01/07/2015

Response document

Substance group: Boron compounds

Substance names and EC-numbers:

Substance name	EC number
Boric acid	233-139-2, 234-343-4
Disodium tetraborate, anhydrous	215-540-4
Diboron trioxide	215-125-8
Tetraboron disodium heptaoxide, hydrate	235-541-3

About this response document

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

Although the responses aim to address individual comments (submitted for individual substances), they have been compiled in a consolidated form structured by thematic block and level of information. This format intends to increase consistency and readability of

[1] The compilation of comments received, along with references to responses , can be found at the following link(s):
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_boric_acid_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_diboron_trioxide_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_disodium_tetraborate_anhydrous_en.pdf
http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_tetraboron_disodium_heptaoxide_hydrate_en.pdf

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responses and promote a better understanding of the authorisation process. In general, comments addressing same or similar issues have been assigned references[1] to the same parts of the current document.

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

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

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

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

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

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

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A. Priority and general issues

A.1 Process information

A.1.1. General, recommendation process

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

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

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

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

2.Legal basis for prioritisation

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

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

Information on the approach currently applied is provided below.

3.Prioritisation approach applied

The prioritisation approach applied by ECHA to the current recommendation round (6th recommendation) was discussed with, and has been agreed by, the Member State Committee (MSC). Please refer to http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

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

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

4.Information taken into consideration for the draft recommendation

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

5.New information and next steps towards the final recommendation

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

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

A.1.2. Prioritisation: Volume

1.Volume in the scope of authorisation

The volume taken into consideration for priority setting is the volume for all uses in the scope of authorisation. The estimation of volumes is based on data from the registration dossiers as provided in section 3.2 and 3.5 of the IUCLID dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted

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

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during public consultation on SVHC identification of the substances. Where available, information on uses falling under the scope of the generic exemptions from authorisation[4] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

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

A.1.3. Prioritisation: Wide-dispersiveness of uses

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.Relevant further considerations

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

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

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

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

1.Potential other regulatory actions

In the process of recommending a Candidate List substance for inclusion in Annex XIV ECHA is not in the position to assess the pertinence of alternative regulatory risk management options to authorisation for the substance or some of its particular uses.

Any suggestion to address the concern raised by the substance via e.g. restriction of certain uses; or better enforcement of existing legislation for protection of workers; or the need to generate further information via substance evaluation prior to taking a decision on including the substance in Annex XIV are beyond the remit of ECHA in the recommendation process. The same applies for views that there is no need to initiate any further regulatory risk management action at this time.

Considerations on the most appropriate risk management options are usually discussed among authorities prior to proposing substances for inclusion to the Candidate List[10].

2. Aim & proportionality of authorisation system - Authorisation is not a ban

The authorisation process aims at enhancing substitution when technically and economically viable alternatives are available. Until this is achieved the aim is to ensure proper control of risks.

Substances included on the Candidate list have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it [11], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

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

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

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

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strong incentive (or duty) to search for and develop suitable alternatives.

3.Use specific scrutiny foreseen at application stage

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

4.Control of risks

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

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

6.Socio-economic benefits of continued use

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

7.Burden for industry and potential

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

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competitive disadvantage

matter whether a supplier is located outside or inside the EU. To the extent the substance may be present in imported articles, ECHA shall investigate after the sunset date if this poses a risk which is not adequately controlled. In that case it shall propose a restriction on these articles as per Article 69(2) of the REACH Regulation.

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

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

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

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

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

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

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

Reference code	Issue raised in the comment(s)	Response
A.2.1	Borates are naturally present in the environment (water, soil, plants). The use of eco-toxicological data obtained in the laboratory claimed to be not relevant given the natural levels of boric acid.	Thank you for the information, and for providing your opinion. It is known that boron substances occur naturally in the environment. However, the fact that a substance occurs naturally does not mean that it cannot be of concern. Indeed, the boron substances in the Candidate List have a harmonised classification as toxic for reproduction, which was the basis for their identification as Substances of Very High Concern and inclusion in the Candidate List. Note that background exposure to boron substances can act together with exposure due to human activities involving use of those substances and therefore affect the overall risk for effects.
A.2.2	Disputing the volume score, claiming that the volume figures used for prioritisation are outdated.	See also **A.1.2. Prioritisation: Volume** As stated in the draft background document (dated 1 September 2014), data used for the priority assessment were reported by the lead registrant in 2014 and refer to the year 2012. These data reflect the market situation of 2012 and are the most up-to-date data that were provided. Note that although the Annex XV report given as reference in the background document might cite data from 2005 – 2008, these were not used in the assessment of the priority of the substance. We have aimed to clarify that further in the updated background document.
A.2.3	As a high fraction of the volume of the substance seems to be used in uses that are out of the scope of Authorisation, the substance should not be prioritised.	Please note that exempted uses will in the future, i.e. after the sunset date, still be possible without authorisation. The allocation of priority scores takes into account only the uses/tonnage in the scope of authorisation. This is because an authorisation requirement will address those uses/tonnage, but not the remaining, exempted uses/tonnage. The uses in the scope of authorisation and their relevance for the human health and/or the environment are independent on whether the remaining uses represent low or high volumes. Therefore, the fact that a certain share of the total tonnage in the EU is applied in uses which may be

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		outside the scope of authorisation does not affect the priority conclusion.
A.2.4	Claim of use as intermediate: - in manufacture of boron glass - in manufacture of frits - manufacture of starch glues - production of fluoroboric acid (CAS 16872-11-0) - in manufacture of boron carbide, boron nitride, titanium boride, zirconium boride and calcium boride	See also **C.1.2. Generic exemptions** For the purpose of prioritisation ECHA did an initial assessment of the intermediate status in the listed uses. Based on the information available, ECHA concluded that these uses could be considered as intermediate in accordance with the definition in Article 3(15) of REACH. ECHA interprets Article 3(15) as explained in ECHA's Guidance on Intermediates (version 2 December 2010) which has been agreed by the relevant EU Authorities. This has been reflected in the background documents and was considered when deciding on the priority of the substance. However it is stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates. It remains the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore is exempted from the authorisation requirement.
A.2.5	Disputing the volume score, claiming various uses of the substance as being outside the scope of authorisation, e.g. the essential use of boric acid as micronutrient.	According to the agreed prioritisation approach, the complete annual volume supplied in the EU to uses not generically exempted from the authorisation requirement is taken as basis for assessing the "volume" criterion. A list of these generic exemptions from the authorisation requirement can be found at http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf. Use (or categories of uses) can also be exempted from authorisation requirement on the basis of Art. 58(2) of REACH. Such exemptions can be recommended by ECHA, however, it is for the Commission to decide whether to grant (or not to grant) exemptions pursuant to Art. 58(2). Therefore, uses that may be granted an exemption based on Art. 58(2) cannot be disregarded when the priority of a substance is assessed. In the specific case of boric acid the prioritisation assessment was done based on the volume data given in your comment. Regarding some of the uses you mention (and their respective volumes)

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		please note: The use of mixtures below the Specific Concentration Limit is indeed generically exempted from authorisation. However, the formulation of these mixtures will require authorisation. Similarly, although the placing on the market or the use of an article containing an Annex XIV substance is not subject to the authorisation requirement, the incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement. Furthermore, please be recommended to check the elements ECHA considers necessary when deciding on recommending Art. 58(2) exemptions: General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV [21 August 2014, http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf] as well as information given in the **C.1 Exemptions** Please refer also to the response given **C.2. Responses to exemption requests referring to other legislation** which *inter alia* refers to the essential use of boric acid as micronutrient. In conclusion, the total score has not been changed.
A.2.6	Substance is used in very low volumes in specific use (and therefore these uses should be exempted, or other risk management activities should be considered)	See also **A.1.2. Prioritisation: Volume** The inclusion in Annex XIV is per substance and not per use (or installation). The use and user specific conditions can be reflected in the authorisation application and 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. Regarding the use in small quantities, please refer also to response **C.3.3 Claim that past model parts should be exempt from authorisation** which refers to current considerations about establishing a potential simplified AfA process in the future, for special cases such as uses in low volumes. However, please be aware that the simplified AfA process currently under discussion would not comprise an exemption from the authorisation requirement.
A.2.7	Claim that uses and precursor uses of (Certified) Reference	Under Article 3(23) REACH, scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year. Thus, scientific research and development can cover analysis, and a

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	Materials should be considered as being covered by provisions for scientific research and development and such uses should therefore be exempted.	substance may be exempted from authorisation under Article 56(3) REACH if used, on its own or in a mixture, in analytical activities such as monitoring and quality control. For instance, routine quality control or release tests in laboratory scale using the substance as extraction solvent or analytical standard fall into the definition of 'scientific research and development' under Article 3(23) REACH and in the scope of the exemption foreseen in Article 56(3) REACH, as long as the quality control or release tests are carried out under controlled conditions and in a volume not exceeding one tonne per year and per legal entity. Furthermore, we would like to add that the uses of a substance upstream preceding an exempted end-use in SRD are also exempted if used in quantities below 1 t/y (of substance ending up in the SRD use) and under controlled conditions. For further information you can also refer to Q&As 0585, 0844 and 1030 on ECHA's website.
A.2.8	Claim that formulation of mixtures where the final concentration of the substance is below the specific concentration limit for classification should fall under the generic exemption of such mixtures.	See also **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 2. Assignment of WDU score based on use types and their associated volumes Please note that uses of mixtures below the applicable Specific Concentration Limits (SCL: 5.5% w/w for boric acid; 4.5% w/w for borax) are generically exempted from authorisation. However, uses of mixtures containing boron substances at or above the SCL in mixtures not covered by any exemptions will require authorisation. The same applies for the formulation of mixtures, in case the starting material is the substance as such or a mixture above the SCL.
A.2.9	ECHA should group the borates on the Candidate List with borates with a harmonised classification that are not yet identified as SVHC. Recommendation should be postponed until all classified boron compounds are	Grouping substances of a similar nature and function for inclusion in Annex XIV does not mean and in regulatory effectiveness terms, does not require to first include all similar substances to the Candidate List, before it would be meaningful to consider further risk management activities (e.g. inclusion in Annex XIV) for the individual substances or the entire group. Grouping for regulatory action should not lead to a situation in which a group of substances cannot be recommended because further substances appear to belong to that group and have not yet been identified as SVHCs. Regulatory effectiveness should therefore be assessed by balancing on the one hand the need to initiate/proceed with regulatory action and on the other hand to do that in a meaningful way (i.e. by addressing substances which could potentially substitute each other in their uses through grouping).

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	included in the Candidate List.	
A.2.10	Claim that the risk from borates should be managed similarly to NMP	Thank you for your comment although we find it difficult to interpret. If you meant that there should be a restriction in place setting binding occupational exposure limits for boric acid (as currently in the process for NMP), please refer to **A.1.5.1: Other RMO**. If you further meant that there are currently no suitable alternatives for the use of boric acid in electroplating, please refer to **A.1.5.5: Availability of suitable alternatives**. Regarding your reference to the recommendation of strontium chromate, please note that the current public consultation is specific to the substances included in the 6th draft recommendation. Comments on already recommended substances cannot be taken into account at this point in time.
A.2.11	Requests authorities to conduct a Risk Management Options Analysis (RMOA) for borates before recommending the substance for Annex XIV	The purpose of the RMO analysis is to clarify whether risk management activities are required for a substance and to identify the most appropriate instrument to address a concern. We fully agree that preparing an RMO analysis early in the process (i.e. before initiating the SVHC identification process) will promote early discussion and will help to get a common understanding on the action pursued. However, it should be noted that preparing and discussing an RMO analysis is not a legally required step in REACH in general or during any phase of the authorisation process as defined in Title VII of REACH but is a voluntary action. As mentioned in the updated prioritisation approach, other potential risk management options and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. ECHA is not in the position to assess the pertinence of alternative regulatory risk management options for the substance or some of its particular uses at this step.
A.2.12	ECHA should not proceed with the 6th recommendation, when the 5th is still open	According to Art. 59 (3), ECHA has an obligation to recommend to the Commission priority substances to be included in Annex XIV. The decision to include substances in Annex XIV is taken by the Commission. It is for the Commission to decide when and how it proceeds with ECHA's recommendations for inclusion of substances in Annex XIV.
A.2.13	Claim that risks for workers are controlled	See also **A.1.1. General, recommendation process:** 2. Legal basis for prioritisation 3. Prioritisation approach applied

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	by other legislation	**A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 4. Control of risks Please note that the main aim of the authorisation requirement is to enhance substitution when technically and economically viable alternatives are available. Until this aim is achieved the aim is to ensure proper control of risks. Therefore, in addition to properly controlling the risks, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives. Prioritisation is a task of comparing the substances on the Candidate List based on certain agreed criteria. It does not intend to assess the risks arising from the uses of substances, but to provide a very basic and general assessment of indicators such as the use pattern and tonnages in the EU. If a substance is included in Annex XIV it is then the obligation of the applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no suitable alternatives available and the socio economic benefits of the use outweigh its risks. One of the tasks of the Risk Assessment Committee during the evaluation of applications is to assess the appropriateness and effectiveness of the described risk management measures; in the case of an authorisation decision there is the possibility to specify further conditions, including monitoring requirements. Please refer also to the response given in **C.2. Responses to exemption requests referring to other legislation**.
A.2.14	Claim that authorisation is not necessary as consumers are protected through the restriction in place	The authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. Until substitution is achieved authorisation aims to ensure the good functioning of the internal market while assuring that risks arising from SVHCs are properly controlled. According to the prioritisation approach, the substances with consumer uses in the scope authorisation receive the highest score for wide-dispersiveness. This was not the case for the boron substances as there are no consumer uses in the scope of authorisation. The total priority score reflected the high volumes and professional uses.

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		The control of risks needs to address the risks to human health and/or the environment from the use(s) of the substance arising from the intrinsic properties of the substance. Risks to human health need to be controlled not only for consumers but also for workers.
A.2.15	Claim that exposure data shows low/no risks	Your point with regard to the hazardous inherent properties of borates is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for the substance and its listing in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008). As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation. According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling elements of a substance in Annex VI shall submit a proposal to the competent authority in one of the member states in which the substance is placed on the market. The MSCA will then decide if it is appropriate to submit a CLH dossier to the Agency in order to review/revise the existing harmonised classification.
A.2.16	Risks should be managed using risk management measures like PPE, LEV, exposure tracking, training	**A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks Please note that the main aim of the authorisation requirement is to enhance substitution when technically and economically viable alternatives are available. Until this aim is achieved the aim is to ensure proper control of risks. Therefore, in addition to properly controlling the risks, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives. The prioritisation is carried out to support the decision in which order substances in the Candidate List are included in Annex XIV. It does not intend to assess the risks arising from the uses of substances. It instead comprises a very basic and general assessment of the substances' use pattern and tonnages in the EU, relying on agreed indicators applied in the same manner to all substances - something driven by the comparative nature of the prioritisation process. Furthermore, even if the assessment of the level of control or exposure levels was considered beneficial during the prioritisation step, there is in this phase of the authorisation process no objective information basis to do so, in particular, whether necessary measures are indeed implemented at sites and what exposure levels occur in different sites using the substance across the EU.

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A.2.17	Claim that borates should not be prioritised as environmental monitoring shows no impact on the environment	It is noted that prioritisation is a basic comparative assessment of substances on the Candidate List, with the aim to propose in which order substances should be included in the Authorisation List. In this context, wide dispersiveness of uses is evaluated taking an approach which relies mainly on the use pattern of a substance. Information that normally requires higher level of assessment (e.g. overall available monitoring data) is beyond the scope of this step of the authorisation process.
A.2.18	As it is a threshold substance effects only occur beyond that threshold. Risk associated with liquid discharge from nuclear power plants not considered a concern.	Please note that a threshold mode of action of a substance does not demonstrate as such that the associated risks arising from the uses of the substance are adequately controlled. Instead, it means that if an applicant is able to demonstrate in his application for authorisation adequate control of risks arising from the applied for uses on the basis of established effects thresholds and his exposure assessment he may be granted an authorisation (authorisation may also be granted if the applicant can demonstrate that there is no suitable alternative to the substance available and that the socio-economic benefits of the uses applied for outweigh the associated risks for health and environment).
A.2.19	Alternative substances are usually less well known and might have a higher risk	Please note that authorisation does not ban 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. The meaning of "(suitable) alternative" in the context of authorisation means the possibility of replacement of the substance in a particular use by another in technical and economic terms feasible substance or technology, thereby reducing the overall risk arising from the use in question. In cases where substitution is considered, we suggest to comparatively assess, in addition to technical and economic feasibility aspects, also the overall risks to human health and the environment exerted by the substance / technology currently used with any potential alternative substance or technology. Your point with regard to the hazardous inherent properties of borates is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for this substance and listed in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008). As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation.

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A.2.20	Claim that the socio-economic impact of inclusion of the substance in Annex XIV would be very high and result in a high burden for industry	See also **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage 6. Socio-economic benefits of continued use 7. Burden for industry and potential competitive disadvantage Please refer also to **B.2.1.Concerns and uncertainties with respect to the authorisation process, in particular for SMEs** Identification of the substance as SVHC and the subsequent prioritisation to recommend it for inclusion in Annex XIV is based on provisions laid down in the REACH Regulation. Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The authorisation application and decision making process involves a systematic scrutiny of applications. This scrutiny by RAC and SEAC covers also the risk management measures and the resulting exposure levels as identified and estimated by the applicant. Furthermore, the Commission can impose additional conditions as part of the authorisation decision. Hence, the authorisation process as whole involves an additional guarantee that the risks of the substances of very high concern are properly controlled. Please also note that companies can apply in a flexible manner either alone or as groups. This can also be done by suppliers in one go for all their clients that use a substance in a similar manner.
A.2.21	Boron is a critical raw material	Although the substance is of high economic importance and apparently difficult to substitute in a range of its uses, 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. Taking account of these conflicting areas, authorisation appears to be an appropriate risk management measure. 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

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		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, which is also one of the recommendations given in the referred to Commission report.
A.2.22	Disputing the harmonised classification	Your point with regard to the hazardous inherent properties of borates is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for the substance and its listing in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008). As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation. According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling elements of a substance in Annex VI shall submit a proposal to the competent authority in one of the member states in which the substance is placed on the market. The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to review/revise the existing harmonised classification.
A.2.23	Claim that authorisation requirement for borates would be in conflict with the EU food law (including food contact materials and food or feedingstuffs legislation)	See also **A.1.5. Aspects not considered in ECHA's prioritisation:** 2. Aim & proportionality of authorisation system - Authorisation is not a ban 3. Use specific scrutiny foreseen at application stage **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** Please note that uses of mixtures below the applicable Specific Concentration Limits (SCL: 5.5% w/w for boric acid; 4.5% w/w for borax) are generically exempted from authorisation. Provided that the boron substances in the uses you refer to are in concentrations below those limits, their use will not require authorisation. Generic exemptions apply also for uses of those substances in food contact materials according to Art. 56(5)(b), as well as in food or feedingstuffs in accordance with Art. 2(5)(b).

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		However, uses of boron substances at or above the SCL in mixtures not covered by any exemptions will require authorisation. The same applies for the formulation of boron substances to mixtures, in case the starting material is the substance as such or a mixture above the SCL.
A.2.24	Predictability of including substances in Annex XIV	The authorisation procedure aims to progressively replace all substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible, thereby reducing the overall risk arising from the use in question. In cases where substitution is considered, we suggest to comparatively assess, in addition to technical and economic feasibility aspects, also the overall risks to human health and the environment exerted by the substance / technology currently used with any potential alternative substance or technology. ECHA considers the predictability of including substances in Annex XIV important to allow companies to consider the best business strategy to address substances of potential concern and to ensure that registration data is up to date. Predictability of the prioritisation of substances to Annex XIV also helps all interested parties to get prepared for public consultation during any subsequent regulatory processes. To increase predictability and transparency of the prioritisation of substances to Annex XIV ECHA has made available the prioritisation approach which it uses to regularly assess the substances from the Candidate List to decide which ones should be included in the Authorisation List as a priority. Substances not prioritised for inclusion are reassessed in the following prioritisation rounds. ECHA encourages interested parties to use the prioritisation results published on ECHA's website (http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf) to get information on the relative priority of the Candidate List substances and a view on which substances are likely to be of highest priority in future recommendation rounds. It should be noted, however, that the relative priority of substances can change due to changes in the uses and/or volumes registered or due to new high priority substances included in the Candidate List. Early information on substances that are scrutinised by authorities and may be included in the Candidate List (and eventually in Annex XIV) in future if the properties of substances and/or need for further regulatory action are confirmed can be found on the ECHA website http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern and in the Public Activities Coordination Tool (PACT) (http://echa.europa.eu/addressing-chemicals-of-

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		concern/substances-of-potential-concern/pact). The SVHC Roadmap to 2020 gives an EU-wide commitment for having all relevant currently known SVHCs included in the Candidate List by 2020. A Member State or ECHA (at the request of the Commission) can carry out a Risk Management Option Analysis (RMOA) in order to conclude whether a substance is a 'relevant SVHC' in the sense of the SVHC Roadmap to 2020. PACT lists the substances for which an RMOA is either under development or has been completed. Finally, ECHA's webpages provide information about intentions for proposing the inclusion of substances in the Candidate List (Registry of Intentions – SVHC; http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions), as well as for submitted proposals (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification).

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B. Timelines

B.1 Process information

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

1.Legal background

Article 58(3) and Recital (77) of REACH provide that the latest application and sunset dates set for the substances included in Annex XIV shall take account of the Agency's capacity to handle applications in the time provided for as well as the workability and practicality for applicants preparing their applications for authorisation. Furthermore, the legal text specifies that the latest application date must be at least 18 months before the sunset date (Article 58(1)(c)(ii)) and the sunset date(s) for uses of a substance should where appropriate take into account the production cycles specified for those uses (Article 58(1)(c)(i)).

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

2.ECHA's proposal for sunset dates

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

3.ECHA's proposal for latest application dates

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

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential applicants concerned by substances in this recommendation. Furthermore, the registration deadline for all substance in this

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recommendation[12] was in 2010. It should also be noted that the requirements on communication of information down and up the supply chain (Title IV of REACH) as well as the downstream user obligations (Title V of REACH) have applied for some years. Implementation of and compliance with these requirements should as well support the organisation of the work within the supply chains related to the preparation of authorisation applications.

Based on the above establishing first LADs earlier than 18 months after inclusion in Annex XIV could even be considered. However, providing sufficient time to the applicants to get organised within sectors and prepare an application that provides a solid basis for the decision making is important. Therefore, it does not seem to be justified to propose shorter LADs.

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

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

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

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

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

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

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

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

1.Extensive time needed in the supply chain to getting 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 a time of about 6 months for getting organised and consulting external expertise. Therefore, the "later" LAD slots can be regarded as sufficiently long deadlines for complex-supply-chain cases.

2.Lack of alternatives, socio-economic aspects

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

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

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Socio-economic or practical considerations are not relevant reasons for prolonging or advancing the latest application dates or sunset dates as these considerations are normally use and sector or even case specific and difficult to take into account in the recommendation phase which considers all uses of the substance. Furthermore, such information would be very difficult to get at the prioritisation stage in a systematic manner. Therefore they are considered at the next phase of the authorisation process.

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

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

B.1.3. Review periods

1.Upfront review periods

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

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

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

Reference code	Issue raised in the comment(s)	Response
B.2.1	Concerns and uncertainties with respect to the authorisation process, in particular for SMEs	See also **A.1.5. Aspects not considered in ECHA's prioritisation:** 7. Burden for industry and potential competitive disadvantage There has been a significant effort to implement the application for authorisation process in a transparent manner, and to provide suitable support to companies to comply with their duties. ECHA's committees have so far adopted more than 60 opinions on applications for authorisation and the European Commission has granted the first authorisations to applicants. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be already improved. ECHA has created a dedicated webpage "applying for authorisation" with the aim of guiding applicants in the preparation of their applications (http://echa.europa.eu/web/guest/applying-for-authorisation). This includes among others guidance documents, technical manuals, Q&As, and approaches agreed by the committees describing how applications are treated and evaluated. The Risk Assessment Committee has been providing, on a pilot basis, DNEL and dose-response relationships for almost all substances so far. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. 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 has also been updating formats and IT-tools to provide more clarity and to streamline the process further. Further clarifications to potential applicants is provided via pre-submission information sessions with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process. ECHA also regularly organises seminars and workshops to improve the understanding of the application process and share experiences. Beyond this, ECHA's authorisation teams maintain personal contact and interaction with the applicants through all the stages of the application process. The current experience and availability of all this information shows that even if the authorisation

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		process is to some extent still perceived as "new" it is nevertheless a carefully thought through process that has been working well for some time already. The level of support available and provided to involved companies (not only by ECHA, but also by many of its stakeholders) has been substantial and broadly acknowledged. ECHA will continue to develop its practices to provide fit-for-purpose support and increase predictability of the application for authorisation process even further.
B.2.2	Concerns about workload, timelines and resources needed for those companies already dealing with Cr(VI) applications.	See also **A.1.5. Aspects not considered in ECHA's prioritisation:** 7. Burden for industry and potential competitive disadvantage **B.1.1. General principles for setting latest application dates / sunset dates** How to best organise and what is the most suitable timing for the preparation of an application for one substance whilst another substance used in the same use is already in the authorisation process will vary case by case.
B.2.3	Regulations and timelines (e.g. with regard to nominal lifetime and decommissioning) for the nuclear industry should be taken into account	See also **B.1.1. General principles for setting latest application dates / sunset dates:** 3. ECHA's proposal for latest application dates Please also note that for the cases of operators who need to continue using an Annex XIV substance in low volumes or for the production of legacy spare parts, the Commission has been considering establishing a streamlined and simplified authorisation process. A public consultation on the Commission's proposal for these cases ran between February and April 2015 (see http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081&lang=en&title=REACH-Authorisation---Consultation-on-applications-for-low-volumes-and-on-extension-of-transitional-arrangements-for-uses-in-legacy-spare-parts-).

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B.2.4	Investment cycles should be taken into account.	The length of the applicant's investment cycle is one criterion considered when setting review periods. For more information, please refer to **B.1.3. Review periods**
B.2.5	Claim that the use fulfils the RAC/SEAC conditions for longer review period.	See also **B.1.3. Review periods** Therefore, if specific conditions prevail that may justify a review period different than the normal length of seven years described in the approach agreed by RAC and SEAC, the committees can recommend a different, appropriate review period. Based on the opinion by the committees, the Commission decides on the length of the review period.
B.2.6	Check effectiveness of harmonised classification before proceeding with further regulatory risk management activities.	The boron compounds were included in the Candidate List following their identification as SVHC based on Art. 57c (Repr 1B). ECHA has the legal obligation to recommend substances from the Candidate List for inclusion in Annex XIV. Therefore, once a substance is added to the Candidate List it can be prioritised applying the agreed prioritisation approach. The specific measures to control the exposure are valuable and will be considered in the authorisation application and decision making phase. However, they are not considered at the prioritisation stage. Please note that the main aim of the authorisation requirement is to enhance substitution when technically and economically viable alternatives are available. Until this is achieved the aim is to ensure proper control of risks. Therefore, in addition to properly controlling the risks, the obligation to apply for authorisation is a strong incentive (or duty) to search for and develop suitable alternatives. The prioritisation is carried out to support the decision in which order substances in the Candidate List are included in Annex XIV. It does not intend to assess the risks arising from the uses of substances. It instead comprises a very basic and general assessment of the substances' use pattern and tonnages in the EU, relying on agreed indicators applied in the same manner to all substances - something driven by the comparative nature of the prioritisation process. Furthermore, even if the assessment of the level of control or exposure levels was considered beneficial during the prioritisation step, there is in this phase of the authorisation process no objective information basis to do so, in particular, whether necessary measures are indeed implemented at all sites and what exposure levels occur in different sites using the substance across the EU.

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		See also: **A.1.1. General, recommendation process:** 1. ECHA's obligation to recommend/prioritise substances on the Candidate List 2. Legal basis for prioritisation 3. Prioritisation approach applied **A.1.5. Aspects not considered in ECHA's prioritisation:** 1. Potential other regulatory actions 2. Aim & proportionality of authorisation system - Authorisation is not a ban 4. Control of risks
B.2.7	Disputing harmonised classification and asking for a hold to the recommendation process.	Your point with regard to the hazardous inherent properties of borates is not relevant for this part of the authorisation process, as the identification of the substance as Substance of Very High Concern has already been agreed by the Member State Committee, based on the harmonised classification in force for the substance and its listing in Annex VI of the CLP-Regulation (Regulation (EC) No 1272/2008). As the cited harmonised classification is applicable law at present, it will not be questioned or discussed in the context of this recommendation. According to Article 37(6) of the CLP Regulation manufactures, importers and downstream users who have new information which may lead to a change of the harmonized classification and labelling of a substance in Annex VI shall submit a proposal to the competent authority in one of the member states in which the substance is placed on the market. The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to review/revise the existing harmonised classification.

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C. Exemptions

C.1 Process information

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

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

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.
The decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH. It should however be recalled that the discretion to grant an exemption provided for in Article 58(2) of the REACH Regulation is an exception to the rule that the placing on the market and the use of substances of very high concern should be subject to authorisation, one of the purposes of which is to ensure they are phased out where economically and technically feasible (Article 55 of REACH).

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

- There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be considered.
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV. Generally, the legislation in question should cover the substance to be included in Annex XIV and address the concern related to its intrinsic properties. This can be the case e.g., where the legislation specifically refers to the substance to be included in Annex XIV either by naming the substance or by referring to the group the

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

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substance belongs to (e.g. by referring to the classification criteria or the Annex XIII criteria).

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

On the basis of the elements above:

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

C.1.2. Generic exemptions

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

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

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[15]. Furthermore, uses can be exempted from the authorisation requirement on the basis of Art 58(2) which depends on the provisions of existing EU legislation.

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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. Responses to exemption requests referring to other legislation

Use	Legislation	Draft response
Cosmetic products	Regulation (EC) No 1223/2009	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. ECHA would suggest that you examine whether the mentioned uses of your substance can be regarded as uses in cosmetic products in accordance with the Regulation (EC) No 1223/2009.
Scientific research and development (SRD)		Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. ECHA would suggest that you examine whether the mentioned uses of your substance can be regarded as uses for scientific research and development purposes in accordance with Art. 3(23) and 56(3) of REACH.
Use in mixtures for the supply for general public and in mixtures < SCL (including fertilisers and photographic processing chemicals)	Annex XVII to REACH Regulation and general exemptions	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. Consumer uses of these borate substances, as such or in mixtures, are either restricted (entry 30 of Annex XVII to REACH Regulation) or, if in mixtures below the

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		classification concentration limit are not in the scope of authorisation. Professional or industrial uses (e.g. relevant formulation steps) of the borate substances as such or in mixtures above the classification concentration limit would require authorisation.
Used as biocide and flame retardant in wood	Biocidal Product Regulation (Regulation (EU) 528/2012)	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. Boric acid, diboron trioxide and disodium tetraborate, anhydrous are approved under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) as active substances in biocidal products to be used as wood preservative (Product Type 8). The BPR includes a risk assessment and authorisation procedure for active substances and products containing these substances. We would suggest that you examine whether the use of your substance can be regarded as fulfilling the requirement of Article 56(4)(b) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 56(4)(b) REACH and no authorisation application would be required to continue the use after the sunset date. It should be noted that the exemption also covers the life-cycle steps preceding the incorporation of the substance into the biocidal product, but only in volumes ending up in the exempted end-use (Q&A 1027). However, where the substance is used as a flame retardant, the BPR does not apply and thus the exemption set out in Article 56(4)(b) cannot apply. It needs to be examined whether an exemption can be granted under Art 58(2) REACH. For the use of the substance as a flame retardant in wood, there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that this use would merit an exemption under Art 58(2). In addition, please see **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks.
Manufacture of corrugated board, adhesives and borosilicate glassware (partially intended for food	Regulation (EC) No 1935/2004 on materials and articles intended to	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. The framework Regulation (EC) No 1935/2004 on materials and articles intended to

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contact materials - FCM)	come into contact with food	come into contact with food sets up general requirements for all food contact materials and articles to ensure that their constituents do not endanger human health and adversely affect the nature or quality of the food, via the transfer of substances, bringing an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. Paper and board, adhesives and glasses are groups of materials and articles, listed in Annex I which may be covered by specific measures. However, for these groups of materials and articles, no specific measures have yet been adopted at EU level. Member States may maintain or adopt national provisions in relation to these groups of FCMs. We would suggest that you examine whether the use of your substance can be regarded as fulfilling the requirement of Article 56(5)(b) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 56(5)(b) REACH and no authorisation would be required to continue the use after the sunset date. The exemption also covers the life-cycle steps preceding the incorporation of the substance into the food contact material, but only in volumes ending up in the exempted end-use (Q&A 1027). It should be noted however that the use of these substances in the manufacture of borosilicate glass appears to be an intermediate use. However, where these substances are used in the production of corrugated board and adhesives that are not intended to come into contact directly or indirectly with food (food contact materials), the FCM legislation does not apply and thus the exemption set out under Art. 56(5)(b) cannot apply. It needs to be examined whether an exemption can be granted under Art 58(2) REACH. For the uses of these substances in the production of corrugated board and adhesives, there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that these uses would merit an exemption under Art 58(2). In addition, please see **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks.
All uses	Occupational Health and Safety legislation	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. In addition, CAD outlines a hierarchy of control and risk reduction measures (with substitution at the top). However, it

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		leaves the determination of the measures to be imposed to the employer and does not provide specific indicators to be used to assess whether a measure higher up in the hierarchy would have been technically possible. There are no binding or indicative occupational exposure limit values for these borate substances. Council Directive 92/85/EEC (Pregnant Workers Directive) seeks 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 Directive aims at encouraging 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. Whilst the Directive identifies substances relevant for reprotoxic potential for particular attention in an assessment, the Directive leaves the determination of the measures to be imposed to the employer. 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. However, 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. On this basis, it is not considered that CAD, Pregnant Workers Directive and the Directive on the protection of young people at work impose minimum requirements for controlling risks to human health. Therefore, these Directives do not seem to be a sufficient basis for exempting uses of these borate substances from authorisation in accordance with Article 58(2) REACH Regulation.

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		The Directive 2004/37/EC (Carcinogens or Mutagens Directive - CMD) introduces a framework of general principles to protect workers against risks to their health (which includes prevention of risk) from exposure to carcinogens or mutagens, as defined in Article 2 of the Directive itself. The borate substances are not in the scope of this Directive, because they are not classified as carcinogens category 1A or 1B, or as mutagens category 1A or 1B.
Use in nuclear power plants (e.g. used in pressurised water in nuclear reactors and as neutron absorbing agent(s))	Directive 2009/71/Euratom, establishing a Community framework for the nuclear safety of nuclear installations Council Directive 2013/59/EURATOM on basic safety standards for protection against the dangers arising from exposure to ionising radiation	Directive 2009/71/Euratom (and its amendment 2014/87/Euratom) establishes a 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. The license holders have as prime responsibility the nuclear safety. They are also responsible for the assessment and continuous improvement of the nuclear safety of installations. 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. This Directive repeals Directive 96/29/Euratom (from 6 February 2018), which establishes the basic safety standards and its provisions apply to normal and emergency situations. 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. Therefore, this Directive only applies to radioactive substances (any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view) and they are excluded from the scope of REACH Regulation (Article 2(1)(a)). The Directives 2009/71/Euratom and 2013/59/EURATOM (Directive 96/29/Euratom) impose minimum requirements for the control of risks of the use of radioactive substances to human health (workers and general public) and the environment. Such requirements are further developed in national legislation and licences. It seems that these Directives do not impose minimum requirements for the control of risks to human health or/and the environment for the use of non-radioactive

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		substances in nuclear power plants. Therefore, these Directives do not appear to be a sufficient justification for exemption under Article 58(2) REACH for uses of the borate substances in nuclear power plants, either when used in pressurised water in nuclear reactors, as neutron absorbing agent(s), or other uses.
Use in nuclear power plants	Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive)	Council Directive 98/83/EC on the quality of water intended for human consumption ('Drinking Water Directive') aims at protecting human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. It applies to all water intended for human consumption apart from natural mineral waters and waters which are medicinal products. It sets essential quality standards for a range of parameters including boron, which must be monitored and tested regularly. The Directive states that '*without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean*'. The Directive does not establish specific emission limits for substances or define risk management measures required. These aspects would be covered e.g. in specific permits issued by national authorities. If the REACH risk management processes are necessary to achieve the objectives of this Directive, then it may not be appropriate to allow an exemption from the authorisation requirement on the basis of this Directive. In addition, and in any event, risks to human health do not appear to be properly controlled at other life cycle stages (e.g. see above in relation to occupational health legislation). Therefore, on its own the Drinking Water Directive does not appear to be sufficient justification for granting an exemption for the use under Article 58(2) REACH.
Manufacture of contact lenses Production of wires Use in surface treatment (plating) Slag stabilizer Semiconductors production	Directive 2010/75/EU on industrial emissions (IED)	Concerning the Directive 2010/75/EU on industrial emissions (IED), Annex II is an indicative list of the main polluting substances and includes large groups of substances. The directive does not specify how to identify polluting substances for which a permit for an installation needs to include an emission limit value. For these reasons the substances for which the minimum requirements set out in the directive apply are not specified in a way that would allow the use of the IED Directive as a reason for exemption under Article 58(2) REACH. 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.

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Manufacture of frits Fluxes in casting processes Production of glass wool		
Used in production of Plant Protection Products (PPPs), as a scavenger (corrosion inhibitor) in the manufacture of the active substance	Regulation (EC) No 1107/2009 (Plant Protection Products Regulation)	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. Regulation (EC) No 1107/2009 (Plant Protection Products, PPP Regulation) includes a risk assessment and authorisation procedure for active substances and products containing these substances. To qualify for the authorisation exemption for a PPP use as an active substance, such use would need to be permitted. Boric acid (as well as disodium tetraborate, anhydrous) are banned when used as active substances for plant protection products (Commission Decision 2004/129/EC). Therefore, there can be no exemption from authorisation based on use as an active substance in PPPs within the scope of the PPP Regulation. In addition, based on the description of the use provided, it appears that boric acid is not incorporated into the final product and therefore would not potentially qualify for an exemption on this basis. However, we recommend that you examine whether your specific use of boric acid qualifies for an exemption under REACH Art 56(4)(a) (see also Q&A 1027). In case the generic exemption under Article 56(4)(a) REACH does not apply, it needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance as a scavenger in the manufacture of PPP active substances, there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that this use would merit an exemption under Art 58(2). In addition, please see **A.1.5. Aspects not considered in ECHA's prioritisation:** 4. Control of risks.
Semiconductors production	WEEE Directive 2012/19/EU	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

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		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 this substance is properly controlled in accordance with Article 58(2) REACH.
Use in surface treatment (plating)	SEVESO Directive (Directive 96/82/EC; Directive 2012/18/EU)	Regarding the Directive 96/82/EC, repealed by Directive 2012/18/EU with effect from 1 June 2015 (SEVESO Directive), it aims at the prevention of major accident hazards involving dangerous substances and at the limitation of the consequences of such accidents for man and the environment in establishments where dangerous substances are present above certain thresholds (Column 2 in Parts 1 and 2 of Annex I of Directive 2012/18/EU). Boric acid is not a named substance included in Part 2 of Annex I, and it does not belong to one of the categories of dangerous substances listed in Part 1 of the same annex of Directive 2012/18/EU. Therefore it seems that boric acid is not within the scope of SEVESO Directive. It should also be noted that the focus of the Directive is relatively limited and does not address protection of man via the environment during normal operating conditions.
Use in surface treatment (plating)	ADR (Directive 2008/68/EC)	The rules of the ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road), RID (Regulations concerning the International Carriage of Dangerous Goods by Rail) and ADN (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways) are applicable within the framework of the Directive 2008/68/EC on the inland transport of dangerous goods. However, according to Art. 2(1) (d) of REACH Regulation, the carriage of dangerous substances and dangerous substances in dangerous mixtures by rail, road, and inland waterway are excluded from the scope of REACH. Therefore, an assessment as to whether the conditions for an exemption apply for transport, pursuant to Article 58(2) of REACH, is not necessary.
Use in fertilisers (as a source of the micronutrient boron)		Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. We would suggest that you examine whether the use of your substance can be regarded as fulfilling any of the exemption requirements, however it appears that this use of

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		borate compounds does not appear to be specifically exempted. Boron substances are used in fertilisers as a source of the micro-nutrient boron according to the Regulation (EC) No. 2003/2003 (Fertilisers Regulation). It needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance in fertilisers, there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that this use would merit an exemption under Art 58(2). A potential streamlined / simplified authorisation process is being considered where an Annex XIV substance is used as a source of a biologically essential element (see document CA/81/2014 of the 16th CARACAL meeting – instructions on how to access CARACAL documents are available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm).
Use in medicinal products (as an excipient or as active ingredient)	Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use Directive 2001/83/EC on the Community code relating to medicinal products for human use Directive 2001/82/EC on the Community code relating to	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. Regarding the use in medicinal products, Regulation (EC) No 726/2004 establishes the operation of European authorisation procedures for the placing of medicinal products on the market in the European Union (EU). Each application for authorisation must be accompanied by the particulars and documents referred to in Directive 2001/83/EC on the Community code relating to medicinal products for human use or in Directive 2001/82/EC relating to the production, placing on the market, labelling, distribution and advertising of veterinary medicinal products. According to Art. 2(5) REACH, substances used in medicinal products for human and veterinary use within the scope of the relevant EU legislation are exempted from the authorisation process. We would suggest that you examine whether the use of your substance as an excipient or an active ingredient can be regarded as fulfilling the requirement of Article 2(5)(a) REACH. If you conclude that your uses of the mentioned substance fulfil the above requirement, the uses can benefit from the exemption from authorisation as set out in Article 2(5)(a) REACH and no authorisation would be required to continue the use after the sunset date. It should be noted that the exemption also covers the life-cycle steps preceding the incorporation of the substance into the medicinal products, but only in volumes

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	veterinary medicinal products	ending up in the exempted end-use (Q&A 1027). If the generic exemption under Article 2(5)(a) REACH does not apply, it needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance in medicinal products, there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that this use would merit an exemption under Art 58(2).
Use in medical devices	Medical Devices Directives (MDD, Directive 93/42/EEC), the Directive on implantable medical devices (Directive 90/385/EEC) and the Directive on diagnostic in vitro medical devices (Directive 98/79/EC)	Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. Regarding the use in medical devices, the Medical Devices Directives (MDD, Directive 93/42/EEC), the Directive on implantable medical devices (Directive 90/385/EEC) and the Directive on diagnostic in vitro medical devices (Directive 98/79/EC) are intended to harmonise the laws relating to medical devices within the EU. In relation to legislation relating to medical devices, ECHA refers to recital 18 of Commission Regulation (EU) No 143/2011 of 17 February 2011, amending Annex XIV to REACH for the first time: *'In accordance with Article 60(2) of the REACH Regulation, the Commission should not consider, when granting authorisations, the human health risks associated with the use of substances in medical devices regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. In addition, Article 62(6) of REACH Regulation provides that applications for authorisation should not include the risks to human health arising from the use of a substance in a medical device regulated under those Directives. It follows that an application for an authorisation should not be required for a substance used in medical devices regulated under Directives 90/385/EEC, 93/42/EEC, or 98/79/EC if such a substance has been identified in Annex XIV to REACH Regulation for human health concerns only. Therefore, an assessment as to whether the conditions for an exemption pursuant to Article 58(2) of Regulation (EC) No 1907/2006 apply is not necessary'.* This is applicable when the substance is used in medical devices or for the uses and

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		corresponding volumes of that substance upstream preceding this end-use (Q&A 1029). Based on the above, ECHA would suggest that you examine whether the mentioned uses of your substances can be regarded as uses in medical devices in accordance with the Directives 90/385/EEC, 93/42/EEC, or 98/79/EC.
Extend exemption to other uses to allow for continued supply of the substance for medicinal products, medical devices and scientific research and development		Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation (which appear to be relevant for your own uses) and C.1.3 for aspects not justifying an exemption from authorisation. Please note that the use of substances in upstream steps preceding the exempted end-uses in medicinal products and medical devices are also covered by the exemption (but only in the volumes ending up in the exempted end use). Please further note that the uses of a substance upstream preceding an exempted end-use in scientific research and development (SRD) are also exempted in quantities of the substance ending up in the SRD use (under 1 t/y) subject to what is set out below. The definition of SRD in Article 3(23) requires any scientific experimentation, analysis or chemical research to be carried out "under controlled conditions" and "in a volume less than one tonne per year". Accordingly, the exemption in Article 56 (3) is delimited by a certain level of control of risks – i.e., use under controlled conditions and in a volume less than 1 tonne per year – which also apply to the upstream life-cycle stages preceding the end-use in SRD.
Bio-essentiality in fermentation processes in the manufacture of food and feedingstuffs, biotechnology, pharmaceuticals and in vitro diagnostics should be exempted		Please see **C.1 Process information** and in particular **C.1.2. Generic exemptions** which provides further information on generic exemptions from authorisation. In relation to medicinal products and medical devices see responses to comments provided above. We would suggest that you examine whether the use of your substance can be regarded as fulfilling any of the generic exemption requirements. If you conclude that your uses of the mentioned substance fulfils a requirement, the uses can benefit from the relevant exemption and no authorisation would be required to continue the use

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		after the sunset date. It should be noted that the exemption may also cover the life-cycle steps preceding the incorporation of the substance into the product, but only in volumes ending up in the exempted end-use (Q&A 1027). It needs to be examined whether an exemption can be granted under Article 58(2) REACH. For the use of the substance in the manufacture of food and feedingstuffs and biotechnology there appears to be no specific EU legislation imposing minimum requirements relating to the protection of human health and the environment in order to ensure that the risk is properly controlled. Therefore it does not appear that these uses would merit an exemption under Art 58(2). A potential streamlined / simplified authorisation process is being considered where an Annex XIV substance is used as a source of a biologically essential element (see document CA/81/2014 of the 16th CARACAL meeting – instructions on how to access CARACAL documents are available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm).

C.3. Responses to further exemption requests (not covered by C.1. and C.2. above)

Reference code	Issue raised in the comment(s)	Response
C.3.1	Claim that solutions below the specific concentration limit should be exempt from authorisation.	See also **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.2. Generic exemptions** **C.2. Responses to exemption requests referring to other legislation** Therefore, the exemption from authorisation mentioned in Article 56(6) applies to the use of a substance in mixtures where it is present below the classification concentration limits referred to in Article 56(6). The preceding uses of the substance on its own or in a mixture above the classification

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		concentration limits would require authorisation, e.g. use of the substance to formulate mixtures containing the substance below the SCL.
C.3.2	Claim that encapsulated uses without release should be exempt from authorisation.	When considering whether to include an exemption of a use of a substance under Art. 58(2) REACH, the following elements have to be considered: there is existing EU legislation addressing the use or categories of use that is proposed to be exempted; the EU legislation imposes minimum requirements for the control of risks of the use; the EU legislation properly controls the risks to human health and/or to the environment from the use of the substance arising from the intrinsic properties of the substance which are specified in Annex XIV to REACH. According to Article 58(2) REACH: 'In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and environment related to the nature of the substance, such as where the risk is modified by the physical form'. Thus, it does not seem that the form is to be considered independently from the mentioned elements in order to exempt uses or categories of uses from the authorisation requirement. In other words, while the form and how it may affect the exposure potential is not alone a sufficient basis for an exemption, the form should be taken into account when assessing whether the existing legislation provides a justification for an exemption. Prioritisation is a task of comparing the substances on the Candidate List based on certain agreed criteria. The prioritisation approach which was agreed and applied here to prioritise and recommend substances from the Candidate List for inclusion in Annex XIV is not intended to assess the risks exerted by the particular applications of a substance at particular sites but to provide a very basic and general assessment of indicators such as the use pattern and tonnages in the EU. Note that it is the obligation of the potential applicant for authorisation to demonstrate that the risks arising from the applied for uses are properly controlled or that there are no suitable alternatives available and the socio-economic benefits of the use outweigh its risks.
C.3.3	Claim that past model parts should be exempt from authorisation.	See also **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.3. Aspects not justifying an exemption from authorisation** Please also note that for the cases of operators who need to continue using an Annex XIV substance

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		in low volumes or for the production of legacy spare parts, the Commission has been considering establishing a streamlined and simplified authorisation process. A public consultation on the Commission's proposal for these cases ran between February and April 2015 (see http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081&lang=en&title=REACH-Authorisation---Consultation-on-applications-for-low-volumes-and-on-extension-of-transitional-arrangements-for-uses-in-legacy-spare-parts-). A potential streamlined / simplified authorisation process is being considered also for other special cases (see document CA/81/2014 of the 16th CARACAL meeting – instructions on how to access CARACAL documents are available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm).
C.3.4	Claim that uses which can replace Cr(VI) should be exempt from authorisation.	See also **C.1.3. Aspects not justifying an exemption from authorisation** We acknowledge that boron substances are used in metal finishing process such as in mixtures developed to substitute Cr(VI) uses in chrome plating. Although boron substances do not have the same toxicity profiles as the Cr(VI) substances, they are as well identified as substances of very high concern (SVHCs) with reprotoxic properties. Hence there is a strong societal interest to protect humans, in particular workers handling the substances, from risks potentially arising from both the uses of Cr(VI) and of boron substances. The main aim of the authorisation process is to enhance substitution of SVHCs when suitable (i.e. safer and technically and economically viable) alternatives are available. When considering substitution of SVHCs, the goal of businesses should normally be substitution with the most suitable alternatives. Please note that there is an EU-wide commitment (the SVHC Roadmap) for having by 2020 all relevant currently known SVHCs included in the Candidate List, which is established for eventual inclusion of substances in Annex XIV. In case the only currently feasible alternative significantly reducing the overall risks appears to be another SVHC, substitution is still a possible strategy - regardless of the actual time at which the latter substance is expected to be included in the Authorisation List. In the case boron substances are included in Annex XIV, for a use such as the formulation of mixtures for trivalent chrome plating it will need to be documented and justified, in an application for

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		authorisation, either that risks are adequately controlled, or that there is lack of suitable alternatives and the socio-economic benefits of the use outweigh the risks arising from it. This information along with information on relevant research and development efforts will be taken into account in the authorisation decision making phase. This use can then continue after the "sunset date" when the Commission has granted an authorisation. This is to be expected in cases where applicants have made a good business case.
C.3.5	Claim that products not containing the substance in the final product should be exempt from authorisation.	See also **C.1.1. General principles for exemptions under Art. 58(2)** **C.1.3. Aspects not justifying an exemption from authorisation** In a potential application for authorisation, the exposure assessment shall consider the emission during the relevant parts of the life-cycle of the substance resulting from each of the uses applied for. If the substance is not present in the end product of the use, e.g. a produced article, the service life of article (and respective potential exposure for consumers or releases to the environment) does not need to be considered. Still, the exposure of workers and of man via the environment during the production process will need to be addressed.

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C.3.6	Claim that uses in healthcare sector in small quantities should be exempt from authorisation.	Please note that uses (or categories of uses) can be exempted from the authorisation requirement on the basis of Article 58(2) of REACH (see section C.1.1. of this document for more information), unless the use falls under the generic exemptions from authorisation (a list of uses exempted from the authorisation requirement at http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf). Regarding the use in small quantities, please refer also to response **C.3.3 Claim that past model parts should be exempt from authorisation**, which refers to current considerations about establishing a potential simplified AfA process in the future, for special cases such as uses in low volumes. However, please be aware that the simplified AfA process currently under discussion would not comprise an exemption from the authorisation requirement. Regarding the request for a potential exemption for uses upstream preceding a use in a medical device, please refer to section C.1.2 of the current document on the generic exemptions and the Q&A 1029 regarding the scope of the generic exemption for use in a medical device found at ECHA's website (http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/1027-1028-1029-1030-1031). Regarding the request for a potential exemption for the supply chain of a use exempted from authorisation based on Article 56(6) of REACH, please note that the exemption from authorisation applies only to the use of a substance in mixtures where it is present below the classification concentration limit referred to in Art. 56(6). The preceding uses of the substance on its own or in a mixture above the classification concentration limits would require authorisation. See also **C.2. Responses to exemption requests referring to other legislation**
C.3.7	Claim that articles should be exempt from authorisation.	See also **A.1.3. Prioritisation: Wide-dispersiveness of uses:** 3. Refinement of WDU score based on article service-life In addition you could refer to Q&A (0564): http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/ids/0564

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