14 April 2021

Response document

Substance name: Terphenyl, hydrogenated

EC number: 262-967-7

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

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

- **A. Priority and general issues**
  covers responses to issues related to the priority of the substances, including ECHA's prioritisation approach and its implementation in assigning priority scores and conclusions; also covers any other generic issue not covered by sections B and C;
- **B. Dates**
  covers responses to issues related to the latest application dates, sunset dates and review periods, including ECHA's approach for determining those timelines;
- **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: https://echa.europa.eu/documents/10162/13640/10th_recom_comref_terphenyl_hydrogenated_en.rtf

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].

[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

2. Authorisation is disproportionate and/or means a ban

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

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

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

3.Use specific considerations

The authorisation process foresees that the level of control of risks, the availability of and the time needed to transfer to suitable alternatives (e.g. due to need for established validation, safety requirements and/or performance standards) and socio-economic considerations such as the magnitude of benefits from continuing a certain use of an SVHC (i.e. adverse impacts of ceasing a use) are not considered in the recommendation phase but are addressed at the application phase of the authorisation process. That is because it is this phase where the respective assessment can be done in an effective manner: based on structured input of information by the applicant, the foreseen dedicated 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

[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.

part of their authorisation application. The Risk Assessment Committee (RAC) will assess the appropriateness and effectiveness of the risk management measures as described in the application. There is also a possibility to specify in the authorisation decision further conditions, including monitoring requirements. This provides an additional level of scrutiny of the appropriateness of the control measures compared to the registration and downstream user obligations.

5.Availability of suitable alternatives

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

6.Socio-economic benefits of continued use

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

7.Potential competitive disadvantage

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

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

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, 26].

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

Reference code	Issue raised in the comment(s)	Response
A.2.01	Request to authorise/regulate all substances used as Heat Transfer Fluids (HTF) simultaneously	While we acknowledge the wish for regulatory consistency (i.e., in this case, regulate all substances used as HTF simultaneously), we also recognise the challenges both in defining the scope of such consistency and in achieving such consistency in general, and in particular during the recommendation step of the authorisation process. Consistency may help (i) in increasing efficiency of the regulatory actions, in particular where the differences in the actions could result in an unwanted transfer to (similar) substances without reducing the risks, and (ii) to support achieving a level playing field. However, when seeking consistency there is a need to ensure that there is no undue delay in proceeding with regulatory actions and that the burden of proof is not reverted to authorities to make an upfront assessment of the substance and all its possible alternatives / similar substances. ECHA wants to remind that: • It is applicant's responsibility to make a proper analysis of alternative • It is the substance manufacturer's/importer's responsibility to fulfil REACH requirement ensuring that correct and well-founded hazard conclusions are available in their registration dossiers and SDSs, allowing potential future users of their substance to duly take this information into account.
A.2.02	Request to postpone the recommendation of terphenyl, hydrogenated until regulatory future for alternative substances is clarified	Currently, ECHA sees no reason to postpone the recommendation of terphenyl, hydrogenated. Terphenyl, hydrogenated is a vPvB substance used in high tonnage. According to REACH Art. 58(3) and the agreed prioritisation approach, it has high priority for inclusion in Annex XIV. Although the work on the alternative substances is very important, it needs to be balanced with the need to regulate an already identified SVHC. Applying a functional grouping approach does not mean (and in regulatory effectiveness terms, does not require), to first clarify the hazard profile of all substances (potentially) used for the same application before it would be meaningful to consider further risk management activities (e.g. inclusion in Annex XIV) for the individual substances or the entire group. Grouping for regulatory action should not lead to a situation in which a substance cannot be recommended because further substances may be used for the same application and have not yet been identified as SVHCs. Regulatory effectiveness should therefore be assessed by balancing on the one hand the need to initiate/proceed with regulatory action and on the other hand to do that in a

		meaningful way (i.e. by addressing substances which could potentially substitute each other in their uses through grouping).
A.2.03	Consider that Finnish RMOA (based on functional grouping approach) includes all alternatives to terphenyl, hydrogenated, for use in heat transfer systems	The main aim of the authorisation process is to improve chemical safety and push for substitution of SVHCs by suitable alternatives. Substituting an SVHC by another substance having the same or a similar hazard profile should be avoided. In order to prevent regrettable substitution the Finnish Competent Authority undertook a limited screening exercise to identify potential alternatives to terphenyl, hydrogenated that may require similar regulatory action (functional grouping approach). The screening exercise resulted in the identification of two substances, screening positively for PBT or vPvB properties. An RMOA covering those two substances has been prepared. Further assessment or data generation processes have been initiated for those substances (as can be seen in PACT[16]). It should however be stressed that the screening exercise performed by the Finnish Authority was limited in scope[17] and targeted to the purpose highlighted above. The screening based on functional grouping should not be considered as an exhaustive review of possible alternative substances to terphenyl, hydrogenated for its use in heat transfer system. The task of identifying alternatives for a given use and to assess their suitability remains the responsibility of the companies applying for authorisation and would need to be reflected in an AoA. **See also response A.2.04. Request to consider that alternative substances used as heat transfer fluids are likely to have similar hazardous properties**
A.2.04	Request to consider that alternative substances used as heat transfer fluids are likely to have similar hazardous properties	**Please refer first to response A.1.5.5 *Availability of suitable alternatives*** Information on the hazard profile of alternative substances cannot be considered during the recommendation phase of the authorisation process but is considered at the AfA stage. In the context of application for authorisation the *suitability* of alternative substances or technologies are assessed from the perspectives of their technical feasibility, economic feasibility and also risk reduction potential. According to REACH Art. 60(5)(a) when assessing whether suitable alternatives are available, it needs to be taken into account whether the transfer to alternatives will result in a reduced overall risk to human health and the environment. If an alternative substance is equally or

[16] ECHA's Public Activities Coordination Tool available at https://echa.europa.eu/pact

[17] Focus only on substances already registered as heat transfer fluid, limited search criteria applied to target such use in the REACH database, all inorganic substances set aside by default, boiling point and information from publicly available sds used to further filter the list

		more hazardous than the Annex XIV substance concerned, this is generally sufficient to show that it is not a suitable alternative and no additional feasibility assessment is normally necessary[18]. Under REACH, the meaning of 'alternative' is wide. An alternative is a possible replacement for the Annex XIV substance. The alternative could be another substance, several substances used together or it could be a technique (e.g. a process, procedure, device, or modification in the end product) or a combination of technical and substance alternatives[3]. Only detailed and specific knowledge of the exact function that the Annex XIV substance is providing (and where and how, i.e. under what conditions, that function must be performed) for a particular use, allows to look for other ways of performing that function. This is why companies need to demonstrate in the application for authorisation (AfA) the initiatives taken to find alternatives for their specific use.
A.2.05	Consider RMOA as a regulatory risk management activity that could justify not recommending terphenyl, hydrogenated	We would like to point out the difference between the concepts of a 'regulatory management option analysis' (RMOA)[19] and 'on-going regulatory risk management activities'. The agreed Annex XIV prioritisation approach, which describes the key principles for deciding on substances to recommend, states that other on-going **regulatory risk management activities** can be considered when deciding on which substances to recommend. The approach also states that other potential **risk management options** and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. ECHA notes that there is currently no ongoing regulatory risk management activity other than recommendation for Authorisation on terphenyl, hydrogenated. We recognise that Evaluation processes are ongoing on two potential alternative substances and these may lead to requests for further hazard information generation. These in turn may lead to further regulatory risk management actions. However, currently, there is no intention in the registries of intention for any such action[20]. There are RMOA conclusion documents available for terphenyl, hydrogenated and for the alternative substances (see ECHA's Public Activities Coordination Tool available at https://echa.europa.eu/pact). However, those are RMOAs and are not considered during the prioritisation step, according to the prioritisation approach.
A.2.06	Suggest that inclusion of terphenyl,	Inclusion of terphenyl, hydrogenated in Annex XIV would lead a number of companies to have to decide either to apply for authorisation for continuing the use of terphenyl, hydrogenated, or to substitute the substance.

[18] See https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf
[19] Previously called 'risk management option analysis'
[20] See Registry of restriction intentions, Registry of SVHC intentions and Registry of CLH intentions

	hydrogenated in Annex XIV will create incentives for regrettable substitution	Substituting a substance by another substance is associated to costs and risks, in particular if the hazard of the alternative substance is unclear. Before moving to alternative substances, companies are advised to duly consider its hazardous properties. Member State Competent Authorities and ECHA have taken steps to improve the level of information available on hazardous properties of some identified potential alternatives and to transparently communicate the outcome of current assessments. However, authorities cannot be aware of all potential alternatives. It is stressed that 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 can 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.
A.2.07	Understand that authorisation requirement is not applicable to HTF used in closed and controlled systems	ECHA notes that the authorisation requirement apply to all the uses of substances included in Annex XIV except to those uses that are *generically* exempted from the authorisation requirement (overview available here) and to those uses that are granted a *specific* exemption under Art. 58(2). The use of heat transfer fluid in closed and controlled conditions does not seem to fall under any of the *generic* exemptions from the authorisation requirement. Some companies commenting during the consultation requested *specific* exemptions for the use of HTF in closed and controlled system. However, no justifications were provided demonstrating that the conditions for granting an Art. 58 (2) exemption are met (See also response C.2.1 - Consider exemping the use as heat transfer fluid (HTF)) It is stressed, too, that the final decision on granting or not Art 58 (2) exemption is taken by the Commission at the next step of the process.
A.2.08	Inclusion of terphenyl, hydrogenated in Annex XIV creates uncertainty on replacement Roadmaps of several other	Due to regulatory processes being initiated at different points in time for different substances it can be that replacement roadmaps for several SVHC substances used in the same applications or in the same sector of applications, need to be developed in parallel. In practice, it would be difficult for Authorities to identify and address jointly all substances used in a given application/sector. The substitution plan and analysis of alternatives will always need to be adapted to reflect new information available and new regulatory developments. Such information will also be considered by the RAC and SEAC Committees when assessing review reports. Although terphenyl, hydrogenated may be an important raw material, e.g. in sealing technologies, it is also identified as a Substance of Very High Concern (SVHC) due to its vPvB properties. Hence there is

	Annex XIV substances	a strong societal interest to protect humans and the environment from risks potentially arising from its uses. By applying the prioritisation criteria, terphenyl, hydrogenated got high priority among Candidate List substances for inclusion in Annex XIV; therefore, ECHA has no ground to postpone its recommendation. It is noted that terphenyl, hydrogenated has been on the regulatory radar for several years. The conclusions from the RMOA undertaken by Finland on this substance have been made publicly available via ECHA's Public Activities Coordination Tool[21] (https://echa.europa.eu/pact) in October 2017 and the substance has been included on the Candidate List in June 2018. Companies should get prepared for the next steps in the regulatory process, at the latest after addition to the Candidate List.
A.2.09	Commenting the burden for SMEs to prepare applications for authorisation	ECHA takes note of the concerns raised in relation to SMEs. Generally, such information is better placed in the call for information by the Commission on the possible socio-economic consequences of the inclusion of the substances in the Authorisation List. Such call was performed in parallel to ECHA's consultation on the Annex XIV recommendation. ECHA wants to stress that in accordance with Art. 62(1, 2) applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream users of a substance and for one or several uses. Applications may be made for the applicant's own uses and/or for uses for which he intends to place the substance on the market. From these specifications it is evident that not each actor on the market has to apply for authorisation of his use(s) because he can benefit from the authorisation granted to an actor up its supply chain. If the authorisation is granted to the upstream actor the SME downstream user companies do not need to apply for authorisation. Instead, they need to notify ECHA free of charge about their use and ensure that they comply with the conditions of the granted authorisation. ECHA further stresses that it is also possible to submit joint applications by a group of actors.
A.2.10	Suggesting a closed loop system as a	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

[21] PACT (ECHA's Public Activities Coordination Tool) can be used by companies to get advance notice on possible regulatory actions by Authorities. PACT provides up-to-date information on the activities planned, ongoing or completed by ECHA and/or MSCAs for a given substance in the following areas (i) Data generation and assessment – dossier evaluation, substance evaluation, informal hazard assessment (PBT/vPvB/ED) (ii) Regulatory management option analysis (RMOA) (iii) Regulatory risk management – harmonised classification and labelling (CLH), SVHC identification, restriction.

	technical alternative to reduce exposure below the recommended threshold	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 vPvB substances (such as terphenyl, hydrogenated) there can be no safe threshold derived. Releases to environmental compartments need to be prevented or minimised as far as technically and practically possible.
A.2.11	Suggest that the priority given to vPvB substances is not right	When prioritising SVHC substances for their inclusion in Annex XIV, ECHA applies the agreed prioritisation approach, developed based on the requirements described in REACH legal text. According to Art. 58(3), priority should be given to PBT and vPvB substances. The legal text and the agreed prioritisation approach do not differentiate PBT and vPvB substances, for the purpose of the prioritisation for inclusion in Annex XIV.

B. Dates

B.1. Process information

B.1.1. General principles for setting latest application dates[22] / sunset dates[23]

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

[22] 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.
[23] 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[24]. 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

[24] 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[25].

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.

[25] 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[26].

[26] 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

Reference code	Issue raised in the comment(s)	Response
B.2.01	Request to set the timelines in a way that the analysis of alternatives can take into account the outcome of ongoing data generation for alternative substances	ECHA sees no justification to diverge from its proposal for latest application dates and sunset date for the uses of terphenyl, hydrogenated on the basis on the level of information currently available on some possible alternatives. Information on technically viable alternatives and on associated remaining uncertainties (such as the extent to which they would lead to an overall reduction of the risk) should be reflected in the Analysis of Alternative (AoA) of the application for authorisation (Afa). **See also responses:** **A.2.01. Request to authorise/regulate all substances used as Heat Transfer Fluids (HTF) simultaneously** **A.2.02. Request to postpone the recommendation of terphenyl, hydrogenated until regulatory future for alternative substances is clarified** **A.2.04. Request to consider that alternative substances used as heat transfer fluids are likely to have similar hazardous properties** **A.2.06. Suggest that inclusion of terphenyl, hydrogenated in Annex XIV will create incentives for regrettable substitution**
B.2.02	Request to assign same sunset date for all substances with similar technical function that are included in Annex XIV, to avoid regrettable substitution	ECHA does not see sufficient basis to align the sunset dates for all substances with similar technical function as terphenyl, hydrogenated that could be included in Annex XIV. Alternative substances identified are currently under Evaluation processes and are not identified as SVHC. In practise, aligning sunset dates would mean to delay significantly the whole regulatory process for terphenyl, hydrogenated. ECHA considers that the efforts made to increase transparency[27] on the envisaged next regulatory steps for the substances already identified as potential alternatives to terphenyl, hydrogenated that are under scrutiny for similar hazard properties should help avoiding regrettable substitution.

[27] E.g. publication of RMOA conclusion documents on PACT (ECHA's Public Activities Coordination Tool available at https://echa.europa.eu/pact)

		See also responses: **A.2.01. Request to authorise/regulate all substances used as Heat Transfer Fluids (HTF) simultaneously** **A.2.02. Request to postpone the recommendation of terphenyl, hydrogenated until regulatory future for alternative substances is clarified** **A.2.04. Request to consider that alternative substances used as heat transfer fluids are likely to have similar hazardous properties** **A.2.06. Suggest that inclusion of terphenyl, hydrogenated in Annex XIV will create incentives for regrettable substitution**
B.2.03	Consider typical authorisation timeframes (LAD, SD, review periods) not suitable for the use as HTF as life-cycles/ investment-cycles are typically longer	**Please refer to the following responses:** **B.1.1. General principles for setting latest application dates / sunset dates 2. ECHA's proposal for sunset dates 3. ECHA's proposal for latest application dates** **B.1.2. Aspects not considered by ECHA when proposing latest application dates/sunset dates** ECHA notes that the length of the applicant's investment cycle is one criterion considered when setting review periods at the application phase of the authorisation process. For more information, **please refer to the response B.1.3.1 Review periods** If specific conditions prevail that may justify a review period different than the normal length of seven years described in the approach agreed by RAC and SEAC, the committees can recommend a different, appropriate review period. The specific conditions that would justify longer review period need to be described by the applicants in the Application for Authorisation. Based on the opinion by the Committees, the Commission decides on the length of the review period.

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[28].
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[29];
(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.

[28] 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[29] (also described in the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[30]):

- 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.

[29] 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*.
[30] 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[28]. 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

Reference code	Issue raised in the comment(s)	Response
C.2.01	Consider exempting the use as heat transfer fluid (HTF)	During the consultation, exemption requests were received by various comment submitters for uses of terphenyl, hydrogenated, as heat transfer fluid/heat exchanger fluid/heat carrier oil (later on generally referred to as HTF). Some comment submitters further specified the uses to be exempted e.g. as follow: • HTF in closed systems; • HTF in closed tight systems without any possibility of leakage; • HTF in close system without any contact with the other installation and equipment; • HTF in closed systems at industrial sites; • HTF in closed, tight, non-pressurised systems requiring an operational temperature of 300 to 345 ºC in industrial processes, provided that operators are trained with respect to Safety and Environmental guidelines published on the Material Safety Data Sheet and that all potential risks are assessed and deemed manageable. The exemption requests were substantiated by the following types of considerations: • the use as HTF always takes place in closed system with hardly any exposure or release to the environment. There are no emissions to atmosphere, no effluents to water or other environment components. Emissions from the installations themselves are non-existent, emissions and exposure during filling are minimised; risks are controlled; • the expected reduction of emission and exposure from the substitution of terphenyl, hydrogenated in its use as HTF are negligible. The use is safe and the product is stable (product can withstand high temperatures). Technically valid alternatives are likely to be equally persistent to the environment; • the benefits of using the substance outweigh the risks; • the complete system where the substance is used as HTF is designed with a lot of different safety equipment according to local rules and authorities request. Annual safety inspections of the plant and oil quality protect the system; the relevant areas of risk are already regulated. The handling is already subject to strict legal requirements (norms/standards/legislation referred to include DIN 4754, VDI 3033, guideline

		resulting from EU Directive 97/23/EC on pressure equipment, AD 2000 rules, national (German) legislation (e.g. BetrSichV, AwSV, WHG) and IED (plant permits)). The uses requested to be exempt do not seem to be covered by any generic exemption from the authorisation requirement (see section **C.1.2. Generic exemptions**). The key principles under which specific exemptions from the authorisation requirement under REACH can be granted are summarised in the section **C.1.1. General principles for exemptions under Art. 58(2).** ECHA reminds that an exemption may only be granted under Art. 58(2) provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. Most justifications provided in the comments to substantiate the exemption requests are not based on existing specific Community legislation and therefore do not qualify for exemptions under Art. 58(2) (**See also section C.1.3. Aspects not justifying an exemption from authorisation**). Some comment submitters referred to existing norms/standards established at Community level and to Community Directives. Those are not considered as sufficient basis for an Article 58(2) exemption (*cf*. elements considered when assessing EU legislation as described in **Section C.1.1**).