12 April 2023

Response document

Substance name: Lead

EC number: 231-100-4

About this response document

The present document provides ECHA's responses to the comments[1] received during the consultation on its draft recommendation to include lead in Annex XIV of the REACH regulation (list of substances subject to authorisation). The consultation was held in the context of ECHA's draft 11th Annex XIV recommendation and took place between 2 February 2022 and 2 May 2022.

Although the responses aim to address individual comments, 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 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;

[1] The compilation of comments received, along with references to responses, can be found at Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)

- **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 consultation. The process information part is identical in all Response documents of the substances included in the draft 11th recommendation for consultation.

2. **Further responses relevant for the substances/substance group**
   Provides, if relevant, responses to comments 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.

Acronyms

AfA Application for Authorisation

COM European Commission

LAD Latest application date

RAC Risk Assessment Committee

SEAC Committee for Socio-economic Analysis

SME Small or medium-sized enterprise

SSD Sunset date

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[2] applied by ECHA was discussed with, and has been agreed by, the Member State Committee (MSC).

[2] Available at Recommendations for inclusion in the Authorisation List - ECHA (europa.eu).

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"[2].

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 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 consultation on the draft recommendation and in the registration dossiers (checked after closure of the 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 consultation on ECHA's recommendation is also used when finalising the substance specific background documents, if relevant, and according to its confidentiality status.

A.1.2. Prioritisation: Volume

1.Volume in the scope of authorisation

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. That volume is derived based on data from the registration dossiers as provided in Section 3.2 and 3.5 of the IUCLID dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during consultation on SVHC identification of the substances. Where available, information on uses falling under the generic exemptions from authorisation[3] 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'[4] and in the 'Practical guide on intermediates'[5], 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 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, 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.

[3] A list of uses exempted from the authorisation requirement available at: Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu)
[4] See Guidance on REACH - ECHA (europa.eu)
[5] See Practical Guides - ECHA (europa.eu)

More information can be found in Section 5.3 of the general prioritisation approach document[2] and in "General approach for prioritisation of SVHCs: practical implementation examples"[2]. 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[6]. 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 halfway 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[7] 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 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.

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[6] or unknown volumes, or ≥ 1t/y if the total volume in the scope of authorisation was < 10t/y

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

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[8].

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

[8] 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

alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it[9], 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 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 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.

[9] 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.

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. 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[10]. It is further possible to submit joint applications by a group of actors.

[10] 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.

8.Uncertainty as to whether authorisation will be granted

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

Several seminars and workshops have been organised with the various stakeholders to explain and provide clarifications on all aspects of the application for authorisation process.

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, check-lists, and approaches agreed by the committees describing how applications are treated and evaluated.

So far the Risk Assessment Committee has been providing DNELs and dose-response relationships for almost all substances for which applications for authorisations have been submitted. 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 opinions. This is normally seven years, but review periods can also be shorter or longer than that[11,1717].

Further clarifications to potential applicants are provided during teleconference-based information sessions (TIS) 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.

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

[11] It should also be noted that i) a review period longer than 12 years can be granted (see criteria in the "Policy guidance for considering review periods for exceptional cases" available at https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf), and ii) 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.

Meanwhile, the Risk Assessment Committee (RAC) and the Socio-economic Committee (SEAC) have adopted final opinions and the Commission issued decisions for a significant number of applications received[12]. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

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

A.2 Further responses relevant for the substance

Reference code	Issue title	Draft response
A.2.01	Questioning the way other Regulatory Risk management activities have been considered when prioritising the substance	In the process of recommending substances for inclusion in Annex XIV, ECHA applies the prioritisation approach discussed and agreed with the Member State Committee (MSC): (https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf). As outlined in the agreed prioritisation approach (section 6), "Other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation. This is to avoid undesired interference between different regulatory actions." When looking at "other ongoing regulatory risk management activities", ECHA primarily assesses whether already adopted or upcoming other regulatory risk management activities might affect the priority of the substance. The priority of the substances is assessed in terms of tonnage and uses falling within the scope of authorisation, considering all registered uses. At this step of the process ECHA takes into account information available on adopted or reasonably foreseeable regulatory risk management action - such as restrictions under REACH or under the POP regulation - that are banning or likely to ban certain uses of the substances and therefore impact the uses and tonnage remaining that fall within the scope of authorisation. As a result of the above-described assessment where it appears that remaining tonnage and uses falling within the scope of authorisation are likely to be limited or highly uncertain, ECHA may suggest to not prioritise a substance (e.g., as was the case for MCCP and 1,4 dioxane). If it appears that the remaining tonnage and uses falling within the scope of authorisation will likely still be high, ECHA suggests the substance to be recommended for inclusion. ECHA strives to apply the above-described approach in a consistent manner for all substances on the Candidate list. It is noted that REACH Art 58(2) foresees the possibility for *specific* exemptions from the authorisation requirement on the basis of existing EU legislation ensuring the control of risks. The decision on *specific* exemptions (as requested by a number of comment submitters based on requirements under e.g. the RoHS, ELV, CAD, IED or DWD Directives, or the Batteries Regulation) is taken by the Commission only after the recommendation of the substance is finalised. As ECHA cannot foresee the outcome of such a decision at the recommendation stage the uses for which there might be stronger ground for potential Art 58(2) exemptions are considered for priority setting purposes. Ongoing regulatory developments in

		areas that may affect a decision on Art. 58(2) are not considered sufficient reason to deprioritise the substance. In the case of lead, concluded and upcoming REACH restrictions have been taken into account. The tonnage and uses of lead already restricted through existing entries in Annex XVII (Substances restricted under REACH - ECHA (europa.eu)), were excluded for prioritisation, even when still reported in registration dossiers (e.g. consumer uses). It is assumed that the tonnage reported in registrations or commented during consultation already reflects the existing measures addressing lead, including the measures under other legislation (e.g. RoHS, ELV, Toys Safety Directive, Cosmetics regulation, foodstuffs). Furthermore, ECHA did assess the impact of the following proposed or completed-but not yet in force restrictions - Lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities (Registry of restriction intentions until outcome - ECHA (europa.eu)) - Restriction on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds (Registry of restriction intentions until outcome - ECHA (europa.eu)) - Restriction on the use of lead shots over wetlands. (Substances restricted under REACH - ECHA (europa.eu)) ECHA concludes based on the information available that the priority of lead remains high even if for the purposes of prioritisation it is considered that there are currently no remaining uses of lead in shot and ammunition and a ban of lead in PVC. ECHA acknowledges that the adoption of the Batteries regulation, the revision of the ELV Directive and the RoHS Directive (including their annexes), - might lead to further uses of lead being restricted/banned in the future. However, the tonnage and uses not covered by any of the above listed regulatory risk management actions/tools appear to still justify the prioritisation of the substance. Uses not covered by REACH restrictions and not covered in the (foreseeable) scope of other upcoming regulatory actions include for example uses in rolled and extruded products or cable sheathing which based on available information on the tonnage breakdown per use still account for > 10.000 t/y and involve industrial uses, professional uses and service life (see Annex I, section 1 of the final background document[2]). Other adopted or foreseeable regulatory risk management action listed in comments or known to ECHA (e.g. BOEL and BLV and their review; IED) increases the level of risk control of the uses they cover,

		but are unlikely to lead to cease or significant decrease of tonnage used. At this stage, the tonnage and uses covered by those regulations are considered for priority setting. Please also refer to response for: C.2.01 on Response to requests for exemptions under Art. 58(2) based on existing legislation. Please also refer to responses to responses A.2.02 and A.2.03 on further details on how this was considered for volumes and WDU respectively.
A.2.02	Questioning the volume score	In the process of recommending substances for inclusion in Annex XIV, ECHA applies the prioritisation approach discussed and agreed with MSC (see response A.1.1.3 for more general information and response A.1.2.1 on how volume is considered). Lead metal is already restricted for specific uses (e.g. REACH Annex XVII entries 30 and 63). Furthermore, ECHA did assess the impact of the following proposed or completed but not yet in force restrictions (see final background document[2]): - Lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities (Registry of restriction intentions until outcome - ECHA (europa.eu)) - Restriction on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds (Registry of restriction intentions until outcome - ECHA (europa.eu)) - Restriction on the use of lead shots over wetlands. (Substances restricted under REACH - ECHA (europa.eu)) The impact of the existing and upcoming restrictions on the volumes in the scope of authorisation has been assessed for the purpose of priority setting. It is assumed that the decreases of volume stemming from restrictions already in force have been reflected in the tonnages reported in registration dossiers. The further decrease of tonnage that may be anticipated from recently adopted/proposed restrictions has been evaluated based on information on tonnage per use provided by industry during recent consultations. Based on information available (both registrations and information from industry during recent consultations) the tonnage for uses not generically exempt from authorisation and not covered by upcoming foreseeable restrictions has been assessed to be above 10 000 t/y, justifying a score of 15.

		The agreed approach does not foresee to refine the scoring based on the level of risk control imposed by other EU legislation for the uses within the scope of authorisation. However, those considerations may be relevant when the Commission decides on exemptions from the authorisation requirement based on Art. 58(2) REACH. The ultimate decision on granting or not granting Art. 58(2) exemptions is taken by the Commission. All volumes for uses that are not 'generically' exempt from authorisation (https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf) are therefore considered for priority setting. Please also refer to the response for: C.2.01 on Response to requests for exemptions under Art. 58(2) based on existing legislation. A.2.03 Suggest lower (WDU) score considering existing EU legislation contributing to improved risk control A.2.01 Questioning the way other Regulatory Risk management activities have been considered when prioritising the substance A.1.5.3 Use specific considerations A.1.5.6 Socio-economic benefits of continued use
A.2.03	Suggest lower (WDU) score considering existing EU legislation contributing to improved risk control	In the process of recommending substances for inclusion in Annex XIV, ECHA applies the prioritisation approach discussed and agreed with MSC (see response A.1.1.3 for more general information and response A.1.3 for further insight on how the WDU criteria is generally assessed). The wide-dispersiveness of uses is primarily assessed based on the types of actors which are relevant for the uses of the substance. The agreed approach differentiates industrial, professional and consumer uses and suggests further refinements to take into account minor uses (<10t/y), relevance of article service-life and to factor in uncertain information. The approach does not suggest further refinement on the basis of existing EU legislation and the extent to which it contributes to improved level of risk control. The WDU assessment is proposed to rely on the above-mentioned basic indicators that can be assessed in a consistent way for all substances in the Candidate List, driven by the comparative nature of the prioritisation and the objective of transparency and predictability.

		ECHA had so far not considered relevant to refine the approach for scoring industrial or professional uses falling in the scope of authorisation on the basis of existing EU legislation contributing to improved risk control as the amount of EU legislation applicable to Candidate list substances in some of their uses may vary depending on the substances and the specific uses and may be difficult to factor in a transparent and predictable manner across all substances. Furthermore, REACH foresees that EU legislation and the way they already address risk should be considered when suggesting Art. 58(2) exemptions. See also responses: C.1.1 General principles for exemptions under Art. 58(2) C.2.01 Response to requests for exemptions under Art. 58(2) based on existing legislation Applying the agreed prioritisation approach (further exemplified in the practical implementation document) ECHA considers that a WDU score of 12 is applicable. An initial score of 10 is justified by confirmed industrial and professional uses in the scope of authorisation above 10 t/y. Two extra points are justified by the presence of the substance in articles produced in the EU above 10 t/y for which releases cannot be excluded. Please also refer to the response for: A.2.01 Questioning the way other Regulatory Risk management activities have been considered when prioritising the substance A.2.04 Questioning the scoring for article service life (+2 score)
A.2.04	Questioning the scoring for article service life (+2 score)	As further outlined in section A.1.1.3, ECHA applies for its prioritisation exercise the approach discussed and agreed with the Member State Committee. According to this approach, if registration data or other relevant information indicate that the substance ends up in articles and that there is no reliable information that releases are unlikely during article service life and waste phase, this can be taken into account in assigning the WDU score. Though the authorisation requirement does not apply to the use in articles, it has been considered relevant to reflect the article service life in the prioritisation phase as it contributes to the overall risks

		stemming from uses falling within the scope of authorisation (risks and benefits related to the article service-life of 'uses applied for' are to be considered in the authorisation application phase). For this assessment, ECHA only takes into account articles (and information on related volumes when available) produced in the EU. Imported articles are not considered as they are not to be covered at the application for authorisation phase. The rules for service life scoring have been further described and exemplified in the 'General prioritisation approach: practical implementation examples' document (https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_impl_examples_2020_en.pdf) and read as follows: "If a substance without consumer uses in the scope of authorisation ends up in articles and there is no reliable information that releases are unlikely during article service life and waste phase, 1 or 2 points are added to the WDU score depending on the total volume of the substance that can be assumed to be present in articles produced in the EU. If the total tonnage in articles is ≥10 t/y or unknown, 2 points are added to the initial WDU score. If the tonnage is <10 t/y, only one point is added." In the case of lead metal, though for some types of articles, releases could be considered negligible (e.g. sealed batteries), there are > 10 t/y of lead in articles produced in the EU for which releases cannot be excluded (e.g. lead sheets in the building sector, stained glass art). Therefore, the additional 2 points for service-life appears justified, leading to a refined WDU score of 12. ECHA notes that the assessment of the type of releases during the article service-life is not a thorough, detailed assessment, as that wouldn't be proportionate neither to the aim of the prioritisation stage in the authorisation process nor to the contribution to the prioritisation score itself. Please also refer to A.1.5.4 Control of risks
A.2.05	Use or sector specific arguments on the prioritisation of lead for its inclusion in Annex XIV	Please note that the prioritisation approach (published on ECHA's website) is applied to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV. Within the priority assessment it is not intended to assess the risks arising from (specific) uses (e.g. ammunition, sanitary, craftsmen, heritage), but to provide a very basic and general assessment of the use pattern and exposure potential the substance may have for humans (workers, consumers) or/and the environment, with the aim to compare it with other substances on the Candidate list. The inclusion

		in Annex XIV is per substance and not per use (or installation). Therefore, the priority score is derived considering all uses of the substance within the scope of authorisation. Based on the prioritisation criteria and the agreed prioritisation approach, lead is concluded of high priority. If the substance is included in Annex XIV the use and user specific conditions can be reflected in an authorisation application. They will be taken into account by ECHA's Committees when developing their opinions on the applications and by the Commission when taking the final decisions. Please also refer to: A.1.1.3 Prioritisation approach applied A.1.2.1 Volume in the scope of authorisation A.1.3.1 Scope of the assessment of wide-dispersiveness of uses A.1.3.2 Assignment of WDU score based on use types and their associated volumes For aspects that cannot be considered for prioritisation of the substance, please consult section A.1.5 of this document. Arguments brought forward on a specific use falling within the scope of authorisation, such as control of risks, socio-economic importance or availability of alternatives, will be considered when applying for an authorisation. Legislations addressing the risks arising from specific uses will be considered when assessing the possibility to grant an exemption from the authorisation requirement for such a use on the basis of Art. 58(2). For replies on exemption requests, please see section C.2 of this document. Please also refer to: C.1.3 Aspects not justifying an exemption from authorisation
A.2.06	Question the added value of the authorisation requirement, stress the risk of double regulation and ask for regulatory coherence	The requirement to apply for authorisation applies to all uses of the substances not exempt from the authorisation requirement. In order to avoid double-regulation, REACH foresees the possibility to exempt uses from the authorisation requirement, provided that existing specific EU legislation is in place to ensure proper risk control. The decision to grant exemption for specific uses under Art 58(2) results from a case-by-case analysis. The ultimate decision on an Art 58(2) exemption is taken by the Commission. ECHA cannot pre-empt such decision. See also responses:

		C.1.1 General principles for exemptions under Art. 58(2) C.2.01 Response to requests for exemptions under Art. 58(2) based on existing legislation Should the Commission decide that there is no sufficient ground for exemption for given uses, the authorisation requirement is a strong incentive to search for alternatives that are technically and economically viable. Please refer to the following section for an analysis of the proportionality of the authorisation requirement: A.1.5 Aspects not considered in ECHA's prioritisation, especially A.1.5.2 (Authorisation is disproportionate and/or means a ban). It is stressed that the authorisation requirement is not a ban. Uses can continue after the sunset date provided that a use-specific and applicant-specific authorisation is applied for and granted. The Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List) taking into account ECHA's recommendation. The Commission is also in charge of the Batteries regulation, ELV, RoHS, Drinking Water Directives and BOEL/BLV under CAD (including setting specific exemptions/conditions for the use of lead under these regulatory frameworks). The Commission is therefore enabled to ensure that the next regulatory steps are taken in a coherent and complementary manner. The recommendation of lead does not prevent or impede such complementary action. Hence, ECHA does not consider it appropriate to postpone the recommendation of lead based on other ongoing-regulatory developments. Please also refer to the response for: A.2.01 Questioning the way other Regulatory Risk management activities have been considered when prioritising the substance.
A.2.07	Impact of binding occupational exposure limit (BOEL) and biological limit value (BLV) on priority score	The binding occupational exposure limit (BOEL) and the binding biological limit value (BLV) set under Directive 98/24/EC aim at controlling the risks for workers' health arising from the use of the substances. However, BOEL and BLV do not ban uses. The uses can continue provided that the conditions set by the limit values are met. In the majority of cases, it is assumed that companies will comply with the limit values rather than ceasing uses or decreasing volume used significantly. The limit values are concluded as not expected to have a major impact on the prioritisation, as the priority of the substances for inclusion in Annex XIV is assessed in terms of uses and volume falling the scope of authorisation. See also response

		A.2.06 Question the added value of the authorisation requirement, stress the risk of double regulation and ask for regulatory coherence ECHA's conclusion on the priority of lead is independent from the justification by the European Commission (COM) to postpone the inclusion of certain other lead compounds in the Authorisation List (Annex XIV). The Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List). During the decision making, the COM can take into account additional considerations, e.g. when they affect the process for applications for authorisation or other policy decisions such as the "*possible adoption of more stringent measures at the workplace*" (6th amendment of Annex XIV (2020/171, 6 Feb 2020). Commission being in charge of both processes of revising workers exposure limit values (BOEL and BLV) and inclusion in Annex XIV, is best placed to define the most appropriate timing and regulatory context for those decisions to be taken. Please also refer to the response for: A.1.5 Aspects not considered in ECHA's prioritisation And in particular A.1.5.4 Control of risks
A.2.08	BOEL more effective to address occupational exposure than Authorisation	ECHA notes that 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 contribute indeed to control the risk for workers health arising from the use of the lead. However, the existence of such limit values is not a sufficient reason as such not to prioritise lead for inclusion in Annex XIV. See responses A.2.01 and A.2.03 for information how existing EU legislation contributing to improved risk control are considered during the prioritisation exercise. The existence of binding limit values is taken into account for potential exemptions on the basis of Art. 58(2) of REACH (see C.2.01 Response to requests for exemptions under Art. 58(2) based on existing legislation). Please also refer to the response for:

		A.1.5 Aspects not considered in ECHA's prioritisation, and in particular A.1.5.1 Potential other regulatory actions.
A.2.09	Need for a consistent regulatory framework between REACH and RoHS	In its Common Understanding Paper on the Interface between REACH and RoHS, ("REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING"), the European Commission highlights that the focuses of REACH and RoHS are complementary. The document describes different scenarios where the interface between the two pieces of legislation needs particular consideration. The situation of lead is described in section B.1 (b) (Substance already in Annex II to RoHS proposed for inclusion in Annex XIV to REACH where RoHS provides for exempt applications). The following main principles are suggested in this situation: 'Where RoHS provides for exempt applications (so that certain EEE containing a given substance may be placed on the market in specified cases), the incorporation of that substance in EEE by EU manufacturers would be subject to the authorisation procedure under REACH. However, the possibility is also open to exempt the uses covered by the RoHS restriction (including its exempted applications) from the authorisation process under REACH pursuant to Article 58(2) of REACH'. The above means that the requirements set by the RoHS Regulation should be duly considered in the context of Art 58(2) exemption assessment under REACH. The final decision on exemption is expected to result from a case-by-case analysis. The Common Understanding Paper indicates that 'a case-by-case analysis may conclude that the restriction of a substance under RoHS with exempted applications does not constitute "proper control" for the purposes of Article 58(2) of REACH. Please see response C.2.01 Response to requests for exemptions under Art. 58(2) based on existing legislation Note that the final decision on Art. 58(2) exemptions is taken by the European Commission. Please also refer to the response for: A.2.06 Question the added value of the authorisation requirement, stress the risk of double regulation and ask for regulatory coherence.

A.2.10	Requirements under RoHS and ELV mirror substitution objective of REACH authorisation	ECHA acknowledges the need for a consistent regulatory framework and, in the case of lead the need for careful consideration on the interactions/complementarity between actions taken under REACH and under RoHS and ELV. RoHS and ELV as product-specific vertical Union legislation are complementary to horizontal legislations such as REACH. While RoHS and ELV mainly address the placing on the market of certain products (i.e EEE, vehicles) and waste treatment, REACH aims to ensure that the risks presented by substances are adequately controlled throughout their whole life cycle, including those occurring in the production phase. In its Common Understanding Paper on the Interface between REACH and RoHS, ("REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING"), the European Commission highlights that the focuses of REACH and RoHS are complementary. From the document it appears clearly that the requirements set by the RoHS Regulation should be duly considered in the context of Art 58(2) exemption assessment under REACH. The same may be concluded by analogy for the ELV regulation. The extent to which the requirements under RoHS and ELV are mirroring the objective of substitution and risk control of the REACH Authorisation procedure are discussed in this context. Please see response C.2.01 Response to requests for exemptions under Art. 58(2) based on existing legislation Note that the final decision on Art. 58(2) exemptions is taken by the European Commission.
A.2.11	Postpone recommendation considering COM decision to postpone inclusion of other recommended lead compounds in Annex XIV	ECHA's conclusion on the priority of lead is independent from the justification by the European Commission to postpone the inclusion of certain other lead compounds in the Authorisation List (Annex XIV). The Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List). During the decision making, the Commission can take into account additional considerations, e.g. when they affect the process for applications for authorisation or other policy decisions such as the "*possible adoption of more stringent measures at the workplace*" (6th amendment of Annex XIV (2020/171, 6 Feb 2020). The Commission being in charge of the processes of revising workers exposure limit values (BOEL and BLV), IED review and inclusion in Annex XIV, is best placed to define the most appropriate timing and regulatory context for those decisions to be taken.

		ECHA further notes that the recommendation of lead metal may facilitate a more consistent and holistic regulatory approach with other lead compounds already recommended, as all substances will be at the same regulatory stage.
A.2.12	Postpone lead recommendation until after ongoing revisions of Batteries regulation, ELV, RoHS, IED, BOEL/BLV under CAD	When assessing the substances on the Candidate List for their priority for inclusion in Annex XIV, ECHA follows the prescriptions of the current REACH regulation and the principles of the approaches discussed and agreed with MSC. Lead is a reprotoxic substance used in high tonnage. According to REACH Art. 58(3) and the agreed prioritisation approach, it has high priority for inclusion in Annex XIV. The Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List) taking into account ECHA's recommendation. The Commission is also in charge of the on-going process for the revision of the Batteries regulation, ELV, RoHS and IED directives as well as the revision of the workers exposure limits value under CAD. The Commission is therefore best placed to define the most appropriate timing and regulatory context for the decision to include the substance in Annex XIV to be taken. The Commission is enabled to ensure that the next regulatory steps are taken in a complementary manner; the recommendation of lead does not prevent or impede such complementary action. ECHA therefore considers it unwarranted to postpone the lead recommendation.
A.2.13	Postpone inclusion in Annex XIV / withdraw recommendation until REACH revision is complete	When assessing the substances on the Candidate List for their priority for inclusion in Annex XIV, ECHA follows the prescriptions of the current REACH regulation and the principles of the approaches discussed and agreed with MSC. Lead has been added to the Candidate List. It is a reprotoxic substance used in high tonnages. According to REACH Art. 58(3) and the agreed prioritisation approach, it has high priority for inclusion in Annex XIV. Therefore, ECHA considers it unwarranted to postpone the recommendation of lead. In the context of the REACH revision, measures may be taken to address some issues identified with the current functioning of Authorisation and Restriction. The Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List) taking into account ECHA's recommendation. The Commission is also in charge of the on-going process for the revision of the REACH Regulation. The Commission is therefore best placed to define the most appropriate timing and regulatory context for the decision to include the substance in Annex XIV to be taken.

A.2.14	Postpone lead prioritisation and authorisation until definition and entry into force of the 'essential use' criteria	Under the current REACH regulation, essential use criteria are not defined but may play a role in the future. ECHA considers it unwarranted to postpone the recommendation of a substance for Annex XIV on the basis that the criteria may change in the future. Arguments linked to the socio-economic impact of authorisation can be considered by ECHA's committees and the Commission in the context of an AfA.
A.2.15	Excessive number of expected AfA to be considered as reason not to recommend lead	The number of expected AfAs associated to one substance and the related workload for the Agency and its Committees has so far not been considered as reason to not recommend a substance concluded of high priority when applying the agreed prioritisation approach. Rather the information on possible workload is considered to decide on the *number* of substances included in each recommendation and on the later application date slots and sunset dates for the individual substances. According to Article 58(3) and Recital (77) of REACH, the number of substances included in each recommendation needs to reflect the capacity of ECHA and the Commission to handle applications in the time provided for and also consider the workability and practicality for applicants preparing their applications for authorisation. Building on past experience and based on information provided by industry actors during the consultation, ECHA has concerns regarding the possible workload the inclusion of lead in Annex XIV would generate for ECHA and its Committees as well as Commission. The workload associated to applications for authorisation for lead might impact the recommendation/inclusion of other substances in Annex XIV in future recommendation rounds. The workload associated to the inclusion of lead in Annex XIV partly depends on the final decision from Commission on uses warranting exemption under Art. 58(2), as well as on the decision and capacity of industry actors to apply for authorisation and on their way to get organised for applying (e.g. jointly or individually). Before including the substance on Annex XIV and once having clarified the possibility for exempting some uses from the authorisation requirement, ECHA suggests the Commission and Member States to consider whether/how additional regulatory risk management measures could be used together with the authorisation requirement in a way to most effectively address the risk of lead and provide the incentive for substitution. On the possibility for ECHA to consider alternative regulatory action than authorisation (e.g. targeted restriction) during the recommendation phase of the authorisation process, please refer to: A.2.16 Targeted restriction more appropriate regulatory risk management action than authorisation.

A.2.16	Targeted restriction more appropriate regulatory risk management action than authorisation	Any suggestion to address the concern raised by the substance via e.g. restriction of certain uses are beyond the remit of ECHA in the recommendation process. The restrictions process is to be initiated by a Member State, or by the European Commission (who will then request ECHA to proceed). ECHA can only initiate restrictions process under the conditions specified in Art. 69(2) (i.e. to address risk from imported articles for substances already included in Annex XIV). Note that all ongoing and intended restrictions of lead as communicated by MSs or Commission and their impact on the priority of the substance have been considered in the prioritisation exercise. See response A.2.02 Questioning the volume score. Based on uses and tonnage remaining in the scope of authorisation, lead has been concluded as high priority for inclusion in Annex XIV. Please also refer to the response for: A.2.15 Excessive number of expected AfA to be considered as reason not to recommend lead.
A.2.17	Main lead emissions result nowadays from uses outside scope of authorisation / drastic decrease of lead emissions over the last decades	ECHA notes the comments received pointing to the fact that the majority of current lead emissions in the EU nowadays results from activities which are not in scope of REACH Authorisation. Addressing such sources of lead emissions is outside the remit of ECHA in this process. ECHA strives to ensure that REACH objectives are met. According to Article 55, the aim of the Authorisation process is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled, and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. The potential for exposure and releases associated to a number of uses of lead and/or certain steps of the life cycle of the substance appears to have decreased over the last decades (This being reflected in some monitoring data e.g. E-PRTR). However, at the same time there are also uses/steps, where control of risks may not be obvious, and where the proper implementation of Risk Management Measures (RMM) is essential. The Authorisation Title under REACH is a regulatory tool that ensures risk control and provides an incentive for substitution in a proportionate manner.

		On one hand, where it can be concluded that existing Community legislation provides a sufficient framework for proper risk control for given uses, the Authorisation title foresees the possibility for exemption from the Authorisation requirement (REACH Article 58(2)). The IED and its provision as well as other key EU legislation dealing with e.g. ambient air, water, drinking water, waste, and food can be considered in this context. On the other hand, where exemptions do not apply, Authorisation does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses.
A.2.18	Essential role of lead metal for Green Deal and circular economy	We acknowledge the comments highlighting the societal and economic importance of lead and the difficulties to substitute it in a number of uses. This said, the substance is reprotoxic. Hence, in accordance with REACH there is a need to protect humans and the environment from risks arising from its uses and promote substitution. The Authorisation requirement is a regulatory tool that can take into account these conflicting areas. It does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits are outweighing the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives. Please also refer to the response for: A.1.5 Aspects not considered in ECHA's prioritisation A.1.5.2 Authorisation is disproportionate and/or means a ban A.1.5.4 Control of risks A.1.5.5 Availability of suitable alternatives A.1.5.6 Socio-economic benefits of continued use.
A.2.19	Authorisation requirement inappropriate and might violate the	Although the substance is considered a strategically important raw material, it is also toxic for reproduction. Hence there is as well a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses.

	EU proportionality principle	Therefore, ECHA is of the opinion that the recommendation of lead for inclusion in Annex is proportionate. Please also refer to the response for: A.1.5 Aspects not considered in ECHA's prioritisation A.1.5.2 Authorisation is disproportionate and/or means a ban A.1.5.4 Control of risks A.1.5.5 Availability of suitable alternatives A.1.5.6 Socio-economic benefits of continued use C.1.1 General principles for exemptions under Art. 58(2) C.2.01. Response to requests for exemptions under Art. 58(2) based on existing legislation.
A.2.20	NGO highlighting toxicity of lead sheets in building	The authorisation process aims to progressively replace all substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible, thereby reducing the overall risk arising from the use in question. Until substitution is achieved, the authorisation process aims to ensure proper control of risks. Would lead be added on the Authorisation List, the use of the substance (on its own or in mixture) will not be allowed anymore after the sunset date, unless the use would be exempt from the authorisation requirement, or an authorisation would be granted. Whether or not there are suitable alternatives available would need to be documented by authorisation applicants and would be considered during the decision making. When assessing whether suitable alternatives are available, the Committees and the Commission take into account whether the transfer to alternatives would result in reduced overall risk and consider the technical and economic feasibility of the alternatives. The above described authorisation requirement may address the concerns expressed in your comment with regards to the risk caused by the use of lead in construction applications and the current insufficient incentive towards substitution.
A.2.21	Borderline between mixtures and articles (Alloys)	Authorisation is required for the use of a substance included in Annex XIV of REACH, either on its own or in a mixture. An AfA is not required for the use of articles. The risks from the use of the articles need however normally to be covered in the AfA of the use leading to the incorporation of the substance into the article.

		To ensure that the relevant actor applies for authorisation, it is therefore important to identify where within the supply chain, the transition from substance/mixture to article takes place. ECHA guidance on SiA[4] includes criteria to support decision on borderline cases between substance/mixture and articles and includes example for the metal sector/alloys. The different uses of lead (as such, in mixture and in articles) should already be described in registration dossiers. ECHA therefore also advises industry actors to consult registrations, and sector-specific guidance that may have been developed by industry associations in this context. On request, ECHA will also provide further support to (groups of) potential applicants.
A.2.22	Clarification on Authorisation requirement for handling finished articles or historic artefacts	When assessing the impact of the authorisation requirement specific attention needs to be given to the scope of such requirement. Authorisation is required for the use of a substance included in Annex XIV of REACH, either **on its own or in a mixture**. The simple handling / transport / storage or placing on the market of **existing articles** (e.g. as can be found in museum or archaeological sites) which contain the Annex XIV substance is not subject to the authorisation requirement. The authorisation requirement applies to the use of lead **on its own or in a mixture** e.g. to produce articles, to coat them or to treat them (as might be the case e.g. during maintenance / restoration activities).
A.2.23	Authorisation requirement for production of spare parts and repair of existing articles	Please note that it is possible to submit a simplified AfA for the following uses of substances included in the Authorisation List (Annex XIV): - to produce spare parts to repair articles or complex products that are no longer produced by the sunset date indicated in the Authorisation List and for which the substance was used in their production; and - to repair articles or complex products that are no longer produced by the sunset date indicated in the Authorisation List and for which the substance was used in their production. For further information please consult the ECHA webpage on Simplified applications for authorisation for legacy spare parts - ECHA (europa.eu).
A.2.24	Applicability of the authorisation requirement for	Some information regarding the applicability of the authorisation requirement for recycling/recovered materials is given below. The principles presented below apply to alloys.

	recycling or recovered materials	Recycling is not considered as 'use' of a substance but as a manufacturing process under REACH[13]. The manufacture of a substance is not subject to the authorisation requirement. Therefore, recycling is not subject to authorisation. After a substance has been manufactured it may have to be handled before it is exported or placed on the EU market. Operations which are necessary for the handling of the substance on its own in the manufacturing for export or placing on the EU market are considered to be part of the manufacturing stage (e.g. filling into appropriate containers, storage, addition of stabiliser, dilution to a safer concentration -if necessary for transport safety). The other uses such as the formulation in a mixture or the incorporation of the substance into articles are however not considered to be part of the manufacturing process. Such formulation of a mixture or incorporation of the substance into articles are considered "uses" within the meaning of Title VII of REACH and are subject to the authorisation requirement whether or not the mixture or articles will be exported or placed on the EU market. Consequently, either the recycler himself, as manufacturer of the substance, or its immediate downstream user(s) need to apply for an authorisation covering the relevant uses of the recovered substances in the supply chain (unless the use of the recovered substance is specifically exempted otherwise). See ECHA Q&A's on authorisation In particular: • Is the manufacture of a substance, whether for export or placing on the EU market, subject to the authorisation requirement? (ID1031) • Are uses of recovered substances exempted from the authorisation requirement? (ID 0566)
A.2.25	Upfront clarification needed on authorisation requirement for alloys as special mixtures	Under the REACH Regulation alloys are referred to as "special mixtures" (Recital (31), Annex I (0.11.), as amended by Regulation (EC) No 1272/2008). However, for registration purposes, an alloy is to be treated in the same way as other mixtures, which means that the alloy as such is not subject to registration but the alloying elements (e.g. metals), irrespectively of the production process of the alloy are (See Q&A on registration). Under the CLP regulation, alloys are not considered as "special mixtures". For the purposes of classification for toxicity to reproduction (i.e. hazard justifying the inclusion of lead in the Candidate list), the normal rules for mixture classification apply. The hazardous component of the alloy has to be

[13] See ECHA's guidance on waste and recovered substances at https://echa.europa.eu/documents/10162/2324906/waste_recovered_en.pdf/657a2803-710c-472b-8922-f5c94642f836

		notified if it is contained in the alloy above generic or specific concentration limits i.e. 0.3% for sizes over 1 mm and 0.03% for particle sized below 1 mm for lead and the alloy needs to be classified according to the mixture rules. (see Q&A 190 at Q&As - ECHA (europa.eu)). It should be noted that additivity rules may apply when several components have same hazard via similar mechanism or Mode of Action. However, for labelling, there may be some exemptions as outlined in ECHA Q&A above. CLP art 12(b, c) may also apply. By analogy with the Registration requirement under REACH and the CLP requirement, ECHA concludes that the Authorisation requirement would apply to the use of alloys containing lead, to the extent lead is present in the alloy above the specific concentration limit of 0.3% for sizes over 1 mm and 0.03% for particle sized below 1 mm. The exemption from the authorisation requirement mentioned in Article 56(6) would apply where lead in the alloy is present below the classification concentration limits of 0.3% for sizes over 1 mm and 0.03% for particle sized below 1 mm. ECHA notes that it is the responsibility of companies to assess which concentration limit applies to their uses and whether their use is in the scope of authorisation.
A.2.26	Perception that other lead compounds would be affected by the inclusion of lead metal (EC 231-100-4) in Annex XIV	When considering the requirement to apply for authorisation, specific attention need to be given to substance identity. The requirement to apply for authorisation applies to the use of the substance as identified in the Annex XIV entries and further described in the SVHC support document In this case, the substance proposed for inclusion in Annex XIV is Lead identified by EC number 231-100-4 (See support document at: https://echa.europa.eu/documents/10162/07a87920-1b8f-b0d9-b6a7-1c0b1c16c8c4). Other lead compounds (e.g. lead silicates or lead pigments) will not require authorisation for continuing their uses provided that they are not in Annex XIV.
A.2.27	Impact of authorisation requirements on actors located in the UK	ECHA notes several references in your comments to the United Kingdom and therefore provides below some clarifications on applicability of the authorisation requirement for actors located in UK. Since 1 February 2020, the United Kingdom has withdrawn from the EU and the transition period ended on 31 December 2020. REACH no longer applies to the United Kingdom and therefore United Kingdom-based actors are no longer bound by the authorisation obligations, except for Northern Ireland (see Q&A 1371). Such actors that use an Annex XIV substance or place it on the United Kingdom market for a use no longer need to apply for authorisation. If they place an Annex XIV substance for a use on the EU/EEA market they will need to rely on their EU/EEA importer or an OR to apply for authorisation for this use.

		See Q&A 1420 (Q&As - ECHA (europa.eu)), and Q&A 1421 (Q&As - ECHA (europa.eu)), Please also refer to How is the UK withdrawal affecting you? - ECHA (europa.eu).
A.2.28	Administrative and financial burden of the AfA requirement for small actors / SMEs	ECHA takes note of the concerns raised in relation to the administrative and financial burden of the Authorisation requirement for small actors/SMEs. Generally, such information is better placed in the call for information by the Commission on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List. Such call was performed in parallel to ECHA's consultation on the Annex XIV recommendation (How to participate in the parallel call for information by the European Commission - ECHA (europa.eu)). ECHA wants to stress 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 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. From these specifications 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. If the authorisation is granted to the upstream actor, the SME downstream user companies do not need to apply for authorisation. Instead, they need to notify ECHA free of charge about their use and ensure that they comply with the conditions of the granted authorisation. ECHA further stresses that it is also possible to submit joint applications by a group of actors.
A.2.29	Questioning the priority of lead, as it has the lowest intrinsic property score	At this step of the process ECHA's task is to assess the priority of the substances based on the approach discussed with and agreed by the MSC. The priority of each Candidate List substances is concluded considering the three prioritisation criteria (intrinsic properties, wide-dispersive use and volume) together. The fact that a substance receives the lowest score among the possible scores for one of the criteria (in this case the intrinsic properties) is not considered as a valid reason to not recommend the substance. The legal text (REACH Art. 58(3)) indicates that priority shall "normally" be given to substances with (a) PBT / vPvB properties or (b) wide dispersive use or (c) high volumes. By indicating that these criteria are alternative grounds (use of the word "or") for prioritisation the legal text does not prevent substances with other hazard properties than PBT and vPvB to be prioritised for inclusion in Annex XIV.

A.2.30	Prioritisation approach prejudices high-density materials	High volumes is one of the three prioritisation criteria set out in Article 58(3). As further outlined in section A.1.1.3, ECHA applies for its prioritisation exercise the approach discussed and agreed with the Member State Committee. As outlined in this approach, ECHA takes as the basis for assessing the volume criteria, the annual volume used falling within the scope of authorisation. The volume falling within the scope of authorisation is expressed in tonnes per year (t/y). The REACH registration requirements under the REACH Regulation are determined on a tonnage-based approach irrespective of the specific properties of the registered substances. The agreed prioritisation approach for inclusion in Annex XIV uses the same approach to refer to volumes, independent of the specific properties of the registered substance.
A.2.31	The role of SCIP in reducing the amount of lead in articles should be considered	SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (2008/98/EC). The aim of the SCIP database is to - Ensure that the information about SVHCs is available throughout the whole life cycle of products - Encourage substitution of these hazardous substances by safer alternatives - Contribute to a better circular economy by helping waste operators ensure that such hazardous substances are not present in recycled materials. See: https://echa.europa.eu/scip-database SCIP contributes to the same objective as the authorisation requirement (protection of human health and the environment), however it does not replace the authorisation requirement. The focus of SCIP is on information in the value chains. However, the reason for making a substance subject to the authorisation requirement under REACH is not to close a current information gap. It is rather aimed to control the uses of a substance of very high concern. Unlike authorisation SCIP does not impose any conditions for the proper control of the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance. SCIP does not define minimum standards to be adopted in the interest of public health or the environment. ECHA therefore considers it unwarranted to postpone the lead recommendation based on the availability of information in the SCIP database.

A.2.32	Difficulties to meet normative requirements under Ecolabel and/or other standards if lead is included in Annex XIV	ECHA is of the opinion that it would be inappropriate to not recommend lead for inclusion in Annex XIV on the basis that this inclusion may make it difficult for companies to meet certain normative standards (e.g. Ecolabel standards, company standards or other national or international standards). The authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible, thereby reducing the overall risk arising from the use in question. There is a strong societal interest to protect humans and the environment from risks potentially arising from the uses of SVHCs like lead. It is the understanding of ECHA that the normative requirements set for SVHCs or Annex XIV substances under Ecolabel or other standards are complementary to the authorisation requirement.
A.2.33	Background document does not reflect sufficiently the available information on certain uses	To decide on the priority of the substance for inclusion in Annex XIV and conclude on the Annex XIV entry (LADs, SSDs, exemptions) ECHA assessed information on uses including from REACH registrations, documentation prepared in the context of SVHC and Restriction processes, including comments received during consultations. When drafting the background document, ECHA does however not intend to present a detailed and exhaustive list of all uses identified during its assessment. ECHA intends rather to present in a concise and understandable way the information justifying its decision. The granularity of the information on uses presented in the background document is in line with the granularity of the factors considered at this stage of the process. Information provided during the consultation has been taken into account and has been reflected in the updated background document, where relevant.
A.2.34	Process of commenting not democratic, as too complex	The consultation on ECHA's draft recommendations are held in line with the Authorisation process according to title VII of REACH and the public procedure describing the process of Prioritisation and Annex XIV recommendation (europa.eu). According to REACH Art. 58(4) "The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement". During the consultation process, ECHA is also seeking comments on its assessment of the uses and volume falling in the scope of authorisation. From the above it can be concluded that the consultation is mainly aimed for users of the substance, who should have good understanding of the substance and its uses and are concerned by REACH. To facilitate the commenting process for actors less familiar with the process ECHA provides all the relevant documentation supporting its decision to include the substance in the draft recommendation as

		well as information on how to participate in the consultation on one central webpage available here: Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu)
A.2.35	Comment on Annex XV restriction dossier	ECHA notes that parts of your comment relate to specific parts of the Annex XV restriction dossier prepared by ECHA in the context of the restriction proposal on the 'Placing on the market and use of lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities' (Submitted restrictions under consideration - ECHA (europa.eu)). The consultation period on the Annex XV report run from 24.03.2021 to 24.09.2021. Comments submitted during that consultation have been considered and replied by ECHA as Dossier submitter under the Restriction process. The information provided in your comment in the present consultation will be considered in the context of the Authorisation process. The consultation period on the Restriction proposal is over. Note that when assessing lead for the purpose of concluding on its priority for Authorisation and preparing the draft and final background documents, ECHA has taken into account relevant information from the Restriction process (including information from comments submitted during the Restriction consultations). Please also refer to the response for: A.2.01 Questioning the way other Regulatory Risk management activities have been considered when prioritising the substance.
A.2.36	Attached COM questionnaire	We note that you have submitted a filled-in questionnaire on "socio-economic consequences of including the substance in the Authorisation List" as part of your comment. This questionnaire relates to the call for information by the Commission, which is parallel but different from ECHA's public consultation on the recommendation. Therefore, your questionnaire has been passed to the Commission. Further information on the "call for information by the Commission" can be found here: How to participate in the parallel call for information by the European Commission - ECHA (europa.eu).

B. Dates

B.1. Process information

B.1.1. General principles for setting latest application dates[14] / sunset dates[15]

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"[2] describes how ECHA implements the above mentioned legal requirements in practice.

2.ECHA's proposal for sunset dates

On the basis of the information available in the registration dossiers and submitted during 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.

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[14] The latest application date is the latest date by which applications for authorisation must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date.

[15] The sunset date is the date from which the placing on the market and the use of that substance shall be prohibited unless an exemption applies, or an authorisation is granted, or an authorisation application has been submitted before the latest application date specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.

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 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.

[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.

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

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

The time differences between the LADs set out in a recommendation are relatively short, typically ranging from 3 to 6 months, compared to the total time reserved for the potential applicants to prepare their applications. ECHA proposes to allocate those substances to the "later" LAD slots for which the available information indicates a relatively high number of uses and/or complex supply chain(s). Furthermore, substances with no registration requirement are allocated to the later slots. ECHA has developed a practical implementation method to support a more consistent and transparent assessment of these criteria[2].

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 straightforward exercise, and so would also the socio-economic analysis which would imply a relatively short LAD. However, ECHA does not normally have such information when preparing the recommendation as this becomes available only at the application stage. Thus, ECHA does not intend to use this as a criterion to shorten the LADs.

Socio-economic or practical considerations are no relevant reasons for prolonging or advancing the latest application dates or sunset dates as these considerations are normally use and sector or even case specific and difficult to take into account in the recommendation phase which considers all uses of the substance. Furthermore, such information would be very difficult to get at the prioritisation stage in a systematic manner. Therefore, they are considered at the next phase of the authorisation process (application for authorisation and granting phase).

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

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

B.1.3. Review periods

1.Upfront review periods

Setting 'upfront' review periods for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. So far, such information was not available to ECHA at the recommendation step. Therefore, ECHA has not proposed any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation. ECHA has published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[17].

[17] SEAC's approach for establishing the length of the review period and RAC's and SEAC's guidance paper on opinion trees for non-threshold substances (both available at Evaluating applications - ECHA (europa.eu))

B.2 Further responses relevant for the substance

Reference code	Issue title	Draft response
B.2.01	Request extra long LAD	In its draft recommendation, ECHA suggested the latest application dates (LAD) of the substances included in the 11th draft recommendation 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 consultation. Having assessed all information received during the consultation, and based on information currently available, ECHA considers that there may be ground for deviating from the standard LAD slots mentioned above for lead. An LAD of at least 36 months is proposed. The anticipated workload associated to lead justifies to not include it in the same slot as any other substance recommended in this round. Furthermore, a number of elements indicates that actors in the supply chain may require more time to prepare applications for authorisation than in standard cases. Indeed, the complexity of the supply chain assessed based on the number of different uses, affected industry sectors, the number of layers in the supply chain, and the number and type of companies concerned (including SMEs), is concluded to be very high. ECHA has developed a practical implementation method to support a consistent and transparent assessment of these criteria. https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf/533e3d4a-b1d2-b024-c724-64715c2f6e8a?t=1643710494447 Lead received a high score compared to other substances assessed so far (see also the lead background document[2] for summary information on the structure and complexity of the supply chain). Both horizontal and vertical complexity of the lead supply chain are high. A high number of industry sectors rely on lead (>10 Sectors of uses (SUs) identified). Lead seems to be essential to a wide variety of products (> 10 Product Categories (PCs) identified). Uses of lead are also relevant for a number of

		articles (5-10 Article Categories (ACs) identified) representing a very wide range of applications. The supply chain seems to be also of high vertical complexity, including formulators, users at industrial sites, professional workers, articles producers, articles assemblers (e.g complex articles manufacturers), as well as recyclers. While in some applications, the number of (industrial) sites seem to be rather limited, for other applications a very high number of actors, are involved. Overall, the number of industrial sites where the substance is used is concluded to be significantly above 100, which is the threshold used to characterised very complex supply chain in the practical implementation document. This has been confirmed by information provided during the consultation. ILA-PbRc (International Lead Association, and Lead REACH Consortium) indicated having carried out a survey of downstream users of lead. 273 responses were received from organisations representing a total of more than 27,000 legal entities, including 25 responses from EU associations representing in total more than 16,600 entities, and 219 responses from EU companies representing more than 4,850 entities in total. Furthermore, ECHA considers that some more time might be needed in the AfA preparation phase to clarify specific questions inherent to lead or the metal supply chains (e.g. borderline between mixtures and articles impacting decision on the actors that need to apply for authorisation; clarification of the scope of the authorisation requirements for uses (partly) covered under other legislation). The above elements related to the time and effort needed for industry to get organised and manage good quality AfAs appears to justify a LAD of at least 36 months (i.e. giving more time as was considered earlier for chromates). As outlined in Art. 58(3) of REACH, when setting LADs, ECHA also needs to consider the Agency's capacity to handle applications in the time provided for. At this stage of the process ECHA can not foresee if the European Commission would exempt some uses of lead from the authorisation requirement based on Art. 58(2) of REACH, reducing the expected number of AfAs. However, ECHA concludes that for some uses covered by existing legislation there is a stronger ground for exemption considering the existing measures for risk controlled addressing some of the life cycle stages and routes of exposure, and considering the existing review mechanism in place for continuing the uses (see response C.2.01). In case such uses (i.e uses that are within the scope of the RoHS Directive, ELV Directive, and Drinking Water Directive, (including upstream uses)) would not be exempt from the Authorisation requirement under Art 58(2), the Commission may contemplate the possibility/added value of defining additional longer LAD(s) and Sunset dates(s) for such uses, with the aim to spread the workload for ECHA, its Committees and Commission when dealing with AfAs, and to facilitate regulatory coherence of

		decisions taken under those specific legislative frameworks and REACH. Such uses might be considered of lower priority for authorisation requirement than other uses of lead considering that some life-cycle stages / routes of exposure are already addressed through existing legislation and considering the existing review mechanism in place for continuing these uses. The sunset date(s) would need to be aligned with the corresponding LAD(s). Please also refer to the response for: A.2.15 Excessive number of expected AfA to be considered as reason not to recommend lead B.2.04 Require longer time between LAD and SSD (e.g. minimum 30 months) considering the considerable number of AfA to be expected and ECHA's capacities.
B.2.02	Difficulty/time needed to prepare joined AfAs and uncertainty whether authorisation will be granted	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 (or any combination thereof). They may be made for one or several uses and they 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). A supplier (manufacturer, importer or downstream user) may cover in his application use(s) of his downstream users. Furthermore, it is possible to submit joint applications by a group of actors. The critical aspect for the applicants (being part of joint, upstream or downstream applications) is to collect all information and arguments related to their specific circumstances and present them in the application. To get the required application(s) ready in time is a matter of communication, organisation and agreement between the relevant actors in the supply chain and efficient allocation of work. In certain circumstances, a joint application for authorisation (AfA) might be beneficial. In other circumstances joining forces when preparing certain parts of the application while still submitting individually may be appropriate. Support in deciding on the best way forward has been provided by ECHA and several industry associations (e.g. All Events - ECHA (europa.eu)). Furthermore, in the meantime, experience has been gained on the AfA process. As several hundred opinions have already been given by RAC and SEAC, future applicants have increasing number of references to help them prepare a fit-for-purpose application.

		ECHA and its committees aim at high efficiency and transparency of the process, by facilitating the work of the applicants, providing extensive support, e.g. in form of guidance (How to apply for authorisation – ECHA (europa.eu)) or Q&As – ECHA (europa.eu), or by a high transparency of the process (Authorisation – ECHA (europa.eu)). Additionally, ECHA offers a Teleconference based Information Session (TIS) (Notify ECHA and request a teleconference based information session – ECHA (europa.eu)), where applicants can ask specific questions when preparing their (joint) application. Overall, both the clarity with regards to information to be present in the applications and predictability of the process is continuously improving. ECHA normally makes its proposals for the LADs 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). Still, in the particular case of lead, considering the very high complexity of the supply chain together with further specific arguments, ECHA suggests to set a LAD of at least 36 months which gives additional time to get organised in the supply chains and prepare a solid AfA. Please also refer to the response for: A.2.15 Excessive number of expected AfA to be considered as reason not to recommend lead.
B.2.03	Joined AfAs result in shorter review periods	The decision on the length of the review period is taken by the Commission in the AfA phase of the authorisation process, on the basis of the RAC and SEAC Committees opinions. The current approach of ECHA's Committees is to recommend to the Commission review periods of four, seven or twelve years. RAC and SEAC have agreed on a general approach to determine the length of the review period: SEAC-20 AP 06.2 Setting the review period – adopted on 13 September 2013 For uploading (europa.eu). The applicants in their applications should provide all information and arguments related to their specific circumstances which are relevant for setting the length of the review period. This information is taken into account by the committees and the Commission. The same approach for setting review periods is applied by ECHA's Committees for joint and individual applications for authorisations. Therefore, where the level of information is adequate, same review periods for joined applications than for individual applications will be granted.

		Authorisation holders can submit a review report 18 months before the end the review period so that the authorised use could be prolonged.
B.2.04	Require longer time between LAD and SSD (e.g. minimum 30 months) considering the considerable number of AfA to be expected and ECHA's capacities	ECHA reminds that an applicant and its downstream users do not have to cease the use of the substance for the use applied for by the sunset date, if an application for the use was submitted before the substance's LAD. In this case, applicant can continue using the substance after its sunset date, until the date of adoption of the European Commission's decision. (See Q&A 1358). Therefore, in case the expected excessive workload would delay the ECHA process, the opinion making or the decision by the European Commission, this would not have an impact on the continued use of the substance. In conclusion, ECHA does not see a reason to deviate from the approach of setting the SSD to 18 months after the LAD on the basis of workload arguments. Please also refer to the response for: B.1.1.1 Legal background B.1.1.2 ECHA's proposal for sunset dates In relation to the anticipated workload of including the substance in Annex XIV, please refer also to the responses A.2.15 Excessive number of expected AfA to be considered as reason not to recommend lead B.2.01 Request extra long LAD.
B.2.05	Due to REACH review more time needed to prepare AfA	ECHA makes its recommendation on the basis of the current REACH regulation and agreed approaches. The outcome of the REACH revision process and whether it will result in changes in the information expected to be submitted in an AfA cannot be predicted and therefore is not a relevant consideration. In any event, any revision of REACH will most likely contain transitional provisions allowing relevant stakeholders to adapt to any changes made. ECHA therefore considers it unwarranted to suggest a longer LAD on the basis of the REACH revision argument.

		Please also refer to the response for: A.2.13 Postpone inclusion in Annex XIV / withdraw recommendation until REACH revision is complete.
B.2.06	Align LAD/Sunset date with DWD timelines for lead	Please refer to the response B.2.01 (Request extra long LAD) for ECHA's view on LADs - including LAD for uses covered by the Drinking Water Directive. As outlined in response A.2.06, the Commission is tasked with the final decision to include substances in Annex XIV (Authorisation List) taking into account ECHA's recommendation. The Commission is also in charge of the Drinking Water Directive. The Commission is therefore enabled to ensure that the next regulatory steps are taken in a coherent and complementary manner, including for aspects related to the timing of the actions under the different regulatory frameworks.
B.2.07	Phasing of LAD and sunset dates (SSD) for complex objects supply chains	ECHA normally makes its proposals for the LADs 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). Still, in the particular case of lead, considering the very high complexity of the supply chain, ECHA suggests an LAD of at least 36 months which gives additional time to get organised in the supply chains and prepare a solid AfA. The high complexity of supply chains is taken into account by ECHA to propose longer LADs and Sunset dates for lead, i.e. giving more time to all actors to get organised, not only to specific actors (e.g. for very complex object manufacturers), as suggested in some comments. ECHA does not have the information to suggest a meaningful phasing of LADs/SSDs in this regard and does not want to pre-define a way by which actors in given supply chains should organise their applications for authorisation. Please also refer to the response for: See response B.2.01 Request extra long LAD.

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[3].
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 and/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 cannot grant an exemption on the basis of Article 58(2) of REACH in respect of the substance listed in Annex XIV of REACH; thus national legislation or non-binding EU acts addressing such use is not a sufficient ground for the Commission to grant such an exemption;

(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 REACH regardless of the outcome of risk assessment.

In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[18] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[2]):

- 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 is too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements which properly control the 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) of REACH. 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.

[18] 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*.

C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at Consultation on draft recommendation for inclusion in the Authorisation List - ECHA (europa.eu). 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[4].

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[3]. Furthermore, uses can be exempted from the authorisation requirement on the basis of Art 58(2) which depends on the provisions of existing EU legislation (See section C.1.1. General principles for exemptions under Art. 58(2)).

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

C.2 Further responses relevant for the substance

C.2.01. Response to requests for exemptions under Art. 58(2) based on existing legislation

Requests for Article 58(2) exemptions for various uses of lead have been received by ECHA, including[19] for uses in batteries; applications exempt under RoHS or ELV exemptions; alloys in contact with drinking water; alloys in solder; alloys in keys and locks; alloys in other

[19] The list presented is not fully exhaustive.

sectors; metal industry (general); semiconductor industry; complex machineries; aerospace industry; new and recent vehicles; spare parts for vehicles, electronics and machinery; historic vehicles; radiation shielding in medical devices; radiation shielding (others); electronic medical devices; cable sheathing; steel wires; military ammunition; other military uses; hunting; shooting; stained glass art; maintenance of art heritage/historical buildings; historic artefacts; archaeological investigations; other uses in construction sector; musical instruments; letter printing; jewellery and watchmaking exempted from restriction; analysis of fineness of gold; extraction medium in recycling and metallurgical processes.

Many of the requests refer to the extensive body of legislation relevant to lead and its compounds. ECHA provides an assessment of these requests taking into account the relevant *existing* EU legislation below. Not yet adopted legislation are not considered in this assessment, as those do not qualify as *existing* legislation according to Art. 58(2) of REACH.

The assessment considers all existing legislation below individually and as a whole.

In assessing Art 58(2) exemption requests for a particular use of a substance it is important to assess whether existing EU legislation imposes minimum requirements to properly control risks to human health via all relevant exposure routes and at all life-cycle stages of that particular use. When assessing individual legislation, attention is therefore given to the use, life cycle stage and route of exposure specifically covered.

While lead and its compounds are of concern both for human health and the environment, lead metal has been included in the Candidate List due to its toxicity to reproduction which is a concern for human health. Consequently, lead can only be included in Annex XIV for this property. In this respect, to cover potential risks of the substance arising from toxicity to reproduction, risks not only for workers dealing directly with the substance need to be considered but also risks for consumers/workers using articles/products containing the substance or risks for humans via the environment.

Occupational health legislation

Summary: ECHA notes that, given the binding occupational exposure limit set out for inorganic lead and its compounds and given the binding biological limit value set out for lead and its ionic compounds under Directive 98/24/EC and amended Directive 2004/37/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 lead when 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.

Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work (**OSH** '**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 (BOEL) for inorganic lead and its compounds and a biological limit value (BLV) 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 the substance. It is noted that in the context of the REACH recommendation process ECHA does not take a position on 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. ECHA notes however that a review of the currently applicable BOEL and BLV for lead and lead compounds is ongoing, following a Commission request from 26 March 2019.

ECHA's Risk Assessment Committee gave its opinion on the scientific relevance of the BOEL and BLV on 11/06/2020[20]. The ongoing process under CAD may lead to an update of the current limit values.

The Carcinogens, mutagens or reprotoxic substances at work Directive 2004/37/EC (**CMD**), as amended by Directive (EU) 2022/431 introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure. The overriding principle is that the employer shall reduce the use of a carcinogen or mutagen (CM) at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its condition of use, is not dangerous or is less dangerous to workers' health and safety. Where substitution is not possible, CMs should be used in closed systems, where technically possible. Furthermore, a hierarchy of measures shall be applied when a CM is used. With the 2022 amendment, reprotoxic substances were added to the scope of the directive and BOEL and BLV of lead included in its annexes, therefore further strengthening the requirements for controlling the risks to workers at the formulation/use life cycle stages of lead.

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

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

[20] For further details on this process, please refer to: https://echa.europa.eu/oels-activity-list/-/substance-rev/41206/term.

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.

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

Directive 2009/71/Euratom (as amended by Directive 2014/87/Euratom) establishes an EU framework for the **nuclear safety of nuclear installations.** This Directive applies to all civilian nuclear installations. These installations are subject to a licence under the national framework. The national frameworks should also include nuclear safety supervision, enforcement actions and the adoption of national nuclear safety requirements. Council Directive 2013/59/EURATOM lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation. It aims at protecting the health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation. Both directives apply to the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Union of radioactive material incorporating radioactive substances.

These Directives do not impose minimum requirements for the control of risks to human health for the use of non-radioactive substances. Moreover, these Directives do not specifically concern the use of lead. Therefore, these Directives do not appear to be a sufficient justification for exemption of lead under Article 58(2) REACH (e.g. for uses in radiation shielding or other uses in nuclear installations).

Product related legislation

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

ECHA further notes that the following uses in products are generically exempt from the authorisation requirement and therefore are not considered relevant for additional exemption under Art 58(2): uses within the scope of Directive 98/70/EC on ***fuel quality****, uses within the scope of Regulation (EC) No 178/2002* ***on food and feedingstuffs***[21]*. Furthermore, in the case of substances added to Annex XIV only because of hazards to human health, the following uses are not subject to authorisation: uses within the scope of Directive 76/768/EC (replaced by Regulation (EC) No 1223/2009) on* ***cosmetics****, uses covered by Regulation (EC) No 1935/2004 on* ***food contact materials,*** *uses within the scope of Directives 90/385/EEC (replaced by regulation 2017/745), 93/42/EEC (replaced by Regulation 2017/745) or 98/79/EC (replaced by Regulation 2017/746) on* ***medical devices****. It is therefore not considered relevant to suggest Art 58(2) exemptions for those uses in the case of lead.*

Directive 2001/95/EC (as amended) on **general product safety** requires firms to ensure that items sold to consumers are safe and to take corrective action when that is found not to be the case. It introduces an EU rapid alert system for dangerous non-food products sold to consumers. This enables national authorities to share information promptly on any measures taken to withdraw such products from sale. This directive however does not impose minimum requirements for the control of risks to human health specifically concerning the use of lead nor in fact of any other chemical substance. Therefore, this Directive cannot be a ground for exempting uses of lead under Article 58(2) REACH.

[21] including uses as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC of 21 December 1988; uses as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988; uses as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; uses in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition

Regulation (EU) No 305/2011 on marketing of **construction products** lays down uniform rules for the marketing of these products and providing a common technical language to assess the performance of construction products. It ensures that reliable information is available to professionals, public authorities, and consumers, so they can compare the performance of products from different manufacturers in different countries. This regulation however does not impose minimum requirements for the control of risks to human health specifically concerning the use of lead nor in fact of any other chemical substance. Therefore, this Regulation cannot be a ground for exempting uses of lead under Article 58(2) REACH.

EU Directive 2004/42 known as the '**Paints** Directive' aims to limit the total content of volatile organic compounds (VOCs) due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products. The directive complements Regulation (EC) No 1272/2008 on the labelling of chemical substances and preparations and places the responsibility on EU countries to ensure that the products concerned are on sale only when they have a VOC content which does not exceed the limits set out in Annex II of the directive. This Directive however does not impose minimum requirements for the control of risks to human health specifically concerning the use of lead. Therefore, this Directive cannot be a ground for exempting uses of lead under Article 58(2) REACH.

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

Neither the Civil Explosives Directive nor the Track and Trace Directive appear to provide for a procedure for the identification of substances contained in the products regulated. The substances regulated are those which manufacturers and importers of explosives for civil uses have identified as having the physico-chemical properties required for such products and do not address the human health- related intrinsic properties of these substances. For this reason, the substances for which the essential requirements set out in the Directives apply seem not to be specified in a way that would allow these Directives to be used as basis for granting an exemption of this use under Article 58(2) REACH.

Directive 69/493/EEC on **crystal glass** lays down rules for the required content of lead oxide in different categories of crystal glass. However, this directive does not appear to impose minimum requirements relating to the protection of human health on the use of lead in crystal glass.

Directive 2009/48/EC on the **safety of toys** sets out the safety requirements that toys made available in the European Union (EU) must meet. These requirements are designed to provide a high level of health and safety, to protect the public and to guarantee free movement of toys in the EU. It identifies the particular responsibilities of different operators in the supply chain from manufacturer to importer/retailer/distributor.

Point 13 of Annex II of the Regulation sets out certain migration limits for toys containing lead. It could be argued that for the articles covered by this Directive the requirements set relating to lead could be seen as "minimum requirements for controlling risks to human health" resulting from the use in articles. The Regulation does however not regulate the actual use of lead for the production of toys and therefore does not appear on its own to be a basis for granting an exemption of uses of lead under Article 58(2).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals **(REACH)** in its Annex XVII restricts the uses of lead and lead compounds in specified applications.

Entry 63 targets the uses in **jewellery articles** (paragraph 1), the use in **articles** supplied to the general public that may, during normal or reasonably foreseeable conditions of use, **be placed in the mouth by children** (paragraph 7), and the use **in gunshot in wetlands** (paragraph 11)[22].

Lead (powder and massive) is also regulated under Entry 30 for its use as such, as constituents of other substances, or **in mixtures for supply to the general public** when present above specified concentration limit.

[22] Restriction entry 63 might be updated following ongoing restriction process on Placing on the market and use of lead in projectiles (for firearms and airguns), and in fishing sinkers and lures for outdoor activities here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840159e6

Entry 72 restricts the use of Lead and its compounds in **clothing, textiles that come into contact with human skin and footwear for use by consumers** if present in homogeneous materials above a maximum concentration limits of 1 mg/kg after extraction.

ECHA considers that the respective entries in Regulation (EC) No 1907/2006 constitute specific Community legislation imposing minimum requirements relating to the protection of human health for the use of a substance within the meaning of Article 58(2) of the REACH Regulation. It could be argued that for the particular life cycle stages and target population restricted under the entries, the conditions of Article 58(2) REACH may be met.

Specific uses are derogated from the above listed REACH Annex XVII entries. ECHA considers that the following situations need to be differentiated to decide whether the REACH restriction could contribute to justify Article 58(2) exemption for those specific derogated uses:

a) The use is derogated from the restriction due to scope considerations (RAC and SEAC did not provide an opinion on risk or socioeconomic aspects of those derogations). In this case ECHA considers that the restriction does not provide sufficient basis for an exemption under Art 58(2). (e.g. articles within the scope of Directive 2011/65/EU (8(k)(iv)):

b) The use is derogated from the restriction based on socio-economic considerations. In this case, ECHA considers that the restriction does not provide sufficient basis for an exemption under Art 58(2) as it cannot be concluded that the restriction "imposes minimum requirements relating to the protection of human health" (e.g. keys, locks, padlocks (point 8e) or musical instruments (Point 8f))

c) The use is derogated from the restriction and imposes minimum requirements relating to the protection of human health. In this case, ECHA considers that the restriction may constitute a basis for an exemption under Art 58(2) (i.e. articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight (8g); internal components of watch timepieces inaccessible to consumers)

In assessing Article 58(2) exemption requests it is important to assess whether existing EU legislation imposes minimum requirements to properly control risks to human health via all relevant exposure routes and at all life-cycle stages of a particular use. The restriction entries do not regulate all the life cycle stages and exposure routes of the uses (e.g. actual use in the production of jewellery, articles placed in the mouth, gunshots, textiles) and therefore do not appear on their own to be a basis for granting an exemption of uses of lead under Article 58(2). Therefore, the restrictions need to be considered in conjunction with other legislation addressing other life-cycle stages of the uses.

Environmental legislation

Summary: In assessing the Art 58(2) requests ECHA has considered the environmental legislation mainly from the point of view of potential risk to man via the environment. ECHA considers that the EU environmental legislation referred to in the Art 58(2) exemption requests, may contribute to control of the risk arising from particular uses of lead.

However, ECHA notes that for the Water Framework Directive (WFD) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. In other words, this Directive expressly contemplates the use of REACH authorisation, rather than precludes it. Furthermore, the WFD does not set forth specific measures, such as emission limits, that provide a minimum standard enforceable throughout the EU. Therefore, considering these limitations and in order not to limit the Commission's possibility to take action, the WFD may not provide an appropriate basis for an exemption from the authorisation requirement. The same considerations may apply to other environmental legislation (e.g. that relating to ambient air).

If the REACH risk management processes are necessary to achieve the objectives of other legislation (e.g. that relating to 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.

ECHA notes however that, for particular uses, the EU legislative regime in place also pushes for substitution in a similar manner to the authorisation requirement (i.e. uses of lead exempt under RoHS/ELV or uses authorised under DWD).

<u>Emissions to Air/Water/Soil/Food & Drinking water</u>

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

However, the Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. It is further noted that pursuant to Article 62(5)(b)(ii) REACH an applicant may justify in his authorisation application that discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive do not need to be considered when deciding on an authorisation. (It can be noted that Article 61(5) of REACH envisages that the Commission may review authorisation applications if the environmental objectives as referred to in Article 4(1) of the WFD are not met.) This implies that a case specific consideration is needed to judge whether risks arising from such discharges are properly controlled. In addition, under Article 7a of Directive 2008/105/EC (as amended by Directive 2013/39/EU) it is foreseen that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation[23]. Therefore, in order not to limit the

[23] 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."

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 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 provided for the WFD (see above). 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.

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

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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.

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 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.

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 below). 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.

Food is considered a major source of exposure to lead for humans. The maximum levels of certain heavy metals (including lead) in **foodstuffs** have been set by Commission Regulation No. 1881/2006 (as last amended in 2022), the framework EU legislation which sets maximum levels for chemical contaminants in foodstuffs. Furthermore provisions can be found in legislations like the one on **food contact materials** (Regulation EC No. 1935/2004) and specific Directive 84/500/EC on ceramics intended to come into contact with foodstuffs as amended by Directive 2005/31/EC, or **other food and feed related legislation**, such as (Regulation (EC) 1881/2006, Regulation (EC) No 1334/2008, Directive 2009/32/EC, Directive 2002/32/EC; Regulation (EU) 1275/2013) to limit the presence of lead in food. These pieces of legislation contribute to the overall protection of man via the environment from this source of exposure (food). Therefore, when considered in conjunction with the other EU legislation applying to lead compounds, they may contribute to the basis for granting an exemption for uses of lead compounds under Article 58(2) REACH.

Directive (EU) 2020/2184 (recasting Council Directive 98/83/EC) on the **quality of water intended for human consumption**, -namely the Drinking Water Directive (DWD)- entered into force on 12 January 2021. It 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. The Directive sets essential quality standards for water intended for human consumption for a range of parameters including lead[24], which must be monitored and tested regularly.

The directive also introduces minimum requirements for materials coming into contact with water intended for human consumption throughout the EU. By 12 January 2025 European positive lists of substances authorised for use in the manufacture of materials or products in contact with water will be established including where appropriate conditions for their use and migration limits. All new materials will have to comply with the conditions and limits set.

With the European positive lists for substances and materials [25], as well as procedures for their establishment and review, it could be argued that the requirements related to lead set out in the Directive are "minimum requirements for controlling risks to human health" via drinking water consumption resulting from the use of the substance in material or products coming into contact with drinking water. In particular, when considering that the conditions established in Annex I to the DWD have to be reviewed by the Commission at least every five years. In relation to authorised uses, the Directive includes a legislative regime by which industry needs to apply for continuing the use in a similar manner to the authorisation requirement.

Therefore, the DWD Directive when considered in conjunction with other EU legislation applying to lead compounds may contribute as a basis for granting an exemption under Article 58(2) REACH for the use of lead in materials coming into contact with drinking water. The directive contributes to the overall protection of man via the environment from drinking water consumption. Therefore, when considered in conjunction with the other EU legislation, it may contribute to the basis for granting an exemption for further uses of lead under Article 58(2) REACH as well.

Waste

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

[24] The new DWD reduces the maximum allowed concentration of lead in drinking water from 10 µg/l to 5 µg/l over a transition period of 15 years.
[25] The European positive lists are not yet established but must be adopted by the Commission by 12 January 2025.

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

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

In relation to the 2011 RoHS Directive the use of lead in certain applications is exempted from restriction including the use of lead in steel, aluminium or copper alloys up to specific percentages; in different soldering materials; lead in shielding for ionising radiation; in counterweights; in certain medical devices and monitoring and control instruments.

In relation to the ELV Directive (and Commission Directive 2013/28/EU amending Annex II of the ELV Directive) certain materials and components are exempt from the above limits. This includes the use of lead in batteries; in steel, aluminium and copper alloys in certain percentages; in soldering materials.

It could be argued that for the articles covered (and exempted) by the RoHS and ELV Directives, the requirements set out in the Directives related to lead could be seen as "minimum requirements for controlling risks to human health" resulting from the waste phase of the articles. In relation to exempted uses, these Directives include a legislative regime to push for substitution in a similar manner to the

authorisation requirement. Therefore, when these Directives are considered in conjunction with the other EU legislation applying to lead compounds, they may contribute to the basis for granting an exemption for use of lead compounds under Article 58(2) REACH.

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

Council Directive 2006/66/EC (as amended) on **batteries and accumulators** and waste batteries and accumulators aims at the minimisation of the negative impacts of batteries and accumulators on the environment. The Directive primarily regulates the placing on the market of batteries or accumulators, and their collection and subsequent treatment as waste, including through recycling. It seeks to improve the environmental performance of batteries and accumulators (as well as the development and marketing of batteries and accumulators which contain smaller quantities of dangerous substances or which contain less polluting substances, in particular as substitutes for mercury, cadmium and lead) and of the activities of all economic operators involved in the life cycle of batteries and accumulators. With some exceptions (military and space use), it applies to all batteries. The Directive prohibits the marketing of batteries containing some hazardous substances (particularly mercury and cadmium), defines measures to establish schemes aiming at high level of collection and recycling, and fixes targets for collection and recycling activities (including for lead-acid batteries and accumulators). The Directive also sets out provisions on labelling of batteries and their removability from equipment. Producers of batteries and accumulators and producers of other products incorporating a battery or accumulator are given responsibility for the waste management of batteries and accumulators that they place on the market, and relevant Member States must promote substitution of hazardous substances in batteries and accumulators, including lead[26]. In relation to lead compounds, the Batteries Directive primarily contributes to protection of human

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

health from the waste life cycle stage of these articles. Therefore, when this Directive is considered in conjunction with the other EU legislation applying to lead compounds, it may contribute to the basis for granting an exemption for the use of lead compounds in batteries under Article 58(2) REACH.

ECHA notes that on 10 December 2020, the Commission adopted the proposal for a Regulation concerning batteries and waste batteries, with a view to replacing the current Batteries Directive. The new **Batteries Regulation** is not yet adopted and therefore does not qualify as *existing* legislation according to Art. 58(2) of REACH. See ECHA's response C.2.02 for further information on the upcoming regulation.

Directive 94/62/EC on **packaging and packaging waste** covers all packaging placed on the European market and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used. The Directive requires EU countries to take measures, such as national programmes, incentives through extended producer responsibility schemes and other economic instruments, to prevent the generation of packaging waste and to minimise the environmental impact of packaging.

Article 11 of the Directive requires Member States to minimise the content of hazardous substances and materials in the packaging material and its components. In particular that provision foresees that Member States shall ensure that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed the limits set out in that article. The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight (or 0,01% w/w). These limits are in place mainly to prevent heavy metals such as lead to enter the waste stream and to avoid subsequent releases to the environment when waste is incinerated or landfilled.
It could be argued that the requirements set relating to lead could be seen as "minimum requirements for controlling risks to human health" resulting from the waste phase of the specific articles covered by these Directives.

Although, these measures ensure that the exposure to lead in packaging products and components is limited, the Regulation does not impose minimum requirements for the control of risks to human health specifically concerning the use of lead to produce such articles. Therefore, this Directive does not appear on its own to qualify as EU legislation for which an exemption can be granted for uses of lead under Article 58(2) REACH.

Conclusion

As set out in section C.1.1, ECHA considers the elements described in the 'General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV'[27] when assessing exemption requests under Art 58(2). The European Commission will make its assessment of the exemption possibilities and include any exemptions the Commission regards as appropriate in its draft decision on Annex XIV inclusion which will be discussed in the REACH Comitology Committee.

Requests have been made for Art 58(2) exemptions for various uses of lead. It should be noted that some uses for which an Article 58(2) exemption has been requested appear to be uses that might fall under a generic exemption from the authorisation requirement (i.e., exemptions from the authorisation requirement that are already listed in the REACH Regulation) and are therefore not considered relevant for additional exemption under Art 58(2) (see also respective responses below).

Comments received refer to the many pieces of EU legislation relating to use and disposal of lead and lead compounds. In particular, in relation to workers health, comments referred to the binding limit values set for inorganic lead and its compounds under Directive 98/24/EC and their foreseen upcoming revision. In addition, comments referred to risks to man via the environment from uses of lead compounds being addressed by legislation dealing with ambient air, water, drinking water, waste and food. Furthermore, a high number of comments referred to certain uses of lead being assessed under other legislation and having received / expect to receive explicit derogations/authorisation (e.g. under ELV, RoHS, DWD, REACH restrictions).

For all exemption requests received, ECHA has assessed whether existing EU legislation imposes minimum requirements to properly control risks to human health via all relevant exposure routes and at all life-cycle stages of that particular use, considering not only the risks for workers dealing directly with the substance but also for man via the environment/consumers.

With regards to exposure of humans via the environment, ECHA notes that the Water Framework Directive (WFD) foresees that the REACH authorisation and restriction processes may be initiated by the Commission to achieve the objectives of that legislation. Therefore, in order not to limit the Commission's possibility to take such action and considering the limitations of the WFD (e.g. no specific emission limits), such legislation does not appear to provide an appropriate basis for an exemption from the authorisation requirement. If the REACH risk management processes are necessary to achieve the objectives of other legislation (e.g. that relating ambient air), then the same considerations may apply as for the WFD. Therefore, taking into account the above points, it is not clear if EU legislation provides a sufficient basis for an Article 58(2) exemption for any uses of lead.

ECHA further 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.

[27] http://echa.europa.eu/documents/10162/17232/recom_general_approach_draft_axiv_entries.pdf

For certain uses of the substance some minimum requirements for controlling risks to human health appear to be in place that appear however to address only specific life-cycle stages/routes of exposure of the uses, such as the Binding Occupational Exposure Limit or Biological Limit Value for lead – this may not address lifecycle issues related to consumer exposure or man via the environment. As highlighted above, it cannot be concluded that all life cycle stages, and routes of exposure are properly addressed. In particular in the case of non-threshold substances such as lead ECHA is of the opinion that a demonstration of proper control could, for example, be strengthened or supported where EU legislation provides a binding substitution regime for the substance with a timeline or review process. ECHA considers that the uses with perhaps the strongest case for Art. 58(2) exemption are those for which a legislative regime is already in place to push for substitution in a similar manner to the authorisation requirement. It could be argued that such a regime applies to those uses of lead compounds which are exempted under the RoHS and ELV legislation. This legislation addresses the risks resulting from the waste phase of particular articles and pushes manufacturers to avoid the use of hazardous substances such as lead and its compounds in articles. The exemptions for uses of lead compounds in particular applications and their regular review could be regarded as similar to the time limited review period set out in authorisation[28], although the role and duties of industry differ.

Similar considerations may apply to the use of lead that will be authorised under the Drinking Water Directive. The Directive addresses the risks resulting from the use phase of particular articles and pushes manufacturers to avoid the use of hazardous substances such as lead and its compounds in articles. The authorisation for uses of lead compounds in particular applications and their regular review could be regarded as similar to the time limited review period set out in authorisation, although the scope of authorisation and role and duties of industry differ.

It should be noted that the RoHS, ELV and DWD Directives do not contain requirements to minimise risks from use of the substance in applications exempt from restriction throughout the whole life cycle and that these risks will need to be addressed under the authorisation regime if Art 58(2) exemptions do not apply.

Therefore, on balance, when considering uses of lead exempted under the RoHS and ELV and DWD legislation holistically with the other Community legislation addressing lead, it appears that these uses may have a stronger case for Art 58(2) exemption than other uses.

In summary, based on the above review it is not clear if there is sufficient basis to propose Art 58(2) exemptions for any uses of lead for which an exemption request has been received. However, if the Commission were to consider Art 58(2) exemptions possible, uses of lead

[28] In relation to the current Batteries Directive, it appears that the substitution provisions differ significantly from the authorisation regime (than the RoHS/ELV Directives) as they do not include a similar regular review of specific (exempted) applications at EU level. The current Batteries Directive is expected to be replaced by a new Batteries Regulation. The possibility to grant exemption from authorisation under Art 58(2) on the basis of the provision of the new Batteries Regulation will need to be assessed in the light of the adopted legal text.

exempted/authorised and subject to regular review under the RoHS, ELV, and DWD legislation may have a stronger case for Art 58(2) exemption than other uses.

Reference code	Issue title	Draft response
C.2.02	Request for exemption under Art. 58(2) based on the future Batteries Regulation	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'. From the above, it is apparent that ECHA can only take into account *existing* community legislation. The currently in force Council Directive 2006/66/EC (as amended) on **batteries and accumulators** and waste batteries and accumulators is assessed in the *detailed analysis in response C.2.01.* On 10 December 2020, the Commission adopted the proposal for a Regulation concerning batteries and waste batteries, with a view to replacing the current Batteries Directive. The new **Batteries Regulation** is currently in the final stages of the law-making process. The European Parliament voted on its position on 9 March 2022. All member states' representatives unanimously supported in ENV council on 17 March the compromise proposal providing broad support to the Council mandate within interinstitutional negotiations. The Regulation is however not yet adopted. From the text of the compromise proposal, in particular recitals 15 to 17, it seems that the new Battery Regulation would be the preferred legal instrument by which restrictions on substances in batteries, at all stages of their life cycle, would need to be addressed. However, in the current draft recitals it is also further specified that it will be necessary to assess whether or not this approach should be maintained, considering possible revision of the REACH Regulation during the current legislative term. It is therefore not possible to determine at this stage whether and how the future Batteries Regulation would constitute ground for exempting the use in batteries from Authorisation under REACH. The decision on possible exemptions on the basis of Art. 58(2) is made by the Commission. If by the time a decision is taken to include the substance in Annex XIV, the Batteries Regulation is in place it will be assessed

		whether it fulfils (possibly in conjunction with other community legislation, see section C.2.01) the conditions set out in Art. 58(2) for lead. ECHA invites the Commission to consider the requirements set under this upcoming regulation before including the substance in Annex XIV.
C.2.03	Exempt uses that have been derogated in existing restrictions addressing other substances than lead	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*'. When assessing exemption requests ECHA considers the following elements (further details in section C.1.1): - There is existing EU legislation addressing the specific use that is proposed to be exempted. - The existing EU legislation properly controls the risks from the use of the substance included in Annex XIV. - The existing EU legislation imposes minimum requirements which properly control the risks of the use. From the above, it is apparent that an exemption from authorisation for uses of lead cannot be granted on the basis that such uses have been derogated in a restriction addressing other substances than lead (e.g. Cadmium or lead-containing pigments).
C.2.04	Exemption request for Scientific research e.g. in universities, public institutions	Users of lead in scientific research are advised to examine whether their uses can be regarded as Uses for Scientific Research and Development (SRD) in accordance with REACH Art. 3(23) and 56(3). Under Art. 3(23), scientific research and development (SRD) means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. According to Art. 56(3) uses meeting the definition of SRD are exempted from authorisation. Please see C.1 Process information and in particular C.1.2. Generic exemptions which provides further information on generic exemptions from authorisation. As regards the obligations arising in case of the inclusion of a substance in Annex XIV, it is the responsibility of each actor to assess whether his/her use is in the scope of authorisation and keep the relevant documentation available for enforcement authorities if wishing to continue the use after the sunset date.
C.2.05	Lead used in analysis of fineness of gold alloys	Users of lead in analysis of precious metals are advised to examine whether their uses can be regarded as Uses for Scientific Research and Development (SRD) in accordance with REACH Art. 3(23) and 56(3).

		Under Art. 3(23), scientific research and development (SRD) means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. According to Art. 56(3) uses meeting the definition of SRD are exempted from authorisation. As regards the obligations arising in case of the inclusion of a substance in Annex XIV, it is the responsibility of companies to assess whether their use is in the scope of authorisation and keep the relevant documentation available for enforcement authorities if wishing to continue the use after the sunset date. Would the use in analysis of precious metals not meet the condition for generic exemption, please note that authorisation is not a ban (see response A.1.5.2 Authorisation is disproportionate and/or means a ban). Please also refer to the response for: C.1 Process information and in particular C.1.2 Generic exemptions.
C.2.06	Exemption request for uses in medical devices	Users of lead are advised to examine whether (some of) their uses can be regarded as uses in medical devices in accordance with REACH Art. 60(2) and 62(6). Pursuant to Articles 60(2) and 62(6) of REACH, an AfA is not required for a substance used in a medical device regulated under Directives 90/385/EEC, 93/42/EEC or 98/79/EC if that substance has been identified in Annex XIV for human health concerns only (as is the case for lead). Nor is an application required in such cases for the incorporation of the substance into the medical device during the manufacturing process or for the uses and corresponding volumes of that substance upstream preceding the end-use. See ECHA's Q&A on authorisation.
C.2.07	Exemption for uses necessary in the interests of defence/military uses	Exemption from the authorisation requirement may only be granted under Art. 58(2) 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. On the basis of the available information, ECHA does not see grounds for proposing a specific exemption for uses of lead in defence/military applications in accordance with REACH Art. 58(2) (see response C.1.1, C.1.3 and C.2.01). However, according to REACH Art. 2(3), Member States may allow for exemptions from REACH Regulation (including from the Authorisation requirement) in specific cases, where necessary in the interests of defence. This exemption does not apply by default. Granting such defence exemptions is a national responsibility.

		At the request of some Member States and in coordination with the Commission, the European Defence Agency (EDA) launched an initiative to support transparency about national policies and procedures in this regard. The initiative also aims at increased harmonization for granting defence exemptions. Further information can be found on EDA REACH web-portal (REACH | EDA Portal (europa.eu)).
C.2.08	Exempt use in art and building sector	Exemption from the authorisation requirement may only be granted under Art. 58(2) 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. Please refer to response C.1.1. for further information on how ECHA assessed that the conditions for Art.58(2) exemptions are met and to response C.2.01 for ECHA's view on uses that may meet the conditions. To substantiate a request from exemption some comments referred to the UNESCO Convention Concerning the Protection of the World Cultural and Natural Heritage (UNESCO, 1972) or the International Charter for the Conservation and Restoration of Monuments and Sites (The Venice Charter 1964). Other comments referred to national legislation, and/or existing norms/standards established at Community or national level. Those elements are not considered as sufficient basis for an Article 58(2) exemption as they do not fulfil the conditions of being existing EU legislation imposing binding and enforceable minimum requirements for the substance(s) used.