1 October 2019

Response document

Substance group: Lead stabilisers

Substance names and EC-numbers:

Substance name	EC number
Dioxobis(stearato)trilead	235-702-8
Fatty acids, C16-18, lead salts	292-966-7
Trilead dioxide phosphonate	235-252-2
Sulfurous acid, lead salt, dibasic	263-467-1
[Phthalato(2-)]dioxotrilead	273-688-5
Trilead bis(carbonate) dihydroxide	215-290-6
Lead oxide sulfate	234-853-7

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 that can be used as stabilisers in PVC 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 9th Annex XIV recommendation and took place between 5 September 2018 and 5 December 2018.

[1] The compilation of comments received, along with references to responses, can be found at the following links:
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_dioxobis-stearato-trilead_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_fatty acids_c16-18_lead salts_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_trilead_dioxide_phosphonate_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_sulfurous_acid_lead_salt_dibasic_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_phthalatodioxotrilead_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_trilead_biscarbonate_dihydroxide_en.rtf
https://echa.europa.eu/documents/10162/13640/9th_recom_comref_lead_oxide_sulfate_en.rtf

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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 9th recommendation for public consultation.

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

The section headings in the process information and captions on the left of 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.1.2.1", "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.

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A. Priority and general issues

A.1. Process information

A.1.1. General, recommendation process

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

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

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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.1.3)). 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.

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.

[2] https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf

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

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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.1.3) – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. It does not comprise an assessment of information such as detailed operational conditions,

[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] https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf
[6] https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf

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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 based on article service-life

Although uses of articles containing a substance in the Authorisation List will not require authorisation, article service-life is still relevant in priority considerations. This is because in the authorisation-application phase the risks and benefits related to any article service-life subsequent to uses applied for need to be considered, too. 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

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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 demonstrate 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.

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

[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: https://echa.europa.eu/pact

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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 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

[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.

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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.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 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 increase in these cases will apparently depend on the application fee and, in particular, on the costs of preparing the application. Its actual effect on the competitiveness of the respective industry in the EU will depend on the specific case (e.g. on the level of the overall production cost, including capital, raw material, and labour cost), but will often be relatively low.

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Furthermore, it should be noted that 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.

8.Uncertainty as to whether authorisation will be granted

ECHA has made considerable effort to run the authorisation process in a transparent manner.

Commission, MSCAs, industry and ECHA have developed approaches and advice on how to prepare streamlined and fit-for-purpose applications.

ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (https://echa.europa.eu/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, and approaches agreed by the committees describing how applications are treated and evaluated.

The Risk Assessment Committee has been providing DNEL and dose-response relationships for almost all substances so far. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. Moreover, the Committee for Socio-economic Analysis has published an explanatory note providing clarifications on how it evaluates economic feasibility as part of applications for authorisation. Furthermore, the Committees have jointly agreed on the principle of the recommended length of the review period, which should increase predictability. ECHA informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinion. This is normally seven years, but a long review period of e.g. 12 years is possible, too[14].

Further clarifications to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process.

In addition, 'trialogues' are organised with applicants, Committee rapporteurs and interested parties during the opinion-making process. Seminars and workshops add to the support available for applicants.

[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.

[14] It should also be noted that an authorised use can be prolonged after the end of the review period. Authorisation holders have to submit a review report 18 months before the end the review period so that the authorised use could be prolonged.

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As a result of these activities, the evaluation of applications for authorisation has become increasingly efficient and transparent.

By September 2019, >160 applications for >260 uses from >260 applicants have been submitted and are at various stages of processing[15]. The Risk Assessment Committee (RAC) and the Socio-economic Committee (SEAC) have adopted final opinions for a substantial number of uses (>200) and sent them to the Commission for decision making. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

[15] Up-to-date statistics on received applications at https://echa.europa.eu/received-applications

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A.2 Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
A.2.01	Questioning scoring and general priority of the substances	As part of the authorisation process, ECHA has the obligation to recommend substances from the Candidate List for inclusion in Annex XIV. For the purpose of the recommendation ECHA considers all relevant information available to it. Registration dossiers are the main source of information. Further information e.g. from Annex XV SVHC dossiers and from SVHC public consultations is also considered, where appropriate. For the purpose of its priority setting for the 9th draft recommendation, ECHA had considered all information available in registration dossiers by 1 February 2018. After the end of the public consultation on 5 December 2018 all comments and any new updates to the registration dossiers were taken into account for finalising the recommendation. ECHA wants to emphasise that it is the registrants' responsibility to ensure that the information in the registration dossiers is clear, consistent and up-to-date. To conclude on the priority of the lead substances that can be used as stabilisers in PVC, ECHA has also assessed the impact of the upcoming restriction of lead compounds in PVC articles on the uses and tonnages falling within the scope of authorisation. Indeed, the proposed restriction is in the final stage of the process: RAC and SEAC Committees have issued opinions on the proposal respectively on 5 December 2017 and 15 March 2018. The Commission has indicated that the adoption of the restriction could be expected in the course of 2019. Based on the information available the **volume score** has been revised for the following substances: • Dioxobis(stearato)trilead • Fatty acid, C16-18, lead salts • Trilead dioxide phosponate • Sulfurous acid, lead salt, dibasic • [Phthalato(2-)]dioxotrilead

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		For *Dioxobis(stearato)trilead, Fatty acid, C16-18, lead salts* and *Trilead dioxide phosponate* some registration dossiers have been updated. The tonnage estimated for uses in the scope of authorisation has been reduced accordingly. It is noted that the stabiliser sector had a voluntary commitment to replace lead-based stabilisers in all their formulations sold in the EU market by the end of 2015. According to the sector, its members completed the replacement. Therefore ECHA assumed that the tonnage reported in registrations relates to uses that are not covered by the voluntary commitment and/or the upcoming restriction. For *Sulfurous acid, lead salt, dibasic and [Phthalato(2-)]dioxotrilead*, all existing registration dossiers have been set to inactive, therefore there appears to remain no manufacturer/importer supplying the substances in the EU anymore (in quantities of above 1 tonne per year). Based on the information available the **wide-dispersive use** score has been revised for the following substances: • Dioxobis(stearato)trilead • Fatty acid, C16-18, lead salts • Sulfurous acid, lead salt, dibasic • [Phthalato(2-)]dioxotrilead For *Dioxobis(stearato)trilead* and *Fatty acid, C16-18, lead salts* it has been considered that the additional score of two, previously assigned for the use in articles, might not be fully justified in this specific case. The sole use in articles reported for those substances is the use as stabiliser in PVC articles. Once the upcoming restriction will apply such use should not happen anymore. It is noted that the restriction covers the use of lead compounds for the production of articles, and the placing on the market of PVC articles stabilised with lead compounds. However, the restriction does not impact the formulation of lead stabilisers (for export). Therefore, the score for the use in formulation has been retained, as this use is still reported in registrations. For *Sulfurous acid, lead salt, dibasic* and *[Phthalato(2-)]dioxotrilead*, as mentioned above, all existing registration dossiers have been set to inactive. Therefore there seems to remain no uses in the scope of authorisation for those substances.

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		In conclusion, the **total priority score** for the substances *Trilead dioxide phosphonate* and *Fatty acids, C16-18, lead salts* remains equal or above 18. Therefore ECHA sees no reason for not including those substances in the final recommendation. The other lead substances in this group (Dioxobis(stearato)trilead, Sulfurous acid, lead salt, dibasic, [Phthalato(2-)]dioxotrilead, Trilead bis(carbonate) dihydroxide and Lead oxide sulfate) have a total priority score below 18. However, they are prioritised for inclusion in the final recommendation based on grouping considerations with the two higher scoring substances. More details on how ECHA has considered the information available are documented in the final background documents which can be found on ECHA's website under "Details" of the relevant substances at https://www.echa.europa.eu/previous-recommendations. **Please also refer to response A.2.04.** (Challenging the grouping of lead oxide sulfate with other lead substances used as stabilisers).
A.2.02	Quantities of legacy lead in recyclate	Thank you for providing this estimation of quantities of lead compounds used in recyclate. This information has however not been considered for priority setting. So far information on volumes of substances manufactured from recycling processes have not been considered for priority setting as this information is generally not available to ECHA and can therefore not be assessed in a systematic way. Recyclers can benefit from an exemption from registration and therefore may not need to report volumes to authorities. Furthermore, in the case of lead stabilisers in PVC recyclate, it is acknowledged that providing exact tonnages of single lead compounds used per year (which would be needed to support a systematic assessment) is difficult to provide. **Please also refer to response A.2.01** (questioning scoring and general priority of the substances).
A.2.03	Claim that a registrant may keep its registration active and report uses as stabiliser to enable recycling even though the substance	According to Article 2(7)(d) of REACH, recovery operators can benefit from an exemption from the registration obligation, provided that the same substance resulting from the recovery process is already registered (see ECHA's guidance on waste and recovered substances for more information: https://echa.europa.eu/documents/10162/23036412/waste_recovered_en.pdf/657a2803-710c-472b-8922-f5c94642f836). ECHA acknowledges the fact that the absence of an active registration for the same substance as a substance resulting from a recovery process may trigger registration obligations at the level of

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	is not produced any more	recovery operators. Therefore, a registrant of the "original" substance (i.e. the substance that became waste and which is recovered from that waste) may decide to keep its registration active, even in situations where he does not manufacture or import the substance anymore, to enable recyclers to benefit from the exemption from the registration requirement for that same substance. It should be noted that obligations related to the life-cycle and supply chain of a substance end with the waste stage. Therefore, uses of a recovered substance do not have to be covered in the exposure scenario (and technical dossier) of the original substance, because the life-cycle of the original substance ends when it ceases to be waste. Accordingly, ECHA considers identified uses reported in registration dossiers as uses of the original substance unless clearly specified otherwise. It is worth noting that recovery operators exempted from registration due to Article 2(7)(d) do not need to perform a chemical safety assessment or complete a chemical safety report of the recovered substance. Even if the use of the recovered substance is not covered by the registration of the original substance, they are not required to: • make an exposure scenario for the use of the recovered substance; • register the recovered substance; • notify the use of the recovered substance. Further information on obligations that apply to recovery operators can be found in ECHA's guidance on waste and recovered substances.
A.2.04	Challenging the grouping of lead oxide sulfate with other lead substances used as stabilisers	Within the priority assessment, as an additional aspect, it is considered whether the available information gives an indication that a substance on the Candidate List could potentially replace substance(s) already recommended or about to be recommended, in (some of) their uses. This is described in Chapter 6 "Further considerations to be taken into account" of the prioritisation approach (https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_e_n.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8). This 'grouping approach' is applied with the aim to avoid replacing high-priority Candidate List substances by other Candidate List substances that are currently of lower priority i.e. avoid regrettable substitution.

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		Lead oxide sulfate has been identified as a substance that could potentially substitute other high scoring lead substances on the Candidate List in some of their uses. ECHA acknowledges that the use as stabiliser indicated as the basis for the grouping in the background document is no longer reported in registration dossiers of lead oxide sulfate and that it was commented that the substance has not been used for that use although it was included in the earlier registration dossier. However, the information provided in the comments received does not allow to conclude that intersubstitutability is not technically feasible, i.e. it is not technically possible that this substance could replace any of the higher scoring lead compounds in their use as PVC stabiliser. It should be noted that the assumed interchangeability is not based on a proof that such replacement can or will happen in practise or is e.g., economically feasible. It should be reminded that the prioritisation is based on reasonable worst case assumptions. In conclusion, ECHA sees no reason to change the grouping consideration for this substance.
A.2.05	Interplay between the restriction of lead in PVC and a potential authorisation requirement for leads in recycled materials	ECHA at the request of the Commission submitted a restriction dossier on lead compounds used as stabilisers in PVC in December 2016. The Commission has indicated that the adoption of the restriction could be expected in the course of 2019. According to this upcoming restriction lead compounds 1. Shall not be used in articles produced from PVC. 2. Articles produced from PVC shall not be placed on the market if the concentration of lead (expressed as Pb metal) is equal to or greater than 0.1% by weight of the PVC material. By way of derogation it is foreseen that certain PVC article types containing PVC recyclate will be allowed to contain lead at concentrations of up to 1% (soft PVC) or 2% (rigid PVC) for a period of 15 years from entry into force. As a general principle ECHA wants to emphasise that authorisation and restriction can be used in a complementary manner to ensure proper control of risk and provide an incentive to (continue to) develop alternatives (i.e. they do not exclude each other). Therefore, the uses of lead substances foreseen to be derogated from the upcoming restriction in general fall within the scope of authorisation. They will become subject to authorisation, unless a specific exemption is granted by the Commission pursuant to Art. 58(2) of REACH.

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		The decisions on the restriction of lead compounds in PVC articles, on the Annex XIV inclusion and on possible exemptions pursuant to Art. 58(2) are taken by the Commission. This enables the Commission to make sure that the regulatory decisions are complementary. **Please also refer to the responses A.2.06** (claim that lead compounds present in PVC recyclate can be considered as impurities) **and C.2.02** (exemption requests for recycling of PVC containing lead).
A.2.06	Claim that lead compounds present in PVC recyclate can be considered as impurities	The interpretation whether lead stabilisers present in recycled PVC (when ceased to be waste) can be considered as impurities as raised in the comment can have implications on registration obligations and on the authorisation requirement. These issues have been clarified in a document from the 25th meeting of competent authorities of REACH and CLP (CARACAL) (CA/98/2017, REACH Authorisation - Relevance of the 80/20% rule used in substance naming and identification in determining authorisation obligations under REACH for recovered substances on their own or in mixtures, Nov. 2017, available at https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/b54cb60f-2073-4eed-a77d-9f0174dd0acd/details, registration required to access the document). As described in the document, recovered PVC materials most likely meet the definition of mixtures and legacy lead substance in recovered PVC are considered mixture components. Furthermore they still provide a stabilising function to the materials. Therefore, legacy lead stabilisers should be taken as intentional and cannot be considered as an impurity. Accordingly, legacy lead substances present in recovered PVC are in general subject to the registration and authorisation requirements. Uses of recovered PVC containing one of the lead substances in concentrations equal or above the concentration limits specified in Article 56(6) of REACH (0.3% by weight for reproductive toxicants category 1A) will be subject to authorisation unless specifically exempted. **Please also refer to responses C.2.02** (exemption request for recycling of PVC containing lead) **and A.2.08** (questioning the practicability of the authorisation requirement for uses of legacy lead compounds in PVC recyclate).
A.2.07	Burden of the Afa requirement (in particular for SMEs in the recycling sector)	Note that 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 that they may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Therefore one application can e.g. cover the same use of

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		several substances. 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. From these specifications of Art. 62 it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. It is also possible to submit joint applications by a homogeneous group of actors (e.g. DUs) operating in the same business sector. To get the required application(s) ready in time is therefore rather a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of resources than dependent on the size and expertise of each and every individual enterprises in the supply chain.
A.2.08	Questioning the practicability of the authorisation requirement for uses of legacy lead compounds in PVC recyclate considering that single substances cannot be differentiated by analytical methods	ECHA acknowledges the issue of differentiating legacy lead compounds in PVC recyclate by standard analytical methods. Nevertheless, the authorisation requirement for lead substances present in PVC recyclate above the specific concentration limit applies once these substances are included in Annex XIV, the sunset date has passed and unless exemptions for the relevant uses of those substances have been granted by the Commission based on Art. 58(2). In general, for any cases where there are doubts about the authorisation requirement for the use of a substance or several substances, it is advised to apply for authorisation. ECHA could also provide support on how to group different substances into one application for authorisation. **Please also refer to response C.2.02** (exemption request for recycling of PVC containing lead).
A.2.09	Simplified authorisation process for low volume end-uses	ECHA notes that information on volume and exposure are evaluated by RAC and SEAC during the processing of the application for authorisation. Currently, no specific or simplified rules have been agreed by the Commission regarding substances used in low quantities.
A.2.10	Document attached to comment relates to different substance	We note that the document provided as attachment to this comment does not relate to the substances dioxobis(stearato)trilead, fatty acids, C16-18, lead salts or sulphurous acid, lead salt, dibasic but to another substance (DOTE) included in ECHA's 9th draft recommendation. Our responses to the observations made in the attachment can be found in the response document for DOTE (EC 239-622-4).

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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 consultations on the draft recommendations, ECHA has so far 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 its draft recommendation.

3.ECHA's proposal for latest application dates

ECHA made its proposals for the latest application dates (LAD) on the basis of the 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 180 opinions have already been given by RAC and SEAC, future applicants are in a better position than the first ones to prepare a fit-for-purpose application.

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential applicants concerned by substances in this recommendation. In this context, for example a step-by-step guide for applicants on how to

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apply for authorisation has been (December 2016) published on ECHA's website. Furthermore, there is ongoing work on applications for the specific cases of low volumes and legacy spare parts. 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[16]. 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.

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

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

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The 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. ECHA has developed a practical implementation method to support a more consistent and transparent assessment of these criteria[17].

B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates

1.Extensive time needed in the supply chain to get organised 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.

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

[17] https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

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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 guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[18].

[18] 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)

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B.2 Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
B.2.01	Longer LAD and SSD required considering the size and number of recycling companies	In its draft recommendation, ECHA suggested the Latest application dates to be the date of inclusion in Annex XIV plus **18, 21 or 24 months.** ECHA indicated that it will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the public consultation. Having assessed all information received during the public consultation, ECHA sees currently no reason to deviate from the three standard LAD slots mentioned above. 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 proposed 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). ECHA has developed a practical implementation method to support a consistent and transparent assessment of these criteria. The aim is to holistically compare a limited number of substances within one recommendation round. https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf Based on the assessment performed, it seems that the supply chain of the lead compounds considered in this group can be concluded as being of high complexity compared to other substances included in the final recommendation. Therefore, a latest application date of 24 months is suggested. **Please also refer to responses B.1.1.3** on ECHA's proposal for latest application dates **and B.1.1.2** on ECHA's proposal for sunset dates.

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C. Exemptions

C.1. Process information

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

Uses (or categories of uses) can be exempted from the authorisation requirement on the basis of Article 58(2) of REACH. Furthermore certain uses fall under the generic exemptions from authorisation[19].
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.

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.

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

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In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[20] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[21]):

- 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 proper 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.

[20] 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) and Others vs European Commission*.
[21] Available at: http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

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C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf. The scope of some of these generic exemptions is further clarified in ECHA's Q&A found at https://www.echa.europa.eu/web/guest/support/qas-support/qas (Q&As 1027, 1028, 1030 and 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 (https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf).

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[19]. 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.

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C.2 Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
C.2.01	Exemption request for the use of recyclate containing legacy lead compounds for the development of new applications (articles)	ECHA notes that uses in Product and Process orientated Research and Development (PPORD) are not generically exempted from the authorisation requirement. However activities to develop products and processes may fall under the definition of Scientific Research & Development (SRD) if they are carried out under controlled conditions in a volume less than one tonne per year. In this case, they are exempted from authorisation. This applies also when a substance is used in a mixture, which might be the case for lead compounds in PVC recyclate. ECHA would therefore suggest that you examine whether the mentioned uses of your substance can be regarded as uses for SRD purposes (in accordance with Art. 3(23) and 56(3) of REACH). For more information, see also ECHA's "Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)" (available at: https://echa.europa.eu/guidance-documents/guidance-on-reach) and ECHA's Q&A's on authorisation (available at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation). **Please also refer to response A.2.06** (claim that lead compounds present in PVC recyclate can be considered as impurities).
C.2.02	Exemption request for recycling of PVC containing lead based on worker safety legislation and upcoming restriction Reference to existing legislation, upcoming restriction, binding EU OEL	**Please refer to response C.1.1.** (General principles for exemptions under Art. 58(2)) **and to the detailed response below this table.**

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C.2.03	Exemption request for uses restricted to industrial processing (such as 'formulation for export')	**Please refer to response C.1.1.** (General principles for exemptions under Art. 58(2)) **and to the detailed response below this table.**

Detailed response to exemption requests C.2.02 and C.2.03 (recycling of PVC containing lead and uses restricted to industrial processing (such as 'formulation for export')

Requests for exemptions from the authorisation requirement have been submitted for the following uses of lead compounds:

- **'Uses restricted to industrial processing (such as formulation for export-only)'**
- **'Recycling of PVC containing lead'**

In those requests comment submitters referred rather generically to existing worker safety legislation established to address risk in and from the workplace relevant for lead and its compounds. Furthermore, for exemption requests for the second use (recycling of PVC containing lead) reference is made to the upcoming restriction of lead compounds in PVC articles.

In the following, ECHA provides an assessment of the exemption requests taking into account the relevant EU legislation mentioned in the comments, but also other pieces of EU legislation known to be relevant for lead and its compounds, as published in 2016 when exemption requests for various uses of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate had been assessed[22].

While lead and its compounds are of concern both for human health and the environment, lead compounds have currently only been identified as substances of very high concern and included in the Candidate List for a human health concern under Article 57(c) (toxicity to reproduction). Consequently these substances can currently only be included in Annex XIV based on this intrinsic property. In this respect,

[22] See Section C.2 of the response document for the substances lead monoxide, orange lead, tetralead trioxide sulphate and pentalead tetraoxide sulphate from ECHA's 7th recommendation for inclusion of substances into the Authorisation List: https://www.echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375.

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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 consumers and man via the environment need to be considered.

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 relevant for a particular use.

Therefore the following aspects are further discussed below:

1. risks at the workplace;
2. risks related to subsequent life cycle stages (e.g. service life in articles, waste stage) and
3. risks for man via the environment.

1. Risks at the workplace:

Submitters of exemption requests referred rather generically to the framework of existing worker safety legislation addressing risk at the workplace without specifying exact Directives or Regulations.

The list of Directives and Regulations addressing risks at the workplace, which ECHA considered for the assessment of the exemption requests is presented below.

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. Therefore, for this particular life cycle stage and target population (workers), the requirements in relation to Art 58(2) REACH may be met.

It should be noted that it is not in the remit of ECHA in the context of the Annex XIV recommendation 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. However, it is noted that the European Commission (DG EMPL) has requested ECHA to prepare a scientific report which shall include, where appropriate, proposals for a review of OEL(s), biological limit value(s), health surveillance measures and/or appropriate notations.

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Detailed assessment of Directives and Regulations addressing risks at the workplace:

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 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*

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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 hazard classification 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.*

2. Risks related to subsequent life-cycle stages (i.e. life cycle stages resulting from the uses at the workplace)

The assessment is done separately for each use for which exemption requests were received.

Uses restricted to industrial processing (such as formulation for export only):

There is no subsequent life-cycle stage within the EU resulting from the industrial use limited to formulation for export only, for which risk would need to be addressed.

The exemption request received appears to cover more widely any "uses restricted to industrial processing". For uses other than formulation for export, it needs to be carefully considered whether there is indeed no further life-cycle stages resulting from the uses which would need to be considered. This requires a case by case assessment which is not possible for ECHA's current recommendation considering the lack of specificity of the request and the level of information available at this stage of the process.

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Recycling of PVC containing lead

Subsequent life cycle stages are expected to result from the recycling of PVC containing lead stabilisers. Indeed the recycling will lead to the presence of the substances in articles and waste. It should therefore be considered whether there is EU legislation imposing minimum requirements to properly control the risks arising from the presence of the substances in articles and waste resulting from the recycling process. The upcoming restriction on lead in PVC articles[23] sets conditions to limit the risk arising from lead compounds in PVC articles and waste. The restriction imposes that lead should not be used in PVC articles in a concentration above 0.1% by weight. By way of derogation, concentrations up to 2% will be allowed for certain types of articles containing recycled PVC limited to a period of 15 years. In ECHA's view the upcoming restriction, if implemented, would fulfil the criteria to be considered in the context of an Art. 58(2) exemption:

- It is EU legislation addressing the specific use (or category of use) that is proposed to be exempted (and its subsequent life cycle stages).
- It addresses the risks to human health and/or the environment from the use of the substances arising from the intrinsic property that will be specified in Annex XIV; it specifically refers to the substances to be included in Annex XIV by referring to a group of substances that is clearly distinct from other substances;
- It imposes minimum requirements relating to the protection of human health and the environment for the proper control of risks of the use (and its subsequent life cycle stage).

3. Risks for man via the environment:

No reference was made in the exemption requests received to any environmental legislation that would address the risks for man via the environment.

The list of Directives and Regulations addressing risks for man via the environment, which ECHA considered for the assessment of the exemption requests is presented below.

Summary: In assessing the Art 58(2) requests ECHA has considered the environmental legislation from the point of view of potential risk to man via the environment. The EU environmental legislation referred to below may contribute to control the risk arising from particular uses of lead substances. 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 this legislation. In other words, the Directive expressly contemplates the use of REACH

[23] See https://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&Dos_ID=18210&DS_ID=63675&Version=1

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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. relating to drinking water, ambient air), then the same considerations 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.

Detailed assessment of Directives and Regulations addressing risks for man via the environment:

*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).*

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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 and restriction processes may be initiated by the Commission to achieve the objectives of that legislation.[24] 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*

[24] 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

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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.

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*

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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.

***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.*

***International conventions (OSPAR, CLRTAP, Basel and HELCOM)**: 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 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.

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Further considerations

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 the use of a SVHC with timeline or review process, in particular in the case of non-threshold substances such as lead compounds.

In this regard, ECHA considers that the uses with perhaps the strongest cases 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 would apply to the use in "recycling of PVC containing lead", if the proposed restriction would be in place.

The upcoming restriction pushes manufacturers to avoid the use of lead compounds in PVC articles. The derogations for uses of lead compounds in articles made from recycled PVC above a specified concentration are time limited and could be regarded as similar to the time limited review period set out in authorisation, although the role and duties of industry differ.

It should be noted that the restriction does not contain requirements to minimise risks from the use of lead compounds in PVC articles throughout the whole life cycle (i.e. during the recycling activities (use by workers at industrial sites)). However these risks should be addressed by the binding occupational exposure limit set out for inorganic lead and its compounds and the binding biological limit value set out for lead and its ionic compounds under Directive 98/24/EC (see above).

Conclusion

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.

Based on the above review, it is not clear if there is sufficient basis to propose Art. 58(2) exemptions for any uses of the lead compounds. However, if the Commission were to consider Art. 58(2) exemptions possible, uses of lead compounds in recycling of PVC may have a stronger case for an Art. 58(2) exemption than other uses, provided that the proposed restriction on lead compounds in PVC articles would be implemented.

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