01/07/2015

Response document

Substance group: Lead substances

Substance names and EC-numbers:

Substance name	EC number
Lead monoxide	215-267-0
Orange lead (lead tetroxide)	215-235-6
Tetralead trioxide sulphate	235-380-9
Pentalead tetraoxide sulphate	235-067-7
Silicic acid, lead salt	234-363-3
Pyrochlore, antimony lead yellow	232-382-1
Acetic acid, lead salt, basic	257-175-3

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About this response document

The present document provides ECHA's responses to the comments[1] received during the public consultation on its draft recommendation to include the lead substances named on page 1 of the current document in Annex XIV of the REACH regulation. The public consultation was held in the context of ECHA's draft 6th Annex XIV recommendation and took place between 1 September and 1 December 2014.

Although the responses aim to address individual comments (submitted for individual substances), they have been compiled in a consolidated form structured by thematic block and level of information. This format intends to increase consistency and readability of responses and promote a better understanding of the authorisation process. In general, comments addressing same or similar issues have been assigned references[1] to the same parts of the current document.

The responses to issues raised during the public consultation have been assigned to three thematic blocks, based on the following structure:

- **A. Priority and general issues**
  covers responses to issues related to the priority of the substances, including ECHA's prioritisation approach and its implementation in assigning priority scores and conclusions; also covers any other generic issue not covered by sections B and C;
- **B. Timelines**
  covers responses to issues related to the latest application dates, sunset dates and review periods, including ECHA's approach for determining those timelines;
- **C. Exemptions**
  covers the responses to exemption requests, including ECHA's approach for evaluating those requests;

Each thematic block (A, B, C) is further divided based on the level of information in the response, as follows:

[1] The compilation of comments received, along with references to responses , can be found at the following link(s):
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_acetic_acid_lead_salt_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_lead_monoxide_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_lead_tetroxide_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_pentalead_tetraoxide_sulphate_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_pyrochlore_antimony_lead_yellow_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_silicic_acid_lead_salt_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_tetralead_trioxide_sulphate_en.pdf

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1. **Process information**
   provides a summary of the principles applied by ECHA for its decision making relevant for each thematic block, as well as further information on aspects generally relevant or non-relevant for that decision. The process information has been developed based on the experience from previous recommendation rounds. It addresses issues commonly raised in comments submitted during the public consultation. The process information part is identical in all Response documents of substances included in the draft 6th recommendation for public consultation.

2. **Further responses relevant for the substances/substance group**
   provides responses to comments relevant for the substances not addressed in the process information.

The section headings in the process information and captions on the left of ECHA's responses provide a summary of the issue addressed per section / response. The headings and captions are also numbered (e.g. "A.1.2", "B.2.2"), to support references to responses in the "Comments and references to responses document"[1] and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.

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A. Priority and general issues

A.1 Process information

A.1.1. General, recommendation process

1.ECHA's obligation to recommend/prioritise substances on the Candidate List

ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of the REACH Regulation).

According to Article 58(3) and Recital (77), the number of substances included in each recommendation needs to reflect the capacity of ECHA and the Commission to handle applications in the time provided for as well as the workability and practicality for applicants preparing their applications for authorisation. Therefore, the workability of the authorisation process necessitates a gradual inclusion of substances in Annex XIV.

The prioritisation is the task of comparing those substances included in the Candidate list to determine which ones should be included first in Annex XIV. Substances not prioritised for this recommendation remain on the Candidate list and will be reassessed for priority in later recommendations together with the new substances included in the Candidate List.

2.Legal basis for prioritisation

According to Article 58(3), priority for inclusion into Annex XIV shall normally be given to substances with
(a) PBT or vPvB properties, or
(b) wide dispersive use, or
(c) high volumes.

Article 58(3) requires taking the mentioned 3 criteria 'normally' into account, but there is no provision how this should be done in practise. Moreover, consideration of further aspects and criteria for priority setting is not excluded. Hence, Article 58(3) leaves discretion regarding the design of an approach used for prioritising Candidate list substances for inclusion in Annex XIV.

Information on the approach currently applied is provided below.

3.Prioritisation approach applied

The prioritisation approach applied by ECHA to the current recommendation round (6th recommendation) was discussed with, and has been agreed by, the Member State Committee (MSC). Please refer to

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http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

It is noted that all priority setting approaches are conventions on how to systematically use the information chosen to be the basis for assessing the prioritisation criteria including how to weight and combine the criteria in qualitative and/or quantitative terms. To draw overall conclusions there is a need to integrate complex pieces of all relevant information. Therefore the assignment of weighting factors and scores remains to be done by expert judgement and by agreement amongst the users of the approach. In the case of the applied prioritisation approach this was done in the MSC.

The results of the priority assessment of all Candidate list substances using the prioritisation approach can be found at ECHA's website[2]. Further information on how the approach is applied in practice, especially on how the wide-dispersive use criterion is assessed, is provided in Annex 2 of the prioritisation results document.

4.Information taken into consideration for the draft recommendation

For the purpose of its draft priority setting ECHA has carefully considered all information available to it. The registration dossiers (including the CSRs) have been the main source of information. It is the registrants' obligation to ensure that the information in the dossiers is clear, consistent and up-to-date. Further information e.g. from Annex XV SVHC dossiers and from SVHC public consultation has been considered, where appropriate (see Section 4 of the prioritisation approach). Downstream user reports, PPORD and SiA notifications were used in addition when relevant.

5.New information and next steps towards the final recommendation

Relevant new information provided during the public consultation on the draft recommendation and in the registration dossiers[3], including any request for exemption, is taken into account (i) by the MSC when preparing its opinion on the draft recommendation (ii) by ECHA when finalising its recommendation. ECHA also takes into account the MSC opinion when finalising its recommendation. The recommendation, together with MSC opinion, all comments received, and the responses to the comments, will be submitted to the European Commission who makes the final decision on which substances to include in Annex XIV and on the details for the respective entries. All non-confidential information is also made available on ECHA's website.

New information provided during the public consultation on ECHA's Recommendation is also considered for inclusion in the background documents, if relevant, and according to its confidentiality status.

A.1.2. Prioritisation: Volume

[2] http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf
[3] As of 1st December 2014 (end of public consultation)

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1.Volume in the scope of authorisation

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. The estimation of volumes is based on data from the registration dossiers as provided in section 3.2 and 3.5 of the IUCLID dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during public consultation on SVHC identification of the substances. Where available, information on uses falling under the scope of the generic exemptions from authorisation[4] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

It is stressed, however, that the assessment of whether a use is in the scope of authorisation is done only for prioritisation purpose and it does not conclude or define the status of a use under the REACH Regulation (which is the responsibility of individual companies and subject to enforcement). In general, in the prioritisation phase of the authorisation process a conservative approach is taken in cases where a clear conclusion on the intermediate status of the use or whether other exemptions apply is not possible on the basis of available data. The definition of intermediates as set out in Article 3(15) of the REACH Regulation, further elaborated/described in Appendix 4 of the 'Guidance on intermediates[5]' and 'Practical guide on intermediates[6]' was used to assess on the basis of available use descriptions (in the registrations incl. CSRs, the Annex XV SVHC reports and information received in SVHC public consultation) whether the identified uses are in the scope of authorisation.

A.1.3. Prioritisation: Wide-dispersiveness of uses

1.Scope of the assessment of wide-dispersiveness of uses

The wide-dispersiveness is assessed for the substance taking into account all uses within the scope of authorisation i.e. not only whether one use could be regarded as wide-dispersive.

The assessment of wide dispersiveness of uses (WDU) comprises a general evaluation of the substance's use pattern, relying on basic indicators specified in the general prioritisation approach document – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. It does not comprise an assessment of information such as detailed operational conditions, recommended/implemented RMM, exposure/risk assessment reported in CSR, or site-specific measurement data. Such assessment is beyond the scope of this step of the authorisation process.

More information can be found in Section 5.3 of the general prioritisation approach document[7] and Annex 2 of the prioritisation results document[2]. Some of the main points are also summarised below.

[4] A list of uses exempted from the authorisation requirement available at: http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
[5] http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf
[6] http://echa.europa.eu/documents/10162/13655/pg16_intermediate_registration_en.pdf
[7] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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2.Assignment of WDU score based on use types and their associated volumes

In the current prioritisation approach the wide-dispersiveness of uses is assessed based primarily on the types of actors which are relevant for the use of a substance. The underlying assumption is that, when moving from consumer to professional to industrial uses, the expected control of releases increases (i.e. "dispersiveness" decreases) and the expected wide-spreadness (i.e. number/distribution of sites) decreases; thus the wide dispersiveness of uses decreases.

The full scores of higher WDU categories (professional and consumer uses) were assigned as long as the respective uses represented absolute volumes > 10 t/y[8]. This is as consumer and professional uses can be regarded as having wide-dispersive pattern, regardless of how high the amount used at industrial sites is. In other words, the allocation of scores is based on the actual tonnage in different type of uses and not the share/percentage of the tonnage in different uses.

If there was reliable information indicating that the volume used by professionals or consumers was below 10 t/y, the WDU score was refined in a way that only half way up to the highest score category (professional or consumer) was assigned.

Furthermore, consumer uses for substances classified as Carc./Repr./Mut. 1A/B were not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[9] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage above the relevant concentration limit was considered in those cases where this information is available in the registration dossiers or in other sufficiently reliable sources.

3.Refinement of WDU score based on article service-life

Although uses of articles containing a substance in the Authorisation List will not require authorisation, article service-life is still relevant in priority considerations; this is because in the authorisation-application phase the risks and benefits related to any article service-life subsequent to uses applied for need to be considered too. Use of articles is usually widespread, with the exception of articles only intended for specific uses in industrial sites. The current prioritisation approach explains how article service-life is taken into account in the assessment of priority.

Where registration data or other relevant information demonstrated that the substance ends up in articles, the initial WDU score (based on the use type) was refined upwards unless there was sufficiently reliable information that releases are unlikely during article service-life and waste phases.

It is stressed that no thorough assessment of exposure is done in this recommendation step of the authorisation process (see A.1.5.3). This applies also for the article service-life and waste phases of articles.

[8] or unknown volumes, or $\geq$ 1t/y if the total volume in the scope of authorisation was < 10t/y

[9] Entries 28 to 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction

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A.1.4. Prioritisation: Further relevant considerations beyond Art.58(3) criteria

1.Relevant further considerations	The final conclusion on priority is drawn based on the assessment of the Article 58(3) criteria and consideration of additional aspects relevant for the recommendation. These additional aspects are i) grouping of substances to take together SVHCs which could potentially replace prioritised/previously recommended SVHCs in some of their uses and ii) parallel on-going regulatory risk management activities to avoid undesired interference between different regulatory actions.

A.1.5. Aspects not considered in ECHA's prioritisation

1.Potential other regulatory actions	In the process of recommending a Candidate List substance for inclusion in Annex XIV ECHA is not in the position to assess the pertinence of alternative regulatory risk management options to authorisation for the substance or some of its particular uses. Any suggestion to address the concern raised by the substance via e.g. restriction of certain uses; or better enforcement of existing legislation for protection of workers; or the need to generate further information via substance evaluation prior to taking a decision on including the substance in Annex XIV are beyond the remit of ECHA in the recommendation process. The same applies for views that there is no need to initiate any further regulatory risk management action at this time. Considerations on the most appropriate risk management options are usually discussed among authorities prior to proposing substances for inclusion to the Candidate List[10].
2. Aim & proportionality of authorisation system - Authorisation is not a ban	The authorisation process aims at enhancing substitution when technically and economically viable alternatives are available. Until this is achieved the aim is to ensure proper control of risks. Substances included on the Candidate list have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse)

[10] The Public Activities Coordination Tool (PACT) lists the substances for which a Risk Management Option Analysis (RMOA) is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013. Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

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impacts of ceasing it [11], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

Authorisation does not ban the use of the substance. The use of substances included in Annex XIV can continue after their sunset date, provided a use-specific and applicant-specific authorisation is applied for and granted. It should be shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are adequately controlled or that there are no alternatives available and the socio-economic benefits outweigh the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives.

3.Use specific scrutiny foreseen at application stage

The authorisation process foresees that the level of control of risks, the availability of and the time needed to transfer to suitable alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) and socio-economic considerations such as the magnitude of benefits from continuing a certain use of an SVHC (i.e. adverse impacts of ceasing a use) are not considered in the recommendation phase but are addressed at the application phase of the authorisation. That is because it is this phase where the respective assessment can be done in an effective manner: based on structured input of information by the applicant, the foreseen dedicated public consultation for scrutinising the information on alternatives and the involvement of Committees having the respective expertise and mandate. Information on these aspects will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

4.Control of risks

ECHA considers that an assessment of the level of control or the level of exposure is not appropriate during the recommendation phase since it would shift the burden of proof back to authorities. Should a substance be included in the authorisation list, such an assessment of exposure will be carried out by applicants for the uses they apply for as part of their authorisation application. The Risk Assessment Committee will assess the appropriateness and effectiveness of the risk management measures as described in the application. There is also a possibility to specify in the authorisation decision further conditions, including monitoring requirements. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and downstream user obligations.

5.Availability of

While for some uses in the short term there may not to be suitable alternatives, the authorisation title of REACH gives

[11] These are impacts associated with the "non-use scenario" (e.g. the use of unsuitable alternatives), such as any acute/chronic effects, climate change impacts, cost of new equipment or production process, social security, employment etc.

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suitable alternatives

a long term incentive to find them and deploy them when these alternatives are technically and economically feasible while enabling continued use where that is justified. Information on (lack of) availability of alternatives as well as on relevant research and development efforts are taken into account in the application and authorisation decision making phase.

6.Socio-economic benefits of continued use

Information about societal and economic benefits associated with a use is important in the application and authorisation decision making phase. In case risks are not demonstrated to be adequately controlled by an applicant or the authorisation can only be granted via the socio-economic route, the Socio-economic Analysis Committee compares the impacts to human health and/or the environment arising from the use of the substance with the benefits of the continued use. This is done when developing an opinion whether to grant an authorisation.

7.Burden for industry and potential competitive disadvantage

Although subjecting the substance to authorisation may have an impact on individual companies in their capacity as manufacturers, importers, suppliers and/or users of the substance, these companies are generally not disadvantaged by this measure as it has the same impact on all other suppliers/users of the substance in the EU market, e.g. no matter whether a supplier is located outside or inside the EU. To the extent the substance may be present in imported articles, ECHA shall investigate after the sunset date if this poses a risk which is not adequately controlled. In that case it shall propose a restriction on these articles as per Article 69(2) of the REACH Regulation.

It is acknowledged that for certain production processes higher costs in comparison with competitors outside the EU may still be the case, if companies need an authorisation. These include for instance use of a substance as process chemical in the production of articles where the substance (or residues) does not end up in the article; or use in formulation of mixtures having concentrations below the limit relevant for authorisation. In these cases the use of the product is outside the scope of authorisation, still its production in the EU would require authorisation. The cost increase in these cases will apparently depend on the application fee and, in particular, on the costs of preparing the application.

It should also be kept in mind that the overall impact of the authorisation requirement depends on the share of the application cost for the substance in the total production cost. In many cases the share of raw materials (in comparison to capital and labour costs) is relatively low. Where this is the case, the overall cost increase would be relatively low and the effect on the competitiveness of the respective industry in the EU would be relatively low, too.

Regarding to the direct costs of the authorisation application process, it is however noted that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. In accordance with Art. 62(1)(2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. It is

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further possible to submit joint applications by a group of actors.

Furthermore, ECHA has taken steps to help ensure that the application process is predictable and proportionate by giving information and guidance on its website (http://echa.europa.eu/web/guest/applying-for-authorisation). This is to support the applicants to focus their applications and thus reduce the application costs.

ECHA also informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too. Market certainty among potential applicants is thus increased.

The overall aim is to facilitate a proportionate and efficient application process so that the exposure to humans and the environment relating to the use of substances of very high concern is minimised while maintaining the competitiveness of the EU industry.

A.2 Further responses relevant for the substances/substance group

Reference code	Issue raised in the comment(s)	Response
A.2.1	Ask ECHA to reconsider the priority scoring for orange lead / Lower WDU score proposed because the substance is mainly used at industrial sites and exposure during article service life is claimed to be negligible	ECHA considered all comments received during the public consultation and all new information provided in registrations as of 1 December 2014 to assess whether the priority scores (volume and uses) needed to be revised. Background information on the prioritisation exercise is provided in the following sections of this document: **A.1.1. General, recommendation process:** 3. Prioritisation approach applied 4. Information taken into consideration for the draft recommendation **A.1.2 Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** 2. Assignment of WDU score based on use types and their associated volumes 3. Refinement of WDU score based on article service-life

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		Uses considered by ECHA as potentially to fulfil the intermediate definition are not considered for the priority scoring (Volume and WDU scores). An analysis of the uses claimed as being intermediate has been carried out and the outcome can be found in the following responses to comments: - **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.2.11 Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate** - **A.2.12 Claim the use in the manufacture of technical ceramic materials as intermediate** **With regards the WDU:** ECHA does not agree with the comment proposing to lower the WDU score from 12 to 5. According to the registration data and information provided by the industry in this public consultation, in addition to the uses of orange lead at industrial sites (e.g. use in the production of batteries, rubber and explosives), the substance is also used by workers in professional settings in anti-corrosive paints in volumes above 10 t/y (approx. 100 t/y according to the industry). Therefore, in accordance with the generic prioritisation approach agreed by the MSC and applied by ECHA, initial WDU score of 10 is justified. Based on the registration data, article service-life seems to be relevant for the use of the substance in paints and there is no reliable information indicating that the release would be negligible. Also use in rubber articles may be relevant for the article service-life. It is considered that non-negligible release may not be excluded for these articles as the integrity and stability of the rubber matrix is difficult to guarantee over time (e.g. in comparison to glass or ceramics). In conclusion, the initial WDU score is refined with 2 additional points due to article service-life in accordance with the generic prioritisation approach. **With regards the volume:**

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		The amount of orange lead manufactured and/or imported into the EU is according to registration data in the range of 10,000-100,000 t/y. Considering the volume for the uses appearing not to be in the scope of authorisation, such as potential intermediate uses in the manufacture of certain pigments, technical ceramics, glass and frits and some uses as laboratory reagent, the volume in the scope of authorisation is estimated to be in the range of 10,000 – 100,000 t/y. This justifies the volume score of 15. **Total priority score:** In conclusion, the priority scores of orange lead are not changed, and therefore the total score remains at (1)+(15)+(12)= 28
A.2.2	Ask ECHA to reconsider the priority scoring for lead monoxide / Lower WDU score proposed because of the professional use limited to the use as laboratory reagent under strictly controlled conditions and because exposure during article service life is claimed to be negligible	ECHA considered all comments received during the public consultation and all new information provided in registrations as of 1 December 2014 to assess whether the priority scores (volume and uses) needed to be revised. Background information on the prioritisation exercise is provided in the following sections of this document: **A.1.1. General, recommendation process:** 3. Prioritisation approach applied 4. Information taken into consideration for the draft recommendation **A.1.2 Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** 2. Assignment of WDU score based on use types and their associated volumes 3. Refinement of WDU score based on article service-life Uses considered by ECHA as potentially to fulfil the intermediate definition are not considered for the priority scoring (Volume and WDU scores). An analysis of the uses claimed as being intermediate has been carried out and can be found in the following responses to comments: - **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**

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		and lead crystal glass) as intermediate - **A.2.10 Claim the use in the manufacture of frits as intermediate** - **A.2.11 Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate** - **A.2.12 Claim the use in the manufacture of technical ceramic materials as intermediate** - **A.2.14 Claim the use of lead monoxide in the manufacture of lead styphnate further used in explosives as intermediate** - **A.2.13 Claim the use of lead monoxide in the manufacture of stabilisers for PVC processing as intermediate** **With regards the WDU:** Taking into account all information available and the uncertainties related to some uses ECHA has revised the WDU score assigned to lead monoxide. The substance receives now a WDU score of 7. The final WDU score of lead monoxide principally results from confirmed IND use (e.g. use in the production of batteries and rubber, use in adsorbent and catalyst), which justifies an initial score of 5, and from the use of the substance in rubber articles. It is considered that non-negligible release may not be excluded for these articles as the integrity and stability of the rubber matrix is difficult to guarantee over time (e.g. in comparison to glass or ceramics). This justifies an additional score of 2. Other elements (described below) were also considered when assigning the score. According to comments received the only relevant professional use of lead monoxide is its use as laboratory reagent which is not in high volume and is typically under controlled conditions. Professional uses as laboratory reagent and in chemical analysis are indeed reported in registrations and the information provided indicates that the conditions for the generic exemption from the authorisation requirement for the uses in Scientific Research and Development may not always be met (based on the tonnage for that use). ECHA has decided however not to assign a full PROF score for that use even if the total tonnage is > 10t/y as it appears that the use may rather

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		fulfil the description of an IND use. The use appears to be limited to industrial facilities and does not seem to be widespread. It is acknowledged that the differentiation between IND and PROF actors is not always straightforward and in some cases consists of a weight of evidence assessment. The updated guidance R12 on use description to be published end 2015/beginning 2016 aims to bring more clarity on this topic. We note that the lead registrant and most of the member registrants have recently updated their registrations. They have, inter alia, removed professional and consumer uses of lead monoxide in paints and pigments from their registrations and they have clarified that the use of lead monoxide as adsorbent is industrial rather than professional. However, there are some members who have not yet updated their registrations, and the professional and consumer uses in paints (and professional use of adsorbents) remain in their dossiers. Other members have updated their dossiers and kept these uses. However these members refer to the lead registrant's CSR which no longer supports these uses. In conclusion, some uncertainties remain regarding the consumer and professional uses. These uncertainties, however, do not appear to justify a higher WDU score than that resulting from the refinement due to the article service life as only one refinement - the one leading to the highest score - is applied. The WDU score assigned intends to reflect in a proportionate way the wide-dispersiveness of the uses and the uncertainties associated to the information available. **With regards the volume:** The amount of lead monoxide manufactured and/or imported into the EU is according to registration data confirmed by information provided by the industry of ~ 500,000 – 540,000 t/y. Considering the volume for the uses appearing not to be in the scope of authorisation, such as potential intermediate uses in the manufacture of PVC stabilisers, certain pigments, explosives, technical ceramics, glass and frits as well as some uses as laboratory reagent and in chemical analysis, the volume in the scope of authorisation is estimated to be in the range of 100,000 - >1,000,000 t/y. This justifies the volume score of 15. **Total priority score:** In conclusion, the revised total score for lead monoxide is (1)+(15)+(7)= 23

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A.2.3	Ask ECHA to reconsider the priority scoring for pentalead tetraoxide sulphate / Lower WDU score proposed due to claimed negligible exposure during article service life	ECHA considered all comments received during the public consultation and all new information provided in registrations as of 1 December 2014 to assess whether the priority scores (Volume and uses) needed to be revised. Background information on the prioritisation exercise is provided in the following sections of this document: **A.1.1. General, recommendation process:** 3. Prioritisation approach applied 4. Information taken into consideration for the draft recommendation **A.1.2 Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** 2. Assignment of WDU score based on use types and their associated volumes 3. Refinement of WDU score based on article service-life Uses falling outside the scope of authorisation are not considered for the priority scoring (Volume and WDU scores). An analysis of the use claimed as being intermediate has therefore been carried out. The outcome can be found in the following response to comments: - **A.2.8 Claim the use in the production of batteries as intermediate** **With regards the WDU:** The WDU score of pentalead tetraoxide sulphate results from confirmed IND use (e.g. use in the production of batteries, use in stabilisers and in PVC processing), which justifies an initial score of 5, and from the use of the substance in articles such as plastic articles. It is considered that non-negligible release may not be excluded for this articles as the integrity and stability of the plastic matrix is difficult to guarantee over time (e.g. in comparison to glass or ceramics). This justifies an additional score of 2. **With regards the volume:** The amount of pentalead tetraoxide sulphate manufactured and/or imported into the EU is according to registration data in the range of 10,000-100,000 t/y. All tonnage appears to be in the scope of authorisation which justifies the score 15. It is noted here that the volume range would not change even if the use in stabilisers (industry has a voluntary commitment to phase out the use in the EU by the end of 2015) is not taken into

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		account. **Total priority score:** In conclusion, the priority scores of pentalead tetraoxide sulphate are not changed, and therefore the total score remains at (1)+(15)+(7)= 23 Please also refer to response **A.2.18.Ask ECHA to consider the fact that the use of lead-stabilisers in PVC is currently being phased-out**.
A.2.4	Ask ECHA to reconsider the priority scoring for tetralead trioxide sulphate / Lower WDU score proposed due to claimed negligible exposure during article service life	ECHA considered all comments received during the public consultation and all new information provided in registrations as of 1 December 2014 to assess whether the priority scores (Volume and uses) needed to be revised. Background information on the prioritisation exercise is provided in the following sections of this document: **A.1.1. General, recommendation process:** 3. Prioritisation approach applied 4. Information taken into consideration for the draft recommendation **A.1.2 Prioritisation: Volume** **A.1.3. Prioritisation: Wide-dispersiveness of uses** 2. Assignment of WDU score based on use types and their associated volumes 3. Refinement of WDU score based on article service-life Uses falling outside the scope of authorisation are not considered for the priority scoring (Volume and WDU scores). An analysis of the use claimed as being intermediate has therefore been carried out. the outcome can be found in the following response to comments: - **A.2.8 Claim the use in the production of batteries as intermediate** **With regards the WDU:** The WDU score of tetralead trioxide sulphate results from confirmed IND use (e.g. use in the production of batteries, use in stabilisers, PVC processing, use in coatings and inks for mirror backing, use as an industrial reactant), which justifies an initial score of 5, and from the use of the

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		substance in articles such as plastic articles. It is considered that non-negligible release may not be excluded for this articles as the integrity and stability of the plastic matrix is difficult to guarantee over time (e.g. in comparison to glass or ceramics). This justifies an additional score of 2. **With regards the volume:** The amount of tetralead trioxide sulphate manufactured and/or imported into the EU is according to registration data in the range of 1,000,000-10,000,000 t/y. All tonnage appears to be in the scope of authorisation which justifies the score 15. It is noted here that the volume range would not changed even if the use in stabilisers (industry has a voluntary commitment to phase out the use in the EU by the end of 2015) is not taken into account. **Total priority score:** In conclusion, the priority scores of tetralead trioxide sulphate are not changed, and therefore the total score remains at (1)+(15)+(7)= 23 Please also refer to response **A.2.18.Ask ECHA to consider the fact that the use of lead-stabilisers in PVC is currently being phased-out**.
A.2.5	Grouping of silicic acid lead salt	In the priority setting, the substance was grouped with lead monoxide and orange lead as based on the registration information they are all used in the production of glass. Based on further analysis of the information provided in the registrations and in this public consultation on the use of these substances in glass production (refer to response **A.2.9 Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate**), it seems that these uses might fulfil the intermediate definition under REACH and fall outside the scope of authorisation. Therefore, there appears to be no reason to group silicic acid lead salt with lead monoxide and orange lead.
A.2.6	Disagree/Agree with the grouping of pyrochlore antimony lead yellow	Grouping can generally be applied for substances on the Candidate List for which the available information gives an indication that they could potentially replace other substances prioritised or already included in Annex XIV, for (some of) their uses.

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	with orange lead.	Based on registration information, both orange lead and pyrochlore antimony lead yellow can be used as pigments. It is in practice impossible and not necessary to provide positive evidence for the compatibility of the substances in all their particular uses as this would require knowledge about all the concrete processes and possible alternative processes, which appears impossible to achieve and not necessary at this stage of the authorisation process. In order to challenge the grouping concept in case of pyrochlore antimony lead yellow, it is therefore deemed more appropriate that industry would document that it is technically not possible to replace the substance in any of its uses by another substance of the group. Complementary, it would as well be necessary to demonstrate that the substance in question cannot replace any other substance of the group in any of its uses. According to registration information and information submitted by industry in this public consultation, pyrochlore, antimony lead yellow is only used as a pigment in the production of ceramic articles whereas orange lead is used as a pigment in anticorrosive paints. Based on the available information, the inter-substitution of these substances seems unlikely due to differences in their physico-chemical properties. Therefore, there may not be sufficiently strong reasons to group these substances.
A.2.7	Disagree/Agree with grouping of acetic acid lead salt with orange lead	Grouping can generally be applied for substances on the Candidate List for which the available information gives an indication that they could potentially replace other substances prioritised or already included in Annex XIV, for (some of) their uses. Based on registration information, both orange lead and acetic acid lead salt, basic can be used in paints. It is in practice impossible and not necessary to provide positive evidence for the compatibility of the substances in all their particular uses as this would require knowledge about all the concrete processes and possible alternative processes, which appears impossible to achieve and not necessary at this stage of the authorisation process. In order to challenge the grouping concept in case of acetic acid lead salt basic, it is therefore

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		deemed more appropriate that industry would document that it is technically not possible to replace the substance in any of its uses by another substance of the group. Complementary, it would as well be necessary to demonstrate that the substance in question cannot replace any other substance of the group in any of its uses. Based on the information provided in this public consultation, it seems that the function of acetic acid lead salt basic in paints is different from that of orange lead. In addition, there are differences in the water solubilities of these substances. Therefore, inter-substitution of acetic acid lead salt and orange lead in paints seems rather unlikely, and hence there appears to be no sufficiently strong reason to group these substances.
A.2.8	Claim the use in the production of batteries as intermediate (*Lead monoxide* *Pentalead tetraoxide sulphate* *Tetralead trioxide sulphate* *Orange lead*)	ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) (http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf) which has been agreed by the relevant EU Authorities. See especially Appendix 4 of this guidance. According to the guidance, as soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH. Based on the information available in the registrations and provided in the public consultation, lead monoxide, orange lead, pentalead tetraoxide sulphate and tetralead trioxide sulphate are used in the production process of batteries, where they undergo chemical reactions. The transformations are an integrated part of the process to produce an article. Consequently, it appears that these substances are used to achieve another function than the manufacturing of other substances, and therefore they may not fulfil the intermediate definition set out in Article 3(15) of the REACH Regulation. It is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates. It remains the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.

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A.2.9	Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) as intermediate *(Lead monoxide* *Orange lead* *Silicic acid lead salt)*	Based on new information provided during the public consultation the use of silicic acid lead salt, lead monoxide and orange lead in the production of lead glass (including lead special glass and lead crystal glass) may fulfil the definition of intermediate according to Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. It is recognized that the intermediate/non-intermediate status of these uses is a complex issue, and stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15). It is the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.10	Claim the use in the manufacture of frits as intermediate *(Lead monoxide* *Orange lead)*	Based on new information provided during the public consultation, the use of lead monoxide and orange lead in the production of frits may fulfil the definition of intermediate according to Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. It is recognized however that the intermediate/non-intermediate status of these uses is a complex issue, it is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates. It remains the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.11	Claim the use in the manufacture of pyrochlore antimony lead yellow as intermediate *(Lead monoxide* *Orange lead)*	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of lead monoxide and orange lead in the manufacture of certain pigments (e.g. pyrochlore antimony lead yellow). Based on the information available, it seemed that these uses could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No new information has been provided during the public consultation that contradicts this assessment. However it is stressed that this prioritisation exercise is not taking a formal position whether

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		certain uses of substances are regarded as uses as intermediates. It remains the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.12	Claim the use in the manufacture of technical ceramic materials as intermediate *(Lead monoxide* *Orange lead)*	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of lead monoxide and orange lead in the production of technical ceramic materials (PZT, PTC, PLZT). Based on the information available, it seemed that these uses could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No new information has been provided during the public consultation that contradicts this assessment. It is stressed however that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15). It is the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.13	Claim the use of lead monoxide in the manufacture of stabilisers for PVC processing as intermediate	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of lead monoxide in the manufacture of stabilisers for PVC processing. Based on the information available, it seemed that this use could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No new information has been provided during the public consultation that contradicts this assessment. It is stressed however that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15).

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		It is the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.14	Claim the use of lead monoxide in the manufacture of lead styphnate further used in explosives as intermediate	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of lead monoxide in the synthesis of lead styphnate. Based on the information available, it seemed that this use could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. This was reflected in the draft background document and was already considered when deciding on the priority of the substance. No new information has been provided during the public consultation that contradicts this assessment. It is stressed however that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15). It is the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
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	When considering the impacts of the inclusion of a Candidate List substance in the Authorisation list, companies need to pay specific attention to the substance identity. The current public consultation, and possible future authorisation requirements relate to the entries of lead monoxide (EC 215-267-0, CAS 1317-36-8) and orange lead (lead tetroxide) (EC 215-235-6, CAS 1314-41-6) from the Candidate List. Importers/users of other substances resulting from the use of lead monoxide or orange lead as intermediate will not have to apply for authorisation unless these substances would be themselves listed in the authorisation list. Furthermore, the use as intermediate is generally exempted from the authorisation requirement. Therefore, if lead monoxide or orange lead are used as intermediate in the manufacture of another substance no authorisation requirement is needed for that use either.

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		Please also refer to the following sections in the responses to comments document: - **C.1.2 Generic exemptions** - **A.1.5 Aspects not considered in ECHA's prioritisation**: 2. Aim & proportionality of authorisation system - Authorisation is not a ban.
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 *(Orange lead* *Lead monoxide* *Pentalead tetraoxide sulphate* *Tetralead trioxide sulphate* *Pyrochlore antimony lead yellow* *Silicic acid lead salt* *Acetic acid lead salt)*	At this step of the process ECHA's task is to assess the priority of the substances based on the approach discussed with and agreed by the MSC. The prioritisation of the substances included in the recommendation results from the application of the criteria agreed. For further background information on the recommendation phase of the authorisation process and on ECHA's role in it, please refer to: **A.1.1** – **General, recommendation process:** 1. ECHA's obligation to recommend/prioritise substances on the Candidate List 2. Legal basis for prioritisation 3. Prioritisation approach applied Also refer to **A.1.5 Aspects not considered in ECHA's prioritisation**(especially subsection 1. Potential other regulatory actions). Consideration on the fact that these substances are already highly regulated in various EU legislation acts are not taken into account in the priority setting but are addressed in the context of Art. 58 (2) exemption requests. Please also refer to the following section for an analysis of the proportionality of the authorisation requirement: **A.1.5 Aspects not considered in ECHA's prioritisation**, especially subsection 2 (Aim & proportionality of authorisation system - Authorisation is not a ban). This section also explains how socio-economic benefits of continuing a use (e.g. in line with existing policies promoting the use of renewable energy or addressing material recycling) is taken into consideration in the authorisation process.

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		On the workload aspect: According to Article 58(3) and Recital (77) of REACH, the number of substances included in each recommendation needs to reflect the capacity of ECHA and the Commission to handle applications in the time provided for and also consider the workability and practicality for applicants preparing their applications for authorisation. Workload considerations are indeed taken into consideration by ECHA when finalising its 6th recommendation: some substances listed in the draft recommendation will not be included in the final recommendation. However it is noted that the justification for not including these substances in the current recommendation is not based on regulatory effectiveness consideration. It is based on a rough estimation of the workload foreseen at the application for authorisation stage using factors like the number of registrations, number of uses and information on volumes per use, and considering the relative priority of the (group of) substances among all those in the draft recommendation. The lowest priority substances among those which cause workload will be left out and will be reconsidered in future prioritisation rounds.
A.2.17	RMOA conducted by one MS concluded that no further regulatory actions is needed (before 2015) *(Pentalead tetraoxide sulphate* *Tetralead trioxide sulphate)*	It needs to be clarified that a Risk Management Option Analysis (RMOA) is an informal step to inform and to promote discussion on possible regulatory actions between the Member State Competent Authorities (MSCA) and the European Commission/ECHA before formal processes, such as identification as SVHC, are initiated. The RMOA is meant to assesss whether risk management activities are required for a substance and to identify the most appropriate instrument to address any concern. However, it should be noted that an RMOA is not legally required and that it reflects the view of the Authority preparing it. Other Authorities might come to different conclusions and can act accordingly, e.g. initiate different regulatory actions. ECHA has a task to recommend substances from the Candidate List for inclusion in Annex XIV to the European Commission. ECHA assesses the priority of the Candidate List substances using the same approach for all substances to increase predictability of the process. Further information on the recommendation process and how it is implemented in practice can be found in the following section of the response to comments document: **A.1.1. General, recommendation process.** As mentioned in the updated prioritisation approach, other potential risk management options and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. ECHA is not in the position to assess the pertinence of alternative

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		regulatory risk management options for the substance or for some of its particular uses at this step. The final conclusion on priority is drawn based on the assessment of the Article 58(3) criteria and on consideration of additional aspects relevant for the recommendation (mainly grouping and parallel on-going regulatory risk management activities). Please also refer to the response: - **A.2.18 Ask ECHA to consider the fact that the use of lead-stabilisers in PVC is currently being phased-out**
A.2.18	Ask ECHA to consider the fact that the use of lead-stabilisers in PVC is currently being phased-out *(Pentalead tetraoxide sulphate* *Tetralead trioxide sulphate)*	ECHA recognises the efforts done by the stabiliser sectors in order to phase out the use of lead substances and emphasises the fact that the current proposal to include the substance in Annex XIV does not contradict these efforts. Indeed the authorisation requirement aims at enhancing substitution when technically and economically viable alternatives are available. Ultimately the impact of the inclusion of pentalead tetraoxide sulphate and tetralead trioxide sulphate on Annex XIV on the stabiliser sector will depend on the phase-out timeline and on the sunset date set by the Commission for the use of these substances. Comments received indicate that the use of lead-based stabilisers has been constantly declining in recent years and is progressing towards the target of completing their substitution by the end of 2015. - If the substitution of the substances included in the Annex XIV happens before the foreseen sunset date, i.e. the date from which the placing on the market and the use of the substance is prohibited unless an authorisation is granted, no application for authorisation of the current use of the substance would be required. - In case more time would be needed to transfer to these alternatives, justification for this can be brought in an application for authorisation and will be taken into account by the SEAC Committee when forming its opinion and by the Commission when taking the final decision. Please also refer to the response **B.2.1. Foreseen timelines for the 6th Recommendation** .

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A.2.19	Predictability of including substances in Annex XIV *(Orange lead* *Lead monoxide* *Tetralead trioxide sulphate)*	The authorisation procedure aims to progressively replace all substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible, thereby reducing the overall risk arising from the use in question. In cases where substitution is considered, we suggest to comparatively assess, in addition to technical and economic feasibility aspects, also the overall risks to human health and the environment exerted by the substance / technology currently used with any potential alternative substance or technology. ECHA considers the predictability of including substances in Annex XIV as important to allow companies to consider the best business strategy to address substances of potential concern and to ensure that registration data is up to date. Predictability of the prioritisation of substances to Annex XIV also helps all interested parties to get prepared for public consultation during any subsequent regulatory processes. To increase predictability and transparency of the prioritisation of substances to Annex XIV ECHA has made available the prioritisation approach which it uses to regularly assess the substances from the Candidate List to decide which ones should be included in the Authorisation List as a priority. Substances not prioritised for inclusion are reassessed in the following prioritisation rounds. ECHA encourages interested parties to use the prioritisation results published on ECHA's website (http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf) to get information on the relative priority of the Candidate List substances and a view on which substances are likely to be of highest priority in future recommendation rounds. It should be noted, however, that the relative priority of substances can change due to changes in the uses and/or volumes registered or due to new high priority substances included in the Candidate List. Early information on substances that are scrutinised by authorities and may be included in the Candidate List (and eventually in Annex XIV) in future if the properties of substances and/or need for further regulatory action are confirmed can be found on the ECHA website http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern and in the Public Activities Coordination Tool (PACT) (http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact). The SVHC Roadmap to 2020 gives an EU-wide commitment for having all relevant currently known SVHCs included in the Candidate List by 2020. A Member State or ECHA (at the request of the Commission) can carry out a Risk Management Option Analysis (RMOA) in order to conclude whether a substance is a 'relevant SVHC' in the sense of the SVHC Roadmap to 2020. PACT lists the substances for which an RMOA is

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		either under development or has been completed. Finally, ECHA's webpages provide information about intentions for proposing the inclusion of substances in the Candidate List (Registry of Intentions – SVHC; http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions), as well as for submitted proposals (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification).
A.2.20	Inclusion of acetic acid, lead salt, basic in Annex XIV may impact the continued availability of the substance in EU	According to Article 55, the aim of the authorisation process is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Substances of very high concern included in Annex XIV may normally be granted an authorisation if the applicant can show adequate control of risks (where applicable in accordance with Art. 60(3) of REACH) arising from the applied for uses or if there is no suitable alternative to the substance available and the socio-economic benefits of a use outweigh the associated risks for health and environment. In general it is not possible to predict the precise reactions of different players to the inclusion of a substance in Annex XIV on the market supply. However, for a downstream user who wishes to continue a use but is concerned about supply in the EU (e.g. concerned that the suppliers in EU will cease manufacture/import), there is also the possibility to consider importing the substance.
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	We understand that in the case your supplier in the EU ceases manufacture/import of the substance you will need to ensure that any new supplier chosen will comply with the requirements for the manufacture of the medicinal product concerned; for instance regarding the grade of the substance and potentially also Good Manufacturing Practices. Commission Regulation (EC) No 1234/2008 specifies the regulatory process for a re-approval of an authorised medicinal product when registering a new supplier of a substance used in its manufacture. Depending on the specific case, re-approval may require either a simple notification or a re-application. Based on the generic information on the process, the review, by the relevant authorities, of a notification or re-application can take up to a few months, which is a short period compared to the period between the inclusion of a substance in Annex XIV and the sunset date (3

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		years at minimum). Should you be unable to identify a supplier complying with the required criteria, before initiating the re-approval process you will need, apparently, to assess the implications e.g. that the new supplier's substance impurity profile has on the safety and quality of the manufactured medicinal product. This could take some time. Therefore, in the event your substance will be recommended by ECHA for inclusion in Annex XIV, you may consider to get in contact with your current and - if needed - other suppliers, to plan the necessary actions and regulatory procedures sufficiently ahead in time. See also response **A.2.20 Inclusion of acetic acid, lead salt, basic in Annex XIV may impact the continued availability of the substance in EU**.
A.2.22	Reconsider inclusion in Annex XIV because of the impact on the recycling of PVC materials *(Pentalead tetraoxide sulphate* *Tetralead trioxide sulphate)*	Some information regarding the applicability of the authorisation requirement for recycling/recycled materials is given below. There are certain aspects which need to be taken into account when considering the use of recycled PVC material potentially containing lead stabilisers. One such aspect is whether the material is considered as waste, or not. In the first case, its use will not require authorisation. A recycled material has the end-of-waste (EoW) status foreseen in the Waste Framework Directive (WFD, 2008/98/EC) only if it meets the criteria set up at European Union level in accordance with Article 6(2) of that Directive or, in the absence of such criteria, each Member State is to decide on a case-by-case basis whether certain waste has ceased to be waste taking into account the applicable case-law (Article 6(4) of the WFD). As harmonised EoW criteria have currently not been established at EU level for plastic wastes, we recommend that you consult your competent authority and/or the Commission to investigate whether companies can decide by themselves when a material has ceased to be waste.

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		Companies *directly* recycling waste into a new article (i.e. without a life-cycle stage involving the use of a recycled material being a non-waste mixture) do not need an authorisation. However, such companies must fulfil requirements set by the waste legislation. A further relevant aspect to consider is whether lead substances in recycled PVC are considered to be constituents/additives or impurities. Provided that their concentration is below 20% and that they do not provide some intended function in the material (i.e. meaning that the recycled PVC could be used in the same way even if lead substances had not been incorporated in the first place), they may be considered to be impurities in mixtures of recycled PVC. In this case, again, no authorisation would be required despite the presence of the lead substances in the matrix. In case the material used is not considered waste and the lead substances are not considered to be impurities, the need or not for authorisation will indeed depend on the content of the lead substance(s) as listed in the Authorisation List. We agree that it may be difficult to know which, if any, of the lead substances used in the production of PVC articles - and at which exact concentration – are contained in recycled PVC materials. Chemical analysis of the lead content of batches of recycled material or a qualitative assessment of their origin may be some of the options in assessing whether the use requires authorisation. If it can be assumed that concentrations of individual lead stabilisers are potentially above the concentration limit relevant for the authorisation requirement for mixtures (i.e. ≥0.3%), then it could be concluded that authorisation is required. In any case, ECHA suggests documenting the procedures followed during such assessment in case of enforcement of REACH requirements by national authorities. Please note that the Commission and ECHA are currently trying to further clarify and address the issue of recycled materials in the REACH Regulation (including the authorisation process). In case of new relevant information on this topic, ECHA's Q&A web-page will be updated accordingly: http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/authorisation
A.2.23	ECHA should not proceed with the 6th recommendation, when the 5th is still open *(Orange lead*	According to Art. 59 (3), ECHA has an obligation to recommend to the Commission priority substances to be included in Annex XIV. The decision to include substances in Annex XIV is taken by the Commission. It is for the Commission to decide when and how it proceeds with ECHA's recommendations for inclusion of substances in Annex XIV.

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	Lead monoxide)	
A.2.24	Raising the need to use a certain substance in past model parts and/or in low volumes *(Lead monoxide* *Orange lead* *Tetralead trioxide sulphate* *Pentalead tetraoxide sulphate)*	Please note that for the cases of operators who need to continue using an Annex XIV substance in low volumes or for the production of legacy spare parts, the Commission has been considering establishing a streamlined and simplified authorisation process. A public consultation on the Commission's proposal for these cases ran between February and April 2015 (see http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081&lang=en&title=REACH-Authorisation---Consultation-on-applications-for-low-volumes-and-on-extension-of-transitional-arrangements-for-uses-in-legacy-spare-parts-).
A.2.25	Concerns and uncertainties with respect to the authorisation process	There has been a significant effort to implement the application for authorisation process in and transparent manner, and to provide suitable support to companies to comply with their duties. ECHA's committees have so far adopted more than 60 opinions on applications for authorisation and the European Commission has granted the first authorisations to applicants. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue. ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, and approaches agreed by the committees describing how applications are treated and evaluated. The Risk Assessment Committee has been providing, on a pilot basis, DNELs and dose-response relationships for almost all substances so far. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. The Committee for Socio-Economic Analysis has published an explanatory note providing clarifications on how it evaluates economic feasibility as part of applications for authorisation. Furthermore, the committees have jointly agreed on the principles of the recommended length of the review period,

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		which should increase predictability. ECHA has also been updating formats and IT-tools to provide more clarity and to streamline the process further. Further clarifications to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. ECHA also regularly organises seminars and workshops to improve the understanding of the application process and share experiences. Beyond this, ECHA's authorisation teams maintain personal contact and interaction with the applicants through all stages of the application process. The current experience and availability of all this information shows that even if the authorisation process is to some extent still perceived as "new" it is nevertheless a carefully thought through process that has been working well for some time already. The level of support available and provided to involved companies (not only by ECHA, but also by many of its stakeholders) has been substantial and broadly acknowledged. ECHA will continue to develop its practices to provide fit-for-purpose support and increase predictability of the application for authorisation process even further.

B. Timelines

B.1 Process information

B.1.1. General principles for setting latest application dates / sunset dates

1.Legal background

Article 58(3) and Recital (77) of REACH provide that the latest application and sunset dates set for the substances included in Annex XIV shall take account of the Agency's capacity to handle applications in the time provided for as well as the workability and practicality for applicants preparing their applications for authorisation. Furthermore, the legal text specifies that the latest application date must be at least 18 months before the sunset date (Article

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58(1)(c)(ii)) and the sunset date(s) for uses of a substance should where appropriate take into account the production cycles specified for those uses (Article 58(1)(c)(i)).

The document "General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV" describes how ECHA implements the above mentioned legal requirements in practice (available at: http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf).

2.ECHA's proposal for sunset dates

On the basis of the information available in the registration dossiers and submitted during public consultation on the recommendation, ECHA has not seen reasons or justification to deviate from the 18 months set out in the legal text or grounds to define criteria for such deviation(s) based on production cycles referred to in Article 58(1)(c)(i). Therefore, ECHA proposes a standard difference of 18 months between the application and sunset dates for all substances included in the 6th recommendation.

3.ECHA's proposal for latest application dates

ECHA made its proposals for the latest application dates (LAD) on the basis of the earlier estimation that the time needed to prepare an authorisation application of sufficient quality might in standard cases require 18 months (roughly 12 months work-time for drafting the application and an additional buffer of 6 months for getting organised and consulting required external expertise). Based on discussions and experience on received applications so far, the applicants have not generally indicated that they have had difficulties with the stipulated time periods. Rather there had been problems for the first applicants preparing applications to have clarity on what information, analysis and justification was required in the applications. As over 50 opinions have already been given by RAC and SEAC, future applicants are in a better position than the first ones to prepare a fit-for-purpose application.

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential applicants concerned by substances in this recommendation. Furthermore, the registration deadline for all substance in this recommendation[12] was in 2010. It should also be noted that the requirements on communication of information down and up the supply chain (Title IV of REACH) as well as the downstream user obligations (Title V of REACH) have applied for some years. Implementation of and compliance with these requirements should as well support the organisation of the work within the supply chains related to the preparation of authorisation applications.

Based on the above establishing first LADs earlier than 18 months after inclusion in Annex XIV could even be considered. However, providing sufficient time to the applicants to get organised within sectors and prepare an

[12] Note that some members of the group "4-Nonylphenol, branched and linear, ethoxylated" (4-NPnEO) are expected to fulfil the REACH definition of polymers and are therefore exempt from registration.

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application that provides a solid basis for the decision making is important. Therefore, it does not seem to be justified to propose shorter LADs.

On the other hand, ECHA further considered if the first LAD should be set later than 18 months after inclusion in Annex XIV. The complexity of the supply chain has been considered to be one, potentially the main, factor affecting how much time is needed in addition to the drafting of the different parts of an application. Structure and complexity of the supply chain has an impact on both the time needed to gather the information and on how to best organise the application (who will apply, which uses will be covered). Indeed, for substances with complex supply chains organisation, planning, and collection of information may require longer time than for short and simple supply chains, especially when applications will be made by actors high up in a complex supply chain. They may need to collect information from many layers of actors in the supply chain and these layers may not have clear contact points and co-ordinators. A longer time might also be needed in case many downstream users decide to make one joint application as this may require extensive communication with different actors to clarify who possesses the required information, who would actually apply and how to establish the knowledge and staff resources needed.

The complexity of the supply chain could potentially be assessed based on the number of different uses, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[13]. However, ECHA has currently no sufficient information to define clearly enough the factors which it should take into account for this assessment nor is ECHA currently able to define precisely what type of information would be used to characterise the above-mentioned factors. Therefore, it is concluded that ECHA currently does not have enough information to justify a prolongation of the first LAD. Better insight into the matter might be available once the applications relating to the third recommendation will have been submitted.

In sum, ECHA considers that a standard LAD of 18 months for the preparation of a well-documented application for authorisation is still valid.

The anticipated workload of ECHA's Committees and Secretariat to process authorisation applications is accounted for by grouping the proposed substances in slots, normally 3 but more slots can be considered on a case-by-case basis, and setting the application dates with 3 months intervals in between the slots. From the applicant's point of view it would be beneficial to have these dates to coincide with (the last days of) the "submission windows" for submitting the applications.

[13] E.g. existence of consortia and their experience, size and location; knowledge about if applications will be made mainly upstream and cover downstream uses, or if rather many downstream applications will be made.

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The time differences between the LADs set out in a recommendation are relatively short, typically ranging from 3 to 6 months, compared to the total time reserved for the potential applicants to prepare their applications. ECHA proposes to allocate those substances to the "later" LAD slots for which the available information indicates a relatively high number of uses. Furthermore, substances with no registration requirement are allocated to the later slots.

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 orga–nised for preparing application (e.g. due to high number of users)

Based on ECHA's approach, substances with more complex supply chains and likely higher number of uses will normally be allocated to the "later" latest application date slots (i.e. 21 or more months after the inclusion in Annex XIV).

Communication, organisation and agreement between the relevant actors in the supply chains and efficient allocation of work are important aspects to get the application(s) ready in time. The standard period of 18 months considered by ECHA as the shortest application date already includes a time of about 6 months for getting organised and consulting external expertise. Therefore, the "later" LAD slots can be regarded as sufficiently long deadlines for complex-supply-chain cases.

2.Lack of alternatives, socio-economic aspects

It is stressed that the present lack of alternatives to (some of) the uses of a substance, the time needed to transfer to alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) as well as other socio-economic or practical considerations are not viable reasons for prolonging the latest application dates or sunset dates.

Should ECHA know that there would not be technically and economically feasible alternative substances or techniques, this could be taken into account. If such evidence existed, the analysis of alternatives would be a straight forward exercise, and so would also the socio-economic analysis which would imply a relatively short LAD. However, ECHA does not normally have such information when preparing the recommendation as this becomes available only at the application stage. Thus, ECHA does not intend to use this as a criterion to shorten the LADs.

Socio-economic or practical considerations are not relevant reasons for prolonging or advancing the latest application dates or sunset dates as these considerations are normally use and sector or even case specific and difficult to take into account in the recommendation phase which considers all uses of the substance.

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Furthermore, such information would be very difficult to get at the prioritisation stage in a systematic manner. Therefore they are considered at the next phase of the authorisation process.

Authorisation, inter alia, aims to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

If a suitable alternative to a substance included in Annex XIV will be available before the foreseen sunset date, i.e. the date from which the placing on the market and the use of the substance is prohibited unless an authorisation is granted (Art. 58 (c) (i) of REACH), no application for authorisation of the current use of the substance would be required.

B.1.3. Review periods

1.Upfront review periods

Setting 'upfront' review periods for any uses requires that the Agency has access to adequate information on different aspects relevant for a decision on the review period. ECHA currently assessed that the information available is not sufficient to conclude on upfront specific review periods. Therefore, ECHA did not propose such review periods in the draft recommendation. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case specific information provided in the applications for authorisation. ECHA has published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[14].

[14] RAC's and SEAC's approach for establishing the length of the review period:
http://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf

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B.2 Further responses relevant for the substances/substance group

Reference code	Issue raised in the comment(s)	Response
B.2.1.	Foreseen timelines for the 6th recommendation	As regards the next steps of the authorisation procedure, ECHA intends to send its final 6th recommendation to the Commission in July 2015. The decision to include substances in the Authorisation list will be taken by the Commission. At this point in time, it would be rather speculative to provide timelines for the next update of the Authorisation list. It is however reasonable to assume that at least one year will be needed between the 6th Recommendation is finalised by ECHA and the update of the Official Journal with substances from the 6th recommendation takes place. ECHA normally recommends the latest application dates to be set at least 18 months after the inclusion of the substances in the Authorisation List and the sunset dates to be set 18 months after the latest application dates.

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C. Exemptions

C.1 Process information

C.1.1. General principles for exemptions under Art. 58(2)

Uses (or categories of uses) can be exempted from the authorisation requirement on the basis of Article 58(2) of REACH. Furthermore certain uses fall under the generic exemptions from authorisation[15].

According to Article 58(2) of REACH it is possible 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 decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH. It should however be recalled that the discretion to grant an exemption provided for in Article 58(2) of the REACH Regulation is an exception to the rule that the placing on the market and the use of substances of very high concern should be subject to authorisation, one of the purposes of which is to ensure they are phased out where economically and technically feasible (Article 55 of REACH).

In preparing its recommendation and when assessing proposals for exemptions from the authorisation requirement in accordance with Article 58(2) that are submitted during the public consultation on the draft recommendation ECHA considers the following elements (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[16]):

- There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) 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 definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be considered.
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV. Generally,

[15] http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
[16] Available at: http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf

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the legislation in question should cover the substance to be included in Annex XIV and address the concern related to its intrinsic properties. This can be the case e.g., where the legislation specifically refers to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to (e.g. by referring to the classification criteria or the Annex XIII criteria).

- The existing EU legislation imposes minimum requirements for the control of risks of the use. 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. This can include EU legislation that allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only the aim of imposing measures (e.g., EU legislation which provides Member States the possibility to impose less stringent requirements than that suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

On the basis of the elements above:

(i) Only existing EU legislation is relevant in the context to be assessed (not national legislation).
(ii) Minimum requirements for controlling risks to human health or/and the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question.
(iii) There need to be binding and enforceable minimum requirements in place for the substance(s) used.

C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf. The scope of some of these generic exemptions is further clarified in ECHA's Q&A found at http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/1027-1028-1029-1030-1031. It should be noted that if a use falls under the generic exemptions from authorisation, there is no need to propose an additional specific exemption.

It is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. Further information on such requirements can be found in the legislation listed at the above link, as well as in Article 3(23) REACH regarding scientific research and development, and in the ECHA Guidance on intermediates (http://www.echa.europa.eu/documents/10162/17224/intermediates_en.pdf)

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C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[15]. Furthermore, uses can be exempted from the authorisation requirement on the basis of Art 58(2) which depends on the provisions of existing EU legislation. While information such as a low level of risk or low tonnage associated to a use, voluntary measures implemented by industry, availability and suitability of alternatives, socioeconomic benefits associated with continuing a use, is important, it cannot be used as basis for an Art. 58(2) exemption. Information regarding these topics needs to be provided as part of the application for authorisation in case the substance is included in Annex XIV. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

C.2. Further responses relevant for the substances/substance group

C.2.1. Response to requests for exemptions under Art. 58(2)

Requests for Article 58(2) exemptions for various uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate, tetralead trioxide sulphate and acetic acid, lead salt, basic have been received by ECHA (table 1). Many of these requests refer to the extensive body of legislation relevant to lead and its compounds. While lead and its compounds are of concern both for human health and the environment, lead compounds have been included in the Candidate List due to their toxicity to reproduction and concern for human health and consequently they can only be included in Annex XIV due to this property. However, to cover potential risks of these substances arising from toxicity to reproduction, risks not only for workers dealing directly with these substances but also for man via the environment need to be considered. Therefore, in assessing Art 58(2) exemption requests for the use of a substance it is important to assess whether existing EU legislation imposes minimum requirements to properly control risks to human health via all relevant exposure routes and at all life-cycle stages of a particular use.

The lead substances are not included in the final 6th recommendation. The assessment of the Art. 58(2) requests for these substances will be made when ECHA includes them to its recommendation in the future.

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Table 1. Uses of lead compounds for which an Article 58(2) exemption request has been received.

Substance	**Use**
lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate	Batteries
Lead monoxide and lead tetroxide	Manufacture of pyrochlore antimony lead yellow
Lead monoxide and lead tetroxide	Technical / Piezo-ceramics
Lead monoxide and lead tetroxide	Frits
Lead monoxide and lead tetroxide	Glass (including special glass and crystal glass)
Lead monoxide	Glass frits (semiconductor industry)
Lead monoxide and lead tetroxide	Rubber
Lead monoxide	Electroplating
Lead monoxide and lead tetroxide	Airlines e.g. lead oxide is used in dry film lubricant products (and in batteries)
Lead monoxide	Processing aid for analysis of precious metal content of secondary and complex materials
Lead monoxide	Propellants in rocket motors
Lead tetroxide	Explosives and detonators
Pentalead tetraoxide sulphate and tetralead trioxide sulphate	PVC stabiliser
Tetralead trioxide sulphate	Production of microporous plastic separators for lead-based batteries
Acetic acid, lead salt, basic	Purifier in the manufacture of an active pharmaceutical ingredient used in medicinal products

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C.2.2. Exemption request for lead monoxide based on proportionality principle with other uses listed as outside the scope of authorisation in the background document

For the purpose of the prioritisation, ECHA did an assessment on whether the uses of lead monoxide seem to be in the scope of authorisation. Based on the available information, ECHA considered that some uses of lead monoxide, e.g. potential use as an intermediate in manufacturing of PVC stabilisers, certain pigments, explosives and technical ceramics, and the use as laboratory reagent and in chemical analysis, may be covered by the generic exemptions from authorisation for intermediates and use in SRD and therefore may fall outside the scope of authorisation. This has been reflected in the background document and was considered when deciding on the priority of the substance.

It is stressed however that this prioritisation exercise is not taking a formal position on whether certain uses of substances fall outside the scope of authorisation.

It is the responsibility of companies to assess whether any of their uses is covered by the generic exemptions from the authorisation requirement. See section C.1.2. of this document for more information.

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