01/07/2015

Comments and references to responses on ECHA's 6th Draft Recommendation for Orange lead (lead tetroxide) (EC number: 215-235-6)

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 Orange lead (lead tetroxide) (EC number: 215-235-6). 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_tetroxide_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).

PUBLIC VERSION

CONTENT

I - General comments on the recommendation to include the substance in Annex XIV 1

II - Transitional arrangements. Comments on the proposed dates.....20

III - Comments on uses that should be exempted from authorisation, including reasons for that 28

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
2520 2014/10/30	Company, United Kingdom	None 2520_Suitable alternatives to lead tetraoxide orange lead.docx	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives

			A.2.12. Claim the use in the manufacture of technical ceramic materials as intermediate **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**
2543 2014/11/17	Berzelius Metall GmbH, Company, 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 #2604 in this section.
2572 2014/11/21	Germany, 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 energy. 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.	**A.2.16. Asking ECHA to assess/ Questioning the regulatory effectiveness of inclusion of lead substances in Annex XIV and stressing the high workload for authorities related to these substances at AfA stage**

2598 2014/11/24	Allgemeine Unfallversicherungsanstalt, National Authority, Austria	We strongly Support orange lead entering Annex XIV. Lead and ist salts demonstrate also carcinogenic properties. 2598_Pb.docx	Thank you for your comment.
2604 2014/11/24	Pb REACH Consortium managed by the International Lead Association-Europe, International organisation, United Kingdom	The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. 2604_ECHA public consultation instructions orange lead 241114.pdf	**A.2.1. Ask ECHA to reconsider the priority scoring for orange lead / Lower WDU score proposed** **A.2.8. Claim the use in the production of batteries as intermediate** **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **A.2.10. Claim the use in the manufacture of frits as intermediate** **B.1.1. General principles for setting latest application dates / sunset dates:** 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest**

			application dates/sunset dates: 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users)
2626 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. 2626_EUROBAT and Lead REACH consortium - Exemption Request document - final 251114.pdf	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions** See also responses referred to in comment #2604 in this section.
2638 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 Orange lead – lead tetroxide (EC 215-235-6). 2638_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf	**A.2.1. Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate** **C.1.1. General principles for exemptions under Art.**

			58(2) **C.2.1. Requests for Art. 58(2) exemptions** See also responses referred to in comment #2604 in this section.
2640 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 Orange lead – lead tetroxide (EC 215-235-6). 2640_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf	**A.2.10. Claim the use in the manufacture of frits as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**. See also responses referred to in comment #2604 in this section.
2642 2014/11/25	Asociación Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC), Industry or trade association, Spain	The "Asociación Nacional de Fabricantes de Fritas, Esmaltes y Colores Cerámicos (ANFFECC)" would like to express its support to the comments issued by the Frit Consortium and the Inorganic Pigments Consortium for substance orange lead (lead tetroxide)	See responses referred to in comments #2640 and #2638 in this section.
2647 2014/11/25	Company, Spain	The use of Orange Lead in the explosives sector is a non-dispersive use and low tonnage. 1. Adequately controlled conditions. The risk to workers during use is reduced by risk management measures. There is no exposure during handling and use of the final explo-sive items that contain Orange-Lead. The end users are industrial users and they will not come into contact with this chemical because it is enclosed within the metallic shell of the Detonator. Please see enclosed file (Section IV) for further details.	**A.1.2. Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment

		2647_MAXAM-Comments-to ECHA-exemption-request-Orange-Lead-Tetroxide-25-November-2014.pdf	of wide-dispersiveness of uses **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 4. Control of risks 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use 7. Burden for industry and potential competitive disadvantage **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2703 2014/11/27	European Special Glass Association + European Domestic Glass Association + International Crystal Federation, Industry or trade association, Belgium	The Pb REACH Consortium has submitted comments in response to this section and EDG/ESGA/ICF support their response 2703_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx	**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)**

			C.1.2. Generic exemptions **C.2.1. Requests for Art. 58(2) exemptions**. See also responses referred to in comment #2604 in this section.
2725 2014/11/27	Exide Technologies, 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 #2604 in this section.
2734 2014/11/27	WirtschaftsVereinigung Metalle, Industry or trade association, Germany	WirtschaftsVereinigung Metalle (WVM), the German Non-Ferrous Metals' Association, represents the German non ferrous (NF) metals industry towards politics and economy. 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. 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. 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. 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 #2604 in this section.
2754 2014/11/28	Preciosa Ornela, a.s., Company,	Nenahraditelnost Pb3O4 ve sklářském průmyslu Chemie olovnatých skel	**A.1.5. Aspects not considered in ECHA's**

	Czech Republic	Použití jako meziprodukt ve sklářském průmyslu 2754_OLOVO.zip	**prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2757 2014/11/28	Company, France	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 #2604 in this section.
2763 2014/11/28	Association of the Glass and Ceramic industry of Czech Republic, Industry or trade association, 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. For details see attached files 2763_Comments of Association of the Glass and Ceramic Industry of the Czech	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban

		Republic.zip	3. Use specific scrutiny foreseen at application stage 4. Control of risks 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use 7. Burden for industry and potential competitive disadvantage **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2.1. Requests for Art. 58(2) exemptions**.
2765 2014/11/28	ELOA (a Cefic industry sector group), Industry or trade association, 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. See also the ELOA specific comments attached, file <ELOA-Pb3O4-comments-to ECHA PC_20141125b.pdf> 2765_ELOA-Pb3O4-comments-to ECHA PC_20141125b.pdf	**A.2.8. Claim the use in the production of batteries as intermediate** **A.2.9. Claim the use in the manufacture of lead glass (including lead**

			special glass and lead crystal glass) as intermediate **A.2.10. Claim the use in the manufacture of frits as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2.1. Requests for Article**

			58(2) exemptions See also responses referred to in comments #2604 and #2779 in this part.
2767 2014/11/28	Europacable, Industry or trade association, United Kingdom	Orange lead is an additive in rubber compounds for insulation, sheathing and accessories in cable manufacturing. Currently no alternative is available that meets the electrical performance specifications in wet conditions.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 3. Use specific scrutiny foreseen at application stage 5. Availability of suitable alternatives
2779 2014/11/28	European Tyre & Rubber Manufacturers' Association (ETRMA), Industry or trade association, Belgium	The Pb REACH Consortium has submitted comments in response to this section and ETRMA supports their response. 2779_20141128 Lead oxides - ETRMA response to ECHA consult.pdf	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**. See also responses referred to in comment #2604 in this section.
2783 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2783_su_86_WKÖ Bleiverbindungen.pdf	**A.2.16. Asking ECHA to assess/ Questioning the regulatory effectiveness of inclusion of lead substances in Annex XIV and stressing the high workload for authorities related to these substances at AfA stage** **A.1.5. Aspects not considered in ECHA's**

			prioritisation: 4. Control of risks 5. Availability of suitable alternatives **A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.3. Aspects not justifying an exemption from authorisation** **C.2.1. Requests for Art. 58(2) exemptions**.
2825 2014/11/28	Norway, 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 orange lead (lead tetroxide) is prioritised for inclusion in Annex XIV.	Thank you for your comment.
2861 2014/11/28	Robert Bosch GmbH, Company, Germany	The Pb REACH Consortium has submitted comments in response to this section,ZVEI and Bosch supports their response. 2861_exemption argument for the industrial use of Piezo ceramics.docx	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**. See also responses referred to in comment #2604 in this section.

2863 2014/11/28	Individual, Germany	The Pb REACH Consortium has submitted comments in response to this section and HOPPECKE supports this response.	See responses referred to in comment #2604 in this section.
2873 2014/11/28	Regional or local authority, 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. One major use of lead tetroxide (in battery production) is not likely to result in high releases to the water environment. However, its other uses may contribute to the total load in the water environment.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban
2897 2014/11/30	Johnson Controls Autobatterie GmbH & Co. KGaA, Company, 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 #2604 in this section.
2902 2014/11/30	Johnson Controls Autobaterie spol. s r.o. , Company, 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 #2604 in this section.
2908 2014/11/30	Johnson Controls Autobaterías, Company, 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 #2604 in this section.
2913 2014/11/30	Johnson Controls Sachsen-Batterien GmbH & Co. KG , Company, 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 #2604 in this section.
2919 2014/11/30	Johnson Controls Recycling GmbH,	The Pb REACH Consortium has submitted comments in response to this section and Johnson Controls Recycling GmbH based in Buchholz, Germany, supports their	See responses referred to in comment #2604 in this

	Company, Germany	response.	section.
2921 2014/11/30	Company, Austria	The Pb REACH Consortium has submitted comments in response to this section and we support their response *Confidential attachment removed*	See responses referred to in comment #2604 in this section. *Responses referring to the confidential attachment removed.*
2937 2014/11/30	Association of European Airlines, Industry or trade association, 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. 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. 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 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. Authorisation of these products – before	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **A.2.25. Concerns and uncertainties with respect to the authorisation process**

		there is a certified alternative in place - is creating a severe disadvantage for the European airline industry. 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"	
2979 2014/12/01	ACEA, Industry or trade association, Belgium	The Pb REACH Consortium has submitted comments in response to this section and ACEA supports their response. 2979_20141201 ACEA Comments Authorisation Lead compounds.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 5. Availability of suitable alternatives 6. Socio-economic benefits of continued use 7. Burden for industry and potential competitive disadvantage **A.2.8. Claim the use in the production of**

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

			58(2) **C.1.3. Aspects not justifying an exemption from authorisation** **C.2.1. Requests for Art. 58(2) exemptions**. See also responses referred to in comment #2604 in this section.
2982 2014/12/01	Individual, 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 #2604 in this section.
2995 2014/12/01	ZVEI, Industry or trade association, Germany	The Pb REACH Consortium has submitted comments in response to this section and the ZVEI supports their response. 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 #2604 in this section.
3005 2014/12/01	Bundesverband Keramische Industrie	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 #2604 and #

	e.V., Industry or trade association, Germany		3010 in this section.
3010 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. Cerame-Unie supports the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium. 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. Lead-containing frits have specific characteristics. Lead is essential to heal the pin-holes in the glaze during the firing 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. PZT itself is not put on the market for consumers, only articles containing	**A.1.5. Aspects not considered in ECHA's prioritisation:** 5. Availability of suitable alternatives **A.2.10. Claim the use in the manufacture of frits as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **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** **You might also be interested in the response:** **C.2.1. Requests for Art. 58(2) exemptions**

		components partly made of PZT are available for the end user. 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). 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 by existing legislation as soon there is a suitable alternative.	See also responses referred to in comments #2604 and # 2640 in this section.
3019 2014/12/01	LightingEurope, Industry or trade association, Belgium	Orange lead (lead tetraoxide) is used as a raw material and is an intermediate in the production of lead containing glass. 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. Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels. 3019_LE_consultation_Orange lead_lead tetroxide_20141201_final.pdf	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not**

			justifying an exemption from authorisation You might also be interested in response: **C.2.1. Requests for Article 58(2) exemptions**

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2520 2014/10/30	Company, United Kingdom	None 2520_Suitable alternatives to lead tetraoxide orange lead.docx	Please see references to responses in section I
2598 2014/11/24	Allgemeine Unfallversicherungsanstalt, National Authority, Austria	 2598_Pb.docx	Thank you for your comment.
2604 2014/11/24	Pb REACH Consortium managed by the International Lead Association-Europe, International organisation, United Kingdom	The response to this question has been provided by the Pb REACH Consortium uploaded in section IV of this public consultation. 2604_ECHA public consultation instructions orange lead 241114.pdf	Please see references to responses in section I.
2626 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. 2626_EUROBAT and Lead REACH consortium - Exemption Request document - final 251114.pdf	Please see references to responses in comment #2604 in section I.

2638 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 Orange lead – lead tetroxide (EC 215-235-6). 2638_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf	Please see references to responses in comment #2604 in section I.
2640 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 Orange lead – lead tetroxide (EC 215-235-6). 2640_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf	Please see references to responses in comment #2604 in section I.
2647 2014/11/25	Company, Spain	N.A. 2647_MAXAM-Comments-to ECHA-exemption-request-Orange-Lead-Tetroxide-25-November-2014.pdf	Please see references to responses in section I.
2703 2014/11/27	European Special Glass Association + European Domestic Glass Association + International Crystal Federation, Industry or trade association, Belgium	The Pb REACH Consortium has submitted comments in response to this section and EDG/ESGA/ICF support their response 2703_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx	Please see references to responses in comment #2604 in section I.
2725 2014/11/27	Exide Technologies, Company, Germany	The Pb REACH Consortium has submitted comments in response to this section and Exide Technologies 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).	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2734 2014/11/27	WirtschaftsVereinigung Metalle, Industry or trade	Also in this respect WVM supports the arguments brought forward.	Please see references to responses in comment #2604 in section I.

	association, Germany		
2754 2014/11/28	Preciosa Ornela, a.s., Company, Czech Republic		Please see references to responses in section I.
		2754_OLOVO.zip	
2763 2014/11/28	Association of the Glass and Ceramic industry of Czech Republic, Industry or trade association, 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. 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. For details see attached files	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects Please see also references to responses in section I.
		2763_Comments of Association of the Glass and Ceramic Industry of the Czech Republic.zip	
2765	ELOA (a Cefic industry	ELOA supports the comment made by ILA Europe:	**B.1.1. General principles**

2014/11/28	sector group), Industry or trade association, Belgium	"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 2765_ELOA-Pb3O4-comments-to ECHA PC_20141125b.pdf	**for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users) See also references to responses in comment #2604 in section I.
2767 2014/11/28	Europacable, Industry or trade association, United Kingdom	Since no alternative is available yet, no statement can be made.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects

2779 2014/11/28	European Tyre & Rubber Manufacturers' Association (ETRMA), Industry or trade association, Belgium	The Pb REACH Consortium has submitted comments in response to this section and ETRMA supports their response. 2779_20141128 Lead oxides - ETRMA response to ECHA consult.pdf	Please see references to responses in comment #2604 in section I.
2781 2014/11/28	Austin Detonator, Company, Czech Republic	We, Austin Detonator, ask for latest LAD slot (24 months) due to following reasons: 1) The supply chain is complicated and many actors are involved (distributors, formulators, downstream users) 2) Austin Detonator is downstream user of Lead tetraoxide. On top of all REACH authorization obligations, we have to prepare CSR and Exposure scenarios for our use and also for all uses of our downstream users (REACH requirement to have CSR in AFA). We can not expect that any manufacturer or importer of lead tetraoxide will prepare and submit Application for Authorization for our use due to very low tonnage used in our use (ca 12 tons per year). We need to get extra time to map and describe all uses within our supply chain. 3) There are confidentiality issues within supply chain, because explosive industry has own rules for manufacture and use of detonators both in civilian and military sectors. To obtain data from the supply chain will require extra time.	**B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 1. Extensive time needed in the supply chain to getting organised for preparing application (e.g. due to high number of users)
2783 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2783_su_86_WKÖ Bleiverbindungen.pdf	Please see references to responses in section I.
2825 2014/11/28	Norway, 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:** 3. ECHA's proposal for latest application dates
2861 2014/11/28	Robert Bosch GmbH, Company,	The Pb REACH Consortium has submitted comments in response to this section,ZVEI and Bosch supports their response.	Please see references to responses in comment

	Germany	2861_exemption argument for the industrial use of Piezo ceramics.docx	#2604 in section I.
2863 2014/11/28	Individual, Germany	The Pb REACH 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)	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2897 2014/11/30	Johnson Controls Autobatterie GmbH & Co. KGaA, Company, 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).	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2902 2014/11/30	Johnson Controls Autobaterie spol. s r.o. , Company, 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).	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2908 2014/11/30	Johnson Controls Autobaterías,	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	Please see references to responses in comment

	Company, Spain	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). 	#2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2913 2014/11/30	Johnson Controls Sachsen-Batterien GmbH & Co. KG , Company, 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). 	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2919 2014/11/30	Johnson Controls Recycling GmbH, Company, 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). 	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2921 2014/11/30	Company, Austria	The Pb REACH Consortium has submitted comments in response to this section and we support their response. *Confidential attachment removed*	Please see references to responses in comment #2604 in section I.
2937	Association of	We clearly ask for the refusal of the inclusion of lead compounds to the authorization	**A.1.5. Aspects not**

2014/11/30	European Airlines, Industry or trade association, Belgium	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	**considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 5. Availability of suitable alternatives 7. Burden for industry and potential competitive disadvantage **A.2.23. ECHA should not proceed with the 6th recommendation, when the 5th is still open** **B.1.1. General principles for setting latest application dates / sunset dates:** 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates:** 2. Lack of alternatives, socio-economic aspects
2979 2014/12/01	ACEA, Industry or trade	The Pb REACH Consortium has submitted comments in response to this section and ACEA supports their response.	Please see references to responses in comment

	association, Belgium	2979_20141201 ACEA Comments Authorisation Lead compounds.pdf	#2604 in section I.
2982 2014/12/01	Individual, 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).	Please see references to responses in comment #2604 in section I. **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
3005 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.	Please see references to responses in comment #2604 in section I.
3010 2014/12/01	Cerame-Unie - the European Ceramics Industry Association, Industry or trade association, Belgium	Cerame-Unie supports the comments submitted in this section by the International Lead Association on behalf of the Pb REACH Consortium.	Please see references to responses in comment #2604 in section I.
3019 2014/12/01	LightingEurope, Industry or trade association, Belgium	3019_LE_consultation_Orange lead_lead tetroxide_20141201_final.pdf	Please see references to responses in section I.

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
2520	Company,	ECHA's draft background document for lead tetroxide states that its use as an	

2014/10/30	United Kingdom	intermediate in manufacture of certain piezoelectric ceramics appears not in scope of Authorisation. If this is the case, then it appears Meggitt's use of lead tetroxide (orange lead) for the manufacture of piezoelectric ceramic components can continue without Authorisation (should the substance be added to Annex XIV). 2520_Suitable alternatives to lead tetraoxide orange lead.docx	**A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **C.1.2. Generic exemptions** **See also references to responses in section I.**
2598 2014/11/24	Allgemeine Unfallversicherungsanstalt, National Authority, Austria	 2598_Pb.docx	Thank you for your comment.
2604 2014/11/24	Pb REACH Consortium managed by the International Lead Association-Europe, International organisation, 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. 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: Industry Associations representing Member Companies using lead monoxide: European Automobile Manufacturers' Association (ACEA): Car, van, truck and bus makers European Domestic Glass (EDG): Other glass uses Federation of European Explosives Manufacturers (FEEM): Explosive manufacturers Frit Consortium: Frits Inorganic Pigments Consortium: Complex Inorganic Pigments International Crystal Federation (ICF): Crystal Glass 2604_ECHA public consultation instructions orange lead 241114.pdf	Please see references to responses in comments #2626, #2979, #2703, #2640, #2638 in this section.
2626 2014/11/25	EUROBAT, Industry or trade	EUROBAT has attached in section IV a joint response by EUROBAT and the Lead REACH Consortium requesting the exemption of orange lead (lead tetroxide) from the	**A.2.8. Claim the use in**

	association, Belgium	authorisation requirement for the industrial use of this substance in the manufacture of lead-based batteries. 2626_EUROBAT and Lead REACH consortium - Exemption Request document - final 251114.pdf	**the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2638 2014/11/25	Inorganic Pigments Consortium, Industry or trade association, Spain	The Inorganic Pigments Consortium considers that according to the indications of the REACH Regulation, the use of orange lead/lead tetroxide 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. 2638_IP Consortium-ECHA PC-intermediate use of lead oxides-pyrochlore antimony lead yellow.pdf	**A.2.1. Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2640 2014/11/25	Frit Consortium, Industry or trade association, Spain	The Frit Consortium considers that according to the indications of the REACH Regulation, the use of orange lead/lead tetroxide in the manufacture of frits should be considered as an intermediate use, and it should therefore be excluded from the authorization process. Furthermore, details on this position can be found in the document attached to this Public Consultation. 2640_Frit Consortium-ECHA PC-intermediate use of lead oxides-frits.pdf	**A.2.10. Claim the use in the manufacture of frits as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2647 2014/11/25	Company, Spain	We request the following exemption for the uses: Use in mixtures incorporated in Detonators for civil (industrial) use manufactured under the provision of civil explosives European legislation, vg. Directive 2010/75/EU, Directive 2012/4/EU and Directive 2014/28/EU. There is no release to the	**C.1.1. General principles for exemptions under Art. 58(2)**

		environment during its use because this chemical is converted into other chemicals during the final use. Moreover, the reaction products are not dangerous substances. Please see enclosed file (Section IV) for further details. 2647_MAXAM-Comments-to ECHA-exemption-request-Orange-Lead-Tetroxide-25-November-2014.pdf	**C.2.1. Requests for Art. 58(2) exemptions**.
2703 2014/11/27	European Special Glass Association + European Domestic Glass Association + International Crystal Federation, Industry or trade association, Belgium	EDG, ESGA and ICF have attached in section IV a response by EDG, ESGA and ICF requesting the exemption of lead tetroxide 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 tetroxide is already heavily regulated in the EU and legislation adequately protects human health and the environment (Art 56(2). Please note that this is the same document as for lead monoxide. 2703_FINAL - 2014 EDG ESGA ICF Description of the use of Lead oxides as intermediates in the manufacture of glass.docx	**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2.1. Requests for Art. 58(2) exemptions**.
2725 2014/11/27	Exide Technologies, Company, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**

2734 2014/11/27	WirtschaftsVereinigung Metalle, Industry or trade association, Germany	Also in this respect WVM supports the arguments brought forward.	Please see references to responses in comment #2604 in this section.
2754 2014/11/28	Preciosa Ornela, a.s., Company, Czech Republic	Sklářský průmysl 2754_OLOVO.zip	**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**. See also references to responses in section I.
2757 2014/11/28	Company, France	We support the comments submitted in this section by FEEM (Federation of European Explosives Manufactures)in order to have explosive sector exempted	Thank you for your comment.
2763 2014/11/28	Association of the Glass and Ceramic industry of Czech Republic, Industry or trade association, 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. For details see attached files 2763_Comments of Association of the Glass and Ceramic Industry of the Czech Republic.zip	**A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**

			C.1.2. Generic exemptions See also references to responses in section I.
2765 2014/11/28	ELOA (a Cefic industry sector group), Industry or trade association, Belgium	The following uses should be excluded from Authorisation for the following reasons: - PbO used as an intermediate - Article 58(2)of REACH Use of the substance as an intermediate in the manufacture of lead-acid batteries; Use of the substance in the manufacture of frits; Use of the substance in the manufacture of technical ceramics; Use of the substance in the manufacture of domestic glass (including crystal glass); Use of the substance in the manufacture of special glasses; See details in the attached file <ELOA-Pb3O4-comments-to ECHA PC_20141125b .pdf> 2765_ELOA-Pb3O4-comments-to ECHA PC_20141125b.pdf	**A.2.8. Claim the use in the production of batteries as intermediate** **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **A.2.10. Claim the use in the manufacture of frits as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2.1. Requests for Art. 58(2) exemptions**. See also references to

			responses in section I.
2767 2014/11/28	Europacable, Industry or trade association, United Kingdom	IND and PROF uses of rubber compounds for the production of cables and accessories which have to meet electrical performance specifications for safety reasons. No alternative has been identified so far.	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.3. Aspects not justifying an exemption from authorisation**
2779 2014/11/28	European Tyre & Rubber Manufacturers' Association (ETRMA), Industry or trade association, 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. 2779_20141128 Lead oxides - ETRMA response to ECHA consult.pdf	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2783 2014/11/28	WKÖ, Other contributor, Austria	See PDF attached. 2783_su_86_WKÖ Bleiverbindungen.pdf	Please see references to responses in section I.
2789 2014/11/28	Company, 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'. 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. 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.	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.

		The following elements shall be considered when deciding whether to include an exemption of a use of a substance in its recommendation. (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. 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 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). (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. 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. 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: a. Worker health controls 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 the provision of Safety Data Sheets to provide downstream users (including workers) with information on hazards and risk management measures. 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). b. Environmental controls 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) (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. 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. 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. 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. Summary & Conclusion 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: • Existing Community legislation already addresses the use categories to be exempted. • The existing legislation provides binding and enforceable minimum requirements for the control of risks from industrial use of 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). • 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. • 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.	
2813 2014/11/28	Industry or trade association, Norway	Comments to the draft recommendation of substances for inclusion in Annex XiV Applications where orange lead is used today: Rubber containing orange lead is used in insulation and lining systems where the material is exposed for sea water. Lead is used as an acid acceptor in chloroprene for bonding the chlorine that decomposes during the curing process and thus avoids the formation of free acid which is detrimental to the properties of the rubber. An additional feature of lead in our compositions is to bind chlorine compounds which decompose when chloroprene is in contact with sea water over time. Chloroprene itself does not have good resistance to sea water and will swell and gradually deteriorate. By adding an acid acceptor such as lead the swelling will be considerably reduced and we get the good corrosion protection in seawater. This mechanism of acid acceptor is also maintaining the long term adhesion for offshore applications	**A.1.3. Prioritisation: Wide-dispersiveness of uses:** 1. Scope of the assessment of wide-dispersiveness of uses 3. Refinement of WDU score based on article service-life **A.1.5. Aspects not considered in ECHA's prioritisation:** 3. Use specific scrutiny

		where cathodic protection is used as a corrosion protection. Handling during production Due to use of orange lead in the application cause a high focus in use of appropriate HSE equipment. Employees that are exposure for orange lead during production are followed up and the exposure scenario is recorded in a special register. It has also been executed blood tests of these employees and no abnormal results are observed. MSDS is made for all uncured compounds. Waste handling The Orange lead is bonded in a polymer, and this raw material has a long shelf life. There is no need for handling the raw material as waste. Rubber waste from production containing lead is tested for leakage of lead, according to storage of waste by deposition. The tests are documented for both unvulcanized and vulcanized rubber. As a result of these reports all rubber waste is destructed by burning. Conclusion Because of the following reasons lead oxide should not be included into the annex XiV: • During article manufacturing, the risk associated to potential exposure to lead-oxides is properly controlled • Lead-oxides-containing rubber products are not sold to consumers and their use is limited to industrial applications • Lead oxides are strictly bound into the matrix, so there is no danger for humans and the environment caused by foreseen use of the lead-oxides-containing rubber products.	foreseen at application stage 4. Control of risks **A.2.1. Ask ECHA to reconsider the priority scoring for orange lead / Lower WDU score proposed** (See especially the part on the WDU)
2825 2014/11/28	Norway, Member State	Norway does not support that any exemptions from the authorisation requirement should be proposed.	Thank you for your comment.
2861	Robert Bosch GmbH,	ZVEI has attached in section IV a response requesting the exemption of lead	**A.2.12. Claim the usein**

2014/11/28	Company, Germany	monoxide and lead teroxide from the authorisation requirement for the industrial use of this substance in the manufacture of piezo ceramic materials. 2861_exemption argument for the industrial use of Piezo ceramics.docx	**the manufacture of technical ceramic materials as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2863 2014/11/28	Individual, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead based batteries; and 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	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2897 2014/11/30	Johnson Controls Autobatterie GmbH & Co. KGaA, Company, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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.	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2902 2014/11/30	Johnson Controls Autobaterie spol. s r.o. ,	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,	**A.2.8. Claim the use in the production of**

	Company, Czech Republic	pentalead tetraoxide sulphate and tetralead trioxide sulphate in lead-based battery production from the authorization requirements for two reasons: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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.	**batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2908 2014/11/30	Johnson Controls Autobaterías, Company, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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.	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2913 2014/11/30	Johnson Controls Sachsen-Batterien GmbH & Co. KG , Company, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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.	**A.2.8. Claim the use in the production of batteries as intermediate** **C.2.1. Requests for Art. 58(2) exemptions**
2919 2014/11/30	Johnson Controls Recycling GmbH, Company, 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	**A.2.8. Claim the use in the production of batteries as intermediate**

		authorization requirements for two reasons: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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.	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
2921 2014/11/30	Company, Austria	We've attached in section V a response requesting the exemption of lead tetraoxide from the authorisation requirement for the industrial use of this substance in the manufacture of piezo, PTC and PLZT ceramic materials *Confidential attachment removed*	**A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2937 2014/11/30	Association of European Airlines, Industry or trade association, Belgium	Lead compounds are already heavily regulated by other legislation such as RoHS and the End-of Life Vehicle Directive.	**C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
2979 2014/12/01	ACEA, Industry or trade association, Belgium	ACEA has attached in section IV a response requesting the exemption of lead tetraoxide 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. 2979_20141201 ACEA Comments Authorisation Lead compounds.pdf	**A.2.8. Claim the use in the production of batteries as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate**

			C.1.1. General principles for exemptions under Art. 58(2) **C.1.3. Aspects not justifying an exemption from authorisation** **C.2.1. Requests for Art. 58(2) exemptions**. See also references to responses in section I.
2982 2014/12/01	Individual, 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: 1. These substances are used as intermediates (in the meaning of Article 3(15) REACH) in the manufacture of lead-based batteries; and 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	**A.2.8. Claim the use in the production of batteries as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**
3005 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.	**A.2.10. Claim the use in the manufacture of frits as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)**

			C.2.1. Requests for Art. 58(2) exemptions.
3010 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. 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. 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. 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 (2002/96/EC) and their recasts (2011/65/EC, 2012/19/EU) and the ELV (2000/53/EC).	**A.2.10. Claim the use in the manufacture of frits as intermediate** **A.2.12. Claim the usein the manufacture of technical ceramic materials as intermediate** **C.1.1. General principles for exemptions under Art. 58(2)** **C.2.1. Requests for Art. 58(2) exemptions**.
3019 2014/12/01	LightingEurope, Industry or trade association, 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. 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. 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. Today, the substance is an essential ingredient and there is no alternative known on the market with the same performance levels.	**A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban **A.2.9. Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate** **C.1.1. General principles for exemptions under Art.**

		3019_LE_consultation_Orange lead_lead tetroxide_20141201_final.pdf	**58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an exemption from authorisation** You might also be interested in response: **C.2.1. Requests for Article 58(2) exemptions**