10 November 2016

Response document

Substance group: Lead compounds

Substance names and EC-numbers:

Substance name	EC number
Lead monoxide (lead oxide)	215-267-0
Orange lead (lead tetroxide)	215-235-6
Tetralead trioxide sulphate	235-380-9
Pentalead tetraoxide sulphate	235-067-7

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 above in Annex XIV of the REACH regulation (list of substances subject to authorisation). The public consultation was held in the context of ECHA's draft 7th Annex XIV recommendation and took place between 18 November 2015 and 18 February 2016.

Orange lead (lead tetroxide), lead monoxide (lead oxide), tetralead trioxide sulphate and pentalead tetraoxide sulphate were also included in the 6th draft recommendation and underwent a three months public consultation in 2014. All comments and responses to comments related to the 6th draft recommendation are available on ECHA's 'Submitted recommendations' web page: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations (See 'Comments and response to comments' in the 'Substance Details' information).

[1] The compilation of comments received, along with references to responses, can be found at the following link(s):
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_pentalead_tetraoxide_sulphate_en.rtf
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_tetralead_trioxide_sulphate_en.rtf
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_orange_lead_en.rtf
https://echa.europa.eu/documents/10162/13640/7th_recom_comref_lead_monoxide_en.rtf

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

The present document compiles only the responses to the comments submitted in the public consultation on the 7th draft recommendation, <u>except</u> for the responses to exemption requests under Art. 58(2) (reference C.2.1.) which cover both requests submitted in the public consultations on the 6th and the 7th draft recommendation.

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 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. Dates**
  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. **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 the substances included in the draft 7th 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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

The section headings in the process information and captions on the left of the substance/group-specific 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 the referencing to responses in the "Comments and references to responses document" and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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

As part of the authorisation process set out in Title VII of the REACH Regulation, ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of REACH).

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 in one recommendation remain on the Candidate List and will be reassessed for priority in later recommendations together with the newly included substances in the Candidate List.

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. The workability of the authorisation process necessitates a gradual inclusion of substances in Annex XIV.

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 three criteria 'normally' into account, but there is no provision how this should be done in practice. Moreover, the 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 applied is provided below.

3.Prioritisation approach applied

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

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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 prioritisation is a comparative exercise supporting the conclusion on which substances to recommend first, i.e. the priority scores need to be considered in relation to each other and should not be seen in isolation.

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 the "General approach for prioritisation of SVHCs: practical implementation examples"[3].

4.Information taken into consideration for the draft recommendation

For the purpose of its draft priority setting ECHA considers all relevant information available to it. The registration dossiers (including the CSRs) are 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 is considered, where appropriate (see Section 4 of the prioritisation approach (linked in A.1.1.3)). Downstream user reports, PPORD and SiA notifications are 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 (checked after closure of the public consultation), including any request for exemption, is taken into account (i) by the MSC when preparing its opinion on the draft recommendation and (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, are 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.

[2] https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_nov_2015_en.pdf
[3] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

New information provided during the public consultation on ECHA's recommendation is also used when finalising the substance specific background documents, if relevant, and according to its confidentiality status.

A.1.2. Prioritisation: Volume

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. That volume is derived 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 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 purposes 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, a realistic worst case 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 and described in Appendix 4 of the 'Guidance on intermediates'[5] and in the 'Practical guide on intermediates'[6], is 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 considered intermediate uses.

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 or not 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 (see A.1.1.3) – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of

[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

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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 in "General approach for prioritisation of SVHCs: practical implementation examples"[8]. Some of the main points are summarised below.

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

In the 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, in general, when moving from consumer uses to professional uses 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) are assigned as long as the respective uses represented absolute volumes ≥ 10 t/y[9]. 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 types of uses and not the share of the tonnage in different uses.

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

Furthermore, consumer uses for substances classified as Carc./Muta./Repr. 1A/B are not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[10] 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 is considered in those cases where this information is available in the registration dossiers or in other sufficiently reliable sources.

3.Refinement of WDU score

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. The use of articles

[7] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[8] http://echa.europa.eu/documents/10162/13640/recom_general_prio_approach_implementation_examples_en.pdf
[9] or unknown volumes, or ≥ 1t/y if the total volume in the scope of authorisation was < 10t/y
[10] Entries 28 to 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

based on article service-life

is usually widespread, with the exception of articles only intended for specific uses in industrial sites. The prioritisation approach explains how article service-life is taken into account in the assessment of priority.

Where registration data or other relevant information demonstrates that the substance ends up in articles, the initial WDU score (based on the use type) is refined upwards unless there is 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.

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 could be e.g. the grouping of substances (to take together SVHCs which could potentially replace prioritised or previously recommended SVHCs in some of their uses). There could be further considerations relevant for the prioritisation. It should also be noted that ECHA always aims to consider such additional aspects in a holistic way for the case at hand.

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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Considerations on the most appropriate risk management options are usually discussed among authorities prior to proposing substances for inclusion in the Candidate List[11].

2. Authorisation is disproportionate and/or means 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) impacts of ceasing it[12], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as a 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 (and duty) to search for and develop suitable alternatives.

3.Use specific considerations

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 process. 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 Committees for Risk Assessment and Socio-Economic Analysis (RAC and SEAC) when forming their opinions and by the Commission when

[11] 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

[12] 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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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 (RAC) 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 suitable alternatives While for some uses in the short term there may not to be suitable alternatives, the authorisation title of REACH gives a long term incentive to find 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 is 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 (SEAC) 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 arise, if companies need an authorisation. These include for instance, the 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 the formulation of mixtures having concentrations below the limit relevant for authorisation. Even though the use of the mixture is outside the scope of authorisation, still its formulation/production in the EU would require authorisation. The cost

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

increase in these cases will apparently depend on the application fee and, in particular, on the costs of preparing the application.

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. In such cases 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.

Not every actor on the market has to apply for authorisation of his use(s). This is because he can benefit from the authorisation granted to an actor up its supply chain[13]. It is further possible to submit joint applications by a group of actors.

Moreover, Commission, MSCAs, industry and ECHA have further developed / are further developing approaches and advice on how to prepare streamlined and fit-for-purpose applications. ECHA has already taken steps to help ensuring that the application process is predictable and proportionate, e.g. by giving information and guidance on its website (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa). This is to support the applicants to focus their applications and thus reduce the application costs.

The overall aim is to facilitate a streamlined 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)	Draft response
A.2.1	**Claim the use in the manufacture of technical ceramic**	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

[13] 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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

	materials as intermediate *(Lead monoxide, orange lead)*	accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (December 2010). This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No information has been provided during the public consultation that changes 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.2.2	**Claim the use in the manufacture of frits as intermediate** *(Lead monoxide, orange lead)*	Based on information provided during the public consultation on the 6th draft recommendation, 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 (December 2010). No information has been provided during the public consultation on the 7th draft recommendation that changes this assessment. 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.2.3.	**Claim the use in the manufacture of complex inorganic pigments (CIPs) 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 pigments, in particular pyrochlore, antimony lead yellow. 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 (December 2010). This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No information has been provided during the public consultation that changes this assessment.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		However 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.2.4.	**Intermediate status of the use of lead monoxide in catalyst applications**	ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (December 2010). 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 provided in the public consultation, it seems that • Lead monoxide used as precursor in the manufacturing of PbS contained in catalysts could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. • Lead monoxide used as such in catalysts does not seem to be used with the main intention to manufacture another substance. The substance seems to be used to perform another function than the manufacturing of another substance. Therefore, use of PbO in the production of PbO containing catalysts may not fulfil the intermediate definition set out in Article 3(15) of the REACH Regulation. 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.2.5.	**Claim the use of lead monoxide in the manufacture of stabilisers for PVC**	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 (December 2010).

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

	processing as intermediate	This was reflected in the draft background documents and was considered when deciding on the priority of the substance. No information has been provided during the public consultation that changes 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).
A.2.6.	**Claim the use of lead monoxide in the manufacture of 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 which is further used in explosives and for which information was available. Based on this information, 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 (December 2010). This was reflected in the draft background document and was already considered when deciding on the priority of the substance. No information has been provided during the public consultation that changes 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.2.7.	**Claim the use in the manufacture of lead glass (including lead special glass and lead crystal glass) 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 lead glass (including lead special glass and lead crystal glass). Based on the information available, it seemed that this use may 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 (December 2010). This was reflected in the draft background document and was considered when deciding on the priority of the substance. No information has been provided during the public consultation that changes this assessment.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		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.2.8.	**Certain uses of lead monoxide and orange lead confirmed as intermediate uses in workshop attended by ECHA's staff in 2015**	ECHA is highly committed to openness and transparency. Regular discussions and participation in seminars and workshops are part of ECHA's mission to actively involve stakeholders as well as supporting them in performing their duties under REACH. Expert workshops give opportunities for industry to provide further information on their substances and/or processes, and for ECHA to explain how such information could be assessed in the regulatory work, thereby allowing for a constructive dialogue. However, such exchange or, as in this case, the attendance of workshops by ECHA staff, cannot be seen as providing a formal ECHA-position, e.g. the confirmation by ECHA of the intermediate status of a use. It remains the responsibility of companies to assess whether their specific use fulfils the intermediate definition.
A.2.9	**Volume overestimated /Ask ECHA to consider that the use of lead-stabilisers in PVC is phased out** *(Pentalead tetraoxide sulphate, tetralead trioxide sulphate)*	The tonnage range indicated in the draft Background Documents took account of all uses reported and all registrations, including the volume per use in PVC stabilisers as still reported in registrations. For the purpose of its draft priority setting ECHA carefully considered all information available to it. The registration dossiers (checked as of 1 June 2015) have been the main source of information. Further information e.g. from the SVHC public consultation and from the public consultation on the draft 6th recommendation has been considered, where appropriate. The plasticiser sector has committed to replace the use of lead stabilisers in PVC by end of 2015. Confirmation is expected in registration dossiers. It is the registrant's obligation to ensure that information in the dossiers is up-to-date. To finalise its recommendation ECHA has considered all new information provided in registration updates after closure of the public consultation and in the public consultation. Based on information available, the tonnage band indicated in the draft background documents does not need to be revised.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		It is to be noted that whether to consider or not the volume for use as stabiliser doesn't change the volume score assigned in the priority assessment.
A.2.10	**WDU score should be lower / Ask ECHA to consider that the use of lead-stabilisers is phased out** *(Pentalead tetraoxide sulphate, tetralead trioxide sulphate)*	The WDU scores of pentalead tetraoxide sulphate and tetralead trioxide sulphate result from confirmed IND use (e.g. use in the production of batteries, use in stabilisers and in PVC processing; for the latter substance also production and application of coatings and inks for mirror backing and use as an industrial reactant), which justifies an initial score of 5, and from the use of the substances in articles such as plastic articles. It is considered that non-negligible release may not be excluded for these articles during their service life and waste phase 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. We note that the assessment of the type of releases during the article service-life is not a thorough assessment as that wouldn't be proportionate neither to the aim of the prioritisation stage in the authorisation process nor to the contribution to the prioritisation score itself. The stabiliser sector has committed to replace the use of lead stabilisers in PVC by end of 2015 and ECHA recognises the efforts done by the sector. Would the substances indeed not be used anymore in articles, a WDU score of 5 would be justified. The priority scores of pentalead tetraoxide sulphate and tetralead trioxide sulphate would have to be revised to 21. (IP:1)+(V:15)+(WDU:5) It is noted that a score of 21 does not change the overall priority of these substances for inclusion in Annex XIV. The phase out of the use in stabilisers needs to be reflected in registration dossiers. It is the registrant's obligation to ensure that information in the dossiers is up-to-date.
A.2.11.	**Ask ECHA to assess/ question the regulatory effectiveness of inclusion of lead substances in AXIV and stresses the high**	Please refer to the responses given to your comment submitted during the public consultation on the 6th draft recommendation (Response A.2.16 in the document available at http://echa.europa.eu/documents/10162/8a3dd6bf-78e1-4097-935c-43021ebe5f1e). On the workload aspect, please note that in contrast to the 6th draft recommendation which you commented on last year (and you still see as valid), the 7th draft recommendation comprises a smaller

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

	workload for authorities related to these substances at AfA stage *(Lead monoxide, orange lead, tetralead trioxide sulphate, pentalead tetraoxide sulphate)*	number of substances for which the anticipated workload is not foreseen to exceed the capacity of ECHA or of the Commission. Please refer also to: **B.1.1 General principles for settings latest application dates / sunset dates**
A.2.12.	**Interrelation between the recommendation (and authorisation process) and the scheduled restriction on the use of lead in PVC** *(Lead monoxide, orange lead, tetralead trioxide sulphate, pentalead tetraoxide sulphate)*	ECHA at the request of the Commission will submit a restriction dossier on lead compounds used as stabilisers in PVC in December 2016 (http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/current-activites-on-restrictions). As indicated in the registry of intention, the scope of the restriction is specific in that it will cover the placing on the market and use of lead compounds to stabilise PVC, and of the placing on the market and use of PVC articles stabilised with lead compounds. Article 58(5) REACH states that after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions [....] covering the risks to human health or the environment from the use [...] arising from the intrinsic properties specified in Annex XIV. Article 58(6) states a substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s). Therefore, there is a clear need to ensure that the restriction and the inclusion of substances in Annex XIV are taken in a complementary manner. The stabiliser industry sector made a voluntary commitment to completely replace lead stabilisers in the production of primary PVC raw material by the end of 2015 across EU-28. This concerns two of the lead substances included in the 7th draft recommendation, namely tetralead trioxide sulphate and pentalead tetraoxide sulphate. From 2016 onwards, it can be expected that the lead stabilisers will not be used anymore in the EU in the production of PVC (which needs still to be reflected in updated registrations).

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		Even if the use as a stabiliser in PVC is indeed phased out, both of the lead oxide sulphates would remain of high priority for inclusion in Annex XIV, due to other use(s). The inclusion in Annex XIV is per substance and not per use. The prioritisation of the other two lead substances included in this draft recommendation (i.e. lead monoxide and orange lead) is not affected either by the intended restriction or by the voluntary phase out, as these two substances seem not to have been used as stabilisers for PVC. Considering the well-defined scope of the restriction, ECHA sees no reason to exclude the lead substances from the current Annex XIV recommendation based on their high priority. Both the decision on the Annex XIV inclusion and on the restriction is taken by the Commission. This enables the Commission to make sure that the next regulatory steps are taken in a complementary manner; the recommendation of the mentioned lead substances does not prevent or impede such complementary action.
A.2.13.	**Assuming that the restriction on lead in PVC is finalised authorisation will be a duplication** *(tetralead trioxide sulphate, pentalead tetraoxide sulphate)*	ECHA does not agree with the view that the Authorisation requirement could duplicate restriction. Indeed a restricted use cannot by definition continue any more in the EU and consequently there will not be a need or possibility for applying for authorisation for that use. Only the uses not covered by the restriction, or explicitly derogated from it, may be subject to authorisation. For those uses the authorisation requirement is a strong long term incentive to search for and develop alternatives. Please also refer to **A.2.14. Applicability of the authorisation requirement for recycling / recycled materials**
A.2.14.	**Applicability of the authorisation requirement for recycling / recycled materials** *(tetralead trioxide sulphate, pentalead tetraoxide 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 materials. 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

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		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). Harmonised EoW criteria have currently not been established at EU level for all types of waste. Where no harmonised criteria exist it is recommended to consult the competent authority and/or the Commission to investigate whether companies can decide by themselves when a material has ceased to be waste. 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 the substances in the recycled material 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 material could be used in the same way even if the substances had not been incorporated in the first place), they may be considered to be impurities in mixtures of recycled material. In this case, again, no authorisation would be required despite the presence of the substances in the matrix. 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.2.15.	**Questionnaire on socio-economic consequences** *(tetralead trioxide sulphate, pentalead tetraoxide sulphate)*	We note that you have submitted a filled-in questionnaire on "socio-economic consequences of including the substance in the Authorisation List" as part of your comment. This questionnaire relates to the call for information by the Commission, which is parallel but different from ECHA's public consultation on the recommendation. Therefore your questionnaire has been passed to the Commission. Further information on the "call for information by the Commission" can be found here: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/call-for-information-by-the-commission

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		An overview of the types of information relevant to submit as part of ECHA's public consultation is available here: (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/public-consultation-in-the-authorisation-process).

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

B. Dates

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 ECHA'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 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/recom_general_approach_draft_axiv_entries.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 draft 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 7th 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 60 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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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. 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 applications for authorisation.

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 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 and affected industry sectors, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[14]. However, ECHA has currently insufficient information to define clearly enough the factors which it should take into account for this assessment. Furthermore, ECHA is currently unable 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, i.e. the 18 months slot. Better insight into the matter might be available once the applications relating to the third recommendation will have been submitted and processed by ECHA and the Commission.

[14] 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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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, and setting the application dates with 3 months intervals in between the slots. From the applicant's point of view it is beneficial to have these dates to coincide with (the last days of) the "submission windows" for submitting the applications.

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 and/or complex supply chain(s). 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 the time for getting organised and consulting external expertise. The application for authorisation is the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List. It is also important to note that the application process is not anymore a "new" process but has been in place for some time now.
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.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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 no 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. 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 (application for authorisation and granting phase).

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 would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. So far such information was not available to ECHA at the recommendation step. Therefore, ECHA has not proposed any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. 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

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[15].

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

Reference code	Issue raised in the comment(s)	Draft response
B.2.1.	**ECHA needs to consider the opinion from the MSC on the 6th draft recommendation adopted on 11th June 2015 in favour of a 35 months' LAD and referring among other to the precedent created by chromate compounds** *(lead monoxide, orange lead)*	Please note that Art. 58(3) of REACH requires ECHA to propose LADs considering its capacity to handle applications in the time provided for. It seems to be a misunderstanding that ECHA does not take into account the time needed to prepare applications by the applicants when recommending LADs. As described in ECHA's general approach for preparing Annex XIV entries (http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf), the distribution of substances to LAD slots takes account of both the application processing needs (aiming at an even spread of processing time per slot) and the application preparation needs (longer LAD recommended when more time is needed to prepare applications, based on factors such as complexity of supply chain). We share the view that for supply chains involving a large number / several layers of DUs important elements such as collecting representative information require longer time. However it is important to note that the application process is not anymore "new" or "unknown". Industrial sectors have collected significant experience in previous years and the overall capacity and experience of consultants has been considerably grown in comparison with the earlier application rounds. ECHA has published adopted opinions for numerous applications and continues to publish material which clarifies the requirements and expectations of its Committees, e.g. opinion trees and checklists for

[15] 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) and RAC's and SEAC's guidance paper on opinion trees for non-threshold substances (http://echa.europa.eu/documents/10162/13637/opinion_trees_non_treshold_subs_en.pdf)

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

		evaluating Chemical Safety Assessments, Analyses of Alternatives and Socio-Economic Analyses. The application for authorisation can be considered as the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List. For the lead substances this is even more the case as they were already included in the 6th draft recommendation. Therefore, ECHA considers that a 24 months period (as proposed for the lead substances in the draft recommendation) should generally be sufficient to organise and prepare applications practically for any substance. There are further reasons for which ECHA generally considers that spreading the substances of any Annex XIV recommendation round over many slots is not desirable. A large spread between the LADs of the substances of a particular recommendation round could lead to a wide overlapping of LADs from different recommendation rounds and an overall less workable system. ECHA aims to have a continuous inflow of applications for authorisations which can be achieved by recommending transitional dates following the standard approach. We note your comment on the precedence of the LAD assigned to Cr^{6+} substances by the European Commission (35 months after the inclusion in A.XIV) and the respective opinion of the MSC for lead substances given on the 6th draft recommendation. The MSC opinion forms indeed an important part of the basis on which ECHA makes its recommendation. However, the final recommendation takes account of all information available to ECHA (such as Annex XV dossiers, comments submitted with the public consultation, etc.) and also makes use of ECHA's and the Committee's experience in the AfA process gained so far. In addition, we consider the MSC opinion that will be given on the 7th draft recommendation as most relevant for the current round.
B.2.2.	**Longer transition period requested for plastic converters and recyclers**	Please refer first to the following responses: **B.1.1. General principles for setting latest application dates / sunset dates** 2. *ECHA's proposal for sunset dates* 3. *ECHA's proposal for latest application dates*

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

	(tetralead trioxide sulphate, pentalead tetraoxide sulphate)	**B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates** In the draft background documents of tetralead trioxide sulphate and pentalead tetraoxide sulphate a latest application date (LAD) of **24** months is proposed. Lead substances have been assigned to the third LAD slot considering among other things that the time needed to prepare application for authorisation may be comparatively longer than for other substances included in this recommendation round. Please also refer to the following responses: **A.2.14. Applicability of the authorisation requirement for recycling / recycled materials** and **B.2.1. ECHA needs to consider the opinion from the MSC on the 6th draft recommendation adopted on 11th June 2015 in favour of a 35 months' LAD and referring among other to the precedent created by chromate compounds**
B.2.3.	**Raising the need to use certain substances in legacy products and request longer LAD**	Regarding the uses of Annex XIV substances in the production of legacy spare parts, you might be aware that the COM (supported by the Task Force on the workability of Applications for Authorisation) currently works on simplifying the AfA for this special case. The use of a substance in legacy spare parts as described above appears not to be a reason to prolong LADs.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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[16].

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, taking into consideration ECHA's recommendation. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH within the limits of EU law, including the proportionality principle. 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).

ECHA further recalls that it is apparent from the terms of Article 58(2) that:
(a) The obtaining of an exemption is a possibility and not an entitlement;
(b) The discretion afforded to the Commission only ever arises where there is specific minimum EU legislation in place imposing minimum requirements relating to the protection of human health or the environment for the use of the substance ensuring the risk is properly controlled; it should be noted that in the absence of existing specific EU legislation in force, the Commission is prohibited from granting an exemption on the basis of Article 58(2) in respect of the substance listed in Annex XIV of REACH; it is therefore not sufficient if there is national legislation governing such use or a Commission communication;
(c) Risk assessment and the question as to whether individual operators are able to control risks associated with the use of a substance of very high concern are not included among the criteria that may constitute a basis for the granting of exemptions of a use. In the absence of specific Union legislation the Commission has no discretion to grant an exemption under Article 58(2) of the REACH Regulation regardless of the outcome of risk assessment.

[16] http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[17] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[18]):

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH 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 assessed;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances. A mere reference to carcinogenic, mutagenic or reprotoxic substances may be too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or 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 and/or 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

[17] For further information, see the judgment of the General Court in Case T-360/13, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) vs European Commission*.
[18] Available at: http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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).

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[16]. 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 (See section C.1.1. General principles for exemptions under Art. 58(2)).

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 and tetralead trioxide sulphate have been received by ECHA (Table 1 below). Many of these requests refer to the extensive body of legislation relevant to lead and its compounds. ECHA provides an assessment of these requests taking into account the relevant EU legislation below. The

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

assessment considers all the legislation below individually and as a whole. 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. In this respect, to cover potential risks of these substances (as sources of the lead atom or lead ion) arising from toxicity to reproduction, risks not only for workers dealing directly with these substances but also for man via the environment/consumers 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.

Occupational health legislation

Summary: ECHA notes that, given the binding occupational exposure limit set out for inorganic lead and its compounds and given the binding biological limit value set out for lead and its ionic compounds under Directive 98/24/EC, minimum requirements relating to the protection of workers health appear to be imposed by EU legislation to properly control the risk for workers health arising from the use of the lead substances recommended for inclusion in Annex XIV which are a source of the lead or its ion. Therefore, for this particular life cycle stage and target population (workers), the requirements in relation to Art 58(2) REACH may be met. However, it should be noted that ECHA was not in a position to assess the adequacy of the limit values for lead and its compounds set down under Directive 98/24/EC for the protection of workers health, the factors on which these limit values where adopted, and whether they meet the conditions of Art 58(2) REACH.

Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work ('Framework Directive') aims at protecting the health and safety of workers at their workplace. This Framework Directive establishes basic rules on protecting the health and safety of workers with the objective of eliminating the risk factors for occupational diseases and accidents. It applies to all sectors of activity, both public and private, except where characteristics particular to certain specific public service activities, such as the armed forces, the police or certain civil protection service activities inevitably conflict with it. It lays down general principles concerning the prevention of risks and protection of workers against occupational accidents and diseases. On the basis of this Framework Directive a series of individual directives were adopted. The Framework Directive with its general principles continues to apply in full to all the areas covered by the individual directives, but where individual directives contain more stringent and/or specific provisions, these special provisions of individual directives prevail.

Council Directive 89/654/EEC concerning the minimum safety and health requirements for the workplace supplements the general provisions of Directive 89/391/EEC on matters of health and safety at work. It includes obligations on the employer to ensure good technical maintenance of the workplace, equipment and devices, and the regular maintenance and checks of safety equipment to prevent and eliminate hazards. Workers and/or their representatives are informed of all measures to be taken in order to protect their health and safety and they are consulted on all issues and measures connected with this area.

While Council Directives 89/391/EEC and 89/654/EEC set out minimum requirements in relation to health and safety at work they do not appear to specifically define the measures to be imposed by the employer, particularly in relation to whether more stringent measures

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

would be technically possible. Therefore, these Directives on their own do not seem to be a sufficient basis for exempting uses of lead compounds from authorisation in accordance with Article 58(2) REACH.

Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) sets out a framework based on the determination and assessment of risk and general principles for the prevention of risk, associated with hazardous chemical agents. CAD outlines a hierarchy of control and risk reduction measures (with substitution of a hazardous chemical agent by the employer at the top). In addition, CAD establishes a binding occupational exposure limit for inorganic lead and its compounds and a biological limit value and health surveillance measures for lead and its ionic compounds.

On this basis it is considered that CAD appears to impose minimum requirements for controlling risks to workers at the formulation/use life cycle stages of these substances.

In relation to Council Directive 92/85/EEC (Pregnant Workers Directive): the objective of this Directive is to protect the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding; thus, this aims to encourage improvements in health and safety at the workplace, and in this case, for a defined sensitive group, through the assessment of risks at the workplace. In case the results of this assessment reveal the existence of a risk to the safety or health of the female worker, provision must be made for the worker to be protected. In addition, pregnant workers and workers who are breastfeeding must not be engaged in activities which have been assessed as revealing a risk of exposure, jeopardizing safety and health, to certain particularly dangerous agents or working conditions; in this respect, the Directive also specifically refers to lead and lead derivatives insofar as these agents are capable of being absorbed by the human organism.

Whilst the Directive identifies substances with R phrases relevant for reprotoxic potential for particular attention in an assessment, the Directive leaves the determination of the measures to be imposed to the employer. On this basis Directive 92/85/EEC does not seem to impose binding minimum requirements for controlling risks to human health in accordance with Article 58(2) of the REACH Regulation, as previously highlighted. Therefore, this Directive on its own seems not to be a sufficient basis for exempting uses of lead compounds from authorisation.

Council Directive 94/33/EC on the protection of young people at work provides that the Member States shall take the necessary measures to prohibit the employment of children and shall ensure that the employment of adolescents is strictly controlled and they are protected under the conditions outlined in the Directive. This includes the requirement to take measures to prohibit the employment of young persons in work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. The provision(s) refer to hazard classification. The Directive, where implemented fully, should prevent exposure to reprotoxic substances for this specific and sensitive group. The Directive also specifically refers to lead and compounds thereof, inasmuch as the agents in question are absorbable by the human organism. The size of the population "at risk" which is addressed by this Directive is likely to be very low and therefore it would not properly control risks to workers health in general. Therefore in itself, the Directive 94/33/EC seems not to be a sufficient basis for exempting uses of lead compounds from authorisation in accordance with Article 58(2) of REACH.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

In relation to the Classification Labelling and Packaging (CLP) of Substances and Mixtures Regulation (EC) No 1272/2008, this Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through the classification and labelling of chemicals. According to Recital 10 CLP Regulation "the objective of this Regulation should be to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated." The Regulation does not however impose sufficient measures to properly control the risks of such substances. Therefore, this Regulation is not a sufficient basis for exempting the uses of lead compounds from authorisation in accordance with Article 58(2) REACH Regulation.

Product related legislation[19]

Summary: ECHA considers that, for the reasons set out below, the product-related legislation referred to in the Art 58(2) exemption requests received do not appear on their own to be a sufficient basis for exempting particular uses of lead substances from authorisation in accordance with Art 58(2) of the REACH Regulation. However, they contribute to the overall protection of consumers.

Explosives

The Civil Explosives Directive 2014/28/EU seeks to ensure safety of human life and health and to prevent damage to property and the environment under normal, foreseeable conditions. It sets essential requirements with which the explosives covered by the Directive are to comply. The process of setting detailed technical standards that establish a presumption of conformity with the essential requirements has been delegated to the European standardisation body, CEN. Manufacturers and importers wishing to place explosives for civil uses on the market must demonstrate that their products are in conformity with the essential requirements before they can affix the CE mark. The essential requirements listed in the Directive (Annex I) do not refer to specific substances or mixtures, but they require certain performance characteristics in order to ensure maximum safety and reliability. On the basis of the essential requirements nearly 60 European standards have been developed. In addition, (the Track and Trace) Directive 2008/43/EC (as amended by Directive 2012/4/EU) sets up a harmonised system for the unique identification and traceability of explosives for civil uses.

Neither the Civil Explosives Directive nor the Track and Trace Directive appear to provide for a procedure for the identification of substances contained in the products regulated. The substances regulated are those which manufacturers and importers of explosives for civil uses have identified as having the physico-chemical properties required for such products and do not address the human health-related intrinsic properties of these substances. For this reason the substances for which the essential requirements set out in the

[19] Some requests for Art. 58(2) exemptions refer to the exemption granted to the use of DEHP in the immediate packaging of medicinal products. ECHA notes that requests for Art. 58(2) exemptions must be assessed on a case-by-case basis in accordance with the criteria set forth under Article 58(2) as interpreted by the General Court. ECHA refers to the preamble of Commission Regulation No. 143/2011 (Recital 17) which provides the justification for granting an exemption for the use of DEHP in the immediate packaging of medicinal products.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

directives apply seem not to be specified in a way that would allow the use of these Directives as a reason for exemption of this use under Article 58(2) REACH.

Glass

Directive 69/493/EEC on crystal glass prescribes the use of lead in crystal glass. It is noted that entry 63 of Annex XVII to Regulation 1907/2206 prohibits the placing on the market or use of lead in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0.05% by weight. However, this restriction does not apply to crystal glass as defined in Directive 69/493/EEC. ECHA takes note of this exemption, however, it is not of itself a reason for exemption of lead substances for this use under Article 58(2) REACH.

Other product-related legislation

Food is considered a major source of exposure to lead for humans. The maximum levels of certain heavy metals (including lead) in foodstuffs have been set by Commission Regulation No. 1881/2006, the framework EU legislation which sets maximum levels for chemical contaminants in foodstuffs and therefore risk to man via the environment from this source appears to be controlled.

An extensive list of other product-related legislation has been included in an appendix to some submissions (e.g. legislation relating to cosmetics (Directive 76/768/EC), fuel quality (Directive 98/70/EC; Directive 2009/30/EC), toys (Directive 2009/48/EC), food contact materials (Directive 84/500/EC on ceramics; Directive 2005/31/EC; Regulation EC No. 1935/2004). While these pieces of legislation contribute to overall protection of consumers they do not appear on their own to be a sufficient basis for any of the uses listed in Table 1 to be exempted from authorisation under Art 58(2). However, they are taken account of generally in this holistic assessment.

Environmental legislation

Summary: In assessing the Art 58(2) requests ECHA has considered the environmental legislation mainly from the point of view of potential risk to man via the environment. ECHA considers that the EU environmental legislation referred to in the Art 58(2) exemption requests, when considered in conjunction with the OHS, food and product legislation, may contribute to control of the risk arising from particular uses of lead substances. It is noted that, for particular uses there is an EU legislative regime (i.e. RoHS/ELV) already in place to push for substitution in a similar manner to the authorisation requirement. However, ECHA notes that for the Water Framework Directive (WFD) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. In other words, this Directive expressly contemplates the use of REACH authorisation, rather than precludes it. Furthermore, the WFD does not set forth specific measures, such as emission limits, that provide a minimum standard enforceable throughout the EU. Therefore, considering these limitations and in order not to limit the Commission's possibility to take action, the WFD may not provide an appropriate basis for an exemption from the authorisation requirement.. If the REACH risk management processes are necessary to achieve the objectives of other legislation (e.g. that relating to drinking water, ambient air), then the same considerations

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

may apply as for the WFD. There is also a potential legislative gap in relation to soils. Therefore, taking into account the above points, it is unclear if the EU environmental legislation provides a sufficient basis for an Article 58(2) exemption.

In relation to Directive 2010/75/EU (IED), Annex II is an indicative list of the main polluting substances and includes large groups of substances (including metals and their compounds). The directive itself does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. (The only specific references to lead and its compounds are in Annex I where certain facilities engaged in processing of non-ferrous metals require a permit; and in Annex VI which sets air and wastewater emission limit values for lead and its compounds in waste incineration plants). Commission Implementing Decision (EU) 2016/1032 establishes best available techniques (BAT) conclusions under the IED on industrial emissions from non-ferrous metals industries and Decision 2012/134/EU establishes best available techniques (BAT) conclusions for the manufacture of glass. These Decisions set BAT-Average Emission Levels (AELs) for lead to water, air and, in the case of the non-ferrous metals industries, soil. However, it should be noted that the IED usually applies to larger scale activities (e.g. for glass it applies to activities where there is manufacturing of glass with a melting capacity exceeding 20 tonnes per day). It is further noted that pursuant to Article 62(5)(b)(i) REACH an applicant may justify in the authorisation application that emissions from an installation for which an IPPC permit has been granted do not need to be considered when deciding on an authorisation. This implies that a case specific consideration is needed to judge whether risks arising from IED installations are properly controlled.

In relation to the Water Framework Directive 2000/60/EC (WFD) (and its daughter Directives 2006/118/EC, 2008/105/EC and 2013/39/EU), these Directives set environmental quality standards for certain substances in the aquatic environment (including for lead and its compounds in surface waters, which are identified as priority substances), and a framework for control of emissions, discharges and losses of these substances into the aquatic environment. The WFD, *inter alia*, obliges Member States to protect, enhance and restore bodies of surface water with the aim of achieving good surface water status by 2015 (with certain derogations) and it also obliges Member States to implement the necessary measures with the aim of progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances (WFD Art 4).

However, the Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. (It can be noted that Article 61(5) of REACH envisages that the Commission may review authorisation applications if the environmental objectives as referred to in Article 4(1) of the WFD are not met.) This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. In addition, under Article 7a of Directive 2008/105/EC (as amended by Directive 2013/39/EU) it is foreseen that the REACH authorisation

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

and restriction processes may be initiated by the Commission to achieve the objectives of that legislation.[20] Therefore, in order not to limit the Commission's possibility to take such action and considering the limitations of the WFD (e.g., no specific emission limits), it may not provide an appropriate basis for an exemption from the authorisation requirement. In conclusion, when the WFD is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH, however this should be weighed up against the possibility that the REACH authorisation process could be used as a measure to achieve the objectives of the WFD.

Council Directive 98/83/EC on the quality of water intended for human consumption aims at protecting human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. It applies to all water intended for human consumption apart from natural mineral waters and waters which are medicinal products. It sets essential quality standards for a range of parameters including lead, which must be monitored and tested regularly. The Directive states that '*without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean*'. The Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. Furthermore, if the REACH risk management processes are necessary to achieve the objectives of this Directive, then the same considerations may apply as for the WFD. In conclusion, when the Directive is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH, however this should be weighed up against the possibility that the REACH authorisation process could be used as a measure to achieve the objectives of this Directive.

[20] See, in particular, Report from the Commission to the European Parliament and the Council on the outcome of the review of Annex X to Directive 2000/60/EC of the European Parliament and of the Council on priority substances in the field of water policy, COM (2011)0875, final, pages 5-6: "*Since then, the legislation to control the authorisation and placing on the market of chemicals has been substantially expanded and improved, in particular with the adoption of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[6] and of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market[7]. This and other existing EU legislation (e.g. biocides and veterinary medicines legislation) contains mechanisms suited to controlling the uses and emissions of most of the priority substances at EU level (e.g. evaluation, restriction, authorisation). These existing mechanisms should therefore be applied before others are developed and should in principle be sufficient to achieve the objectives of the WFD.*"
See also Directive 2013/39/EU, recital 12: "*The progressive reduction of pollution from priority substances and the cessation or phasing out of discharges, emissions and losses of priority hazardous substances, as required by Directive 2000/60/EC, may often be achieved most cost-effectively through Union substance-specific measures at source, for example pursuant to Regulations (EC) No 1907/2006….*"
and the Commission Staff Working Paper – Impact assessment accompanying the document "Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy SEC(2011) 1547 final

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Council Directive 2008/50/EC on ambient air quality and cleaner air for Europe ('Air Quality Directive') defines and establishes objectives for ambient air quality which are designed to avoid, prevent or reduce harmful effects on human health and the environment as a whole. It sets limit values for certain substances in ambient air including lead. Member States are required to ensure that, throughout their zones and agglomerations, levels of these substances in ambient air do not exceed the respective limit values. It also includes rules on the monitoring, assessment and management of ambient air quality. For example, where, in given zones or agglomerations, the levels of pollutants in ambient air exceed any limit value or target value, plus any relevant margin of tolerance in each case, Member States shall ensure that air quality plans are established for those zones and agglomerations in order to achieve the related limit value or target value. The Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. If the REACH risk management processes are necessary to achieve the objectives of this Directive, then the same considerations may apply as for the WFD. In conclusion, when the Directive is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH, however this should be weighed up against the possibility that the REACH authorisation process could be used as a measure to achieve the objectives of this Directive.

The Waste Framework Directive (2008/98/EC) aims at, inter alia, protecting the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste (including hazardous waste). Wastes classified as hazardous are considered to display one or more of the properties listed in Annex III of the Directive - which includes CMR properties. Wastes classified as hazardous feature on the list established by Commission Decision 2000/532/EC. Wastes from industrial activities containing lead are listed as hazardous waste and need to be treated accordingly. The Waste Framework Directive in general contributes to environmental protection at the waste life cycle stage. Waste including lead is specifically listed as hazardous waste and therefore there appears to be minimum requirements to control risk to man via the environment related to the waste stage of the use of these substances. Therefore, when the Directive is considered in conjunction with the other EU legislation applying to lead compounds, this Directive may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH.

Council Regulation 1013/2006 on shipments of waste ('Waste Shipment Regulation'), as amended by Regulation (EU) 660/2014, aims at strengthening, simplifying and specifying the procedures for controlling waste shipments to improve environmental protection. It also seeks to include into EU legislation the provisions of the Basel Convention (approved by Council Decisions 93/98/EEC and 97/640/EC) as well as the revision of the Decision on the control of transboundary movements of wastes destined for recovery operations, adopted by the OECD in 2001. The Regulation concerns almost all types of waste shipped (including waste containing lead and its compounds). Only radioactive waste and a few other types of waste do not fall within its application, insofar as they are subject to separate control regimes. The Waste Shipment Regulation in general contributes to environmental protection at the waste life cycle stage.

Both Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ('RoHS'), and Directive 2000/53/EC on end-of life vehicles ('ELV') set a maximum concentration value of 0,1 % by weight in homogeneous materials for certain substances including lead. These limits are in place mainly to prevent heavy metals such as lead entering the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

In relation to the 2011 RoHS Directive the use of lead in certain applications is exempted from restriction including the use of lead in the glass of cathode ray tubes; in certain electrical and electronic components containing lead in a glass or ceramic e.g. piezoelectronic devices; in white glasses used for optical applications; printing inks for the application of enamels on glasses; lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC; in certain medical devices and monitoring and control instruments.

In relation to the ELV Directive (and Commission Directive 2013/28/EU amending Annex II of the ELV Directive) certain materials and components are exempt from the above limits. This includes the use of lead and lead compounds in batteries (under review in 2015); as vulcanising agents and stabilisers for elastomers in brake hoses, fuel hoses, air ventilation hoses, elastomer/metal parts in the chassis applications, and engine mountings as spare parts for vehicles put on the market before 1 July 2005; certain electrical and electronic components which contain lead in a glass or ceramic, in a glass or ceramic matrix compound, in a glass-ceramic material, or in a glass-ceramic matrix compound; in PZT based dielectric ceramic materials of capacitors being part of integrated circuits or discrete semiconductors.

It could be argued that for the articles covered (and exempted) by the RoHS and ELV Directives, the requirements set out in the Directives related to lead could be seen as "minimum requirements for controlling risks to human health and the environment" resulting from the waste phase of the articles. In relation to exempted uses, these Directives include a legislative regime to push for substitution in a similar manner to the authorisation requirement. Therefore, when these Directives are considered in conjunction with the other EU legislation applying to lead compounds, they may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH.

The Directive 2012/19/EU on waste electrical and electronic equipment ('WEEE') aims at protecting the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste from electrical and electronic equipment (WEEE) and by reducing overall impacts of resource use and improving the efficiency of such use, thereby contributing to sustainable development. The WEEE Directive requires Member States to take the necessary measures to ensure that producers provide reuse and treatment information for each type of new EEE put on the market. This information shall identify, as far as it is needed by reuse centres, treatment and recycling facilities in order to comply with the WEEE Directive, the different EEE components and materials, as well as the location of dangerous substances and mixtures in EEE. While the WEEE Directive contributes to environmental protection at the waste life cycle stage of these articles, it does not appear to impose minimum requirements to ensure that the risk from lead compounds are properly controlled in accordance with Article 58(2) REACH.

Council Directive 2006/66/EC (as amended) on batteries and accumulators and waste batteries and accumulators aims at the minimisation of the negative impacts of batteries and accumulators on the environment. The Directive primarily regulates the placing on the market of batteries or accumulators, and their collection and subsequent treatment as waste, including through recycling. It seeks to improve the environmental performance of batteries and accumulators (as well as the development and marketing of batteries and accumulators which contain smaller quantities of dangerous substances or which contain less polluting substances, in particular as substitutes for mercury, cadmium and lead) and of the activities of all economic operators involved in the life cycle of batteries and accumulators. With some exceptions (military and space use), it applies to all batteries. The Directive prohibits the marketing of batteries containing some

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

hazardous substances (particularly mercury and cadmium), defines measures to establish schemes aiming at high level of collection and recycling, and fixes targets for collection and recycling activities (including for lead-acid batteries and accumulators). The Directive also sets out provisions on labelling of batteries and their removability from equipment. Producers of batteries and accumulators and producers of other products incorporating a battery or accumulator are given responsibility for the waste management of batteries and accumulators that they place on the market, and relevant Member States must promote substitution of hazardous substances in batteries and accumulators, including lead.[21] In relation to lead compounds, the Batteries Directive primarily contributes to protection of human health and the environment at the waste life cycle stage of these articles. Therefore, when this Directive is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for the use of lead compounds in batteries under Article 58(2) REACH.

Council Directive 86/278/EEC on the protection of the environment, and in particular soil, when sewage sludge is used in agriculture seeks to encourage the use of sewage sludge in agriculture and to regulate its use in such a way as to prevent harmful effects on soil, vegetation, animals and man. To this end, it prohibits the use of untreated sludge on agricultural land unless it is injected or incorporated into the soil. It includes limit values for concentrations of heavy metals (including lead) in the soil (Annex 1A) and in sludge (Annex 1B) and sets out limit values for the amounts of heavy metals which may be added annually to agricultural land (Annex 1C). It requires analysis of the levels of heavy metals in sludge and in soil. The Sewage Sludge Directive in general contributes to environmental protection at the waste life cycle stage. However, it should be pointed out that there does not appear to be EU legislation in place setting standards for lead in soils generally. This is at least partially addressed by the standards for lead set in food legislation (see section on product-related legislation). However, there is the possibility that humans, in particular children, may be exposed to lead deposited in soils as a result of the uses of lead compounds.

It is noted that information on certain international conventions (OSPAR, CLRTAP, Basel and HELCOM) has been included in an appendix to some submissions. Decision 98/249/EC approved on behalf of the Community the OSPAR Convention for Protection of the Marine Environment of the North-East Atlantic. Decisions 94/156/EC and 94/157/EC enabled the Union to accede to the Convention on the Protection of the Marine Environment of the Baltic Sea Area (Helsinki Convention, HELCOM). However, these Conventions are not applicable to all Member States of the Community.

Decision 81/462/EEC approved on behalf of the Union the Geneva Convention on Long-Range Transboundary Air Pollution (CLRTAP). This Convention establishes a framework for intergovernmental cooperation with the aim of protecting health and the environment from air pollution that is liable to affect several countries. This cooperation covers the development of appropriate policies, the exchange of information, research and the implementation and development of a monitoring system. The CLRTAP has been extended by a series of specific protocols, one of which, the Aarhus Protocol, relates to heavy metals (Decision 2001/379/EC). The aim of this Protocol is to

[21] Art. 5: "*Member States which have manufacturers established on their territory shall promote research and encourage improvements in the overall environmental performance of batteries and accumulators throughout their entire life cycle as well as the development and marketing of batteries and accumulators which contain smaller quantities of dangerous substances or which contain less polluting substances, in particular as substitutes for mercury, cadmium and lead.*"

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

reduce emissions from heavy metals caused by anthropogenic activities that are subject to long-range transboundary atmospheric transport and are likely to have serious adverse effects on human health and the environment. To this end, it stipulates the reduction of total annual emissions into the atmosphere of certain heavy metals including lead, and the application of product control measures (including for batteries). Signatory parties must apply the best available technologies vis-à-vis all the major sources of heavy metals existing, or due to be created, on their territory. The parties must respect the emission limit values specified in Annex V and apply regulatory measures on products, as specified in Annex VI of the Protocol. This Convention and Protocol therefore contribute to protection of environment and human health at the manufacture, use and waste life cycle stages. Therefore, when this Convention is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH.

Conclusion

As set out in C.1.1, ECHA considers the elements described in the 'General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV'[22] when assessing exemption requests under Art 58(2). The European Commission will make its assessment of the exemption possibilities and include any exemptions the Commission regards as appropriate in its draft decision on Annex XIV inclusion which will be discussed in the REACH Comitology Committee.

Requests have been made for Art 58(2) exemptions for various uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate, and tetralead trioxide sulphate. It should be noted that some uses for which an Article 58(2) exemption has been requested appear to be uses as intermediates (which are exempted from the authorisation requirement) and therefore responses to comments on this issue should also be consulted.

Comments received refer to the many pieces of EU legislation relating to use and disposal of lead and lead compounds. For example, in relation to workers health, inorganic lead and its compounds is currently the only group of substances under Directive 98/24/EC to have a binding OEL and lead and its ionic compounds are the only substances for which a binding biological limit value and health surveillance measures are set out. In addition, risks to man via the environment from uses of lead compounds is addressed by legislation dealing with ambient air, water, drinking water, waste and food (though there is uncertainty related to soil coverage). However, ECHA notes that for the Water Framework Directive (WFD) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. Therefore, in order not to limit the Commission's possibility to take such action and considering the limitations of the WFD (e.g., no specific emission limits), it may not provide an appropriate basis for an exemption from the authorisation requirement. If the REACH risk management processes are necessary to achieve the objectives of other legislation (e.g. that relating to drinking water, ambient air), then the same considerations may apply as for the WFD. Therefore, taking into account the above points, it is not clear if EU legislation provides a sufficient basis for an Article 58(2) exemption for any uses of lead compounds.

[22] http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

ECHA notes that Article 58(2) requires that the risk be "properly controlled" on the basis of existing EU legislation, which must be assessed on a case-by-case basis. A demonstration of proper control could, for example, be strengthened or supported if EU legislation provides a binding substitution regime for a SVHC with timeline or review process, in particular in the case of non-threshold substances such as lead compounds. ECHA considers that the uses with perhaps the strongest case for Art 58(2) exemption are those for which a legislative regime is already in place to push for substitution in a similar manner to the authorisation requirement. It could be argued that such a regime applies to those uses of lead compounds which are exempted under the RoHS and ELV legislation (e.g. ~75 % of lead batteries). This legislation addresses the risks resulting from the waste phase of particular articles and pushes manufacturers to avoid the use of hazardous substances such as lead and its compounds in articles. The exemptions for uses of lead compounds in particular applications and their regular review could be regarded as similar to the time limited review period set out in authorisation[23], although the role and duties of industry differ. It should be noted that the RoHS and ELV Directives do not contain requirements to minimise risks from use of substances in applications exempt from restriction throughout the whole life cycle and that these risks would need to be addressed under the authorisation regime if Art 58(2) exemptions did not apply. The other parts of this assessment reflect the latter point. Therefore, on balance, when considering uses of lead compounds exempted under the RoHS and ELV legislation holistically with the other Community legislation addressing lead compounds, it appears that these uses may have a stronger case for Art 58(2) exemption than other uses.

In summary, based on the above review it is not clear if there is sufficient basis to propose Art 58(2) exemptions for any uses of lead compounds. However, if the Commission were to consider Art 58(2) exemptions possible, uses of lead compounds exempted and subject to regular review under RoHS and ELV legislation may have a stronger case for Art 58(2) exemption than other uses.

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)

[23] In relation to the Batteries Directive, it appears that the substitution provisions differ much more significantly from the authorisation regime (than the RoHS/ELV Directives) as they do not include a similar regular review of specific (exempted) applications at EU level.

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

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	Laboratory reagent / processing aid for analysis of precious metal content of secondary and complex materials
Lead monoxide	Propellants in rocket motors
Lead monoxide	Catalysts and adsorbents
Lead monoxide and lead tetroxide	Explosives and detonators
Pentalead tetraoxide sulphate and tetralead trioxide sulphate	PVC stabiliser (virgin and recycled PVC)
Lead monoxide	Manufacture of PVC stabilisers
Tetralead trioxide sulphate	Production of microporous plastic separators for lead-based batteries

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

C.2.2.	**Recycling of lead containing PVC: specifics of that industry need to be considered by e.g. realistic limit values or exemption** *(tetralead trioxide sulphate, pentalead tetraoxide sulphate)*	ECHA, at the request of the Commission, intends to submit a restriction dossier on lead compounds used as stabilisers in PVC in December 2016 (http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/current-activites-on-restrictions). The restriction intention is specific in that it will cover the placing on the market and use of lead compounds to stabilise PVC, and the placing on the market and use of PVC articles stabilised with lead compounds. However the precise scope (including potential derogations) of the proposed restriction is currently under development and maybe subject to further changes. The recycling has already been raised as an important issue that will need to be thoroughly analysed and a decision made how to address it. The scope of the restriction will also be further discussed in the restriction opinion making process. Therefore, it is premature to take a stand on the possible exemptions based on this possible future restriction. Both the decisions on the Annex XIV entries (including any exemption from the authorisation requirement) and on the restriction are taken by the Commission. This enables the Commission to make sure that the next regulatory steps are taken in a complementary manner; the recommendation of tetralead trioxide sulphate and pentalead tetraoxide sulphate does not prevent or impede such complementary action. Please refer also to **C.1.1. General principles for exemptions under Art. 58(2)** and **C.1.2. Generic exemptions**. Furthermore, please see ECHA's response to the issue **A.2.14. Applicability of the authorisation requirement for recycling / recycled materials** In addition, you might find it useful to refer to Q&As 0566 on ECHA's website.
C.2.3.	**Request for exemption of use in R&D acc. to Art. 56(3)**	It is unclear from the comment received whether it refers to SRD according to Art. 3(23). Under Article 3(23) REACH, scientific research and development (**SRD**) means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. Authorisation is not required for uses that fall within the definition of SRD acc. to Art. 3(23). Product and process orientated research and development (**PPORD**) is any scientific development related to product or process development and/or application of a new or

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

	(tetralead trioxide sulphate, pentalead tetraoxide sulphate)	already existing substance, irrespective of the tonnage. Authorisation is required for substances used in PPORD unless specifically exempted. Based on the information available to ECHA, we are not in the position to conclude whether your use(s) fulfil the conditions of SRD. Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. For further information you can also refer to Q&As 0585, 1030 and 1153 on ECHA's website (http://echa.europa.eu/support/qas-support/search-qas) as well as to the ECHA guidance on SRD and PPORD (http://echa.europa.eu/documents/10162/13632/ppord_en.pdf).

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu