01/07/2015

Response document

Substance name: 1-bromopropane; n-propyl bromide

EC number: 203-445-0

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

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

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

[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_bromopropane_en.pdf

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

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 substance**
   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.

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

A. Priority and general issues

A.1 Process information

A.1.1. General, recommendation process

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

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

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

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

The 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

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

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

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

authorisation

dossiers and/or in the CSRs, along with information presented in the Annex XV SVHC reports or information submitted during public consultation on SVHC identification of the substances. Where available, information on uses falling under the scope of the generic exemptions from authorisation[4] and on their related tonnage is assessed to estimate the volume relevant for the priority setting.

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

A.1.3. Prioritisation: Wide-dispersiveness of uses

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

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

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

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

2.Assignment of WDU score based

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

[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

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

on use types and their associated volumes

expected wide-spreadness (i.e. number/distribution of sites) decreases; thus the wide dispersiveness of uses decreases.

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

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

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

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

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

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

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

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

[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

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

1.Relevant further considerations

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

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

1.Potential other regulatory actions

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

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

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

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

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

Substances included on the Candidate list have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) 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.

[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.

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

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

3.Use specific scrutiny foreseen at application stage

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

4.Control of risks

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

5.Availability of 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

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

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

benefits of continued use

the authorisation can only be granted via the socio-economic route, the Socio-economic Analysis Committee compares the impacts to human health and/or the environment arising from the use of the substance with the benefits of the continued use. This is done when developing an opinion whether to grant an authorisation.

7.Burden for industry and potential competitive disadvantage

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

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

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

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

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

possible, too. Market certainty among potential applicants is thus increased.

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

A.2 Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
A.2.1	**Volume in the scope of authorisation is overestimated**	The estimation of volumes in the scope of authorisation for priority setting relies mainly on data from the registration dossiers as provided in Section 3.2 and 3.5 of the IUCLID dossiers and in the CSR. Further information (especially on tonnages per uses) from SVHC Annex XV reports and public consultations can be considered if the representativeness and reliability of the information can be assessed. Based on the registration data it is estimated that the volume of 1-bromopropane used in the scope of authorisation is in the range of 1,000 - < 10,000 t/y which justifies the volume score of 12. We would like to note that this estimation is not changed even when taking into account the estimation of the REACH Consortium for Brominated substances on the share of the volume used in the scope of authorisation (30% of the total EU volume) referred to in this public consultation. It should be noted, however, that for some registrants the total manufactured/imported volume reported in the dossiers corresponds to years at the time of first registration. ECHA notes that there are differences in the information reported in the registrations and submitted in this public consultation regarding the volumes used in the scope of authorisation. In the comments submitted in this public consultation, industry claims that based on current EU market information the use in the scope of authorisation is less than 1000 t/y. ECHA considers that the information provided in the comments is not sufficient to disregard the registration data on volumes. Having the correct volumes reported in the registrations is the responsibility of the registrants.
A.2.2	**Disagree with WDU score: The substance**	Background information on the scope of the assessment of wide-dispersiveness of uses (WDU) as well as on the assignment of WDU score based on use types and their associated volumes can be found in Section A.1.3 of this document.

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

	is not used by professional workers	Assessment of the wide-dispersiveness of uses relies mainly on data from the registration dossiers as provided in Section 3.5 of the IUCLID dossiers and in the CSR. In the registration data (including the lead registrant's updated dossier), there are indications that professional use of the substance may occur but it is difficult to conclude it from the available information with high certainty. It is acknowledged that the differentiation between industrial and professional actors is not always straightforward but may sometimes require a weight of evidence assessment. The updated guidance R12 on use description to be published end 2015/beginning 2016 aims to bring more clarity on this topic. Acknowledging the uncertainties regarding PROF use, that result from contradictory information in the registrations and the comments submitted in this public consultation claiming that the substance is only used at industrial sites, ECHA has decided to change the WDU score from the full professional use score (WDU=10) to a middle value (WDU=7) between the industrial and professional uses scores.
A.2.3	**The substance is not a PBT and therefore not a priority for inclusion in Annex XIV**	Please see section A.1.1. (subsections2 and 3) of this document for information on the legal basis for prioritisation and the generic prioritisation approach applied by ECHA. Please note that the inherent properties of a substance is not the only criterion for prioritisation. According to the prioritisation approach agreed by the MSC and applied by ECHA, all three criteria (inherent properties, wide-dispersiveness of uses and volume in the scope of authorisation) set out in Art. 58(3) of REACH are taken into account; along with any further considerations relevant for the recommendation, e.g. grouping. 1-bromopropane is identified as SVHC and included in the Candidate List due to its toxic to reproduction properties. Therefore, in accordance with the prioritisation approach, the substance receives the lowest score for the inherent properties criterion. Based on the total priority score for the three Art 58(3) criteria and grouping considerations, the substance receives the priority indicated in the background document (http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_backgdoc_bromopropane_en.pdf).
A.2.4	**Disagree with the total priority**	After assessing the updated registration information and the comments submitted in this public consultation, ECHA has decided to slightly modify the WDU score of the substance due to uncertainties related to professional use (see response A.2.2). The revised total priority score of the substance is 20 (Inh.prop.=1 , Vol.=12, WDU=7). Please note that 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, e.g. grouping of substances. 1-

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

		bromopropane was included in the 6th draft recommendation not only due to its total priority score, but also due to grouping considerations: based on the information submitted by the industry in this public consultation and in the previous one on the SVHC identification, the substance may be used to substitute trichloroethylene (already in Annex XIV) in vapour degreasing and surface cleaning. Based on the total priority score for the three Art 58(3) criteria and grouping considerations, the substance receives the priority indicated in the background document (http://echa.europa.eu/documents/10162/13640/6th_axiv_rec_backgdoc_bromopropane_en.pdf).
A.2.5	**Most of the tonnage used as intermediate and the remaining uses are controlled under worker exposure legislation**	Regarding the comment that most of the tonnage is used as intermediate, please note that 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 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 outside the scope of authorisation does not affect the priority conclusion. Considerations on whether the risks are properly controlled by other Community legislation are not taken into account in the priority setting and do not affect the priority conclusions. Such considerations are relevant when deciding on whether any uses could be exempted from the authorisation requirement based on Art. 58(2). Please see response C.2.1. regarding this issue.
A.2.6	**Used as a safer replacement for carcinogenic solvents, e.g. trichloroethylene**	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. Please note that 1-bromopropane, although not having the same toxicity profile as trichloroethylene (already in Annex XIV), is as well identified as SVHC due to its 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 1-bromopropane and trichloroethylene. Authorisation does not restrict the use of the substance as long as it is shown in the authorisation applications (and supported in the authorisation granting process) that either the risks arising from the use(s) applied for are properly controlled or that there are no alternatives available and the socio-economic benefits outweigh the risks arising from the uses. Concomitantly, the obligation to apply for authorisation is a strong incentive (or duty) to

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

		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. When considering substitution, we would suggest companies to comparatively assess, apart from technical and economic aspects, also the overall risks to human health and the environment exerted by the substance / technology currently used and by any potential alternative substance or technology.
A.2.7	**Disagree with SVHC identification**	Information on the hazardous inherent properties of 1-bromopropane 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). 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.

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

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

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 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

[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.

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

justified to propose shorter LADs.

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

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

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

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

The time differences between the LADs set out in a recommendation are relatively short, typically ranging from 3

[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.

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

to 6 months, compared to the total time reserved for the potential applicants to prepare their applications. ECHA proposes to allocate those substances to the "later" LAD slots for which the available information indicates a relatively high number of uses. Furthermore, substances with no registration requirement are allocated to the later slots.

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

1.Extensive time needed in the supply chain to getting orga–nised for preparing application (e.g. due to high number of users)

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

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

2.Lack of alternatives, socio-economic aspects

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

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

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

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

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].

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].

[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

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

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

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 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

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

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

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. 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

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

granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

C.2 Further responses relevant for the substance

Reference code	Issue raised in the comment(s)	Response
C.2.1	Art 58(2) exemption request for use in industrial vapour degreasing due to CAD	Refer to process information section C.1.1 on the general principles for exemption under Art. 58(2). The relevant EU legislation referred to by the commenting party is assessed below. 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 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. In addition, there is no binding or indicative occupational exposure limit value for this substance. On this basis it is not considered that CAD imposes minimum requirements for controlling risks to human health. Therefore, CAD may not be regarded as a sufficient basis for exempting uses of 1-bromopropane from authorisation in accordance with Article 58(2) REACH Regulation.

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