14 April 2021

Response document

Substance group: Cyclosiloxanes D4, D5 and D6

Substance names and EC-numbers:

Substance name	EC number
Octamethylcyclotetrasiloxane (D4)	209-136-7
Decamethylcyclopentasiloxane (D5)	208-764-9
Dodecamethylcyclohexasiloxane (D6)	208-762-8

About this response document

The present document provides ECHA's responses to the comments[1] received during the consultation on its draft recommendation to include cyclosiloxanes D4, D5 and D6 in Annex XIV of the REACH regulation (list of substances subject to authorisation). The consultation was held in the context of ECHA's draft 10th Annex XIV recommendation and took place between 5 March 2020 and 5 June 2020.

Although the responses aim to address individual comments (submitted for individual substances), they have been compiled in a consolidated form structured by thematic block and level of information. This format intends to increase consistency and readability of responses and promote a better understanding of the authorisation process. In general, comments addressing same or similar issues have been assigned references to the same parts of the current document.

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

[1] The compilation of comments received, along with references to responses, can be found at the following links:
https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d4_en.rtf,
https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d5_en.rtf,
https://echa.europa.eu/documents/10162/13640/10th_recom_comref_d6_en.rtf

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

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

1. **Process information**
   provides a summary of the principles applied by ECHA for its decision making relevant for each thematic block, as well as further information on aspects generally relevant (or non-relevant) for that decision. The process information has been developed based on the experience from previous recommendation rounds. It addresses issues commonly raised in comments submitted during the consultation. The process information part is identical in all Response documents of the substances included in the draft 10th recommendation for consultation.

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

The section headings in the process information and captions on the left of the substance-specific responses provide a summary of the issue addressed per section / response. The headings and captions are also numbered (e.g. "A.1.2.1", "B.2.2"), to support the referencing to responses in the "Comments and references to responses document" and vice-versa; i.e. to allow tracking of the comment(s) the specific section/response in the current document refers to.

A. Priority and general issues

A.1. Process information

A.1.1. General, recommendation process

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

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

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

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

2.Legal basis for prioritisation

According to Article 58(3), priority for inclusion into Annex XIV shall normally be given to substances with

(a) PBT or vPvB properties, or

(b) wide dispersive use, or

(c) high volumes.

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

Information on the approach applied is provided below.

3.Prioritisation approach applied

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

https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf.

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

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

The results of the priority assessment of all Candidate List substances using the prioritisation approach can be found at ECHA's website[2]. Further information on how the approach is applied in practice, especially on how the wide-dispersive use criterion is assessed, is provided in the "General approach for prioritisation of SVHCs: practical implementation examples"[3].

4.Information taken into consideration for the draft recommendation

For the purpose of its draft priority setting ECHA considers all relevant information available to it. The registration dossiers (including the CSRs) are the main source of information. It is the registrants' obligation to ensure that the information in the dossiers is clear, consistent and up-to-date. Further information e.g. from Annex XV SVHC dossiers and from SVHC consultation is considered, where appropriate (see Section 4 of the prioritisation approach (linked in A.1.3)). Downstream user reports, PPORD and SiA notifications are used in addition when relevant.

5.New information and next steps towards the final recommendation

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

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

[2] https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf

[3] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_impl_examples_2020_en.pdf

A.1.2. Prioritisation: Volume

1.Volume in the scope of authorisation

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

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

A.1.3. Prioritisation: Wide-dispersiveness of uses

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

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

The assessment of wide dispersiveness of uses (WDU) comprises a general evaluation of the substance's use pattern, relying on basic indicators specified in the general prioritisation approach document (see A.1.3) – a methodology which ECHA has strived to apply in a consistent way for all substances assessed, driven by the comparative nature of the prioritisation process. It does not comprise an assessment of information such as detailed operational conditions, recommended/implemented RMM, exposure/risk assessment reported in CSR, or site-specific measurement data. Such assessment is beyond the scope of this step of the authorisation process.

[4] A list of uses exempted from the authorisation requirement available at: https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf
[5] https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf
[6] https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf

More information can be found in Section 5.3 of the general prioritisation approach document[7] and in "General approach for prioritisation of SVHCs: practical implementation examples"[8]. Some of the main points are summarised below.

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

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

The full scores of higher WDU categories (professional and consumer uses) are assigned as long as the respective uses represented absolute volumes ≥ 10 t/y[9]. This is as consumer and professional uses can be regarded as having wide-dispersive pattern, regardless of how high the amount used at industrial sites is. In other words, the allocation of scores is based on the actual tonnage in different types of uses and not the share of the tonnage in different uses.

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

Furthermore, consumer uses for substances classified as Carc./Muta./Repr. 1A/B are not considered in the prioritisation score regardless of whether identified in registrations or not (as those are restricted[10] or, if in mixtures below the classification concentration limit, not in the scope of authorisation). For professional and industrial uses only the tonnage above the relevant concentration limit is considered in those cases where this information is available in the registration dossiers or in other sufficiently reliable sources.

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

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

[7] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf
[8] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_impl_examples_2020_en.pdf
[9] or unknown volumes, or ≥ 1t/y if the total volume in the scope of authorisation was < 10t/y
[10] Entries 28 to 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction

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

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

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

1.Relevant further considerations

The final conclusion on priority is drawn based on the assessment of the Article 58(3) criteria and consideration of additional aspects relevant for the recommendation. These additional aspects could be e.g. the grouping of substances (to take together SVHCs which could potentially replace prioritised or previously recommended SVHCs in some of their uses). There could be further considerations relevant for the prioritisation. It should also be noted that ECHA always aims to consider such additional aspects in a holistic way for the case at hand.

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

1.Potential other regulatory actions

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

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

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

2. Authorisation is disproportionate

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.

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

and/or means a ban

Substances included on the Candidate List have been identified as substances of very high concern based on their hazardous properties. There is a societal interest to protect humans and/or the environment from risks potentially arising from the uses of these substances. At the same time, aspects such as the availability and suitability of alternatives, socio-economic, human health or environmental benefits of continuing a particular use or the (adverse) impacts of ceasing it[12], as well as information on the actual level of risk associated to a use of such substances are important. The authorisation process as a whole (inclusion in the Candidate List, inclusion in Annex XIV and application and granting the authorisations) takes into account and aims to balance these interests and aspects.

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

3.Use specific considerations

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

4.Control of risks

ECHA considers that an assessment of the level of control or the level of exposure is not appropriate during the recommendation phase since it would shift the burden of proof back to authorities. Should a substance be included in the Authorisation List, such an assessment of exposure will be carried out by applicants for the uses they apply for as part of their authorisation application. The Risk Assessment Committee (RAC) will assess the appropriateness and effectiveness of the risk management measures as described in the application. There is also a possibility to specify

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

in the authorisation decision further conditions, including monitoring requirements. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and downstream user obligations.

5.Availability of suitable alternatives

While for some uses in the short term there may not to be suitable alternatives, the authorisation title of REACH gives a long term incentive to find and deploy them when these alternatives are technically and economically feasible while enabling continued use where that is justified. Information on (lack of) availability of alternatives as well as on relevant research and development efforts is taken into account in the application and authorisation decision making phase.

6.Socio-economic benefits of continued use

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

7.Potential competitive disadvantage

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

It is acknowledged that for certain production processes higher costs in comparison with competitors outside the EU may arise, if companies need an authorisation. These include for instance use of a substance as process chemical in the production of articles where the substance (or residues) does not end up in the article; or use in the formulation of mixtures having concentrations below the limit relevant for authorisation. Even though the use of the mixture is outside the scope of authorisation, still its formulation/production in the EU would require authorisation. The cost increase in these cases will apparently depend on the application fee and, in particular, on the costs of preparing the application. Its actual effect on the competitiveness of the respective industry in the EU will depend on the specific case (e.g. on the level of the overall production cost, including capital, raw material, and labour cost), but will often be relatively low.

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

8.Uncertainty as to whether authorisation will be granted

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

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

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

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

So far the Risk Assessment Committee has been providing DNELs and dose-response relationships for almost all substances for which applications for authorisations have been submitted. This is a practice which it intends to continue, thus saving substantial time for the applicants and increasing the predictability of the process. Moreover, the Committee for Socio-economic Analysis has published an explanatory note providing clarifications on how it evaluates economic feasibility as part of applications for authorisation. Furthermore, the Committees have jointly agreed on the principle of the recommended length of the review period, which should increase predictability. ECHA informs on its website about the length of the review periods that its Socio-economic Analysis Committee proposes to the Commission in its opinions. This is normally seven years, but review periods can also be shorter or longer than that.[14, 21]

Further clarifications to potential applicants are provided during teleconference-based information sessions (TIS) with ECHA, in which future applicants for authorisation have the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process.

[13] In accordance with Art. 62(1)(2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market.

[14] It should also be noted that i) a review period longer than 12 years can be granted (see criteria in the "Policy guidance for considering review periods for exceptional cases" available at https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf), and ii) an authorised use can be prolonged after the end of the review period. Authorisation holders have to submit a review report 18 months before the end the review period so that the authorised use could be prolonged.

In addition, 'trialogues' are organised with applicants, Committee rapporteurs and interested parties during the opinion-making process.

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

Meanwhile, the Risk Assessment Committee (RAC) and the Socio-economic Committee (SEAC) have adopted final opinions and the Commission issued decisions for a significant number of applications received[15]. With the conclusions of each of those evaluations communicated at ECHA's website, predictability of the authorisation process should be less of an issue.

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

A.2 Further responses relevant for the substance group

Reference code	Issue raised in the comment(s)	Response
A.2.01	Interplay between restriction and authorisation with regard to prioritisation	As a general principle ECHA wants to emphasise that authorisation and restriction can be used in a complementary manner to ensure proper control of risk and provide an incentive to (continue to) substitute the SVHCs (i.e. they do not exclude each other). As outlined in the background documents of D4, D5 and D6, ECHA has considered in its prioritisation the restrictions as follows: - The placing on the market of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in wash-off cosmetic products in a concentration equal to or above 0.1 % is restricted (entry 70 of Annex XVII to REACH at https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e182463cd3). Those uses were not considered for the prioritisation. - Furthermore, ECHA at the request of the Commission submitted in January 2019 a proposal to restrict octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) in consumer and professional products. The scope of the upcoming restriction[16] as currently defined, and further information, can be found in the background document to the final RAC and SEAC opinion (adopted on 12 March 2020) together with further relevant documentation under the link given further below. The final opinion and all background material were provided to the Commission in May 2020 for decision making (the status of this restriction proposal can be followed at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade). For prioritisation purposes, ECHA made two assessments, one for the current situation (i.e. only taking into account the entry 70 in Annex XVII) and another one assessing the impact on the prioritisation if the upcoming restriction on D4, D5 and D6 was adopted with its current scope. Both assessments, including their scoring and conclusions are documented in the prioritisation table and the background documents available under Submitted recommendations - ECHA (europa.eu).

[16] In this document the term "upcoming restriction" is used when referring to the restriction proposal submitted by ECHA (on the request of the Commission) in 2019, on which the final RAC/SEAC opinion was adopted on 12 March 2020.

		Even though the upcoming restriction would reduce the priority of D5 and D6, this group of substances would still have high priority among the substances on the Candidate List on the basis of the prioritisation criteria further strengthened by grouping considerations. Therefore, the substances are recommended for inclusion in Annex XIV. The decisions on the restriction of D4, D5 and D6, on the Annex XIV inclusion and on possible exemptions pursuant to Art. 58(2) are taken by the Commission. This enables the Commission to make sure that the regulatory decisions are taken in a complementary manner. The recommendation of the substance does not prevent or impede such complementary action. It should be noted that in the process of recommending a substance on the Candidate List 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.
A.2.02	Claim that industry was unprepared for draft recommendation without further notice	Regarding the interplay between restriction and authorisation processes, please refer to reply A.2.01 and for general information on the recommendation process, see A.1.1. As part of the authorisation process, ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV to the European Commission (Article 58 of REACH). To this end ECHA applies the prioritisation approach (https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930). Additionally, ECHA has taken steps to improve transparency and predictability of its processes. ECHA's dissemination website (https://echa.europa.eu/search-for-chemicals) provides an overview under which REACH or CLP related process(es) a substance has been, currently is, or is intended to be managed. In addition the so-called Public Activities Coordination Tool (PACT) (also available on ECHA Website: https://echa.europa.eu/pact) gives advance notice of the substances that are in the focus of authorities for exploring the potential need for regulatory risk management. In this case, authorities have been working since 2011/2012 on D4, D5 and D6 under REACH and the CLP Regulation, carrying out activities in line with ECHA's Integrated Regulatory Strategy (further details can be accessed from the PACT linked above).
A.2.03	Recognition that volumes remain	ECHA recognises the view of DE CA expressed. The tonnage of uses relevant for authorisation remain relatively high even if the upcoming restriction[16] entered into force. As described in the prioritisation approach, ECHA considers all relevant information available to it when preparing the recommendation. Registration dossiers are the main source of information. Further information e.g.

	high after upcoming restriction will apply	from Annex XV SVHC dossiers, from SVHC consultation and from relevant documents on the existing and/or upcoming restriction is also considered, where appropriate. After the end of the public consultation on 5 June 2020 all relevant comments and updates to the registration dossiers were taken into account for finalising the recommendation. Even though the upcoming restriction will likely reduce the scores of D5 and D6, on the basis of the prioritisation criteria further strengthened by grouping considerations, D4, D5 and D6 still receive high priority among the substances on the Candidate List. Both the decision on the Annex XIV inclusion and on the restriction are taken by the Commission. This enables the Commission to make sure that the next regulatory steps are taken in a complementary manner. Please also refer to the response for: A.2.01 Interplay between restriction and authorisation with regard to prioritisation A.2.02 Claim that industry was unprepared for draft recommendation without further notice
A.2.04	Restriction route considered as most appropriate by the SVHC or Restriction dossier submitter, RAC and SEAC	RAC and SEAC considered in their joint opinion that the upcoming restriction[16] is the most appropriate EU wide measure to address the risks posed by the use of D4, D5 and D6 in consumer and professional products. However, the committees did not take a stand on uses not covered by the restriction proposal. The dossier submitters (UK and ECHA per Commission request) have addressed the uses for which they considered restriction to be the most appropriate risk management measure. Unless authorities conclude that further restrictions on D4, D5 and D6 would be needed, authorisation requirement can be used to address the remaining uses in a complementary manner ensuring a high level of protection of human health and the environment, also further promoting substitution. Please also refer to the response for: A.2.01 Interplay between restriction and authorisation with regard to prioritisation A.2.02 Claim that industry was unprepared for draft recommendation without further notice A.2.03 Expectation that only small volumes would remain after upcoming restriction will apply A.1.1.1 on ECHA’s obligation to recommend/prioritise substances on the Candidate List and A.1.5.1 on potential other regulatory actions.

A.2.05	Questioning the intrinsic properties of siloxanes as PBT/vPvB substances	Your point in regard to the hazardous inherent properties of D4, D5 and D6 is not relevant for this part of the authorisation process, as the identification of the substances as Substances of Very High Concern has already been agreed by the Member State Committee, based on the PBT and vPvB properties of the substances. Please refer to link below for relevant documents related to the Candidate Listing of D4, D5 and D6: https://echa.europa.eu/candidate-list-table
A.2.06	Claim that no risk assessment was performed during restriction	Regarding the claim that no risk assessment was performed during the processing of the upcoming restriction[16]: REACH sets out that a quantitative risk assessment cannot be carried out with sufficient reliability for PBT/vPvB substances and, therefore, the calculation of a Risk Characterisation Ratio (RCR) is not appropriate. Instead, a separate PBT/vPvB assessment is required and releases of PBT/vPvB substances shall be minimised. This was also outlined and further detailed by the dossier submitter and RAC rapporteur in the "Response to comments document (RCOM) on the Annex XV dossier proposing restriction on Siloxanes D4/D5/D6, which is available on ECHA's website under https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade Please also refer to the response for: A.2.01 Interplay between restriction and authorisation with regard to prioritisation A.2.05 Questioning the intrinsic properties of siloxanes as PBT/vPvB substances
A.2.07	Claim that for its draft recommendation, ECHA has not considered comments submitted during Restriction process	ECHA assesses all the available information relevant for the prioritisation assessment. In this context, information collected during the development of the Annex XV SVHC and restriction dossiers, information from registration dossiers as well as data submitted during the consultations are taken into account for the recommendation process. All relevant documents are listed in the references of the substance specific background documents.

A.2.08	Claim that volume of D5 used for formulation for export would not be above 1,000 t/y	For details on the upcoming restriction[16], please refer to the response for: A.2.01 Interplay between restriction and authorisation with regard to prioritisation When preparing its restriction proposal, ECHA assessed the registration data, held two calls for evidence and contacted industry for further information. From the information provided, ECHA concluded in its background document to the final RAC and SEAC opinion (https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978) that about 5,000 t/y of D5 and D6 are currently used for formulation for direct export outside the EU. This was taken as a reasonable worst case assumption for the situation also after the restriction was in place. During its prioritisation and draft recommendation ECHA followed the same approach, i.e. assuming a volume of about 5,000 t/y formulated for export for D5 and D6. Again, following the approach taken in the restriction background document, the majority of this volume (> 1,000 t/y) was assumed to be D5, and a minor part D6 (< 1,000 t/y). Based on the information provided during the consultation on ECHA's draft recommendation and in updated registrations, ECHA recognises that these volumes might indeed drop considerably in the future. Taking into account the uncertainties related to how the volumes may change as a result of the upcoming restriction, ECHA now considers for the prioritisation ranges of the volumes in the scope of authorisation and adjusts the volume scores accordingly, i.e. 100-10,000 t/y (score 9-12) for D5 and 10-1,000 t/y (score 6-9) for D6.
A.2.09	Request to include D4 in some derogations for D5 and D6 in upcoming restriction	Regarding the request to include D4 in some of the derogations identified for D5 and/or D6 in the upcoming restriction, we would like to refer you to the documentation of the restriction process. The final scope of the upcoming restriction[16] and the reasoning behind was documented in the final opinion of RAC and SEAC and the related documentation, available on ECHA's website at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade. For information on how to submit information within the restriction process, please refer to the restriction consultation guidance here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c. Please also refer to response: A.2.01 Interplay between restriction and authorisation with regard to prioritisation

A.2.10	Understanding that the use of D4, D5 or D6 in the production of (silicone) polymers is intermediate use	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the use of D4, D5 and/or D6 as monomers in the manufacture of silicone polymers and other polymers. Based on the information provided, this use of the substance and the related volumes (including unreacted monomers) has not been taken into account for prioritisation purposes. However, considering the current state of play of the interpretation of the intermediate status following the European Court of Justice's judgment in Case C-650/15 P, ECHA is not taking a position whether the use qualifies as intermediate use. Please note that not taking into account for prioritisation the volumes related to this use does not change the priority of this group of substances. The priority of D4, D5 and D6 is high in any of the situations considered and the substances are recommended for inclusion into Annex XIV. Taking into account those volumes would only increase the priority and further strengthen the conclusion to recommend D4, D5 and D6 for inclusion in Annex XIV. More details on how uses have been assessed within the prioritisation are documented in the final background documents which can be found on ECHA's website under "Details" of the relevant substances at Submitted recommendations - ECHA (europa.eu). It is the responsibility of companies to assess whether any of their uses fulfils the intermediate definition and therefore are exempt from the authorisation requirement.
A.2.11	Understanding that use of D4 in production of high purity quartz glass for fibres is intermediate use	Please note that the use of D4 in the production of quartz glass might be restricted, once the upcoming restriction[16] on placing on the market of D4, D5 and D6 enters into force with its current scope. The derogations from that upcoming restriction seem not to cover the production of quartz glass. This restriction is currently at the Commission decision stage (see also reply A.2.01). For the case, the use of D4 in the production of quartz glass would be covered by a derogation from the above mentioned upcoming restriction, ECHA made an initial assessment of the intermediate status of that use for the purpose of prioritisation. Based on the information provided, this use of the substance and the related volumes has not been taken into account for prioritisation purposes. However, considering the current state of play of the interpretation of the intermediate status following the European Court of Justice's judgment in Case C-650/15 P, ECHA is not taking a position whether that use qualifies as intermediate use.

A.2.12	Understanding that the use of D4 in non-metal surface treatment is intermediate use	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the uses of D4 in non-metal surface treatment. Based on the information available and the current state of play of the interpretation of the intermediate status following the European Court of Justice's judgment in Case C-650/15 P, ECHA is not taking a position whether the use qualifies as intermediate use. Therefore, ECHA applies a reasonable worst case approach in order to respect the overall aim of the REACH Regulation and of the authorisation procedure. Accordingly, this use of the substance and the related volumes are taken into account for prioritisation purposes.
A.2.13	Understanding that use of D4 in chemical vapour deposition is intermediate use	For the purpose of prioritisation ECHA did an initial assessment of the intermediate status of the uses of D4 in chemical vapour deposition (CVD). Based on the information available and the current state of play of the interpretation of the intermediate status following the European Court of Justice's judgment in Case C-650/15 P, ECHA is not taking a position whether the use qualifies as intermediate use. Therefore, ECHA applies a reasonable worst case approach in order to respect the overall aim of the REACH Regulation and of the authorisation procedure. Accordingly, this use of the substance and the related volumes are taken into account for prioritisation purposes.
A.2.14	Claim that there are no wide-dispersive uses of D4	In general, when assessing whether the use of a substance falls within the scope of authorisation it is crucial to take into account whether the use can be considered as intermediate use and whether the substance is used at concentrations equal or above the concentration limits specified in Art. 56(6). According to the initial assessment of the intermediate status of the uses of D4 performed by ECHA for the purpose of prioritisation only the uses of D4 in non-metal surface treatment and production of electronics (e.g. in chemical vapour deposition, chemical mechanical planarization, in situ coatings or potting agents) and the related volumes are taken into account for prioritisation purposes (please refer to responses A.2.12 and A.2.13). Please also refer to response A.2.10 Understanding that the use of D4, D5 or D6 in the production of (silicone) polymers is intermediate use. Information on obligations resulting from the presence of Candidate List substances in articles can be found on ECHA's website at: https://www.echa.europa.eu/web/guest/regulations/reach/candidate-list-substances-in-articles.

A.2.15	Questioning the volume of D4 estimated for uses in the manufacture of electronic articles and claiming that those uses are wrongly reported in registration dossiers	Some uses of D4 in the manufacture of electronic articles are considered to be outside the scope of authorisation, e.g. the manufacture of polymer silicones (see A.2.10). Their intermediate status has been initially assessed and it appears that those uses may be considered as intermediate uses. However, other uses taking place in the electronics sector are considered to be in the scope of authorisation (see A.2.12 and A.2.13) and their volumes have been taken into account for prioritisation purposes. For further details on how the estimation of the volumes in scope of authorisation was done, please refer to the final background document (https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_d4_en.pdf). For finalising the recommendation ECHA considered any relevant new information provided in registration dossiers by the end of the consultation on 5 June 2020. As further outlined in section A.1.1.3, ECHA applies the prioritisation approach. Accordingly, the prioritisation is per substance and ECHA does not consider process or site specific details. Use and user specific conditions can be reflected in the authorisation application and 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. ECHA wants to emphasise that it is the registrants' responsibility to ensure that the information in the registration dossiers is clear, consistent and up-to-date, including tonnage data and use descriptions. It is the obligation of downstream users to ensure that the exposure scenarios cover their own use of the substance and their conditions of use or, otherwise, take alternative action (see https://echa.europa.eu/regulations/reach/downstream-users).
A.2.16	Claim that D4 is not present in electronic articles and therefore no WDU score for use in articles should be assigned	According to the prioritisation approach (see A.1.1.3) and based on data from registration dossiers or other relevant sources, the presence of the substance in articles is used to refine the WDU score if there is no reliable information that releases are unlikely during article service life and waste phase. In the case of D4 and D5 and their presence from uses of the substance in electronic articles, ECHA made an initial assessment of the available information (from registration and consultation). For some applications, e.g. chemical vapour deposition or planarization (see A.2.13), it seems that according to the information available, D4 or D5 are not present in the articles manufactured. However, there seem to be other applications, such as surface treatment (see A.2.12) of electronic articles described in some CSR, e.g. the use in sealants, for in-situ coatings or to fill recessed cavities

		of an electronic substrate, where the presence of the substance in the final article, and releases therefrom cannot be excluded. From the information provided in registrations and from commenting, applying reasonable worst case assumptions, ECHA concluded that the volume of D4 ending up in articles could be above 10 t/y, corresponding to an additional score of 2. However, registration information on D5 indicates that this volume is rather below 10 t/y, corresponding to an additional score of 1 (see prioritisation approach). For further details, please refer to the substance specific background document (https://echa.europa.eu/documents/10162/13640/10th_recom_final_backgdoc_d4_en.pdf).
A.2.17	Claim that Authorisation does not address siloxanes as impurities in silicone polymers and is therefore not an adequate risk management option	As part of the authorisation process, ECHA has the obligation to recommend substances from the Candidate List for inclusion in Annex XIV. As outlined in the background documents of D4, D5 and D6, as well as in reply A.2.10, the use of the substances as monomers in the manufacturing of silicone polymers and other polymers is not considered for prioritisation purposes. Nonetheless D4, D5 and D6 are of high priority based on their uses in the scope of authorisation and were therefore included in ECHA's draft recommendation. During consultation and in registration updates, ECHA did not receive any information that would change this conclusion. Therefore, ECHA recommends D4, D5 and D6 for inclusion in Annex XIV. To address concerns for human health and the environment from the presence of the siloxanes as unreacted monomers in silicone polymers or other polymers via the authorisation process, a Member State or ECHA (on the request of the European Commission) would need to propose those polymers containing siloxanes as unreacted monomers to be identified as substances of very high concern.
A.2.18	Difficulty to provide comments during the current global health and social crisis	We appreciate that it might have been more challenging to submit comments during the consultation due to the unusual circumstances caused by the coronavirus pandemic. ECHA values all efforts to maintain the high standard of comments submitted during the consultation. Relevant information provided during the consultation has been taken into account by ECHA when finalising its recommendation for inclusion of substances in Annex XIV.

A.2.19	Importance of siloxanes and silicone polymers to achieve the green deal	We acknowledge the comments highlighting the societal and economic importance of D4, D5 and D6 and the difficulties to substitute in a number of their uses. This said, these substances are persistent, bioaccumulative and toxic (PBT), as well as very persistent and very bioaccumulative (vPvB). Hence, in accordance with REACH there is a need to protect humans and the environment from risks arising from their uses and promote substitution. Information about societal and economic benefits associated with a use is important in the application and authorisation decision making phase (see A.1.5.6). Regarding the uses of the substance as unreacted monomers in silicone polymers, see also reply A.2.10
A.2.20	Considering Candidate listing sufficient to trigger minimization of releases	The inclusion of SVHCs in the Candidate List for eventual inclusion in Authorisation List triggers certain obligations, e.g. for substances with PBT/vPvB properties to minimise exposures and emissions to humans and the environment, see also https://echa.europa.eu/candidate-list-obligations). Given these obligations ECHA considers it crucial that registrants identify, recommend and communicate risk management measures and operational conditions required to minimise the emissions as well as that registrants and downstream users do implement these measures. However, the authorisation process aims to progressively replace all substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. Until substitution is achieved, the authorisation process aims to ensure proper control of risks. Based on the obligation to recommend substances from the Candidate List for inclusion in Annex XIV and due to the high priority of the substances we recommend D4, D5 and D6 for inclusion in the Authorisation List. See also reply A.1.1.1.
A.2.21	Suggesting a closed loop system as a technical alternative to reduce exposure below the recommended threshold	Thank you for the information. Please note that closed loop system technologies are not considered as 'technical alternative' in the meaning of 'alternative' under REACH. Under REACH, an alternative is understood as a possible replacement for the Annex XIV substance. The alternative should be able to replace the function that the Annex XIV substance performs. It is noted that an alternative can be another substance, a combination of substances, other techniques, including those which do not require the function to be delivered.

		Closed loop system technologies are considered as 'risk management measures'. They can contribute to the minimisation of release but do not act as a replacement for the Annex XIV substance. Note that for PBT/vPvB substances (such as D4, D5 and D6) there can be no safe threshold derived. Releases to environmental compartments need to be prevented or minimised as far as technically and practically possible.

B. Dates

B.1. Process information

B.1.1. General principles for setting latest application dates[17] / sunset dates[18]

1.Legal background

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

The document "General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV" describes how ECHA implements the above mentioned legal requirements in practice (available at: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf).

2.ECHA's proposal for sunset dates

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

3.ECHA's proposal for latest application dates

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

[17] The latest application date is the latest date by which applications for authorisation must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date.
[18] The sunset date is the date from which the placing on the market and the use of that substance shall be prohibited unless an exemption applies, or an authorisation is granted, or an authorisation application has been submitted before the latest application date specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.

required in the applications. As over 180 opinions have already been given by RAC and SEAC, future applicants are in a better position than the first ones to prepare a fit-for-purpose application.

The work done and ongoing by the Commission, MSCAs, industry and ECHA to further develop approaches and advice on how to prepare a streamlined and fit-for-purpose application will also support the potential applicants concerned by substances in this recommendation. In this context, for example a step-by-step guide for applicants on how to apply for authorisation has been (December 2016) published on ECHA's website. Furthermore, there is ongoing work on applications for the specific cases of low volumes and legacy spare parts. It should also be noted that the requirements on communication of information down and up the supply chain (Title IV of REACH) as well as the downstream user obligations (Title V of REACH) have applied for some years. Implementation of and compliance with these requirements should as well support the organisation of the work within the supply chains related to the preparation of applications for authorisation.

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

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

The complexity of the supply chain could potentially be assessed based on the number of different uses and affected industry sectors, the number of layers in the supply chain, the number and type of companies concerned, and the way potential future applications will be organised[19]. However, ECHA has currently insufficient information to define clearly enough the factors which it should take into account for this assessment. Furthermore, ECHA is currently unable to define precisely what type of information would be used to characterise the above-mentioned factors. Therefore, it is

[19] 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.

concluded that ECHA currently does not have enough information to justify a prolongation of the first LAD, i.e. the 18 months slot.

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

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

The time differences between the LADs set out in a recommendation are relatively short, typically ranging from 3 to 6 months, compared to the total time reserved for the potential applicants to prepare their applications. ECHA proposes to allocate those substances to the "later" LAD slots for which the available information indicates a relatively high number of uses and/or complex supply chain(s). Furthermore, substances with no registration requirement are allocated to the later slots. ECHA has developed a practical implementation method to support a more consistent and transparent assessment of these criteria[20].

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

1.Extensive time needed in the supply chain to get organised for preparing application (e.g. due to high number of users)

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

Communication, organisation and agreement between the relevant actors in the supply chains and efficient allocation of work are important aspects to get the application(s) ready in time. The standard period of 18 months considered by ECHA as the shortest application date already includes the time for getting organised and consulting external expertise.

The application for authorisation is the last step of a multi-step process where previous steps should already raise awareness about the substances under consideration for inclusion in the Authorisation List. It is also important to note that the application process is not anymore a "new" process but has been in place for some time now.

2.Lack of alternatives, socio-economic aspects

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

[20] https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

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

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

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

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

B.1.3. Review periods

1.Upfront review periods

Setting 'upfront' review periods for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. So far, such information was not available to ECHA at the recommendation step. Therefore, ECHA has not proposed any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. It is to be stressed that all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation. ECHA has published guidance on the type of information in an application for authorisation which may impact the review period when granting an authorisation[21].

[21] SEAC's approach for establishing the length of the review period (http://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf) and RAC's and SEAC's guidance paper on opinion trees for non-threshold substances (http://echa.europa.eu/documents/10162/13637/opinion_trees_non_treshold_subs_en.pdf)

B.2 Further responses relevant for the substance group

Reference code	Issue raised in the comment(s)	Response
B.2.01.	Request a LAD of 24 months, because of high complexity of supply chain	In its draft recommendation, ECHA suggested the latest application dates (LAD) to be the date of inclusion in Annex XIV plus 18, 21 or 24 months. ECHA indicated that it will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. Having assessed all available information, it seems that the supply chains of D4, D5 and D6 can be concluded as being of higher complexity when compared to other substances included in the final recommendation. Therefore, a latest application date of 24 months is recommended. Please also refer to responses B.1.1.3 on ECHA's proposal for latest application dates, B.1.1.2 on ECHA's proposal for sunset dates and B.1.2 on aspects not considered by ECHA when proposing latest application and sunset dates.
B.2.02	Long shelf life of the products would allow existence of products after unsuccessful AfA	As detailed in B.2.01, ECHA suggests a latest application date of 24 months after inclusion of D4, D5 and D6 in Annex XIV. According to Article 56 of REACH, the authorisation obligation applies to manufacturers, importers and downstream users. Consumers are not considered downstream users and are therefore not required to apply for authorisation. However, a medical doctor using the substance in the course of a professional activity could qualify as a "downstream user". Therefore, to use the substance after the sunset date, it would require an authorisation, independently whether the substance is in stock or purchased at that time. As further outlined under B.1.2 (Aspects not considered by ECHA when proposing latest application dates/sunset dates), such sector specific practical considerations are difficult to take into account in the recommendation phase which considers all uses of the substance. Furthermore, 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.2.03	Transitional arrangements to be aligned with restriction transitional period	Please also refer to the response for: B.2.01 Request a LAD of 24 months, because of high complexity of supply chain As outlined before in response A.2.01, the decisions on the upcoming restriction[16] of D4, D5 and D6, on the Annex XIV inclusion and on possible exemptions from the authorisation requirement pursuant to Art. 58(2) are taken by the European Commission. This enables the Commission to make sure that the timing of the regulatory decisions is made in the most effective and efficient way further strengthening the complementary nature of the authorisation and restriction processes for these substances. On the setting of latest application dates, please refer to B.1.1.3.

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[22].
According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

- The decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission, taking into consideration ECHA's recommendation. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) REACH within the limits of EU law, including the proportionality principle.

ECHA further recalls that it is apparent from the terms of Article 58(2) that:

(a) The obtaining of an exemption is a possibility and not an entitlement;
(b) The discretion afforded to the Commission only ever arises where there is specific minimum EU legislation in place imposing minimum requirements relating to the protection of human health and/or the environment for the use of the substance ensuring the risk is properly controlled; it should be noted that in the absence of existing specific EU legislation in force, the Commission cannot grant an exemption on the basis of Article 58(2) of REACH in respect of the substance listed in Annex XIV of REACH; thus national legislation or non-binding EU acts addressing such use is not a sufficient ground for the Commission to grant such an exemption[23];
(c) Risk assessment and the question as to whether individual operators are able to control risks associated with the use of a substance of very high concern are not included among the criteria that may constitute a basis for the granting of exemptions of a use. In the absence of specific Union legislation the Commission has no discretion to grant an exemption under Article 58(2) of REACH regardless of the outcome of risk assessment.

[22] https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf

In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[23] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[24]):

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances. A mere reference to carcinogenic, mutagenic or reprotoxic substances is too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements which properly control the risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures (e.g. EU legislation which provides Member States the possibility to impose less stringent requirements than that suggested by the EU legislation in question) or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2) of REACH. Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

On the basis of the elements above:

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

[23] For further information, see the judgment of the General Court in Case T-360/13: *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) and Others vs European Commission*.
[24] Available at: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf

C.1.2. Generic exemptions

A list of uses exempted from the authorisation requirement according to the REACH Regulation can be found at https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf. The scope of some of these generic exemptions is further clarified in ECHA's Q&A found at https://www.echa.europa.eu/web/guest/support/qas-support/qas (Q&As 1027, 1028, 1030 and 1031). It should be noted that if a use falls under the generic exemptions from authorisation, there is no need to propose an additional specific exemption.

It is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. Further information on such requirements can be found in the legislation listed at the above link, as well as in Article 3(23) REACH regarding scientific research and development, and in the ECHA Guidance on intermediates (https://www.echa.europa.eu/documents/10162/23036412/intermediates_en.pdf).

C.1.3. Aspects not justifying an exemption from authorisation

There are several generic exemptions from the authorisation requirement[22]. Furthermore, uses can be exempted from the authorisation requirement on the basis of Art 58(2) which depends on the provisions of existing EU legislation (See section C.1.1. General principles for exemptions under Art. 58(2)).

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

C.2 Further responses relevant for the substance group

Reference code	Issue raised in the comment(s)	Response
C.2.01	Request to clarify generic exemption for laboratory use	Scientific research and development, i.e., use in scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year is generically exempt from authorisation (Art. 3(23) and 56(3) REACH). According to Q&A 1153 (https://www.echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1153) sampling is part of the use where this activity takes place. Please note, that as outlined under C.1.2., it is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses.
C.2.02	Generic exemption of the uses in medical devices and/or medicinal products	As D4, D5 and D6 are PBT/vPvB substances, their use in medicinal products is exempted from the authorisation requirement (Art. 2(5)(a) REACH), however, their use in medical devices is not exempt (Art. 60(2) and 62(6) REACH). As outlined in C.1.2., it is the responsibility of companies to assess whether any of their uses complies with the requirements relevant for each of the exempted uses. However, this has no direct impact on the Annex XIV recommendation process, unless the respective volumes are relevant for prioritisation purposes. Therefore, ECHA took into account for prioritisation only the volumes of D5 and D6 used in medical devices (confirmed use) where use specific volume information was available, e.g. in the restriction background document of the upcoming restriction[16] (https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978). Please also refer to the response for: A.2.01 Interplay between restriction and authorisation with regard to prioritisation A.2.10 Understanding that the use of D4, D5 or D6 in the production of (silicone) polymers is intermediate use
C.2.03	Request for exemption based on derogations	As a general principle ECHA wants to emphasise that authorisation and restriction can be used in a complementary manner to ensure proper control of risk and provide an incentive to (continue to) develop alternatives (i.e. they do not exclude each other).

	from upcoming restriction	Therefore, the uses of D4, D5 and D6 foreseen to be derogated from the upcoming restriction[16] in general fall within the scope of authorisation. Once the substances are included in Annex XIV, they will become subject to authorisation, unless they fall under the generic exemptions from the authorisation requirement or a specific exemption is granted by the Commission pursuant to Art. 58(2) of REACH. When assessing the specific requests for exemptions, ECHA took into account: - The specific conditions and basis for the derogations from the upcoming restriction - Whether the use would benefit from the generic exemptions from the authorisation requirement. - Whether the use might fulfil the conditions to be granted a specific exemption under Article 58(2) (see below) An exemption can be granted under Article 58(2) if three conditions are met: i. Only existing EU legislation is relevant in the context to be assessed, i.e. the upcoming restriction needs to be adopted. ii. Minimum requirements for controlling risks to human health and/or the environment need to be imposed in a way that they cover the life cycle stages that are exerting the risks resulting from the uses in question. iii. There need to be binding and enforceable minimum requirements in place for the substance(s) used. ECHA notes that requests for exemptions submitted during the consultation did not refer to any further legislation which could serve as basis for an exemption pursuant to Art. 58(2). Please note, that the below considerations are only relevant in case the restriction would be adopted in accordance with the final opinion by RAC and SEAC (see condition i) above). This can lead to the following situations: a) The use is derogated from the restriction due to scope considerations (RAC and SEAC did not provide an opinion on risk or socioeconomic aspects of those derogations) and within the scope of authorisation (e.g. the industrial use in non-metal surface treatment): in this case an application for authorisation is required as conditions ii) and iii) above are not met. b) The use is derogated from the restriction and is generically exempted from the authorisation requirement (e.g. the industrial use as a monomer in the production of silicone polymer would be exempted from authorisation on the basis of Article 2(8)(b) of REACH): in this case, no

		application for authorisation is needed. For those uses the conditions of Art. 58(2) are not relevant. c) The use is not derogated and therefore covered by the restriction, independently whether it falls within the scope of authorisation or not (e.g. the use of D4 as functional fluid): these uses would be restricted once the restriction came into force. d) The use is derogated based on socio-economic considerations (e.g. the derogation of D5 and D6 in medical devices for scar and wound treatment): those uses do not appear to fulfil the Art. 58(2) condition of "imposing minimum requirements relating to the protection of human health and/or the environment" (conditions ii) and iii) may not be met). e) The use is derogated from the restriction but imposing minimum requirements relating to the protection of human health or the environment (i.e. the derogation of D5 for dry cleaning in closed systems). Such a use might be exempted on the basis of Art. 58(2) (possibly fulfilling conditions ii) and iii) above) in case it is considered that with the imposed requirements "for the use of the substance, the risk is properly controlled." The decisions on the upcoming restriction of D4, D5 and D6, on the Annex XIV inclusion and on possible exemptions from the authorisation requirement pursuant to Art. 58(2) are taken by the Commission. This enables the Commission to make sure that the regulatory decisions are complementary.
C.2.04	Questioning that formulation for export requires AfA	The manufacture (for export) of a substance on the Authorisation List does not require authorisation. On the other hand, though derogated from the upcoming restriction[16], the use of D5 and D6 in formulation (for export) is a use that requires authorisation. As stated in the background document of the Annex XIV recommendation as well as of the upcoming restriction on D4, D5 and D6, it is assumed that once the restriction comes into force, a proportion of cosmetics containing D5 and D6 will still be formulated in Europe and exported directly – as it is today. Please also refer to the responses A.2.08 and C.2.03
C.2.05	Claim that the use of silicone polymers and their mixtures are generically	Regarding the intermediate status of D4, D5 and D6 in the production of silicone polymers, please refer to response A.2.10. As outlined in the Q&A (ID: 0565, link): "The authorisation requirement applies to the placing on the market and use of a substance on its own as listed in Annex XIV. Therefore, it usually does not apply if the Annex XIV substance is only an impurity or additive or constituent of another substance, unless this

	exempt from authorisation	is specified in the Annex XIV entry (e.g. substance W and substances X, Y and Z containing substance W in a concentration ≥ x %) or the other substance is also listed in Annex XIV". Silicone polymers are currently neither included in the Candidate List nor in Annex XIV. Therefore, if D4, D5 or D6 (as unreacted monomer) can be considered as an impurity or constituent of the silicone polymer, such uses would not require authorisation. On the other hand, if a substance listed in Annex XIV is included as a component in a mixture, the authorisation requirement applies for this use (i.e. the formulation of the mixture). Further, the placing on the market and use of such mixtures require authorisation, unless the Annex XIV substance is present in the mixture below the concentration limits set out in REACH Article 56(6). So, if D4, D5 or D6 are added intentionally to a mixture (that might also contain silicones) above the concentration limit of 0.1 %, such a use would require authorisation. It is the responsibility of companies to assess their specific situation and whether the authorisation requirement would apply for their uses.