers to the official ASD statement and the paper from the AIA which was handed in to this public consultation as well.<br><br>Lead compounds are widely used within the Aerospace industry. Lead compounds are used in very low volumes (2 digits kilogram area) for maintenance of existing fleets. Due to their properties | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>5. Availability of suitable alternatives<br>7. Burden for industry and potential competitive disadvantage<br><br>**A.2.25. Concerns and uncertainties with respect to the authorisation process**<br><br>See also responses referred to in comment #2949 in this section. |

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| | | their use within the aircraft is specific and directly linked to maintain airworthiness. Aviation materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In addition, they must resist attack by aggressive fluids such as hydraulic fluids and de-icing agents. E.g. lead oxide is used in Dry Film Lubricant Products. These products provide lubrication and corrosion protection on critical aerospace products as the lead oxide particles contained in the lubricant provide a type of self-healing mechanism by spreading to the damaged areas facilitating ongoing corrosion protection.<br>Authorisation of these products – before there is a certified alternative in place - is creating a severe disadvantage for the European airline industry.<br>The aviation industry and especially the companies who perform the MRO services are directly dependent on processes, products and maintenance procedures developed by the OEMs and certified by the airworthiness authorities (European Aviation Safety Agency (EASA) and United States Federal Aviation Administration (FAA)). Due to the strict airworthiness requirements OEMs are responsible for the safety of the aircraft system as well as for sufficient maintenance procedures. Therefore airlines and MRO providers are in the first place bound to the research and developments done by OEMs. AEA members and MRO companies are not in the position to perform the important REACH process of "Analysis of Alternatives". Nevertheless – looking at on-going REACH authorization processes for e.g. Chromium Trioxide many AEA members are heavily burdened by securing the product availability and handling the unknown and inexperienced REACH authorization process. For further details of the certification and qualification and industrialization process we refer to the joint paper developed between industry EASA and ECHA "An elaboration of key aspects of the authorisation process in the context of aviation industry" | |

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| 2949<br>2014/12/01 | ASD,<br>Industry or trade association,<br>Belgium | 1- Lead Compounds<br>These substances are widely used throughout the European Aerospace,Defence and Security sectors and are already heavily regulated by other legislation such as RoHS and the End-of Life Vehicle Directive.<br>1.1- Lead Oxide CAS 1317-36-8<br>Dry Film Lubricant Products:-<br>These products provide lubrication and corrosion protection on critical aerospace products. While many lead oxide-based processes and products are used in other industries, the technical requirements of the aerospace and defence industry are significantly more demanding. Dry film lubricants utilize lead monoxide due to its thermal stability and low coefficient of friction in temperatures up to 650C. Specialty uses include rings, seals,and bearing races. Lead oxide containing dry film lubricants provides<br>lifetime protection for components which are inaccessible after assembly,but nevertheless must continue to function reliably.<br>Alternatives to Dry Film Lubricant Products:-<br>Several candidate alternative formulations exist however proven alternatives are less readily available and once identified the speed of change is cautiously slow. For some applications there is no known alternative proven to exist. Many dry film lubricants on the market utilise graphite, molybdenum disulfide or polytetrafluoroethylene as the contact lubricant. These technologies often do not support applications above 370C in dry, oxidizing environments<br>Potential alternative contact lubricants may exist that can provide similar or greater temperature stability in dry, oxidizing environments but aerospace will require extensive qualification and certification requirements for each contact application.<br><br>Rechargeable Lead Acid Batteries:-<br>Highly prevalent in automotive industry, lead acid batteries are also used in the aerospace industry. They provide current to turn the starter motors of engines. The roles of the rechargeable lead | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>5. Availability of suitable alternatives<br>7. Burden for industry and potential competitive disadvantage<br><br>**B.1.1. General principles for setting latest application dates / sunset dates**<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects<br><br>Also refer to:<br>**C.2.1. Requests for Article 58(2) exemptions** |

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| | | acid batteries are to start<br>engines (either reciprocating or'turbine) and the auxiliary power unit (APU) that may be on board. Another role of these batteries is to ensure a properly rated power supply (amperage and voltage) is supplied to the equipment connected to it. Batteries are crucial components of the power system on board any aircraft. Should an engine or APU stall or flame out during flight, the on board power system can be restarted to restore engine functionality or maintain emergency electrical power to the instruments on board.<br><br>Alternatives to Lead Acid Batteries:-<br>Alternative battery technology does exist for some aviation applications,but not all. The size of the aircraft, engine type, charging systems and mounts will all influence which battery type is compatible for use. Nickel Cadmium batteries are generally more prevalent on larger turbine aircraft and are often many times the cost of a similarly rated lead acid battery. Lithium ion batteries are becoming more popular on new large turbine aircraft due to the significant weight advantage they provides over other battery technologies, but the costs are still very high. For general aviation and light aircraft, rechargeable lead acid batteries are most commonly specified for use.<br><br>1.2- Why Aerospace Industry uses Lead Oxide containing products.<br>The aerospace industry uses lead oxides to meet Airworthiness requirements. The lifetime lubrication and corrosion protection offered by lead oxides on products that experience a wide range of atmospheric and usage conditions throughout their significant lifecycle is required. The lead oxide particles contained in the lubricant provide a type of self-healing mechanism by spreading to the damaged areas facilitating ongoing<br>corrosion protection.<br>Aerospace materials must be able to withstand extreme conditions including temperatures, humidity, altitude, pressure, friction, and rapid, repeated cycling during normal use. In | |

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| | | addition, they must resist attack<br>by aggressive fluids such as hydraulic fluids and de-icing agents. Many areas of the components coated with lead oxide containing products are inaccessible and difficult to inspect for damage following product delivery without disassembly. These product areas are expected to last for the anticipated product lifespan which can exceed 25 years.<br>Today there are no qualified commercially available alternatives that meet the aerospace and defense industry performance criteria of longevity,reliability and compatibility exhibited by lead oxide for many applications.<br><br>1.4- Economic Impact to Airline Operators<br>The further restriction, or ban, on aerospace critical substances such as lead oxides that are central to the corrosion protection and lubrication of aerospace products, many of which do not have alternatives, will severely<br>impact the aircraft maintenance sector in Europe. The potential impacts include supply chain and operations disruptions of EU operators.<br>If this proposed restriction proceeds with no qualified commercially available alternatives, it will not allow the industry to identify and qualify viable alternatives and ultimately jeopardizing the competitiveness of the<br>EU operators by restricting their' ability to perform scheduled maintenance or on-wing repairs. This EU restriction on lead oxides can ultimately incentivise the aviation industry to move operations to non-EU countries.<br><br>1.5- Impact of Pb to the environment<br>The quantity of Lead Oxide used in Aerospace and Defence is a very small compared to the usage in the Automotive or Glass sectors in the EU.<br>Monitoring of Lead, rather than Lead Oxide has shown very low airborne background levels.<br>Background airborne levels reported from Canada in 2012 were shown as being consistently below 0.02micrograms/m3( ref 1). | |

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| | | Manufacture of Lead (and therefore Lead Oxide) is tightly controlled by other EU regulations (ref 2). A maximum of 0.5 micrograms/m3 already applies across the EU.<br>References<br>1- "Final Human Health State of the Science Report on Lead" Health Canada<br>Pub 2012 and available from www.hc-sc.gc.ca<br>2- European Commission Environment Air Quality August 2014<br><br>1.6- Summary<br>In conclusion Lead Oxide is a necessary material for aerospace, defence and security applications with a proven record of performance that has yet to find a complete replacement . | |
| | | 2949_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf | |
| 2958<br>2014/12/01 | ADS Group,<br>Industry or trade association,<br>United Kingdom | ADS fully supports the comments made by ASD, and the comments made by MEGGITT concerning use of Lead oxide in PZT products. | See responses referred to in comments #2949 and #2519 in this section. |
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| 2970<br>2014/12/01 | Individual,<br>Italy | The Pb REACH Consortium has submitted comments in response to this section and FIAMM SPA supports their response. | See responses referred to in comment #2602 in this section. |
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| 2978<br>2014/12/01 | ACEA,<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments in response to this section and ACEA supports their response. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage<br><br>**A.2.8. Claim the use in the** |

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| | | | **production of batteries as intermediate**<br><br>**A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br><br>**A.2.19. Predictability of including substances in Annex XIV**<br><br>**A.2.24. Raising the need to use a certain substance in past model parts and/or in low volumes**<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users)<br>2. Lack of alternatives, socio-economic aspects<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation** |

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| | | | **C.2.1. Requests for Art. 58(2) exemptions**.<br><br>See also responses referred to in comment #2745 and #2602 in this section. |
| | | 2978_20141201 ACEA Comments Authorisation Lead compounds.pdf | |
| 2994<br>2014/12/01 | ZVEI,<br>Industry or trade association,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and the ZVEI supports their response.<br><br>The 'ZVEI - German Electrical and Electronic Manufacturers' Association' promotes the industry's joint economic, technological and environmental policy interests on a national, European and global level. The ZVEI represents more than 1,600 companies, mostly SMEs. The sector has 838,000 employees in Germany plus 692,000 employees all over the world. In 2013 the turnover was approximately €167 billion. More than 20 percent of all industrial R+D spending comes from this industry. The German battery industry is a central building block for the manufacturing and research location Germany, delivering key technologies for the future. It develops reliable and powerful storage systems for a wide range of industry sectors, e.g. the electrical industry, engineering, automobile industry, medical engineering and the energy sector. The German battery industry employs over 8,000 workers and has an annual turnover of €1.8 billion. | See responses referred to in comment #2602 in this section. |
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| 2997<br>2014/12/01 | ELSA (ESPA),<br>Industry or trade association,<br>Belgium | We support the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium.<br><br>ELSA, the European Lead Stabilisers Association, is a sub-Association of ESPA, the European Stabilisers Producers Association www.stabilisers.eu | See responses referred to in comment #2602 in this section. |

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| | | ELSA is an associated member of ILA Europe, the International Lead Association –Europe<br><br>The following companies are members of ELSA:<br><br>ASUA (Spain)<br>Baerlocher (Germany)<br>Chemson Polymer Additives (Austria)<br>IKA (Germany)<br>Reagens (Italy) | |
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| 3004<br>2014/12/01 | Bundesverband Keramische Industrie e.V., Industry or trade association, Germany | The Pb REACH Consortium and Cerame-Unie had submitted comments in response to this section and Bundesverband Keramische Industrie e.V. fully supports this. | See also responses referred to in comments #2602 and #3009 in this section. |
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| 3009<br>2014/12/01 | Cerame-Unie - the European Ceramics Industry Association, Industry or trade association, Belgium | The European Ceramic Industry, Cerame-Unie, covers a wide range of products including brick & roof tiles, clay pipes, wall & floor tiles, refractory products, sanitary ware, table & decorative ware, technical ceramics, abrasives and enamels. It accounts for more than 200.000 direct employments and a turnover of € 25 billion within the EU.<br><br>Cerame-Unie supports the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium.<br><br>Lead monoxide and lead tetroxide are used as intermediates in the production of frits. The production of frit does not occur at the ceramic plant. Ceramic manufacturers buy the frits as a downstream user from the frits manufacturer. Cerame-Unie fully supports the views expressed by the Frits consortium in this respect.<br><br>Lead-containing frits have specific characteristics. Lead is essential to heal the pin-holes in the glaze during the firing | **A.2.10. Claim the use in the manufacture of frits as intermediate**<br><br>**A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br><br>**A.2.15. Inclusion of lead monoxide and orange lead in the authorisation list impacts companies using substances resulting from the use of these substances as intermediates**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>5. Availability of suitable alternatives<br><br>Also refer to: |

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| | | stage. This characteristic is essential to ensure a smooth surface. These frits also allow the glazes to be fired at lower temperatures and create a more uniform glaze. In addition, the use of lead containing frits also enhances the colours used for decoration. Alternatives are already in place where possible; however it has not been possible to find effective alternatives for all applications and colours. Some alternatives using other metals failed to provide satisfactory manufacturing tolerances e.g. insufficient coverage of the article to be glazed, recurrent faults in the firing process or failure to provide sufficient durability in use. It should be noted that leaded and unleaded systems cannot be used side by side in the same production. This means that a switch can only take place if an alternative solution is found for all applications and colours used at the site. Lead monoxide and lead tetroxide are used as intermediates in the production of PZT, PTC and PLZT ceramic materials. The oxides of lead, zirconium oxide and titanium oxide are sintered together to produce lead titanium zirconium oxide (abbreviation PZT). Lead is the most influential compound giving the high piezoelectric interaction and properties in PZT ceramics.<br><br>PZT itself is not put on the market for consumers, only articles containing components partly made of PZT are available for the end user.<br><br>Piezoceramics are used in many essential applications such as piezoelectric injectors and knock sensors for the use in combustion engines (which lead to reduced consumption and pollution).<br><br>PZT is already covered by existing specific legislation such as RoHS (2002/95/EC), WEEE (2002/96/EC) and their recasts (2011/65/EC, 2012/19/EU) and the ELV (2000/53/EC), where PZT are exempted in particular applications due to their essential properties and absence of alternatives. These exemptions are reviewed on a regular basis, considering the scientific and technical progress. This means that substitution will be enforced | **C.2.1. Requests for Art. 58(2) exemptions**<br><br>See also responses referred to in comments #2602 and #2651 in this section. |

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| | | by existing legislation as soon there is a suitable alternative. | |
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| 3017<br>2014/12/01 | LightingEurope,<br>Industry or trade association,<br>Belgium | Lead monoxide is used as a raw material in intermediate use in the production of lead containing glass. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>Also refer to:<br><br>**C.2.1. Requests for Article 58(2) exemptions** |
| | | 3017_LE_consultation_Lead monoxide_20141201_final.pdf | |
| 3020<br>2014/12/01 | European Semiconductor Industry Association,<br>Industry or trade association,<br>Belgium | General context<br>Semiconductor manufacturing uses highly sophisticated technologies and relies on a complex global supply chain in the world. Manufacturing takes place in a highly controlled environment, ensuring minimization of product contamination risks and employees' exposure control.<br><br>Glass frits description<br>Glass frits paste is a mixture of an extremely finely grinded | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**A.2.10. Claim the use in the manufacture of frits as intermediate** |

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| | | glass, with an inert filler material, together with a binding resin and solvent. These components mixed together form a glass frits paste.<br>Lead monoxide and Diboron trioxide are among the constituents of the formulation of a Low-Temperature (Low-T) melting glass (i.e. the glass component in the glass frits paste). Lead monoxide lowers the melting Temperature of the glass, rendering the glass compatible with the Aluminium metal in the device. Diboron trioxide gives the glass properties of chemical and mechanical resistance.<br>Based on the chemical reactions for production of glass and frits, Lead monoxide and Diboron trioxide are used specifically in order to be transformed into another substance (i.e. the glass or frits), rather than being added to other substances to modify their properties. Therefore, the use is in line with the definition of intermediates and exempt from authorization.<br>www.glassallianceeurope.eu<br>During the glass "melting" process, the different raw materials react chemically to produce the substance glass, which is an amorphous network of elements bonded together with oxygen ions between cations. For practical reasons, the elemental analyses of glass are expressed in the form of their oxides, but this must not be confused with a mixture of the different oxides. In conclusion, the substance glass does not contain any raw material used as starting materials and particularly does not contain any Lead monoxide or Diboron trioxide.<br>Glass frits used in Semiconductor Manufacturing Industry may be described, however, in terms of Lead monoxide (CAS 1317-36-8). In the Draft background document for Lead monoxide, while the use of technical glass frits is mentioned, a formal position is not taken. Therefore a response to the current consultation is submitted (Draft background document for Lead monoxide - ECHA 01/09/2014).<br>In conclusion, due to the above described "melting" process, the SVHC Lead monoxide is not present in the glass as such and lead is chemically bonded in the glass amorphous structure. For this reason, it is believed that the use of frits in the specific | **A.1.3. Prioritisation: Wide-dispersiveness of uses:**<br>1. Scope of the assessment of wide-dispersiveness of uses<br>2. Assignment of WDU score based on use types and their associated volumes<br>3. Refinement of WDU score based on article service-life<br><br>**A.2.2. Ask ECHA to reconsider the priority scoring for lead monoxide / Lower WDU score proposed** |

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| | | application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization.<br><br>Conditions of use<br>Glass frits are used in semiconductor manufacturing, with the scope of hermetically sealing microelectronic devices.<br>Low Temperature (Low-T) Lead monoxide based glass frits are used in wafer-to-wafer bonding process of MEMS (Micro Electro Mechanical Systems) devices. MEMS devices, such as accelerometers or gyroscopes, are well-known components of smartphones, tablets and several games consoles.<br>All processes are performed in clean room environment and in controlled equipment.<br>In terms of processing, glass frits paste is screen printed on the wafer, transformed into melted glass at high temperature and used to bond 2 wafers together.<br>The used screens are cleaned in dedicated closed circuit screen cleaner equipment. The solvent used for cleaning the screens is filtered and re-circulated. The spent solvent is collected separately in a dedicated solvent drain, and sent for incineration.<br>The glass frit contaminated filters are collected separately and sent for incineration. All operations take place under local exhaust ventilation and ensuring appropriate solvent containment.<br>The whole process takes place in a controlled environment applying strict risk management measures, ensuring controlled release to the environment and minimizing employees' exposure.<br>Chemical Industrial hygiene monitoring performed regularly in the working areas ensured all Pb results below applicable TLV.<br>Exhausts are installed in all relevant area and air emissions are regularly monitored ensuring results below relevant local limit.<br>Controlled discharge to water is expected being plant waste water regularly monitored ensuring results for below applicable emission limit. | |

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| | | Glass frits are used in the region of 450 Kg/year, equivalent to 0.00027 % of the total quantity of Lead monoxide in the authorization scope (Draft background document for Lead monoxide - ECHA 01/09/2014).<br>This quantity is relevant to the production of 500 Million unit/y electronics components. Each electronic component may contain about 0.1 mg Lead in a concentration up to 0.5 %, depending on the component dimensions and weight.<br>MEMS plastic packages have thickness of less than 1.0 mm ranging from 7x5 mm2, 5x5 mm2 , 3x5 mm2 , 4x4 mm2 ,3x3 mm2<br>Glass frits are imported into Europe and, due to low quantity used, are not registered for the specific use in the semiconductor industry.<br><br>Use descriptor<br>The relevant descriptor as per Appendix R.12.1 to R.12.6 of the ECHA Guidance on Use Descriptor System (R12) and based on the ECHA-10-R-005-EN publication EXPOSURE SCENARIOS FOR THE SEMICONDUCTOR INDUSTRY EXAMPLES – August 2010<br>Sector of use (SU): SU 3 Industrial manufacturing<br>Chemical product category (PC): PC1 Adhesives, sealants<br>Process category (PROC): PROC 2 Use in closed, continuous process with occasional controlled exposure (e.g. sampling) - Industrial setting; Some process could take place not only in continuous process but also in batch operations with occasional control exposure, only<br>Environmental release category : ERC5 Industrial use resulting in inclusion into or onto a matrix Article category and Environmental release category are relate to glass frits<br><br>Non applicability of the wide dispersive criteria<br><br>With reference to the Draft background document for Lead monoxide - ECHA 01/09/2014 - there is a further clarification need: the total quantity of glass frits paste used is only 450 Kg/y. The number of potentially exposed employees is very | |

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| | | limited (40 employees), therefore the use of frits in the specific application of MEMS manufacturing in the semiconductor industry cannot be considered to contribute to the wide dispersive use criteria for prioritization.<br>There is no release to the environment from the article (semiconductor device) since the Lead monoxide, as already explained, is not present in the glass as such and Lead is chemically bonded in the glass amorphous structure. Moreover the semiconductor device is assembled into a matrix resin, to produce the semiconductor component, finally used in the electric or electronic equipment. Waste of electric and electronic components are managed according to the WEEE Directive, therefore there is no consumers exposure. | |
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## II - Transitional arrangements. Comments on the proposed dates

| Number / Date | Submitted by (name, submitter type, country) | Comment | Reference to responses |
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| 2519<br>2014/10/30 | Company,<br>United Kingdom | None | See responses referred to in comment #2519 in section I. |
| | | 2519_Suitable alternatives to lead monoxide.docx | |
| 2563<br>2014/11/20 | DALIC SAS,<br>Company,<br>France | Unthinkable as no alternatives have been studied for plating based on lead substances. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>5. Availability of suitable alternatives<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |

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| 2597<br>2014/11/24 | Allgemeine Unfallversicherungsanstalt, National Authority, Austria | | See responses referred to in comment #2597 in section I. |
| | | 2597_Pb.docx | |
| 2602<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe, Industry or trade association, United Kingdom | The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. | See responses referred to in #2602 in section I. |
| | | 2602_ECHA public consultation instructions lead monoxide_241114.pdf | |
| 2603<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe, Industry or trade association, United Kingdom | The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. | See responses referred to in #2602 in section I. |
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| 2625<br>2014/11/25 | EUROBAT, Industry or trade association, Belgium | The Lead REACH Consortium has submitted comments in response to this section and EUROBAT supports their response. | See responses referred to in comments #2602 and #2625 in section I. |
| | | 2625_EUROBAT and Lead REACH consortium - Exemption Request document - final_251114.pdf | |
| 2635<br>2014/11/25 | Inorganic Pigments Consortium, Industry or trade association, Spain | The Inorganic Pigments Consortium would like to express its support to the comments provided by the International Lead Association on behalf of the Pb REACH Consortium to the Public Consultation for substance lead monoxide (EC 215-267-0). | See responses referred to in comments #2602 and #2635 in section I. |
| | | 2635_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf | |
| 2636<br>2014/11/25 | Frit Consortium, Industry or trade association, Spain | The Frit Consortium would like to express its support to the comments provided by the International Lead Association on behalf of the Pb REACH Consortium to the Public Consultation for substance lead monoxide (EC 215-267-0). | See responses referred to in comments #2602 and #2636 in section I. |
| | | 2636_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf | |

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| 2651<br>2014/11/25 | CeramTec GmbH,<br>Company,<br>Germany | no comment | See responses referred to in comment #2651 in section I. |
| | | 2651_20141118_AUTH PC SEA Q FINAL_20140717_ceramTec.zip | |
| 2657<br>2014/11/25 | Company,<br>United Kingdom | no comment | - |
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| 2669<br>2014/11/26 | Robert-Bosch-GmbH,<br>Company,<br>Germany | | See responses referred to in comment #2669 in section I. |
| | | 2669_Bosch-Papers.zip | |
| 2702<br>2014/11/27 | European Special Glass Association, European Domestic Glass Association and International Crystal Federation,<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments to this section and EDG, ESGA and ICF support their response | See responses referred to in comments #2602 and #2702 in section I. |
| | | 2702_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx | |
| 2720<br>2014/11/27 | Company,<br>United Kingdom | If lead monoxide is included in Annex XIV without exemptions from authorisation, current expected sunset dates won't give Roxel sufficient time to continue R & D research and implement alternatives. This is based on previous attempts to identify replacements, which have failed.<br>We have been advised that after the public consultation closes it is expected that the final recommendation goes to the Commission in December, if there weren't (m)any comments; otherwise it is estimated as February - March 2015. It is anticipated that it will be at least a year before the Official Journal is updated to include the substances agreed for authorisation, (the prioritisation process and subsequent inclusion in Annex XIV takes around 18 months in total).<br>Further advice has stated that the sunset date must be at least 18 months after the latest application date and usually at least three years after the regulation is published in the Official Journal.<br>Consequently:<br>Worst Case. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects<br><br>**B.1.2. Foreseen timelines for the 6th Recommendation** |

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| | | December 2014 (recommended to go to commission) ---- December 2015 (Official Journal updated) ---- December 2018 (sunset date)(therefore latest application June 2017).<br>Best Case.<br>March 2015 (recommended to go to commission) ---- March 2016 (Official Journal updated) ---- March 2019 (sunset date)(therefore latest application September 2017).<br>If the authorisation date is too early or an exemption is not granted this could result in unacceptable changes in product performance or even the withdrawal of products.<br>The Aerospace and Defence industry operates very long life cycle products. It is heavily regulated and the introduction of new approved materials (and possibly processes) takes a considerable amount of time and funding. | |
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| 2722<br>2014/11/27 | Company,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section and Exide Technologies supports their response.<br>In addition, as a battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2727<br>2014/11/27 | Company,<br>Germany | | See responses referred to in comment #2727 in section I. |
| | | 2727_Public consultation_20141127.docx | |
| 2729<br>2014/11/27 | WirtschaftsVereinigung Metalle,<br>Industry or trade association,<br>Germany | Also in this respect WVM supports the arguments brought forward. | See responses referred to in comment #2602 in section I. |
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| 2745<br>2014/11/27 | ELOA (a Cefic industry sector group),<br>Industry or trade association,<br>Belgium | ELOA supports the comment made by ILA Europe:<br>"In the event an exemption is not recommended by ECHA for any or some of the uses we would like to request to have the latest application date (LAD) be extended to 36 months rather than the proposed 21 months proposed by ECHA on the following reasons: … " – see full text in ILA's comments | See responses referred to in comment #2602 in section I. |
| | | 2745_ELOA-PbO-comments-to ECHA PC_20141125b.pdf | |

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| 2753<br>2014/11/28 | Preciosa Ornela, a.s.,<br>Company,<br>Czech Republic | | See responses referred to in comment #2753 in section I. |
| | | 2753_OLOVO.zip | |
| 2758<br>2014/11/28 | Europacable,<br>Industry or trade association,<br>United Kingdom | Since no alternative is identified yet, the possibility to meet the proposed dates is not clear. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |
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| 2760<br>2014/11/28 | Association of the Glass and Ceramic industry of Czech Republic,<br>Industry or trade association,<br>Czech Republic | PbO Lead monoxide and Pb3O4 Lead tetroxide are intermediates uses in the production of lead crystal glass, we would therefore not apply for an authorization. Therefore we don't expect any terms and sunset dates.<br>As there is no alternative to PbO and Pb3O4 to the production of lead crystal glass, a ban would mean the closure of all lead crystal manufacturers.<br><br>For details see attached files | **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>1. Potential other regulatory actions<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>3. Use specific scrutiny foreseen at application stage<br>4. Control of risks<br>5. Availability of suitable alternatives<br>6. Socio-economic benefits of continued use<br>7. Burden for industry and potential competitive disadvantage<br><br>**C.1.1. General principles for** |

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| | | | **exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.2.1. Requests for Art. 58(2) exemptions**. |
| | | 2760_Comments of Association of the Glass and Ceramic Industry of the Czech Republic.zip | |
| 2762<br>2014/11/28 | Europacable,<br>Industry or trade association,<br>United Kingdom | Since no alternative is identified yet, the possibility to meet the proposed dates is not clear. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |
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| 2777<br>2014/11/28 | European Tyre & Rubber Manufacturers' Association (ETRMA),<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments in response to this section and ETRMA supports it. | See responses referred to in comments #2602 and #2777 in section I. |
| | | 2777_20141128 Lead oxides - ETRMA response to ECHA consult.pdf | |
| 2780<br>2014/11/28 | Aurubis AG,<br>Company,<br>Germany | | See responses referred to in comment #2780 in section I. |
| | | *Confidential attachment removed* | |
| 2782<br>2014/11/28 | WKÖ,<br>Other contributor,<br>Austria | See PDF attached. | See responses referred to in comment #2782 in section I. |
| | | 2782_su_86_WKÖ Bleiverbindungen.pdf | |
| 2819<br>2014/11/28 | Norway,<br>Member State | In general, we are in favour that a regulation should enter into force as soon as possible. Hence we are in favour of the shortest LAD slot. | **B.1.1. General principles for setting latest application dates / sunset dates:** |

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| | | | 3. ECHA's proposal for latest application dates |
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| 2859<br>2014/11/28 | Individual,<br>Germany | The Pb REACG Consortium has submitted comments in response to this section and HOPPECKE has supports their response. In additional, as a battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement ( Please see next section) | See responses referred to in comment #2602 in section I. |
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| 2860<br>2014/11/28 | Robert Bosch GmbH,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments in response to this section,ZVEI and Bosch supports their response. | See responses referred to in comments #2602 and #2860 in section I. |
| | | 2860_exemption argument for the industrial use of Piezo ceramics.docx | |
| 2883<br>2014/11/28 | Company,<br>Italy | Time line for glass frits substitution<br><br>As of today, alternative Lead-free glass frits materials do not demonstrate all the necessary requirements of Lead-based glass, moreover implementation implies long time research project with associated costs and investments. Alternative technologies exist, but not all technologies are compatible with the processing of MEMS devices.<br>Boron, phosphorus, zinc, tin, bismuth, etc. and their relatives oxides have been investigated as materials for substituting lead as a constituent element of glass frits used as a wafer-to-wafer bonding and sealing layers for MEMS devices.<br>However, these new type of glasses and glass frits are still in the investigation phase and have to fully demonstrate to meet the requirements necessary for substituting adequately the described Lead-based glass frits application.<br>Among the requirements to meet, some must be taken into account: the sealing properties (MEMS gyroscopes sensors, in order to work, must operate in a strict vacuum environment) and the excellent mechanical resistance. This point is especially important to note, being the market of MEMS sensors one of the fastest growing markets of the last years (for example, the incorporation of MEMS sensors, such as accelerometers, | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |

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| | | gyroscopes, pressure sensors, into smartphones).<br>Moreover some of the possible replacement materials are obtained using glasses made from Diboron trioxide. These glasses, although Boron is chemically bonded in the glass amorphous structure, may still be included in the scope of the authorization for Diboron trioxide (Draft background document for Diboron trioxide - ECHA 01/09/2014).<br><br>A typical time frame for a substitution process in the semiconductor industry would be as described in Fig. 1.<br><br>Figure 1<br>Assuming that after 2 years of new process trials, a suitable candidate is considered for the manufacturing of components and positively qualified (after almost 2 years), then the product is tested for acceptance by customers selected for the criticality of their applications (which will take about other 2 years). After the selected customers' acceptance, a PCN (product/process change notification) will be issued (high level classification) for global customers' acceptance and the mass production will start only after positive returns.<br><br>There is no clear visibility of a possible substitute availability and, therefore, of authorization needs in less than 4 years' timeframe.<br>Although it is believed that the use of frits in the specific application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization, in case this position is not agreed upon, it would be suitable to have the latest application date 48 months after the Annex XIV publication date, instead of the actual proposal of 24 months. | |
| | | 2883_LEAD_OX_autho_template_prop20141128.pdf | |
| 2895<br>2014/11/30 | Individual,<br>Germany | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports their response. In addition as | See responses referred to in comment #2602 in section I. |

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| | | battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | |
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| 2896<br>2014/11/30 | Johnson Controls Autobatterie GmbH & Co. KGaA,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports their response. In addition as battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2900<br>2014/11/30 | Johnson Controls Autobaterie spol. s r.o.,<br>Company,<br>Czech Republic | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Autobaterie spol. s r.o. based in Ceská Lípa, Czech Republic, supports their response. In addition as battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2907<br>2014/11/30 | Johnson Controls Autobaterías, S.A,<br>Company,<br>Spain | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Autobaterías, S.A based in Madrid, which operates two battery production sites in Burgos and Guardamar del Segura (Alicante), Spain, supports their response. In addition as battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2912<br>2014/11/30 | Johnson Controls Sachsen-Batterien GmbH & Co. KG,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Sachsen-Batterien GmbH & Co. KG based in Zwickau, Germany, supports their response. In addition as battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2916<br>2014/11/30 | Japan Business Council in Europe ( JBCE ),<br>Industry or trade association, | Nothing to comment | See responses referred to in comment #2916 in section I. |
| | | 2916_JBCE response for REACH authorization_REACH vs RoHS.pdf | |

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| | Belgium | | |
| 2920<br>2014/11/30 | Johnson Controls Recycling GmbH,<br>Company,<br>Germany | The Pb REACH Consortium has submitted comments to this section. Johnson Controls Recycling GmbH based in Buchholz, Germany, supports their response. In addition we believe in good reason that an exemption for this substance from a potential authorization requirement should be given (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2940<br>2014/11/30 | Association of European Airlines,<br>Industry or trade association,<br>Belgium | We clearly ask for the refusal of the inclusion of lead compounds to the authorization list, recognizing 5th recommendation is still open and a huge burden on the whole industry which is struggling by the on-going authorization procedures. Due to the industry's characteristics the search for alternatives requires at least more than 10 years for every substance and use combination. Therefore - in line with the ASD and AIA position - including lead compounds in the authorization list seems to be not proportional. | **A.2.23. ECHA should not proceed with the 6th recommendation, when the 5th is still open**<br><br>**A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>5. Availability of suitable alternatives<br>7. Burden for industry and potential competitive disadvantage<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>2. ECHA's proposal for sunset dates<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects<br><br>See also responses referred to in to the comment #2949 in Section I. |

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| 2949<br>2014/12/01 | ASD,<br>Industry or trade association,<br>Belgium | See attachment in Section IV | See responses referred to in comment #2949 in section I. |
| | | 2949_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf | |
| 2958<br>2014/12/01 | ADS Group,<br>Industry or trade association,<br>United Kingdom | ADS fully supports the comments made by ASD, and the comments made by MEGGITT concerning use of Lead oxide in PZT products. | See responses referred to in comments #2949 and #2519 in section I. |
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| 2970<br>2014/12/01 | Individual,<br>Italy | The Pb REACH Consortium has submitted comments in response to this section and FIAMM SPA supports their response. In addition, as a battery producer we believe in good reason to get an exemption for this substance from a potential authorization requirement (please refer to the next comment). | See responses referred to in comment #2602 in section I. |
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| 2978<br>2014/12/01 | ACEA,<br>Industry or trade association,<br>Belgium | The Pb REACH Consortium has submitted comments in response to this section and ACEA supports their response. | See responses referred to in comments #2602 and #2978 in section I. |
| | | 2978_20141201 ACEA Comments Authorisation Lead compounds.pdf | |
| 3004<br>2014/12/01 | Bundesverband Keramische Industrie e.V.,<br>Industry or trade association,<br>Germany | The Pb REACH Consortium and Cerame-Unie had submitted comments in response to this section and Bundesverband Keramische Industrie e.V. fully supports this. | See responses referred to in comments #2602 and #3009 in section I. |
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| 3009<br>2014/12/01 | Cerame-Unie - the European Ceramics Industry Association,<br>Industry or trade association,<br>Belgium | Cerame-Unie supports the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium. | See responses referred to in comments #2602 in section I. |
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| 3017<br>2014/12/01 | LightingEurope,<br>Industry or trade association,<br>Belgium | | See responses referred to in comment #3017 in section I. |
| | | 3017_LE_consultation_Lead monoxide_20141201_final.pdf | |
| 3020<br>2014/12/01 | European Semiconductor Industry Association,<br>Industry or trade | Time line for glass frits substitution<br><br>As of today, alternative Lead-free glass frits materials do not | See responses referred to in comment #2883 in section I. |

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| | association, Belgium | demonstrate all the necessary requirements of Lead-based glass, moreover implementation implies long time research project with associated costs and investments. Alternative technologies exist, but not all technologies are compatible with the processing of MEMS devices.<br>Boron, phosphorus, zinc, tin, bismuth, etc. and their relatives oxides have been investigated as materials for substituting lead as a constituent element of glass frits used as a wafer-to-wafer bonding and sealing layers for MEMS devices.<br>However, these new type of glasses and glass frits are still in the investigation phase and have to fully demonstrate to meet the requirements necessary for substituting adequately the described Lead-based glass frits application.<br>Among the requirements to meet, some must be taken into account: the sealing properties (MEMS gyroscopes sensors, in order to work, must operate in a strict vacuum environment) and the excellent mechanical resistance. This point is especially important to note, being the market of MEMS sensors one of the fastest growing markets of the last years (for example, the incorporation of MEMS sensors, such as accelerometers, gyroscopes, pressure sensors, into smartphones).<br>Moreover some of the possible replacement materials are obtained using glasses made from Diboron trioxide. These glasses, although Boron is chemically bonded in the glass amorphous structure, may still be included in the scope of the authorization for Diboron trioxide (Draft background document for Diboron trioxide - ECHA 01/09/2014).<br><br>The nature of material substitution as it applies within the semiconductor industry is not at all well understood outside of the industry. Material substitution requires first an invention in many cases and much research and development activity from the material and equipment suppliers, a significant lead-time for stringent material qualification, and then subsequent integration and verification of technical performance into individual company and customers technologies. Only after these aspects have been successful, can the act of final replacement be attempted in | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |

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| | | volume manufacturing. In the region of 8-10 years. There is no clear visibility of a possible substitute candidate available in this area. Therefore a longer timeframe is required for authorisation. Although it is believed that the use of frits in the specific application of MEMS manufacturing in the semiconductor industry is to be considered out of the scope of the authorization, in case this position is not agreed upon, it would be suitable to have the latest application date 48 months after the Annex XIV publication date, instead of the actual proposal of 24 months. | |
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## III - Comments on uses that should be exempted from authorisation, including reasons for that

| Number / Date | Submitted by (name, submitter type, country) | Comment | Reference to responses |
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| 2519<br>2014/10/30 | Company,<br>United Kingdom | ECHA's draft background document for lead monoxide states that its use as a technical ceramic appears not in scope of Authorisation. If this is the case, then it appears Meggitt's use of lead monoxide for the manufacture of piezoelectric ceramic components can continue without Authorisation (should the substance be added). | See responses referred to in comment #2519 in section I. |
| | | 2519_Suitable alternatives to lead monoxide.docx | |
| 2563<br>2014/11/20 | DALIC SAS,<br>Company,<br>France | Manufacture of plating solutions under controlled conditions.<br>Uses involving small quantities of lead oxide.<br>SME | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation** |
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| 2597<br>2014/11/24 | Allgemeine Unfallversicherungsanstalt,<br>National Authority, | | See responses referred to in response to comment #2597 in section I. |
| | | 2597_Pb.docx | |

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| | Austria | | |
| 2602<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe,<br>Industry or trade association,<br>United Kingdom | In addition, the Pb REACH Consortium would also like to point out that we also support the comments made on the exemption arguments made by the following Trade Associations/Consortia:<br>Industry Associations representing Member Companies using lead monoxide:<br>European Automobile Manufacturers' Association (ACEA): Car, van, truck and bus makers<br>European Domestic Glass (EDG): Other glass uses<br>European Lead Stabilizers Association (ELSA): Lead stabiliser producers<br>European Special Glass association (ESGA): special glass<br>Federation of European Explosives Manufacturers (FEEM): Explosive manufacturers<br>Frit Consortium: Frits<br>Glass Alliance Europe: Glass<br>Inorganic Pigments Consortium: Complex Inorganic Pigments<br>International Crystal Federation (ICF): Crystal Glass | See responses referred to in comment #2602 in section I.<br><br>See also responses referred to in comments #2978, #2702, #2636, #2997 and #2635. |
| | | 2602_ECHA public consultation instructions lead monoxide_241114.pdf | |
| 2603<br>2014/11/24 | Pb REACH Consortium managed by the International Lead Association-Europe,<br>Industry or trade association,<br>United Kingdom | The Pb REACH Consortium would like to point out that all the downstream user sectors will be submitting their comments into this section of the public consultation on exemptions. The joint Pb REACH Consortium exemption argument for battery use compiled by ILA/Pb REACH Consortium will be submitted by Eurobat.<br>In addition, the Pb REACH Consortium would also like to point out that we also support the comments made on the exemption arguments made by the following Trade Associations/Consortia:<br>Industry Associations representing Member Companies using lead monoxide:<br>European Automobile Manufacturers' Association (ACEA): Car, van, truck and bus makers<br>European Domestic Glass (EDG): Other glass uses<br>European Lead Stabilizers Association (ELSA): Lead stabiliser producers | See responses referred to in comment #2625 (EuroBat) in section I.<br><br>See also responses referred to in comments #2978, #2702, #2636, #2997 and #2635. |

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| | | European Special Glass association (ESGA): special glass<br>Federation of European Explosives Manufacturers (FEEM): Explosive manufacturers<br>Frit Consortium: Frits<br>Glass Alliance Europe: Glass<br>Inorganic Pigments Consortium: Complex Inorganic Pigments<br>International Crystal Federation (ICF): Crystal Glass | |
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| 2625<br>2014/11/25 | EUROBAT,<br>Industry or trade association,<br>Belgium | EUROBAT has attached in section IV a joint response by EUROBAT and the Lead REACH Consortium requesting the exemption of lead monoxide from the authorisation requirement for the industrial use of this substance in the manufacture of lead-based batteries. | See responses referred to in comment #2625 in section I. |
| | | 2625_EUROBAT and Lead REACH consortium - Exemption Request document - final_251114.pdf | |
| 2635<br>2014/11/25 | Inorganic Pigments Consortium,<br>Industry or trade association,<br>Spain | The Inorganic Pigments Consortium considers that according to the indications of the REACH Regulation, the use of lead monoxide in the manufacture of pyrochlore, antimony lead yellow should be considered as an intermediate use, and it should therefore be excluded from the authorization process. Furthermore, a REACH 58(2) exemption can also be claimed for this use. Details on this position can be found in the document attached to this Public Consultation. | See responses referred to in comment #2635 in section I. |
| | | 2635_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf | |
| 2636<br>2014/11/25 | Frit Consortium,<br>Industry or trade association,<br>Spain | The Frit Consortium considers that according to the indications of the REACH Regulation, the use of lead monoxide in the manufacture of frits should be considered as an intermediate use, and it should therefore be excluded from the authorization process. Furthermore, a REACH 58(2) exemption can also be claimed for this use. Details on this position can be found in the document attached to this Public Consultation. | See responses referred to in comment #2635 in section I. |
| | | 2636_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf | |
| 2651<br>2014/11/25 | CeramTec GmbH,<br>Company, | Use of PbO for the production of Piezoceramics (e.g.PZT) | See responses referred to in comment #2635 in section I. |

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| | Germany | | |
| | | 2651_20141118_AUTH PC SEA Q FINAL_20140717_ceramTec.zip | |
| 2657<br>2014/11/25 | Company,<br>United Kingdom | The electroplating industry has taken great strides in recent years to develop lead free materials. However there are some significant areas of application for lead based electroplating that still remain.<br>The use of lead in bearings for equipment such as larger engines and compressors is necessary; a fact acknowledged by the EU in the size limitations applied in the ELV and RoHS regulations.<br>Electroplating is a key technology used in the manufacture of these components.<br>The electroplating of lead is a process that is already very well controlled by UK regulations such as CLAW (Control of Lead at Work) and CoSHH (Control of substances hazardous to health) and their EU equivalents. Within our business we carry out rigorous occupational health checks as per the regulations and have never recorded any adverse effects on our workers.<br>If the use of lead monoxide and other plating salts necessary to manufacture these products is not exempted then manufacture of these products will be exported outside the EU with the loss of hundreds of jobs. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |
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| 2669<br>2014/11/26 | Robert-Bosch-GmbH,<br>Company,<br>Germany | Production and use of PZT/PTC, see attached documents | See responses referred to in comment #2669 in section I. |
| | | 2669_Bosch-Papers.zip | |
| 2686<br>2014/11/26 | Company,<br>Germany | PbO in use in Catalyst<br>It is known that in a very special use of lead acetate the substance PbO could be formed in catalysts e.g. "Lindlar catalyst" in small amounts (e.g. 30kg in 10t Catalyst). The catalyst<br>Is fully recycled (because the basis of such a catalyst is Palladium)<br>has low likelihood of exposure/risk to man and the environment | See responses referred to in comment #2727 in section I. |

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| | | has a very low amount of formed PbO, far below of the registration limit of 1t<br>Although much effort has been spent already on both, substituting the Pb component of the catalyst and on the search for an alternative catalyst, there is no alternative available for the catalyst in the process<br>we believe that these special use should be considered as it is stated : "Some uses appear not to be in the scope of authorisation, such as use in manufacturing of PVC stabilisers, certain pigments, explosives and technical ceramics, and use as laboratory reagent and in chemical analysis"<br>As not to fall under the authorisation process taking into account the proportionality principle. | |
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| 2702<br>2014/11/27 | European Special Glass Association, European Domestic Glass Association and International Crystal Federation,<br>Industry or trade association,<br>Belgium | EDG, ESGA and ICF have attached in section IV a response by EDG, ESGA and ICF requesting the exemption of lead monoxide from the authorization requirement for the intermediate use of this substance in the production of the substance glass (Art 3.15). Some applications also fall outside of the scope of authorization : food contact materials (Art. 56(5). Some applications already enjoy an exemption Under the ROHS and could be considered for an exemption ("Common Understanding Doc."). Lead oxide is already heavily regulated in the EU and legislation adequately protects human health and the environment (Art 56(2) | See responses referred to in comment #2702 in section I. |
| | | 2702_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx | |
| 2720<br>2014/11/27 | Company,<br>United Kingdom | Exemption of these substances would ensure the maintaining of the Defence of the Realm Act (DORA) ie to secure the safety of her majesty's forces and ships.<br>Roxel asks that, if they are included in Annex XIV, they may be exempted from the necessity for authorisation for use in the manufacture of rocket motors.<br>Roxel is certified according to :<br>i) ISO9001:2008.<br>ii) EN9100:2009. | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an** |

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| | | iii) ISO14001:2004.<br>When lead based ingredients are incorporated into Roxel materials on site, registered legislation is followed. These being/including:<br>i) Workplace (Health, Safety, Welfare) Regulations 1992.<br>ii) Health and Safety at Work Act 1974.<br>iii) Management of Health and Safety at Work Regulations 1999.<br>iv) Control of lead at Work Regulations 1998.<br>v) PPE at Work Regulations 1992.<br>vi) COSHH 2002.<br>vii) COSHH procedure as defined in on site Safety Manuals.<br>viii) Health and Safety policy as defined in on site Environmental Policies.<br>ix) Risk Assessments as covered by HSWA 1974.<br>x) Manufacturing Methods.<br>xi) CLP (Classification, Labelling and Packaging Regulation).<br>xii) Source Technical Safety Data Sheets.<br>xiii) On site Danger Area Rules.<br>xiv) On site Emergency Response Team.<br>xv) Use of a registered company for the dusposal of contaminated waste. | **exemption from authorisation**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |
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| 2722<br>2014/11/27 | Company,<br>Germany | Exide Technologies supports the joint EUROBAT and the Pb REACH Consortium document submitted by Eurobat requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead - based batteries would in any case meet the conditions for an exemption under Article 58(2) REACH | See responses referred to in comment #2625 in section I. |
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| 2727<br>2014/11/27 | Company,<br>Germany | Use of PbO in "manufacturing of catalysts" | See responses referred to in comment #2727 in section I. |

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| | | In the preparation of special catalysts (e.g. Lindlar catalyst) lead acetate is used to obtain a selective performance. It is known, that in the preparation process oxygen-containing lead compounds (e.g. PbO) could be formed in small amounts (e.g. appr. 3 kg per 1 tonne catalyst, corresponding to 0.3 % w/w).<br><br>Due to the content of precious metals the catalyst itself is fully recycled.<br><br>During manufacturing and use of these special catalysts, PbO has a low likelihood of exposure/risk to man and the environment.<br><br>Although much effort has been spent already on both, substituting the Pb component of the catalyst and on the search for an alternative catalyst, there is no alternative available for the catalyst in the process.<br><br>Referring to the proportionality principle we therefore believe, that this special use of PbO in "manufacturing of catalysts" should not appear in the scope of authorisation such as it is stated for the "use in manufacturing of PVC stabilisers, certain pigments, explosives and technical ceramics, and the use as laboratory reagent and in chemical analysis". | |
| | | 2727_Public consultation_20141127.docx | |
| 2729<br>2014/11/27 | WirtschaftsVereinigung Metalle,<br>Industry or trade association,<br>Germany | Also in this respect WVM supports the arguments brought forward. | See responses referred to in comment #2602 in section I. |
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| 2731<br>2014/11/27 | Wirtschaftsverband der deutschen Kautschukindustrie e. V. (wdk),<br>Industry or trade association, | Conclusion<br>Lead monoxide use in rubber industry is a matter of specific and limited applications. However these applications are essential for running the production lines in a wide range of customer industries. Including PbO in Annex XIV of 1907/2006/EU in general will lead to serious constrain for rubber industry and its | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>1. Potential other regulatory actions<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>7. Burden for industry and potential |

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| | Germany | customers as well.<br>The safe use of lead oxide in certain rubber industry applications is demonstrated by measuring mass concentration at the workplace and by conducted bio-monitoring over the last 10 years.<br>In case of an Annex XIV approach the authorization procedure is not an option for PbO uses in rubber industry. Because of the small quantity of PbO in relation to the costs and administrative efforts for an application procedure lead monoxide suppliers and the concerned downstream users will very probably not apply for an authorization.<br>Regulatory measures should concentrate precisely on real risks appearing with the use of lead monoxide. If there are hazards clearly identified due to unsafe uses in a production chain, the necessary requirements can be set more precisely in Annex XVII.<br><br>German rubber industry is ready to collaborate and to give useful input. | competitive disadvantage<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>Also refer to:<br>**C.2.1. Requests for Article 58(2) exemptions** |
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| 2745<br>2014/11/27 | ELOA (a Cefic industry sector group),<br>Industry or trade association,<br>Belgium | The following uses should be excluded from Authorisation for the following reasons:<br>- PbO used as an intermediate<br>- Article 58(2)of REACH<br><br>Use of the substance as an intermediate in the manufacture of lead-acid batteries<br>Use of the substance for manufacturing of heat stabilisers for PVC processing<br>Use of the substance in the manufacture of frits<br>Use of the substance in the manufacture of technical ceramics<br>Use of the substance in the manufacture of domestic glass (including crystal glass)<br>Use of the substance in the manufacture of special glasses<br><br>See details in the attached file < ELOA-PbO-comments-to ECHA | **A.2.8. Claim the use in the production of batteries as intermediate**<br><br>**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**<br><br>**A.2.10. Claim the use in the manufacture of frits as intermediate** |

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| | | PC_20141125b.pdf> | **A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate**<br><br>**A.2.13. Claim the use of lead monoxide in the manufacture of stabilisers for PVC processing as intermediate**<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.2.1. Requests for Article 58(2) exemptions**<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>2. Lack of alternatives, socio-economic aspects |

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| | | 2745_ELOA-PbO-comments-to ECHA PC_20141125b.pdf | |
| 2753<br>2014/11/28 | Preciosa Ornela, a.s.,<br>Company,<br>Czech Republic | Glass industry | See responses referred to in comment #2735 in section I. |
| | | 2753_OLOVO.zip | |
| 2758<br>2014/11/28 | Europacable,<br>Industry or trade association,<br>United Kingdom | IND and PROF uses for rubber compounds for cable insulation, sheathing and accessories in wet conditions. | **C.1.1. General principles for exemptions under Art. 58(2)** |
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| 2760<br>2014/11/28 | Association of the Glass and Ceramic industry of Czech Republic,<br>Industry or trade association,<br>Czech Republic | In our case, lead monoxide and lead tetroxide are used in production of lead crystal glass and the use is in line with the definition of intermediates (in the meaning of Article 3(15) REACH ) and is exempted from authorization.<br><br>For details see attached files | See responses referred to in comment #2760 in section I. |
| | | 2760_Comments of Association of the Glass and Ceramic Industry of the Czech Republic.zip | |
| 2762<br>2014/11/28 | Europacable,<br>Industry or trade association,<br>United Kingdom | IND and PROF uses for rubber compounds for cable insulation, sheathing and accessories in wet conditions. | **C.1.1. General principles for exemptions under Art. 58(2)** |
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| 2777<br>2014/11/28 | European Tyre & Rubber Manufacturers' Association (ETRMA),<br>Industry or trade association,<br>Belgium | ETRMA has attached in section IV a response requesting the exemption of lead monoxide from the authorisation requirement for the industrial use of this substance in the manufacture of rubber products. | See responses referred to in comment #2777 in section I. |
| | | 2777_20141128 Lead oxides - ETRMA response to ECHA consult.pdf | |
| 2780<br>2014/11/28 | Aurubis AG,<br>Company,<br>Germany | See detailed information in the attachment (section V). | See responses referred to in comment #2780 in section I. |
| | | *Confidential attachment removed* | |
| 2782<br>2014/11/28 | WKÖ,<br>Other contributor,<br>Austria | See PDF attached. | See responses referred to in comment #2782 in section I. |
| | | 2782_su_86_WKÖ Bleiverbindungen.pdf | |

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| 2787<br>2014/11/28 | Company,<br>Germany | Article 58(2) of REACH allows to exempt from the authorisation requirement uses or categories of uses 'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'.<br>The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper.<br>According to guidance issued by the European Chemicals Agency, legislation imposing "minimum requirements" means that Member States may adopt more stringent, but not less stringent requirements when implementing the specific EU legislation in question. By contrast, harmonization measures such as legislation imposing EU-wide occupational exposure limits amount to maximum requirements; the European Chemicals Agency states in its guidance on Article 58(2) of REACH that where occupational exposure limits exist, applications for an exemption under that provision is more likely to succeed.<br>The following elements shall be considered when deciding whether to include an exemption of a use of a substance in its recommendation.<br><br>(i) There is existing Community legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed.<br>Existing lead specific Community legislation exists for industrial use of lead monoxide and lead tetroxide in manufacturing of rubber goods, as follows: Directive 98/24/EC (protection of the health & safety of workers from the risks related to chemical agents at work), Directive 92/85/EEC (Protection of | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.2.1. Requests for Article 58(2) exemptions** |

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| | | pregnant/breast feeding workers), Directive 94/33/EC (protection of young people at work), Directive 2010/75/EC (Industrial Emissions), Directive 2008/50/EC (ambient air quality), Directive 2000/60/EC (water policy), Directive 98/83/EC (quality of water for human consumption), Directive 2006/118/EC (groundwater protection).<br><br>(ii) This Community 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.<br>Lead monoxide and lead tetroxide were identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as they are classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1A, [H360D ("May damage the unborn child")], and were therefore included in the candidate list for authorisation on 19/12/2012, following ECHA's decision ED/169/2012. It is this intrinsic property that can result in their proposal for inclusion in Annex XIV.<br>It is therefore important to assess whether existing community legislation already properly controls risks to human health and the environment arising from this intrinsic property. In doing so, ECHA has to conduct a detailed assessment of the relevant legislation so as to determine not only whether such legislation exists but also whether it sets out measures that already adequately control the relevant risks. Such assessment must be conducted by ECHA in concreto on a case-by-case basis. This analysis is described below:<br>a. Worker health controls<br>The health hazards of lead monoxide and lead tetroxide are well established and an EU wide harmonised classification exists through an entry in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008. This triggers requirements for specific packaging and labelling and through REACH article 31 | |

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| | | the provision of Safety Data Sheets to provide downstream users (including workers) with information on hazards and risk management measures.<br>During the industrial use of lead monoxide and lead tetroxide in manufacturing of rubber goods, the health risk associated with lead exposure is properly controlled by the specific requirements of three of the aforementioned legislative acts: Council Directive 98/24/EC (protection of the health & safety of workers from the risks related to chemical agents at work), Council Directive 92/85/EEC (protection of pregnant/breast feeding workers), and Council Directive 94/33/EC (protection of young people at work). Moreover, the so called OSH "Framework Directive" (Council Directive 89/391/EC) also contains minimum safety and health requirements throughout Europe that are applicable to workers employed in the rubber industry such as use of personal protective equipment (through Directive 89/656).<br>b. Environmental controls<br>Although the proposal for inclusion of lead monoxide and lead tetroxide in Annex XIV relates predominantly to health risks it is also relevant to report that manufacturing facilities using lead and its compounds are also covered by existing Community legislation ensuring that environmental releases are appropriately managed: 2008/50/EC (Ambient Air Quality Directive), 2010/75/EC (Industrial Emissions Directive), 2000/60/EC (Water Framework Directive)<br><br>(iii) This Community legislation imposes minimum requirements for the control of risks of the use. 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.<br>From the analysis made above it would appear that the existing workplace legislation for lead imposes specific minimum requirements for the control of health risks of the industrial use of the lead monoxide and lead tetroxide used in the rubber industry. Whilst not directly applicable to the intrinsic hazards for which inclusion in Annex XIV is being considered (i.e. | |

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| | | reproductive toxicity) it is also evident that existing environmental legislation contains elements intended to properly control the risks to human health and/or the environment resulting from release of lead from of rubber manufacturing facilities.<br>Lead and lead compounds also have an additional plethora of existing EU legislation to mitigate residual risks and drive substitution in products where technically and economically feasible. REACH authorisation for use of lead oxides in the rubber industry would not be an appropriate regulatory action in terms of proportionality.<br><br>Summary & Conclusion<br>The use of lead monoxide and lead tetroxide in the rubber industry should be granted a REACH Article 58 (2) exemption on the following grounds:<br>• Existing Community legislation already addresses the use categories to be exempted.<br>• The existing legislation provides binding and enforceable minimum requirements for the control of risks from industrial use of lead monoxide and lead tetroxide in the rubber industry. 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).<br>• Existing National statistics and exposure data gathered by Industry to support development of REACH chemical safety reports and voluntary lead reduction targets shows the effectiveness of the measures already in place under existing Community legislation such that it properly controls risk to human health from the use of the substances arising from their intrinsic properties specified in Annex XIV.<br>• The existing legislation covers the risks related to the lifecycle stages resulting from the use of the substances in rubber products and this is further supported by additional legislation. | |

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| 2803<br>2014/11/28 | Company,<br>Poland | We use lead monoxide in the mixtures (adsorbents) designed for the removal of arsine and sulfur compounds from hydrocarbon streams (e.g. cracked gases). This is only industrial use (we are the industrial downstream user) and the whole process is closed. Adsorbents are not regenerated, they are removed from the closed system as waste.<br>To our best knowledge, there is no alternative substance for purification of C3 fraction (with methyloacetylene and propadiene) and C4 fraction (with acetylene compounds and butadiene) at our production site. Our supplier informed us that we should NOT use Copper based products due to Cu-acetylides (explosive substances).<br>The descriptors of uses are: SU8; ERC6a; PROC1, PROC2, PROC8b; PC2<br>The amount of adsorbents used in the purification of hydrocarbon streams is <50 t/year (the concentration of lead monoxide in adsorbents is 10-25%).<br>The use of lead monoxide in adsorbents is not the common use and is not the consumer use. Lead monoxide is mainly used in the production of lead-acid batteries (over 90% of total uses in a range of EU). | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation** |
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| 2819<br>2014/11/28 | Norway,<br>Member State | Norway do not support that any exemptions from the authorisation requirement should be proposed. | **A.1.1. General, recommendation process:**<br>5. New information and next steps towards the final recommendation |
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| 2859<br>2014/11/28 | Individual,<br>Germany | HOPPECKE supports the joint EUROBAT and the Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxid sulphate and tetralead trioxid sulphate in lead based battery production from the authorization for two reasons: | See responses referred to in comment #2625 in section I. |

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| | | 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead based batteries; and<br><br>2. The use of these substances in the manufacture of lead based batteries would in any case meet the conditions for an exemption under Article 58(2) REACH | |
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| 2860<br>2014/11/28 | Robert Bosch GmbH,<br>Company,<br>Germany | ZVEI has attached in section IV a response requesting the exemption of lead monoxide and lead teroxide from the authorisation requirement for the industrial use of this substance in the manufacture of piezo ceramic materials. | See responses referred to in comment #2860 in section I. |
| | | 2860_exemption argument for the industrial use of Piezo ceramics.docx | |
| 2883<br>2014/11/28 | Company,<br>Italy | Applicability of art 58.2 criteria<br>On the basis of the following section of EU legislation that regulates semiconductor factory operations and products, the semiconductor industry believes that these substances are appropriately regulated already. In addition, any potential future nomination or inclusion in the candidate list of lead compounds for semiconductor usage should identify an exemption for the semiconductor sector from an authorization as being the most effective and appropriate measure.<br><br>–Restriction of Hazardous Substances<br>RoHS recast article 6, states that the review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006 so there should be no overlaps, as restrictions of the specific use of substances in EEE under RoHS, should not also be duplicated by being addressed in REACH. This nomination of substances contradicts the proportionality principle.<br>Use of glass frits is regulated under the Annex III exemption n 7 c I | **C.2.1. Requests for Article 58(2) exemptions**<br><br>See also responses referred to in comment #2883 in section I. |

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| | | –End of Life Vehicle Directive 2000/53/EC<br>The End-of-Life Vehicles (ELV) Directive 'lays down measures which aim, at first priority, at the prevention of waste from vehicles as well as at the improvement in environmental performance of all the economic operators involved in the life cycle of vehicles' (Article 1). Under this remit, the ELV Directive ensures that regular reviews on the use of Lead in automotive is carried out. The Oeko Institute's report concluded that 'the short-term substitution by lead-free alternatives would reduce the functionality and reliability of vehicles, the use of lead in this function is hence unavoidable at the time being and in the near future'.<br>Use of glass frits is regulated under the Annex II exemption n 10 a<br><br>- Protection of Workers: Occupational Exposure Limits and industry standards<br>European Occupational Exposure Limit for Lead and Lead Compounds (Directive 98/24/EC) Lead and lead compounds have a Binding Occupational Exposure Limit in Europe of 70 µg/dL blood and 0.15mg/m3 (8hr time weighted average) in air. This sets a minimum standard that is mandatory in all EU Member States to control occupational exposures. In the semiconductor industry there are engineering systems in place to ensure those limit are fulfilled and measurements are conducted regularly. Relevant analysis are regularly conducted to ensure that limits are respected.<br><br>- EU. Directive 2010/75/EU on Industrial Pollution Prevention Controls (IPPC), Annex II, L 334/17, 24 November 2010<br>Competent Authorities set pollutant emission limit values in permit conditions in to achieve a high level of protection for the environment.<br>Presence of glass frits is used to define the applicable emission limit regulated under the relevant local permit. | |
| | | 2883_LEAD_OX_autho_template_prop20141128.pdf | |

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| 2887<br>2014/11/28 | SFEPA Syndicat des Fabricants d'Explosifs de Pyrotechnie et d'Artifices,<br>Industry or trade association,<br>France | Use of Lead Monoxide for the synthesis of Lead Styphnate before detonators manufacturing or initiators for civilian and military applications.<br>No possible alternative exists.<br>Very low quantity used. Manufacturing process inducing low probability of personnel exposure as risk management prevention measures.<br>No release during all the life cycle.<br>Exemption requested for explosives and pyrotechnic components. | **C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.1.2. Generic exemptions**<br><br>**C.1.3. Aspects not justifying an exemption from authorisation**<br><br>Also refer to:<br>**A.2.14. Claim the use of lead monoxide in the manufacture of lead styphnate further used in explosives as intermediate** |
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| 2895<br>2014/11/30 | Individual,<br>Germany | Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an exemption under Article 58(2) REACH. | See responses referred to in comment #2625 in section I. |
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| 2896<br>2014/11/30 | Johnson Controls Autobatterie GmbH & Co. KGaA,<br>Company,<br>Germany | Johnson Controls Autobatterie GmbH & Co. KGaA based in Hannover, Germany, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization | See responses referred to in comment #2625 in section I. |

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| | | requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an exemption under Article 58(2) REACH. | |
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| 2900<br>2014/11/30 | Johnson Controls Autobaterie spol. s r.o.,<br>Company,<br>Czech Republic | Johnson Controls Autobaterie spol. s r.o. based in Ceská Lípa, Czech Republic, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an exemption under Article 58(2) REACH. | See responses referred to in comment #2625 in section I. |
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| 2907<br>2014/11/30 | Johnson Controls Autobaterías, S.A,<br>Company,<br>Spain | Johnson Controls Autobaterías, S.A based in Madrid, which operates two battery production sites in Burgos and Guardamar del Segura (Alicante), Spain, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an | See responses referred to in comment #2625 in section I. |

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| | | exemption under Article 58(2) REACH. | |
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| 2912<br>2014/11/30 | Johnson Controls Sachsen-Batterien GmbH & Co. KG,<br>Company,<br>Germany | Johnson Controls Sachsen-Batterien GmbH & Co. KG based in Zwickau, Germany, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an exemption under Article 58(2) REACH. | See response to comment #2625 in section I. |
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| 2916<br>2014/11/30 | Japan Business Council in Europe ( JBCE ),<br>Industry or trade association,<br>Belgium | Please see an attached file. | See responses referred to in comment #2916 in section I. |
| | | 2916_JBCE response for REACH authorization_REACH vs RoHS.pdf | |
| 2920<br>2014/11/30 | Johnson Controls Recycling GmbH,<br>Company,<br>Germany | Johnson Controls Recycling GmbH based in Buchholz, Germany, supports the joint EUROBAT and Pb REACH Consortium document submitted by EUROBAT requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead-based batteries would in any case meet conditions for an exemption under Article 58(2) REACH. | See responses referred to in comment #2625 in section I. |
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| 2940<br>2014/11/30 | Association of European Airlines,<br>Industry or trade association,<br>Belgium | Lead compounds are already heavily regulated by other legislation such as RoHS and the End-of Life Vehicle Directive. | **A.2.16. Ask ECHA to assess/ Question the regulatory effectiveness of inclusion of lead substances in AXIV**<br><br>Also refer to:<br><br>**C.1.1. General principles for exemptions under Art. 58(2)**<br><br>**C.2.1. Requests for Art. 58(2) exemptions**. |
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| 2949<br>2014/12/01 | ASD,<br>Industry or trade association,<br>Belgium | | **A.1.5. Aspects not considered in ECHA's prioritisation:**<br>2. Aim & proportionality of authorisation system - Authorisation is not a ban<br>7. Burden for industry and potential competitive disadvantage<br><br>**B.1.1. General principles for setting latest application dates / sunset dates:**<br>1. Legal background<br>2. ECHA's proposal for sunset dates<br>3. ECHA's proposal for latest application dates<br><br>**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:**<br>1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of |

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| | | | users)<br>2. Lack of alternatives, socio-economic aspects |
| | | 2949_ASD answer to ECHA consultation_General Conclusions for all Boron and lead compounds_281114.pdf | |
| 2958<br>2014/12/01 | ADS Group,<br>Industry or trade association,<br>United Kingdom | ADS fully supports the comments made by ASD, and the comments made by MEGGITT concerning use of Lead oxide in PZT products. | See responses referred to in comments #2949 and #2519. |
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| 2970<br>2014/12/01 | Individual,<br>Italy | FIAMM SPA supports the joint EUROBAT and the Pb REACH Consortium document submitted by Eurobat requesting an exemption of the use of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons:<br>1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and<br>2. The use of these substances in the manufacture of lead -based batteries would in any case meet the conditions for an exemption under Article 58(2) REACH | See responses referred to in comment #2625 in section I. |
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| 2978<br>2014/12/01 | ACEA,<br>Industry or trade association,<br>Belgium | ACEA has attached in section IV a response requesting the exemption of lead monoxide from the authorisation requirement for the industrial use of this substance in the manufacture of lead-based batteries and industrial use in the manufacture of PZT based dielectric ceramics. | See responses referred toin comment #2978 in section I. |
| | | 2978_20141201 ACEA Comments Authorisation Lead compounds.pdf | |
| 2997<br>2014/12/01 | ELSA (ESPA),<br>Industry or trade association,<br>Belgium | LEAD MONOXIDE USE AS AN INTERMEDIATE FOR MANUFACTURING OF STABILISERS FOR PVC PROCESSING<br><br>Lead-based stabilizers are substances derived from reactions of lead monoxide (PbO) with different acids, e.g. C16-C18 Fatty | **A.2.13. Claim the use of lead monoxide in the manufacture of stabilisers for PVC processing as intermediate** |

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| | | Acids, Phosphorous Acid (H3PO3), Sulfuric Acid, etc. PbO is completely converted in other substances and thus corresponds to the definition of " Intermediate" in Reach Art. 3(15). Therefore this substance is exempted from Authorisation (article 2(8) of REACH) for this use.<br><br>In addition it must be highlighted that the use of lead-based stabilisers is subject to a voluntary phase out from the EU-28 by end of 2015. See www.vinylplus.eu With respect to the year 2007 the volume of lead-based stabilisers at the end of 2014 is expected to have decreased by more than 85 % already. The volume of PbO consumed for this use is thus expected to have decreased in a similar way. | |
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| 3004<br>2014/12/01 | Bundesverband Keramische Industrie e.V., Industry or trade association, Germany | Cerame-unie has attached in section IV a response requesting the exemption of lead monoxide and lead tetraoxide from the authorization requirement for the industrial use of these substances in the manufacture of piezo ceramic materials and in the production of other ceramic materials or glazes. | See responses referred to in comments #2519 and #3009 in section I. |
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| 3009<br>2014/12/01 | Cerame-Unie - the European Ceramics Industry Association, Industry or trade association, Belgium | In respect to the manufacture of frits, we refer to the argumentation put together by the Frits consortium.<br><br>The use of lead monoxide and lead tetroxide in the manufacture of frits as well as the manufacture of PZT is exempted from REACH authorisation as these uses are considered as intermediate use under Article 3(15) of the REACH Regulation.<br><br>In addition it should be noted that and their use in the manufacture of frits and piezo ceramic materials would in any case meet the conditions for an exemption under Article 58(2) REACH.<br><br>In respect to the manufacture of PZT, we draw the attention to the fact that this substance is already regulated through existing specific legislation such as RoHS (2002/95/EC), WEEE | See responses referred to in comment #2636 in section I (Frits consortium).<br><br>See also responses referred to in comment #3009 (Cerame-Unie). |

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| | | (2002/96/EC) and their recasts (2011/65/EC, 2012/19/EU) and the ELV (2000/53/EC). | |
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| 3017<br>2014/12/01 | LightingEurope,<br>Industry or trade association,<br>Belgium | Raw materials, used in the manufacture of glass meet the definition of intermediates as much as they are transformed into a new substance, namely glass. They are transported isolated intermediates, since they are produced elsewhere and transformed at the sites of LightingEurope member companies.<br><br>Lead oxides are used to manufacture the glass article, they are not present in the final article anymore as glass is a non-crystalline or virtuous inorganic macromolecular structure, which does not contain the chemical components of the different raw materials.<br><br>Under REACH glass is classified as a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials - CAS number is 65997-17-3). It is exempted from the registration requirement under REACH under certain conditions laid down in Annex V (11) REACH.<br><br>Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels. We therefore request an exemption from authorization for this use. | See responses referred to in comment #3017 in section I. |
| | | 3017_LE_consultation_Lead monoxide_20141201_final.pdf | |
| 3020<br>2014/12/01 | European Semiconductor Industry Association,<br>Industry or trade association,<br>Belgium | Applicability of art 58.2 criteria<br>On the basis of the following section of EU legislation that regulates semiconductor factory operations and products, the semiconductor industry believes that these substances are appropriately regulated already. In addition, any potential future nomination or inclusion in the candidate list of lead compounds for semiconductor usage should identify an exemption for the semiconductor sector from an authorization as being the most effective and appropriate measure. | **C.2.1. Requests for Article 58(2) exemptions** |

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| | | –Restriction of Hazardous Substances<br>RoHS recast article 6, states that the review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006 so there should be no overlaps, as restrictions of the specific use of substances in EEE under RoHS, should not also be duplicated by being addressed in REACH. This nomination of substances contradicts the proportionality principle.<br>Use of glass frits is regulated under the Annex III exemption n 7 c I<br><br>–End of Life Vehicle Directive 2000/53/EC<br>The End-of-Life Vehicles (ELV) Directive 'lays down measures which aim, at first priority, at the prevention of waste from vehicles as well as at the improvement in environmental performance of all the economic operators involved in the life cycle of vehicles' (Article 1). Under this remit, the ELV Directive ensures that regular reviews on the use of Lead in automotive is carried out. The Oeko Institute's report concluded that 'the short-term substitution by lead-free alternatives would reduce the functionality and reliability of vehicles, the use of lead in this function is hence unavoidable at the time being and in the near future'.<br>Use of glass frits is regulated under the Annex II exemption n 10 a<br><br>- Protection of Workers: Occupational Exposure Limits and industry standards<br>European Occupational Exposure Limit for Lead and Lead Compounds (Directive 98/24/EC) Lead and lead compounds have a Binding Occupational Exposure Limit in Europe of 70 µg/dL blood and 0.15mg/m3 (8hr time weighted average) in air. This sets a minimum standard that is mandatory in all EU Member States to control occupational exposures. In the semiconductor industry there are engineering systems in place to ensure those limit are fulfilled and measurements are | |

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| | | conducted regularly. Relevant analysis are regularly conducted to ensure that limits are respected.<br><br>- EU. Directive 2010/75/EU on Industrial Pollution Prevention Controls (IPPC), Annex II, L 334/17, 24 November 2010 Competent Authorities set pollutant emission limit values in permit conditions in to achieve a high level of protection for the environment.<br>Presence of glass frits is used to define the applicable emission limit regulated under the relevant local permit. | |
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