01/07/2015

Comments and references to responses on ECHA's 6th Draft Recommendation for Acetic acid, lead salt, basic (EC number: 257-175-3)

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 Acetic acid, lead salt, basic (EC number: 257-175-3). The public consultation took place between 1 September and 1 December 2014.

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

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2509 2014/10/03	Company, Thailand	Acetic is the good for preservative mince products.	Thank you for your comment.
2596 2014/11/24	Allgemeine Unfallversicherungsanstalt	We Support the inclusion of these lead salts in Annex XIV	Thank you for your comment.

	, National Authority, Austria	*Confidential attachment removed*	
2613 2014/11/24	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**
2799 2014/11/28	Pharmachemical Ireland, Industry or trade association, Ireland	We request that ECHA reconsider prioritisation of this substance until a thorough assessment of substitution potential has been completed. In addition we would urge that an evaluation of the regulatory effectiveness of including this substance onto Annex XIV be conducted.	**A.2.7. Disagree/Agree with grouping of acetic acid lead salt with orange lead** **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
2811 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 support that on the basis of further considerations (grouping with lead monoxide and lead tetroxide) acetic acid, lead salt, basic, should be prioritised for inclusion in Annex XIV.	**A.2.7. Disagree/Agree with grouping of acetic acid lead salt with orange lead**
2847 2014/11/28	Cara Partners, Company, Ireland	The substance is used in the manufacture of a unique and specialised API and is handled at site under controlled conditions. There are few suppliers of this substance in the EU as reflected in the registration dossiers, therefore it is anticipated that listing this substance onto Annex XIV will impact the continued availability of the substance in the EU. Alternative supply form outside the EU, should it be secured would be subjected to re-approval and validations for use in manufacture of a medicinal product. Such approvals may not be complete ahead of the proposed sunset date. In addition as there is currently no known substitutes for this use of the substance, it is possible that production of this (niche market) API would move outside of the EU resulting in significant economic loss. Cara Partners therefore opposes the inclusion of the substance acetic acid, lead salt basic onto Annex XIV of REACH. Challenges to the Prioritisation Score: In relation to the assigned prioritisation score, it is clear from ECHAs background document that the criteria laid down in Article 58(3) of REACH as applied to this substance would not alone result in the substance being prioritised for inclusion onto Annex XIV. While it is acknowledged that substances can be prioritised due to further considerations, the ECHA background document does not clearly demonstrate that this substance has been fully assessed under these further considerations. Instead it puts forward that the substance is being proposed because it is considered a potential substitute for two other lead compounds for a single use, in paints at industrial sites. According to the available literature, the use of lead compounds in paint is steadily declining in the EU due to the impact of regulatory measures. However, lead monoxide	**A.1.1. General, recommendation process:** 2. Legal basis for prioritisation 3. Prioritisation approach applied **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 7. Burden for industry and potential competitive disadvantage

		and tetroxide are still used in paints in the EU, reportedly as pigments for rubber and as protective primers for objects. Both compounds are insoluble in water. On the other hand, acetic acid lead salt basic, is water soluble and acts mainly as a mordant or drier in paints and as a fixing agent of dyes in fabrics. As the substances (owing to their divergent chemistry) are performing different functions, prioritising acetic acid lead salt basic on the grounds of possible substitution for use in paints does not appear to be technically feasible. In addition the lead oxides are readily available and relatively low cost substances, acetic acid, lead salt basic, a more complex salt is not as widely available and the market price is up to 5 times greater than that of the lead oxides. A direct substitution for these compounds in paint does not appear likely. The prioritisation does not take account of the proportionality of the measure and appears to contradict ECHAs prioritisation document (Prioritisation of SVHCs for inclusion in the Authorisation List 10 February 2014) which states that the purpose of prioritisation is to recommend the substances on the Candidate List in such an order that the more relevant substances are included in Annex XIV before less relevant substances. Including the substance onto Annex XIV would be a disproportionate measure should it be shown to be technically possible to substitute acetic acid, lead salt basic for the lead oxides in paints or in other 'common uses'. It would almost certainly contradict ECHAs own guidance as it would not be 'in line with the role and purpose of the recommendation step'. As it does not appear to be either technically or economically feasible to substitute acetic acid lead salt basic for the lead oxides in paint, the substance should not be considered for inclusion onto Annex XIV using the grouping approach outlined in ECHAs background document. We would therefore request ECHA to reconsider prioritisation of this substance until a thorough assessment of substitution potential has been completed. In addition we would urge that an evaluation of the regulatory effectiveness of including this substance onto Annex XIV be conducted.	**A.2.7. Disagree with grouping of acetic acid lead salt with orange lead** **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.2.20. Inclusion of acetic acid, lead salt, basic in Annex XIV may impact the continued availability of the substance in EU** **A.2.21. Re-approval of acetic acid, lead salt, basic supplied from outside EU for use in manufacture of medicinal products may not be possible before the sunset date**

II - Transitional arrangements. Comments on the proposed dates

Number / Date	Submitted by (name, submitter type, country)	Comment	Reference to responses
2596 2014/11/24	Allgemeine Unfallversicherungsanstalt , National Authority, Austria	*Confidential attachment removed*	Thank you for your comment.
2811 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

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
2596 2014/11/24	Allgemeine Unfallversicherungsanstalt , National Authority, Austria	*Confidential attachment removed*	Thank you for your comment.
2755 2014/11/28	Company, Germany	The substance is exclusively used as such for sugar analytics. The application is a routine analytical use in a laboratory within the scope of scientific R&D. The risk for the	**C.1.2. Generic exemptions**

		environment and consumers is very low. Usually the volumes and the concentration of the substance are low. The disposal of the substance is also controlled. The use of lead acetate as analytical reagent is exempted from authorisation (Art. 56 (3), scientific R&D). Therefore,necessary upstream processes like packaging/refilling of the pure substance into small packages for this use should be exempted.	
2799 2014/11/28	Pharmachemical Ireland, Industry or trade association, Ireland	Acetic acid, lead salt basic is used in a specialised process in the manufacture of an API used in medicinal products for human use regulated under the medicinal products directive. This request for exempted use reflects the use of the substance in this key process. This application, using limited quantities of the substance, is of vital importance in the purification of this specialised API. The process is carried out under controlled conditions and in accordance with Good Manufacturing Practices (GMP). Use of lead compounds are already tightly controlled under worker protection legislation that requires the monitoring of exposure and maintaining exposure below Occupational Exposure Limit Values as specified under The Chemicals Agents Directive. The acetic acid lead salt basic is entirely removed from the process to waste stream and is handled in accordance with waste legislation.	**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** **C.2.1. Requests for Art. 58(2) exemptions**
2811 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.
2847 2014/11/28	Cara Partners, Company, Ireland	Acetic acid, lead salt basic is used in a specialised process in the manufacture of an API used in medicinal products for human use regulated under the medicinal products directive. This request for exempted use reflects the use of the substance in this key process. This application, using limited quantities of the substance is of vital importance in the purification of this specialised API. The process is carried out under controlled conditions and in accordance with Good Manufacturing Practices (GMP). Use of lead compounds are already tightly controlled under worker protection legislation that requires the monitoring of exposure and maintaining exposure below Occupational Exposure Limit	**C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.1.3. Aspects not justifying an**

		Values as specified under The Chemicals Agents Directive. The acetic acid lead salt basic is entirely removed from the process to waste stream and is handled in accordance with waste legislation. We request that the exemptions that apply to the final medicinal product also applies to the extent that the substance is used in the process resulting in the final production of a medicinal product, falling within the scope of the medicinal products directive.	**exemption from authorisation** **C.2.1. Requests for Art. 58(2) exemptions**