Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Terphenyl, hydrogenated

ECHA/RAC/RES-O-0000007224-79-01/F

ECHA/SEAC/RES-O-0000007305-77-01/F

Date: 9 June 2023

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): **Terphenyl, hydrogenated**

EC No.: **262-967-7**

CAS No.: **61788-32-7**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Italy has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration on **20 June 2022**. Interested parties were invited to submit comments and contributions by **20 December 2022**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Laure Geoffroy**

Co-rapporteur, appointed by RAC: **Geneviève Deviller**

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on 16/03/2023.

The opinion takes into account the comments of interested parties provided in accordance

with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Marit Måge**

Co-rapporteur, appointed by SEAC: **Manuel Rodriguez Hernandez**

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **10 March 2023.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation in accordance with Article 69(6)(a).

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration on **15/03/2023**. Interested parties were invited to submit comments and contributions by **15/05/2023**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **9 June 2023.**

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by simple majority.** The minority position, including its grounds, is made available in a separate document which has been published at the same time as the opinion.

Contents

Tables

1. OPINION OF RAC AND SEAC

The proposed wording of the restriction set out below aims to express the intention of the Dossier Submitter. Should a restriction be adopted then the final wording of the entry in Annex XVII of REACH will be decided by the European Commission.

Table 1 The restriction proposed by the Dossier Submitter

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Terphenyl, hydrogenated, CAS No: 61788-32-7 EC No: 262-967-7	1. Shall not be placed on the market from [18 months after entry into force]: a) As a substance on its own. b) As a constituent of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w. c) In articles or any parts thereof containing terphenyl, hydrogenated in concentrations equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply for the use and placing on the market as a heat transfer fluid, provided that such sites implement strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions. 3. By way of derogation, Paragraph 1 shall not apply to the use and placing on the market in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats, as long as these applications are covered by the WEEE Directive (2012/19/EU). 4. By way of derogation, Paragraph 1 shall not apply after entry into force +5 years, for the use and placing on the market in aerospace and defence

	applications and their spare parts, maintenance and repairs.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **terphenyl, hydrogenated** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

RAC points out that ortho-terphenyl/o-terphenyl (the constituent of terphenyl, hydrogenated that warrants restriction due to its vPvB properties) may be present as a constituent of other substances in addition to terphenyl, hydrogenated. RAC recommends that the risks posed by o-terphenyl resulting from the use of these substances if confirmed could be further investigated and addressed.

The conditions of the restriction proposed by RAC are:

Table 2: The restriction proposed by RAC

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Terphenyl, hydrogenated CAS No: 61788-32-7 EC No: 262-967-7	1. Shall not be placed on the market, or used, from [18 months after entry into force]: a) as a substance on its own. b) in other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w. c) in articles or any parts thereof in a concentration equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply to the use and the placing on the market for use as a heat transfer fluid in industrial sites, provided that such sites have implemented strictly controlled closed systems with technical containment and organisational measures to prevent environmental

	emissions *[as set out in Appendix 2 to this opinion]*[1]. The implementation of the strictly controlled systems shall be monitored by a representative program. This derogation shall end by [x year(s) after entry into force of the restriction][2]. Paragraph 1 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].

Notes:

[1] **Column 2, paragraph 2:** technical containment and organisational measures to prevent environmental emissions in strictly controlled closed systems shall comply with the organisational and technical requirements described in Appendix 5 in the Annexes of the Background Document by the date of entry into force of the restriction. Additionally, the industrial sites shall implement a monitoring program to assess environmental releases and confirm further the appropriateness and effectiveness of the operational conditions (OCs) and risk management measures (RMMs) in place.

[2] **Column 2, paragraph 2**: [x year(s)] to be considered by SEAC. RAC supports the shortest possible time limit to minimise environmental emission as much as possible.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on terphenyl, hydrogenated is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, considering the proportionality of its socio-economic benefits to its socio-economic costs. This is provided that the conditions are modified as proposed by SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Table 3: The restriction proposed by SEAC

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Terphenyl, hydrogenated	1. Shall not be placed on the market, or used, from [18 months after entry into force]: i. as a substance on its

CAS No: 61788-32-7 EC No: 262-967-7	own. ii. in other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w. iii. in articles or any parts thereof in a concentration equal or greater than 0.1% w/w. 2. By way of derogation, Paragraph 1 shall not apply to the use and the placing on the market for use as a heat transfer fluid (temperature range 250°C- 350 °C) for use in industrial sites, provided that such sites have implemented strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions. 3. By way of derogation, Paragraph 1 shall not apply to the use and the placing on the market for use in aerospace and defence applications and their spare parts, maintenance and repairs. This derogation shall end by [10 year(s) after entry into force of the restriction]. 4. Paragraph 1 shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force]. 5. Paragraph 2 shall be reviewed in ten years after EiF of the restriction to evaluate the availability for new installations of suitable alternatives that do not pose concerns for regrettable substitution.

Explanatory notes:

Column 2, paragraph 2: technical containment and organisational measures to prevent environmental emissions in strictly controlled closed systems (SCCS) shall comply at minimum and without undue delay with the organisational and technical requirements described in Appendix 5 of the Annex XV Annexes. Additionally, the industrial sites shall

implement a monitoring program to assess environmental releases and confirm further the appropriateness and effectiveness of the OCs and RMMs in place.

SEAC recommends limiting the derogation for heat transfer fluids to a temperature range of 250° to 350°. This is to ensure that the use of the substance is limited to its intended use for specific high temperature heat transfer fluids (this range has been confirmed by an industry stakeholder manufacturer of the substance).

SEAC recommends that the need for further regulatory action on two potential alternatives for terphenyl, hydrogenated (dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene) identified as such by Tukes in an RMOA, is further assessed. This is further discussed in section 3.4.1

SEAC recommends that progress in substitution possibilities is reviewed 10 years after entry into force of the restriction to assess whether new information has become available that would indicate that alternatives that would not pose risk of regrettable substitution would be available for the use as a heat transfer fluid. If the review finds that safer substitutes have become available, then legislative action affecting new installations only could be considered.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The restriction aims at reducing risks to health and the environment from the use of terphenyl, hydrogenated, which was identified by ECHA (2018) as a Substance of Very High Concern (SVHC) because of its very persistent and very bioaccumulating properties (vPvB). This 'Substance of Unknown or Variable composition, Complex reaction products or Biological materials' (UVCB) was assessed by evaluating the properties of different relevant constituents. At least one of these constituents (ortho-terphenyl, later also referred to as o-terphenyl) fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1%), terphenyl, hydrogenated is considered to fulfil vPvB criteria.

Terphenyl, hydrogenated is not manufactured in the European Union (EU) and the imported volume is estimated to be 7 500 tonnes (2020). The main use, accounting for approximately 90% of the annual volume is as a heat transfer fluid (HTF). When terphenyl, hydrogenated is used as an HTF, it is consistently contained within a closed system with limited discharges identified. However, exposure to the environment cannot be disregarded according to the Dossier Submitter. For all non-HTF uses, e.g. as a processing solvent and plasticiser, an unacceptable risk for the environment and human health has been identified.

According to REACH Annex I para 6.5, the risk to the environment and human health cannot be adequately controlled for PBT/vPvB substances. There is no safe concentration for such substances, nor can a threshold be determined for PBT/vPvB substances. Furthermore, as vPvB and PBT chemicals are treated as non-threshold substances, even low levels of emissions could pose a risk to the environment. Therefore, a REACH Restriction was identified as the most relevant and proportionate Regulatory Management Option (RMO) by the Dossier Submitter.

Three restriction options (RO1, RO2, RO3) are analysed in the impact assessment, all of which restrict the manufacture, use and placing on the market of terphenyl, hydrogenated in concentrations ≥ 0.1% by the end of a transition period of 18 months.

No feasible alternatives for terphenyl, hydrogenated are currently available, without creating a situation of regrettable substitution.

RO1 and RO2 both include derogations of varying scope and length for uses as HTF, i.e. by far the most important use. RO1 includes additional derogations for the use and placing on the market of terphenyl, hydrogenated in aerospace and defence applications and in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats. Restriction option (RO3) does not include any derogations.

Based on an analysis of the effectiveness, proportionality, practicality and monitorability of the three restriction options, RO1 is proposed by the Dossier Submitter to be the most appropriate risk management option because it is effective and reduces potential risks to an acceptable level within a reasonable period of time.

2.2. Summary of opinion

2.2.1. RAC opinion summary

The Committee for Risk Assessment (RAC) supports a restriction on terphenyl, hydrogenated.

Terphenyl, hydrogenated is used mainly as a HTF in industrial installations (90% of the total volume), in various articles from different sectors (e.g. electrical and electronic equipment (EEE) and in other minor uses (e.g., as a process solvent and a laboratory chemical). Releases and ongoing exposures to the environment and to humans have been confirmed by a limited

set of monitoring data. Due to large uncertainties in the quantitative assessment of releases presented by the Dossier Submitter, RAC qualitatively evaluated the potential for release from different uses, and the effectiveness of the proposed restriction to prevent such releases andconcluded that releases to the environment are likely from all uses within the scope of the proposed restriction. RAC concludes that current regulatory obligations do not directly lead to a reduction of emissions of terphenyl, hydrogenated and that a REACH authorisation would be less effective to control the risk considering the time required for the process and the exclusion of the articles. RAC is of the opinion that a broad EU-wide restriction with targeted derogations and transition periods is the most appropriated measure to reduce the risks of terphenyl, hydrogenated.

RAC supports the proposed ban for uses where based on the current level of information, it is not possible to implement risk management measures to minimise emissions, especially during the service-life of various articles incorporating terphenyl, hydrogenated.

RAC supports a time-limited derogation under specified conditions for the placing on the market and for the main use as HTF in industrial installations. RAC is of the opinion that the mandatory compliance with strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions as described by the Dossier Submitter in a guidance document attached as an annex to this opinion as a minimum requirement for the industrial sites using HTF containing terphenyl, hydrogenated. Moreover, due to uncertainties with the effectiveness of the proposed conditions of use and risk management measures, RAC supports a mandatory monitoring program to assess the environmental releases at industrial sites. RAC also supports the derogation with a time limit to promote the development of safer alternatives but recognises that setting such a time limit is within the merits of SEAC.

RAC does not support the derogation for the use of terphenyl, hydrogenated in aerospace and defence applications. Overall, RAC considers this as potentially a wide-dispersive use due to the professional use of various formulations. RAC notes that even if the volume of the substance related to aerospace and defence applications is not known with precision, it represents <10% of the imported tonnage range estimated at approximately 730 T/y. However, there is not enough risk-based information to ensure minimisation of emissions of terphenyl, hydrogenated from such formulations used in the aerospace and defence sector.

RAC does not support the proposed derogation for the use of terphenyl, hydrogenated in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats, noting that consumer uses are advised against in the registration dossier for terphenyl, hydrogenated. RAC considers the consumer use of thermostats as wide-dispersive use for which environmental releases are assumed and especially at the waste stage. RAC notes that there is no robust information on existing RMMs in the sector. RAC considers that there is not enough risk-based information to ensure minimisation of emissions of terphenyl, hydrogenated for the use of terphenyl, hydrogenated in these articles (consumer use) to support a derogation. RAC notes that standard analytical methods for all matrices within the scope of the proposed restriction need to be developed which especially in articles could be challenging to achieve required concentration limits. However, based on the available analytical methods, RAC is of the opinion that it would be feasible to develop standardised analytical methods for the enforcement of this restriction.

RAC estimates that inconsistent information related to the various risk management measures in place to minimise the release of terphenyl, hydrogenated used as HTF and the lack of information regarding non-HTF uses constitute significant uncertainties in the risk and effectiveness assessment of this proposed restriction. The Committee emphasises that to address this uncertainty, the OCs and RMMs listed in (Annex 2 of this opinion) need to be applied as part of the Commission’s decision on this restriction.

RAC concludes that overall, the proposed restriction will draw attention to the necessity for appropriate risk management measures, particularly for the use in HTF and is therefore

effective in minimising the risks resulting from the use of terphenyl, hydrogenated and is enforceable.

RAC notes that this restriction proposal is focused on terphenyl, hydrogenated, because of its content of o-terphenyl. However, RAC points out that a wider restriction proposal focused on o-terphenyl and all other uses of o-terphenyl (in other substances) could have been more effective.

2.2.2. SEAC opinion summary

SEAC has developed its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties, the opinion of RAC, Forum's advice on enforceability as well as other available information as recorded in the Background Document.

SEAC supports the view that any necessary action to address risks associated with terphenyl, hydrogenated should be implemented on an EU-wide basis, based on the key principles of ensuring a consistent level of protection of human health and the environment across the EU and of maintaining the free movement of goods within the union.

The Dossier Submitter analysed three restriction options that are progressively stricter in terms of their scope, with proposed derogation for the use of terphenyl, hydrogenated in heat transfer fluids (RO1, RO2), a time- limited (five years) derogation for the aviation and defence sector (RO1) as well as a derogation for the use of terphenyl, hydrogenated in thermostats for ovens and stoves (RO1 and RO2) or a total ban (RO3). SEAC considers these restriction options to be well-defined.

The Dossier Submitter proposed RO1 as the preferred option. RO1 would set a limit to the content for terphenyl, hydrogenated at 0.1% w/w. The choice of RO1 is motivated by (i) the lack of suitable alternatives for the use of terphenyl, hydrogenated as a heat transfer fluid and the minimisation of emissions that can be achieved via strictly controlled systems with technical containment and organisational measures; (ii) additional time (five years) needed in the aviation and defence sector to substitute terphenyl, hydrogenated ; and (iii) the limited volume compared with industrial use and containment achieved in the use of terphenyl, hydrogenated in thermostats for ovens and stoves and that any waste originating from this uses would be covered und er the WEEE Directive.

Due to the PBT properties of terphenyl, hydrogenated, the Dossier Submitter considered emission reduction as a proxy for both the risks and the benefits of the proposed restriction, and estimated the expected reductions in emissions for each RO. However, SEAC takes note of RAC’s conclusion that the estimation of emissions is not robust enough to be used in a quantitative approach, but that releases to the environment from all uses within the scope of the proposed restriction are expected.

The quantified costs include estimates of the loss of profits, substitution costs, job losses, and the additional administrative costs for society. SEAC agrees with the approach taken for estimating costs but notes that the estimated costs are subject to significant uncertainty. SEAC considers that the cost of a full ban for the uses of the substance as an HTF and in the aviation and defence sector are significantly underestimated by the dossier submitter. SEAC considers that there is convincing evidence to suggest that the cost associated with this restriction in all other sectors is low.

The Dossier Submitter used a cost-effectiveness approach to assess and compare the proportionality of the restriction options. However, given RAC’s conclusions regarding the Dossier Submitter’s estimation of emissions, SEAC considers that a cost-effectiveness approach is not possible in this case, and follows a qualitative approach similar to the

approach used in the PFHxA restriction. SEAC bases its evaluation of benefits on i) concern on persistency of terphenyl, hydrogenated, ii) emission minimisation used as a proxy for risk reduction/benefits assessment and iii) the potential for regrettable substation.

Information from the consultation on the Annex XV report supports SEAC's conclusion that any substitution that may take place will be regrettable for the use as HTF under RO3, since all potential alternatives identified will lead to regrettable substitution, and this situation is not foreseen to change in the future (due to the inherent properties needed by the substance). SEAC notes that emissions can be minimised via the definition of SCCS as provided by the Dossier Submitter, and that RAC confirms that these SCCS, are indeed appropriate and effective in minimising emissions.

Information from the consultation and other sources further indicates that for the A&D sector, substitution could be possible, but additional time is required for certification and approvals etc.

When it comes to the other sectors and uses as plasticisers and other uses, there is scarce information. There could be a risk for regrettable substitution, but it is uncertain.

SEAC stresses that there are arguments in favour of proportionality, based on available, overall qualitative information in the Annex XV dossier, information provided during the consultation on the Annex XV report as well as RAC's conclusion on uses and emission minimisation per sector or identified use. In this respect, SEAC recognises that there are large uncertainties on the exact magnitude of the socio-economic impacts of the restriction and of the emissions for specific sectors.

SEAC agrees with the Dossier Submitter that RO1 after an 18-months transition period can be considered proportionate provided certain modifications are made to the scope of this RO.

SEAC finds that a change in RO1, prolonging of the derogation for the A&D sector from 5 (as proposed by the DS) to 10 years will avoid the significant costs associated with a full ban for this sector and would likely be proportionate.

For the HTF use, SEAC takes note of RAC's conclusion that the specified requirements for strictly controlled closed systems will minimise emissions. As the costs of implementing these conditions are expected to be small, and, given the large costs and the expected regrettable substitution associated with a full ban, the derogation for HTF use in RO1 and RO2 is likely proportionate. On RAC's suggestion, SEAC has evaluated the option of a time limit derogation. Considering the information received during the consultation on the SEAC Draft Opinion and the arguments provided in section 3, SEAC considers that a time-unlimited derogation is proportionate but that a time limited derogation would not be proportionate.

SEAC proposes to limit the use of heat transfer fluid to a temperature range of 250°C- 350 °C to better align with the intended use of the substance (high temperature heat transfer fluid) for which no non-regrettable substitutes are available.

SEAC, however, concludes that progress in substitution possibilities should be reviewed 10 years after entry into force to assess whether new information has become available that would indicate the availability of suitable alternatives that do not pose a risk of regrettable substitution. If the review finds that safer substitutes have become available, then legislative action affecting new installations only could be considered.

SEAC recommends that further regulatory action is taken on the two foremost alternatives (EC-No 258-649-2 and EC-No. 400-370-7) to terphenyl, hydrogenated (CAS 61788-32-7) to lower the risk of regrettable substitution in this use.

SEAC takes note of RAC's conclusion that it is not possible to conclude, based on the limited

information provided by the Dossier Submitter, if the requirements of the WEEE Directive (respectively the national transpositions) are sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided. Observing the lack of socio-economic data to support a derogation, SEAC cannot support a derogation for the consumer use of terphenyl, hydrogenated ovens and thermostats.

SEAC finds that a ban for the use as plasticiser and other uses in other sectors, is likely proportionate as there will be a substantial reduction in emissions and the lack of information on the potential costs indicates that the costs are low.

SEAC takes note of the Forum advice and concludes that the proposed restrictions would be practicable and monitorable.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. RISK ASSESSMENT

3.1.1. Description of and justification for targeting (substance and use scope)

Summary of Dossier Submitter's assessment

The proposed restriction is primarily targeted to the exposure situations that are of most concern, e.g., the use of terphenyl, hydrogenated as a plasticiser and during the life-cycle stage of articles. The Dossier Submitter considers that the proposed restriction is effective and will reduce potential risks to an acceptable level within a reasonable period of time.

Terphenyl, hydrogenated is a UVCB- substance and was identified as a Substance of Very High Concern (SVHC) in 2018, because of its very persistent and very bioaccumulating properties (vPvB). The scope of the proposed restriction covers the UVCB substance. At least one of these constituents (o-terphenyl) fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1%), terphenyl, hydrogenated is also considered to fulfil vPvB criteria.

Regarding the composition of terphenyl, hydrogenated, o-terphenyl is part of the UVCB substance (as the other individual components) and cannot be considered in a separate way. O-terphenyl (CAS 84-15-1) is not a chemical product itself and it is not marketed as an individual substance in the EU. Furthermore, the substance has not been registered under REACH.

RAC conclusion(s):

RAC considers that the scope and targeting of the proposed restriction are clear.

RAC notes that the scope of the risk assessment performed by the Dossier Submitter is limited to terphenyl, hydrogenated while o-terphenyl is the constituent that warrantsSVHC-status due to its vPvB properties (see further discussion in section 3.4.1 and 3.5.1). According to the evidence gathered by RAC, there are additional substances that may contain o-terphenyl as a constituent.

RAC considers that these substances could have been targeted in the present restriction proposal and that a broader restriction proposal focused on o-terphenyl and all other uses of o-terphenyl (in other substances) could have been more efficient.

Key elements underpinning the RAC conclusion:

1. The scope of the hazard assessment is justified

REACH annex 1, 6.4 defines that risks of PBT and/or vPvB substances cannot be adequately controlled and terphenyl, hydrogenated identified as vPvB may cause severe and irreversible adverse effects if released to the environment (see Section 3.1.2).

RAC takes note of the assessment and conclusions of MSC regarding the vPvB properties of terphenyl, hydrogenated, which provide a reliable basis and do not warrant further assessment by RAC. A risk assessment based on vPvB, i.e. environmental properties is enough to justify a restriction and therefore an assessment of potential human health hazards is not deemed necessary for the purpose of this restriction.

2. The substance within the scope of the risk assessment is clearly described by the Dossier Submitter

Terphenyl, hydrogenated was identified as a vPvB, and was included in the Candidate List on

27 June 2018. It was assessed by evaluating its constituents and at least one of these constituents (o-terphenyl) fulfils both the vP and vB criteria. Although o-terphenyl is the constituent that leads to terphenyl, hydrogenated meeting the criteria for a vPvB substance, the restriction proposal of the Dossier Submitter applies to the UVCB substance as a whole. The Dossier Submitter considers that o-terphenyl is part of the UVCB substance (as the other individual components) and cannot be considered separately. Consequently, the Dossier Submitter targeted the scope of the restriction on terphenyl, hydrogenated (CAS 61788-32-7) and argues that o-terphenyl (CAS 84-15-1) is not a chemical substance itself and is not marketed as a substance in the EU because it is not registered under the REACH regulation.

RAC concludes that the risk assessment as provided for terphenyl, hydrogenated has a clear scope. The Dossier Submitter has identified the risks for the substance terphenyl, hydrogenated.

Further to the Dossier Submitter's proposed scope and approach, RAC observes several aspects related to the potential risks arising from o-terphenyl:

a. O-terphenyl (purity > 99%, CAS 84-15-1), p-terphenyl (purity > 99%, CAS 92-94-4), m-terphenyl (purity 99%, CAS 92-06-8) are available on the market for laboratory uses. Moreover, the registration status of a substance is dependent of the quantity produced by the legal entity and the absence of registration does not mean that the substance is not marketed in the EU but that no legal entity places more than 1 tpa of o-, m- or p-terphenyl on the EU market individually.

b. On the ECHA website, in the ECHA 'search our chemicals' database[1], more than 100 entries contain the term terphenyl. Among them, o-terphenyl can be found alone or included in other reaction mass substances. One of these, reaction mass of o-terphenyl and m-terphenyl, that might contain p-terphenyl as an impurity, has been registered (EC 904-797-4) and is imported/manufactured in a volume lower than 100 tonnes per year.

c. The approach claimed by the Dossier Submitter is not in line with the ECHA document on 'Regulating substances based on constituents' presented to CARACAL (ECHA, 2020) in which it is supported to address the risk caused by constituents within the UVCB substance via targeting the constituent rather than the UVCB substance of which the constituents form a part.

Therefore, RAC considers that the use of o-terphenyl as a constituent in substances other than terphenyl, hydrogenated could have been considered by the Dossier Submitter, at least as a restriction option. In addition, RAC performed a preliminary screening and has identified several petroleum substances as well as others from the terphenyl group that would indicate the presence of o-terphenyl at relevant concentrations in substances other than terphenyl, hydrogenated.

The scope is targeted to the exposure situations that are of most concern for the use of terphenyl, hydrogenated, i.e., its use as a plasticiser and the life-cycle stages of articles containing terphenyl, hydrogenated.

RAC supports the general approach that the restriction proposal covers the uses resulting from the presence of terphenyl, hydrogenated in substances and/or in mixtures in a concentration equal to or greater than 0.1% w/w and in articles in a concentration equal to or greater than 0.1% w/w, because this triggers the information requirement under REACH Article 31. However, RAC notes that the Dossier Submitter did not assess the scenario setting

[1] ECHA website, search for chemicals, "terphenyl", 31/01/2023, Search for Chemicals - ECHA (europa.eu). The results of this request do not distinguish active/inactive registered substances, meaning only that the substance had been quoted in the IT system

a lower or higher concentration limit, whereas the measurement of terphenyl, hydrogenated is based on its constituent o-terphenyl, for which the highest concentration of 7.1% (detected by GC/MS analysis) is assumed (see section 2.7.2 of the Background Document).

3.1.2. Hazard(s)

Summary of Dossier Submitter's assessment:

The hazard assessment of the Dossier Submitter is based on the assessment of the ECHA Member State Committee, carried out for the purpose of identifying terphenyl, hydrogenated as a Substance of Very High Concern (SVHC) in 2018, on the basis of the presence of o-terphenyl which fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), terphenyl, hydrogenated is considered to fulfil the vPvB criteria. In conclusion, terphenyl, hydrogenated meets the criteria to be considered a vPvB substance according to Article 57(e) of REACH (see Annex B4).

According to REACH Annex I para 6.5, the risk to the environment and to human health cannot be adequately controlled for PBT/vPvB substances. No safe concentration, thus no threshold, can be determined for PBT/vPvB substances. Due to these intrinsic substance properties, terphenyl, hydrogenated may cause severe and irreversible adverse effects on the environment and on human health if the releases are not minimised.

RAC conclusion(s):

RAC takes note of ECHA's Member State Committee decision that terphenyl, hydrogenated meets the REACH Annex XIII criteria for very persistent and very bioaccumulative substances (vPvB) based on the conclusion on the constituent o-terphenyl.

Key elements underpinning the RAC conclusion(s):

The RAC opinion on the hazard of terphenyl, hydrogenated is based on Section 1.2.4 of the Background Document, Annex B.4 and the information submitted in the consultation. The decision by ECHA's Member State Committee is not further evaluated by RAC in this opinion. According to the Support Document for identification of the substance as an SVHC because of its vPvB properties (ECHA, 2018a): "*As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), terphenyl, hydrogenated is considered to fulfil the vPvB criteria. In conclusion, terphenyl, hydrogenated meets the criteria for a vPvB substance according to Article 57 (e) REACH*".

3.1.3. Emissions and exposures

Summary of Dossier Submitter's assessment:

Terphenyl, hydrogenated is widely used in the EU and is imported as a substance, in mixtures and in articles. There are currently 6 active registrants of terphenyl, hydrogenated under REACH. There is no manufacture of terphenyl, hydrogenated within EU since the withdrawal of the United Kingdom from the EU (see section 1.1 of the background document and Annex A.1)

Based on information received in the consultation, the global volume of terphenyl, hydrogenated manufactured in 2020 is approximately 32 000 tonnes per year. The total volume imported in 2020 into the EU is assumed to be up to 7 500 tonnes per year which includes as well estimates of imports in articles and formulations in the order of 100 tonnes per year.

Exposure of terphenyl, hydrogenated mainly occurs from releases to air and water from point sources as well as via diffuse emissions. After emission to the environment the substance is

distributed by various processes such as deposition from air to soil/water bodies and adsorption to sludge in the sewage treatment plant (STP).

Terphenyl, hydrogenated's main use in the EU (90% of annual use volume) is as a high-temperature Heat Transfer Fluid (HTF) in industrial installations, i.e. a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source. Selection of the most suitable HTF is based on the type of industrial applications, stable temperature range for safe operation and lifetime of the HTF.

The second main use in the EU (10% of total annual use volume) is as a plasticiser for the production of coatings, sealants, and adhesives and in polymer applications. The final coatings, sealants, and adhesives are used in a wide variety of sectors, for example the aerospace industry. Additionally, plasticisers are also used by the cable industry (e.g., for the protection of joints of buried high voltage cables).

The remaining registered uses (both industrial and professional) involve less than 1% of the amount of substance imported into the EU. According to the lead registrant, all uses as HTF should be considered as industrial and no uses are considered professional. Consumer uses and intermediate uses have not been registered. The SCIP database confirms that terphenyl, hydrogenated is used in articles, which are used in complex objects, such as vehicles (cars, trains, planes), EEE, construction and building components, or furnishings.

Specific information on the releases to the environment of terphenyl, hydrogenated during its use as HTF at industrial sites was obtained in the Exposure & Release Questionnaire (2018). In order to obtain updated information on potential environmental emissions of terphenyl, hydrogenated from industrial uses as HTF, a monitoring program was designed and developed at a number of industrial sites that use terphenyl, hydrogenated in this application. Companies that participated in this program were requested to collect both air and soil samples, from locations at which releases of terphenyl, hydrogenated could be regarded to be more likely (see section B.9.3.3).

Very little specific information regarding the use of terphenyl, hydrogenated, mainly as plasticiser, for the production of coatings, paints and inks, and as additive in plastic applications, was provided in the different consultations issued for this substance: the Lead Registrant Socio-Economic Analysis questionnaire from 2018, the socio-economic impact questionnaire from the European Commission 2020, the responses to the 10th Recommendation received by ECHA in 2020[2], and the Dossier Submitter Socio-Economic Analysis questionnaire from 2021. Also, the Dossier Submitter did not find information regarding these uses via internet search.

Taking into account the (lack of) available information, two type of assessments were conducted: a quantitative estimation of releases into the environment as well as a qualitative assessment. For the main identified uses with a potential to be widely dispersive, the quantitative information to minimise exposure was missing. In these cases, where no effective RMMs can be expected or information on RMMs was lacking, the qualitative assessment is applied.

Quantitative assessment

For each exposure scenario, the Dossier Submitter provided an overview table with the input parameters and the resulting emissions to air, water and soil (see Annex B9 to the Background Document).

[2] Submitted recommendations - ECHA (europa.eu)

The environmental exposure assessment is based on the default release factors in accordance with ECHA Guidance R.16 (ECHA, 2016). In general, the high emission scenario represents a worst-case assumption whereby e.g., the above default release factors are used. Hence, this emission scenario is generally regarded as a very conservative approach overestimating the actual exposure. The low emission scenario considers more specific information from, e.g., SpERCs, made available through the Exposure & Release Questionnaire (2018) by the Lead Registrant and/or via the consultation on the Annex XV dossier.

Qualitative assessment

Taking into account the available information, including the information received via the consultation on the Annex XV dossier, a qualitative assessment was performed for various uses, which were arranged based on the market sector as follows:

- HTF uses at industrial sites,
- adhesives/sealants,
- coatings/inks,
- miscellaneous uses, and
- consumer use as HTF in thermostats.

The qualitative assessment is based on estimated use in the market sector and likelihood of possible release in relation to availability and possible effectives of risk management measures (see section B.9.23 in the Annex to the Background Document). The prioritization of the market sectors and their respective contribution to the identified risk are listed in Table 65 of section B.9.23.2 of the Annex to the Background Document.

RAC conclusion(s):

RAC concludes that the methodologies used to assess environmental releases of terphenyl, hydrogenated are not robust enough to draw **quantitative** conclusions on emissions and emission reduction, due to insufficient justification provided, various inconsistencies in reporting between different sections of the Background Document and significant data gaps for some use scenarios.

Based on a **qualitative** evaluation of the available information (section 3.4.3), RAC concludes that releases to the environment from all uses within the scope of the proposed restriction are expected (i.e. current information specifying operational conditions and risk management measures cannot guarantee that releases are controlled under the conditions of use).

Key elements underpinning the RAC conclusion(s):

The Dossier Submitter has used information for the main use as HTF and relevant life cycle stages of terphenyl, hydrogenated from the REACH registration dossier (ECHA, 2021a). Currently, there is one joint registration for terphenyl, hydrogenated (active since 2010 and last updated in October 2022) covering six active registrants. RAC agrees in principle with this approach but notes that the Dossier Submitter has not considered it necessary to address the manufacturing life cycle stage in the context of this restriction proposal. The reason is that only the lead registrant is manufacturing terphenyl, hydrogenated at a plant in UK (Newport) but since the UK left the EU , terphenyl, hydrogenated is not manufactured anymore within the EU. However, RAC notes that the properties of terphenyl, hydrogenated i.e. persistency, bioaccumulation, adsorption to soil and sediment, raise a concern of potential long-range transport via suspended particles in air.

Additionally, the Dossier Submitter has not taken into account the potential use of HTF at professional sites, which based on information received from the REACH lead registrant of the substance is known to occur.

Finally, RAC notes that the consumer use is advised against in the REACH registration dossier and that the Dossier Submitter has correctly considered based on the review of the SCIP database and manufacturer declarations available online that the use as HTF in thermostats in electromechanical temperature controls takes place in ovens and stoves. The Dossier Submitter's assessment is only of qualitative character and no quantitative estimation of environmental release has been made.

Quantitative assessment

Where no specific information was available, the Dossier Submitter based their assessment of environmental emissions on default release factors (ERC in accordance with ECHA Guidance R.16) further referred to as "upper estimate". For most of the identified uses, the exposure assessment has been refined using applicable SpERCs, OECD Emission Scenario Document and specific information from stakeholder consultations i.e. the Lead Registrant Exposure and Release Questionnaire (LR - SEA 2018), the Commission - Socio-Economic Impact Questionnaire (COM, 2020) and the Dossier Submitter - SEA Questionnaire, (DS SEA 2021), and the results from a monitoring program performed at industrial sites using HTF. Table 4 presents the use scenarios considered in the exposure assessment, their input data and release estimates as reported in the Background Document and the accompanying Excel sheet detailing the calculations (Further estimation for the Expo Ass).

Table 4 Overall assumptions of the Dossier Submitter for release estimations

Life-cycle stage	Covered uses	Total volume input	Share of total volume input	Amount used to estimate releases (T/y)	Upper estimate: Release fractions and Total Release (TR)	Lower estimate: Release fractions and Total Release
Formulation	Formulation, transfer, and packing of terphenyl, hydrogenated used as solvent/process medium or as laboratory chemical	Imported volume (7 471 T/y)	0.49%	36.5	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 Solid waste: none TR= 1646 kg/y	None
	Formulation of adhesives and sealants	Imported volume (7 471 T/y)	6.42%	480	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 FEICA / EFCC SpERC 2.1a.v3 Solid waste: 0.03 TR= 36048 kg/y	FEICA / EFCC SpERC 2.1a.v3 Air: 0.0008 Wastewater: 0.0002 Soil: 0 Solid waste: 0.002 TR= 1440 kg/y
	Formulation of coatings or inks	Imported volume (7 471 T/y)	3.4%	254	ERC 2 Air: 0.025 Wastewater: 0.02 Soil: 0.0001 CEPE SpERC 2.1c.v2 Solid waste: 0.01 TR= 13995 kg/y	CEPE SpERC 2.1c.v2 Air: 9.5E-5 Wastewater: 5E-5 Soil: 0 TR= 37 kg/y
Uses at industrial sites	Use as HTF	Theoretical installed volume in the EU (taking into account the installed volume at the largest plant ofn1 200 T and a number of sites of 100.	100 %	120 000	ERC 7 Air: 0.05 Wastewater: 0.05 Soil: 0.05 Solid waste: none TR= 18 000 T/y	Exposure & Release Questionaire (2018) Monitoring program Air: 0 Wastewater: 0 Soil: 0 Solid waste: None TR= 0 T/y
	Use as adhesive and sealants	Imported volume (7 471 T/y)	5.14%	384	ERC 5 Air: 0.5 Wastewater: 0.5 Soil: 0.01 FEICA SpERC 5.1a.v3 Solid waste: 0.06 TR= 410880 kg/y	FEICA SpERC 5.1a.v3 Air: 0.017 Wastewater: 0 Soil: 0 Solid waste: 0 TR= 6528 kg/y
	Use as solvent or process medium	Imported volume (7 471 T/y)	0.47%	35	ERC 4 Air: 1 Wastewater: 1 Soil: 0.05 Solid waste: 0.05 TR= 7350 kg/y	ESVOC SpERC 4.1.z.v2 Air: 0.00001 Wastewater: 0.00001 Soil: 0.0001 Solid waste: 0.05 TR= 175 kg/y
	Use for coatings or inks applications	Imported volume (7 471 T/y)	2.73%	204	ERC 5 Air: 0.5 Wastewater: 0.5 Soil: 0.01 CEPE SpERC 5.1a.v2 Solid waste: 0.52 TR= 312120 kg/y	CEPE SpERC 5.1a.v2 Air: 0.015 Wastewater: 0 Soil: 0 Solid waste: 0.1 TR= 23460 kg/y
	Use in laboratory analysis (use of HTF at industrial sites)	Based on the assumption that each site within the EU sends a 1 L sample for analysis (0.15 T/y)	100 %	0.15	ERC 6b Air: 0.001 Wastewater: 0.05 Soil: 0.00025 Solid waste: none TR= 7.7 kg/y	Exposure&Release Questionaire (2018) Air: 0.001 Wastewater: 0 Soil: 0.00025 Solid waste: None TR= 0.19 kg/y
U s e s b	Use as adhesive and sealants	Imported volume	1.28%	96	ERC 8f (outdoor) Air: 0.15	FEICA / EFCC SpERC 8f.1a.v2

		(7 471 T/y)			Wastewater: 0.05 Soil: 0.005 FEICA / EFCC SpERC 8f.1a.v2 Solid waste: 0.25 TR= 43680 kg/y	Air: 0 Wastewater: 0.015 Soil: 0 Solid waste: 0.04 TR= 5280 kg/y
	Use for coatings or inks applications	Imported volume (7 471 T/y)	0.68%	50	ERC 8c (outdoor) Air: 0.15 Wastewater: 0.05 Soil: 0.005 CEPE SpERC 8f.3a.v2 Solid waste: 0.3 TR= 25520 kg/y	CEPE SpERC 8f.3a.v2 Air: 0 Wastewater: 0.02 Soil: 0.02 Solid waste: 0.09 TR= 6500 kg/y
	Use as laboratory chemical	Imported volume (7 471 T/y)	0.02%	1.5	ERC 9a Air: 0.05 Wastewater: 0.05 Soil: 0 Solid waste: none TR= 150 kg/y	None
Article service life (workers only)	Articles produced from use of coatings and inks	Imported volume (7 471 T/y)	3.4%	254	ERC 10a Air: 0.0005 Wastewater: 0.032 Soil: 0.032 Solid waste: none TR= 127 kg/y	None Migration modelling to confirm HES (polysulfide sealant in aerospace industry)
	Articles produced from use as plasticizer in adhesives and sealants	Imported volume (7 471 T/y)	6.24%	480	ERC 10a Air: 0.0005 Wastewater: 0.032 Soil: 0.032 Solid waste: none TR= 15360 kg/y	None Migration modelling to confirm HES (epoxy topcoat used in aerospace industry and cable joint sealant)

Use as a heat transfer fluid in industrial installations

The main use of terphenyl, hydrogenated is as a HTF in industrial installations of various sectors, which accounts for approximately 90% of the total tonnage used. A HTF is a liquid or a gas that is specifically manufactured for the transmission of heat. RAC notes that no emission assessment for the formulation of HTF is reported in the Background Document because terphenyl, hydrogenated does not need to be formulated in order to be used as a HTF.

Environmental releases of terphenyl, hydrogenated from use as a HTF at industrial sites have been estimated by the Dossier Submitter, who assumed that these would only occur through spills/leakages and during periodic quality checks of HTF (sampling/analysis). Nevertheless, RAC notes that other potential activities are relevant as sources of release, e.g. the periodic collection of degradation products and top-up (or refill) operations, the complete draining of the heat transfer system and the dismantling of the installation, for which no emissions are estimated in the Background Document. As these operations are identified by the Dossier Submitter as managed outside of the heat transfer system but have the potential to lead to emissions of terphenyl, hydrogenated, RAC considers that these releases are closely associated and are also relevant.

The release estimation from leakage for the use of HTF at industrial sites is based on the worst-case installed volume of terphenyl, hydrogenated of 12 000 000 tonnes (12 000 tonnes per site * 1000 sites). However, RAC identified contradictory information in the Background Document considering the worst-case installed volume (1 300 tonnes at industrial site S-02 of the monitoring programme) and the number of sites in the EU (1 300 and 100 sites are cited). Moreover, the estimated EU installed base of terphenyl, hydrogenated in industrial sites using HTF was estimated at approximately 25 000 tonnes based on feedback from the consultations and individual communications (e.g. Table 4, Annex of the Background Document). RAC notes that it is unclear whether the estimated installed volume is expressed

on a yearly basis and assumes that a higher yearly tonnage can be used at a site than the installed volume due to refill, draining and leakage processes. Similarly, the total tonnage used in laboratory analysis is set at 0.15 T/y based on the assumption that 150 sites within the EU sample 1 L/y of terphenyl, hydrogenated in the HTF system for analysis. Therefore, it is not clear to RAC if the Dossier Submitter has taken the most relevant values for the release calculations.

The assumption of negligible emissions at industrial sites using HTF is considered reliable by the Dossier Submitter based on:

- the answers provided by companies from various industrial sectors via the Exposure & Release Questionnaire (LR SEA 2018);
- the consultation to the Annex XV report (44 HTF-users) and supported by;
- the results of the monitoring programme at industrial sites presented in the Background Document.

RAC notes that the information provided by the companies, claims that RMMs are in place to avoid leakages or manage them to avoid environmental release at industrial sites. However, no monitoring data was provided by the responding companies to support this statement and that some companies mention releases directed to their wastewater treatment plants (#3637, #3665). RAC estimates that the assumption that spills of terphenyl, hydrogenated are properly managed is in contradiction with the results of the monitoring programme at industrial sites that reports unmanaged leakage or soil contamination with terphenyl, hydrogenated at 2 of the 13 monitored HTF systems. This could indicate that releases of terphenyl, hydrogenated from HTF at industrial sites do occur and cannot be considered as isolated incidents. Furthermore, the assumption that there is no solid waste generated during the use of terphenyl, hydrogenated as HTF at industrial sites is not supported by the information provided by the Dossier Submitter and the responders to the consultation of the Annex XV report, on:

- the collection of accidental spills on sealed areas with absorbent material;
- the use of equipment for laboratory analysis and
- the management of dismantled HTF installations.

RAC considers that the monitoring dataset available for industrial sites is not sufficiently representative for the EU (1% of the sites and 9.8% of the installed volume) and is insufficiently reliable due to the monitoring design and lack of information[3] to assess the emissions of terphenyl, hydrogenated from HTF systems but demonstrate that the 0% release factors cannot be applied to all existing installations. RAC notes that the use of the ESVOC 7.13a.u.v2 SpERC release fractions for HTF use at industrial sites would provide a more reliable estimation of the releases than the use of the monitoring data chosen by the Dossier Submitter, since ESVOC 7.13 SpERC is designed for functional fluids in closed systems and is applicable to heat transfers agents and covers release from waste. RAC notes that it has been used to estimate the releases in the REACH registration dossier. RAC is of the opinion that the Dossier Submitter has not sufficiently justified why it considers that this applicable SpERC is not suitable for its assessment.

Use in articles – plasticiser

Concerning the use of terphenyl, hydrogenated in articles, the Dossier Submitter identified the use of the substance as a plasticiser for the production of coatings, adhesives & sealants and in polymer application as the second most relevant use and assessed the release from two main categories: adhesives & sealants and coatings & inks.

The Dossier Submitter recognises that very little information regarding the use of terphenyl,

[3] E.g. relevance of air sampling, low number of samples; analytical method validation for terphenyl, hydrogenated in air and soil, detection of o-terphenyl representing <1% of terphenyl, hydrogenated.

hydrogenated as a plasticiser, for the production of coatings, paints and inks, and as additive in plastic applications, was provided in the different consultations (LR SEA 2018, COM 2020, DS SEA 2021). Similar default release factors (ERC in accordance with ECHA Guidance R.16) were used for both categories but the "upper estimates" were refined using applicable SpERCs for adhesives & sealants (FEICA / EFCC SpERC) and coatings & inks (CEPE SpERCs) except for the article service life scenarios. A total volume input (i.e., imported tonnage) of 7471 T/y and an overall share of the total volume input of 30% for the uses in adhesives & sealants and coatings & inks (i.e., formulation, industrial and professional uses and articles service life) has been used to estimate the amount used to estimate the releases. RAC notes that this is not in line with the information in the Annex XV report mentioning an imported volume of 6700 T/y and a share of only 9% for plasticiser uses.

The Dossier Submitter commented that the decreasing participation in the SEA questionnaires from 2018 to 2021 suggests that the industry involved in these uses has already started the reformulation/substitution process of the substance. Nevertheless, in December 2022, the SCIP database contained more than 24 000 notifications[4] related to terphenyl, hydrogenated. The Dossier Submitter reported that the majority of SCIP notifications relate to the following article categories:

- Electrical machinery and equipment and components thereof
- Base metals and articles of base metal
- Machinery and mechanical appliances and components thereof
- Vehicles, aircraft, vessels and associated transport equipment and parts thereof
- Components and accessories of optical, photographic, cinematographic, measuring instruments and apparatuses
- Articles of stone, plaster, cement, asbestos, mica or similar materials
- Plastics and articles thereof
- Products of the chemical or allied industries
- Pulp of wood or of other fibrous cellulosic material
- Miscellaneous manufactured articles
- Textiles and textile articles, knitted or crocheted fabrics

A relevant mixture category incorporated in notified articles is the use as HTF in electrical machinery and equipment and base metals/ articles of base metal. Further investigation of these entries via a web search revealed that terphenyl, hydrogenated is used as a HTF in articles for consumer use i.e. in thermostats of household ovens (different models from different brands). The Dossier Submitter has considered the use of terphenyl, hydrogenated as HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats and assessed qualitatively its environmental releases).

Additional information was also received during the consultation on the Annex XV dossier: two responses from the Aerospace, Security and Defence Association of Europe (#3655, #3707) and one response from a downstream user using different formulations to manufacture various types of articles (#3662). Their responses indicate that terphenyl, hydrogenated is used as an ingredient in formulations for catalysts, adhesives, encapsulants paints and varnishes in the aerospace and defence (A&D) industry and also in some medical, scientific and industrial applications. Terphenyl, hydrogenated is present at various concentrations in the mixtures for the different uses (e.g. 5-10% in catalysts for encapsulant resins on probe stems of meters used in medical, scientific & industrial applications and for adhesives in medical & aerospace magnetic applications; 10-30% in catalysts for adhesives

[4] This number includes duplicates and double counting as it includes dossiers with "referencing and Simplified SCIP notification (SSN). More information on SSN and referencing can be found in the manual "Tools to refer to SCIP data already submitted to ECHA" available at: https://echa.europa.eu/documents/10162/13567/tools_to_refer_to_already_submitted_sip_data_en.pdf/50ca0226-83d4-d967-f45e-203d04717ddd.

in aerospace power supply applications and in adhesives in circuit card assemblies in motor controllers; 20-50% in varnishes applied to vibration monitoring unit housings for unmanned defence aircraft in extreme environments; up to 50% in sealant/adhesive formulations used by the A&D sector. Some manufacturing may take place outside of the EU, final products are exported to the EU. The technical function of terphenyl, hydrogenated in the aerospace and defence industry seems to be predominantly the use as a plasticiser, but in addition uses as a dispersant or a carrier were reported.

RAC considers that it is uncertain if the assessment performed by the Dossier Submitter properly addresses all the types of articles potentially affected by the restriction. RAC notes that the origin of articles containing terphenyl, hydrogenated and whether they are imported into the EU or exported to third countries is uncertain. The concentration ranges of terphenyl, hydrogenated ordinarily applied in articles to retain its function is not known in most cases.

RAC concludes that overall, the lack of information regarding articles brings a significant uncertainty in the release and risk assessment of terphenyl, hydrogenated.

Additionally, RAC agrees with the Dossier Submitter that there is a significant data gap related to the information on the waste life-cycle stage of articles. RAC points out that generally the waste stage can be expected to be the source of highest emissions of all the life-cycle-stages of articles containing PBT/vPvB substances. This has already been thoroughly discussed in previous restriction cases on PBT/vPvB substances such as Dechlorane Plus. Migration modelling was conducted by the Dossier Submitter to assess the net mass transfer of terphenyl, hydrogenated from articles into another medium (i.e. air and soil) in order to confirm the estimated releases based on the default factors in the service life of articles scenarios. However, RAC is of the opinion that the migration scenario used to confirm the releases resulting from the service life of articles produced from use of coatings and inks is not relevant as it is based on an article containing a sealant (i.e. polysulfide sealant used in the aerospace industry) and not a coating or ink. Similarly, RAC considers that the migration scenario used to confirm the release resulting from the service life of articles produced from use of adhesives and sealants is not relevant as it is based on the leaching of a special epoxy topcoat used in the aerospace industry and not an adhesive or sealant.

RAC has evaluated the following migration scenarios for the use scenarios as described in the Table 5.

Table 5 Upper and lower release estimates for service life of articles produced from use of adhesives/sealants and coatings/inks

Use scenario	Migration scenario	Upper release estimate (based on ERC)	Lower release estimate (based on migration modelling)
Service life of articles produced from use as plasticizer in adhesives and sealants	Migration from polysulfide sealant used in the aerospace industry to the air	0.05% (0.24 T/y released from 480T/y total volume)	10 years: 0.03% (0.5T released from 1800T used) 20 years: 0.044% (1.6T released from 3600T used)
Service life of articles produced from use as plasticizer in adhesives and sealants	Migration from a plasticiser use in joint seals for underground cables into the soil	3.2% (15.36 T/y released from 480T/y total volume)	10 years: 80% (80T released from 100T used) 20 years: 85% (85T released from

			100T used)
Service life of articles produced from use of coatings and inks	Leaching of a special epoxy topcoat used in aerospace industry into the air	0.05% (0.127 T/y released from 254 T/y total volume)	10 years: 8% (200T released from 2500T used) 20 years: 11% (550T released from 5000T used)

The migration modelling confirms the considered release fraction in air for the articles produced from use in adhesives and sealants but not for the release fraction in soil from the same type of article nor the release fraction in air from articles produced from use of coatings and inks.

Overall, RAC considers that the quantitative assessment of environmental releases for the uses of terphenyl, hydrogenated suffers from a number of information gaps, unrealistic assumptions and a number of uncertainties.

Qualitative assessment

A qualitative assessment was performed by the Dossier Submitter using the results of the quantitative assessment if specific information was lacking and information received via the consultation on the Annex XV report.

- Use of HTF in industrial installations:

According to the information from the Dossier Submitter, no releases of HTF take place at industrial installation or they can be considered negligible. The volume for this use represents 90% of all uses of terphenyl, hydrogenated. More than 44 companies have responded via the LR - SEA Questionnaire (2018) and the Public Consultation that OCs and RMMs are in place in their industrial installations to avoid release of HTF. However, RAC notes that although the industrial use of HTF takes place in closed systems, some companies have reported leakages in their installations. In addition, no monitoring data are presented to support the absence of emissions at industrial sites. RAC concludes that releases cannot be considered negligeable due to the uncertainties regarding the occurrence of leakages during use, noting the high volume of terphenyl, hydrogenated used as HTF.

According to the information from the Dossier Submitter no emissions result from the sampling and laboratory analysis of terphenyl, hydrogenated used as HTF at industrial sites. RAC notes that the RMMs in place at industrial sites to support the absence of releases for the sampling operations are not described in the Background Document. In response to the consultation of the Annex XV report, only one company (#3709) refers to the use taking place under Strictly Controlled Conditions. However, RAC agrees that the total volume of sampling is expected to be small compared to the other uses and therefore the environmental releases can be considered as negligeable.

- Use as HTF in thermostats in electromechanical temperature controls of ovens and stoves (consumer use):

As reported in the Background Document, the quantity sold for this use is assumed to be <1 T/y, equivalent to 100 000 thermostats or 100 000 ovens per year, according to the lead registrant.

RAC is of the opinion that this volume is low compared to HTF use in industrial installations but significant compared to other uses of terphenyl, hydrogenated. Moreover, RAC anticipates

a widespread release due to the consumer uses of these products.

The Dossier Submitter supposes that during the use of the product by consumers, there is no relevant release of terphenyl, hydrogenated since it is contained in a closed vessel which is installed in the end product.

RAC agrees with this assumption even if spills from thermostats and accidental releases cannot be disregarded. It is assumed that at the end of their service life, ovens and stoves are collected through take-back schemes at their end-use location. Requirement at the end-of life of electrical and electronic equipment are laid down by waste legislation, specifically the WEEE Directive (2012/19/EU) and related national implementing legislation. The Dossier Submitter assumes that any risk is mitigated by the compliance with this legislation. RAC acknowledges that household ovens are in the scope of the WEEE Directive which requires the Member States to ensure proper treatment i.e. removal of all fluids and a selective treatment in accordance with Annex VII. RAC notes that hydrocarbons are listed in Annex VII to the WEEE Directive, hence terphenyl, hydrogenated needs to be removed and treated separately. However, the Dossier Submitter did not provide any information on current practices in the Member States and therefore RAC cannot conclude on the environmental release at waste disposal from ovens and stoves.

- Use in articles- plasticiser

These uses represent 9% of all uses of terphenyl, hydrogenated. The Dossier Submitter estimates that releases during formulation and industrial use are assumed to be minor due to the RMMs that should be in place, but no information is provided in the Background Document to support this assumption. The Dossier Submitter also assumes that professional use (especially the outdoor use) and service life of articles are associated with emissions in the environment in the absence of specific information on the RMMs. Overall, RAC agrees with this assessment and notes that the information provided during the consultation of the Annex XV restriction report for the Aerospace and Defence sector (#3655, #3707) confirm the assumptions on RMMs at industrial sites. Overall, RAC considers the aerospace and defence applications as a potentially wide-dispersive use due to the professional use of various formulations at a wide range and number of sites. RAC concludes that releases cannot be considered negligeable for the use of articles and service-life including waste disposal is anticipated to be of major concern. Nevertheless, RAC notes that the service-life including waste disposal for articles was only scrutinized, i.e. on the applicability of the WEEE directive for the use as HTF in ovens and stoves.

- Miscellaneous uses

These uses represent 1% of all uses of terphenyl, hydrogenated and includes solvent/process medium and laboratory chemical (professional use). In the absence of information on RMMs for those uses, the Dossier Submitter concludes that formulation, industrial use as solvent/process medium and use as laboratory chemical by professionals can generate releases into the environment. RAC concludes that releases cannot be considered negligeable for these uses in the absence of information on RMMs in place at industrial and professional sites.

Prioritisation of uses based on qualitative assessment of releases

RAC does not agree with the prioritisation of uses performed by the Dossier Submitter based on the qualitative assessment of their contribution to the identified risk. The Dossier Submitter did not appear to take into account the major volume of terphenyl, hydrogenated used as HTF in industrial installations. For HTF at industrial sites, even accidental leakages can bring significant releases compared to the other uses since this use represents 90% of the total volume used in the EU. Further details of RAC's qualitative evaluation are reported in the section 3.4.3 "Effectiveness in reducing the identified risks".

3.1.4. Risk characterisation

Summary of Dossier Submitter's assessment:

The Dossier Submitter states under section 1.2.6 of the Background Document that it is neither relevant nor scientifically possible to perform a quantitative risk assessment of vPvB substances. This is due to the uncertainties regarding long-term fate and behaviour, exposure and effects. Therefore, the risks of vPvB substances, such as terphenyl, hydrogenated, to the environment or to humans cannot be adequately addressed in a quantitative way. The overall aim for vPvB substances is to minimise the emissions and any exposures to humans and to the environment (Annex I, para 6.5 of REACH).

RAC conclusion(s):

- RAC agrees that the risk assessment of terphenyl, hydrogenated cannot be described on a quantitative basis due to the vPvB properties of the substance.

- RAC concludes that total releases of terphenyl, hydrogenated to the environment should be used as a proxy for risk.

- RAC considers that the uncertainties in the share of total emission of terphenyl, hydrogenated for the different uses and scenarios does not allow to estimate realistically which activities result in the highest emissions and hence the highest risk.

- RAC concludes that based on the information provided in the Background Document, it is evident that current uses cause emissions and exposures and hence, there is a risk to address. RAC notes that terphenyls and hydrogenated terphenyls have been detected in several compartments of the environment and human food, confirming that emissions have led to environmental and human exposures.

- Based on a qualitative evaluation of the available information, RAC concludes that releases to the environment from all uses within the scope of the proposed restriction are likely (i.e., current information specifying operational conditions and risk management measures cannot guarantee that releases are controlled under the conditions of use).

Key elements underpinning the RAC conclusion(s):

The RAC Opinion is based on the Background Document section 1.2.6 and Annex B.10.

It is not possible to derive a reliable threshold for the effects of PBT/vPvB substances. Therefore, any releases should be regarded as a proxy for risk to the environment and human health. Manufacturer or importers of PBT/vPvB substances should recommend risk management measures for downstream users to minimise exposure and emissions to humans and environment throughout the lifecycle of the substance that results from manufacture or identified uses (Annex I para 6.5 of REACH). As discussed in the hazards section, the vPvB properties of terphenyl, hydrogenated result in an intrinsic hazard. A continuous and irreversible exposure of the environment and humans may lead to unpredictable long-term adverse effects. A risk characterisation where releases and exposures are regarded as a proxy for a risk to the environment and human health is appropriate. The emission and exposure assessment of the uses of terphenyl, hydrogenated performed by the Dossier Submitter (section 3.1.3) contains many uncertainties (section 3.1.6) impairing the accurate identification of the risks related to each activity and which human populations or environmental compartments are most at risk. Releases of vPvB substances should be minimised in all sectors of use to reduce adverse effects.

3.1.5. Existing risk management measures and operational conditions

Summary of Dossier Submitter's assessment:

When terphenyl, hydrogenated is used as an HTF, it is constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated under Annex B.9. (Exposure Assessment) to the Background Document. During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.). Potential emissions to the environment are prevented by the implementation of stringent containment measures and control during the design stage of the closed system. The Dossier Submitter considered that a HTF installation should comply with strictly controlled closed systems as are defined in Appendix 5 of the Annexes to the Background Document.

Concerning the use of terphenyl, hydrogenated in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations for which it was reported, the Dossier Submitter considered that there are currently no alternatives available. Terphenyl, hydrogenated is used due to their ease of application, ease of field repair, flexibility, solvent and chemical resistance, low moisture permeability, and adherence to many metals, composite, and coated substrates. The Dossier submitter did not provide any further information on the RMMs concerning the use of terphenyl, hydrogenated in the aerospace industry.

Concerning the release of terphenyl, hydrogenated from ovens and stoves the disposal of EEE is regulated by the WEEE Directive (2012/19/EU)[5] and the Waste Framework Directive 2008/98/EC[6]. Large household appliances like electric stoves, the large appliances used for cooking and other processing of food, cockers and thermostats are explicitly covered according to Annexes 1 and 2 of this Directive. According to Article 8 of the WEEE Directive removal of all fluids from WEEE is required. Fluids must be safely removed prior to crushing or shredding operations. According to the Dossier Submitter, this use is not considered to contribute significantly to the overall risk that is associated with the use of terphenyl, hydrogenated and any risks are covered by existing EU legislation (WEEE Directive).

When terphenyl, hydrogenated is used as a plasticiser it may be released into the environment during the various life cycle stages. During the disposal at a waste treatment plant terphenyl, hydrogenated may be released into the environment. The Dossier Submitter assumes, that at the waste life-cycle stage of articles, due the wide-spread, complex and partly unknown use, the operational conditions and risk management measures are not sufficient and effective enough to control the risks of terphenyl, hydrogenated.

Therefore, a complete restriction of terphenyl, hydrogenated use in articles (≥ 0.1% w/w) is the most appropriate risk management measure, except for the article use of terphenyl, hydrogenated as plasticiser in the aviation industry (with a 5-year derogation (after EiF)) and for the use as HTF in thermostat.

RAC conclusion(s):

- RAC is of the opinion that the risk management measures and operational conditions currently in place at industrial sites using HTF systems, are not sufficient to minimise the releases of terphenyl, hydrogenated and control the risk. RAC supports the

[5] EUR-Lex - 02012L0019-20180704 - EN - EUR-Lex (europa.eu)
[6] EUR-Lex - 32008L0098 - EN - EUR-Lex (europa.eu)

implementation of strictly controlled conditions as described in REACH Article 18(4) for the use of HTF at industrial sites to prevent environmental emissions.

- RAC concludes that the reported information for the use of adhesives and sealants in aerospace and defence applications is insufficient to assume negligeable emissions. Emissions are expected during the service life and waste disposal of the articles.

- RAC considers that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the requirements of the WEEE Directive (respectively the national transpositions) are currently sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided.

- RAC notes that there is no information on existing risk management measures and operational conditions related to the uses of terphenyl, hydrogenated as a solvent/process medium, laboratory chemical (professional use) and as part of mixtures incorporated in articles allowing to conclude on their capacity to control the risk.

- RAC agrees that articles containing terphenyl, hydrogenated may lead to significant releases to the environment at the end of life and final disposal.

- RAC concludes that the measurements of terphenyl, hydrogenated in the environment and other media demonstrate that current risk management measures and operational conditions are not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

Use as HTF in industrial installations:

The Dossier Submitter assumes that HTF at industrial installations is included in closed systems and that potential releases to the environment can be considered negligible based on the 27 responses received to its SEA questionnaire (2021) and the 44 responses received during the consultation on the Annex XV report. The responses received represent approximatively 6% of the industrial sites using HTF (of a total of 1300 sites in the EU). RAC agrees that the described RMMs and OCs may be efficient to reduce the release of terphenyl, hydrogenated to the environment. However, those RMMs and OCs are not always comparable between the different sites. For example, the sampling of HTF for periodic quality control occurs weekly in one site (#3656) when a yearly sampling occurs in two sites (#3698, #3658) and the latter is assumed as the general case by the Dossier Submitter in their assessment. Also, disposal of the exhausted terphenyl, hydrogenated is not always treated through licensed waste handling companies but can be directed into the site wastewater treatment plant (#3637, #3665). The frequency of HTF system leakages is also not very clear, and the results of the monitoring programme presented in the Background Document show that unmanaged leakage or soil contamination occurred in 15% of the monitored sites. The Dossier Submitter refers to the Pressure Equipment Directive (PED 2014/68/EU) as the main European legislation that should be considered and to national guidelines as technical requirements for the design, construction, adaptation, and operation of HTF installation (DIN 4754-1). However, RAC notes that the objectives of these legislations are not targeted specifically to minimise environmental release of HTF but to protect safety of persons or property. If some conditions contribute to reduce the environmental release, such as the provisions for the resistance of the equipment material and for filling and discharge of HTF, they cannot be compared to strictly controlled conditions under REACH. Additionally, strong legal restrictions are only applicable to systems with high potential for danger (Article 14 PED). So, HTF systems are rated into modules and if they are not in high module, they will be inspected only according to the manual of the manufacturer. Also, the majority of HTF systems were installed before the entering into force of these legislations and can be aged up to 40 years as demonstrated by the monitoring program in industrial sites. There is no reference to former PED in the Background Document, so the baseline number of compliant

installations is unknown.

Representative monitoring data are missing to support the Dossier Submitter's assumption of negligeable emissions in all industrial sites. RAC concludes that the risk managements measures and operational conditions currently in place in all HTF installations using terphenyl, hydrogenated cannot be considered sufficient to control the risk.

- Aerospace and Defence applications:

No feedback was received during the stakeholder consultations (LR SEA 2018, COM 2020, DS SEA 2021) on RMMs and OCs for these applications. During the consultation of the Annex XV report, the Aerospace and Defence Association of Europe (ASD) and the Aerospace Industrial Association (AIA) submitted some basic information on RMMs and OCs at factory/industrial settings including repairs at airports. They include trained workers, compliance with the SDS, no wastewater releases for sealant/adhesive formulations which are not water-miscible, waste management during formulation and repair/maintenance procedures. Formulation and mixing of polysulfide sealants/adhesives also containing octylphenol ethoxylate (OPE) are managed according to the RMMs and OCs of the REACH authorisation (AfA 0203-02). However, as OPE is only present at <0.1% in the sealants etc. they are not further subject to authorisation and information on the service life is sparse. As already noted, the waste disposal of the articles is expected to be the major source of releases for these uses. RAC also notes that environmental release of OPE during service life is assumed to be low due to its interaction with the matrix and that no re-use and hazardous waste treatment at the end of the service life are performed as part of aviation requirement. However, there is not sufficient information to assume that the RMM/OCs in place for the polysulfide sealants can be extrapolated to all formulations used in the A&D sector that include not only sealants/adhesives but also finished paints and topcoats. Moreover, terphenyl, hydrogenated is more volatile and used at far higher concentration than OPE in the formulations which could potentially lead to an increased environmental release. Overall, RAC is of the opinion that the information on risk for Aerospace and Defence applications are insufficient to assume negligeable emissions which are expected to be likely during the service life and waste disposal of the articles.

- Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves:

There is no information in the Background Document related to the RMMs and OCs applied by companies that are using terphenyl, hydrogenated as HTF in thermostats of ovens and stoves. The Dossier Submitter assumed that at the end of their service life, ovens and stoves are disposed according to the WEEE Directive (2012/19/EU) and that any risk is covered. RAC is of the opinion that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the WEEE requirements (respectively the national transpositions) are sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided.

- Other uses:

No specific risk management measures and operational conditions are described in the Background Document for the other uses of terphenyl, hydrogenated as sealant/adhesive and coating/paint mixtures incorporated in articles, as solvent/process medium and as laboratory chemical (professional use). In particular, there is no information on the end of the article's service life representing a specific concern of release and accumulation in the environment over long periods of time. RAC agrees with the Dossier Submitter that the final disposal of these articles could lead to uncontrolled risk.

A screening programme conducted in 2018 by NILU and NIVA (NILU, 2018), shows that terphenyl, hydrogenated was found in marine sediments, surface water and buildings and it was recommended that the chemical should consequently be studied in more detail. Additionally, Moh et al. (2002) describe accidental contamination of food items with terphenyl,

hydrogenated, and Sturaro et al. (1995) detected the substance as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Based on these results, RAC concludes that current risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk.

3.1.6. Uncertainties in the risk assessment

Summary of Dossier Submitter's assessment:

Relevant uncertainties concern the release factors used for different environmental compartments and uses (see Annex F.2 of the Background Document). Only for the use of HTF some measurement data were used. For the other uses of terphenyl, hydrogenated, volumes associated with the identified uses are uncertain, limited information is available. In the absence of specific information, the Dossier Submitter used a combination of appropriate default release factors from ECHA Guidance R.16, OECD Emission Scenario Documents (ESD) and industry specific environmental release categories (SPERCs).

RAC conclusion(s):

- RAC concludes that there are significant uncertainties related to the total use volume, operational conditions, and environmental releases for the use of HTF in industrial installations.
- RAC considers that significant uncertainties arise for the risk assessment of HTF related uses as the Dossier Submitter did not consider all identified sources of releases from the use of HTF in industrial installations in the assessment, i.e., the periodical collection of degradation products and the top-up (or refill) operations, the complete drain of the heat transfer system and the dismantling of the installation. The Dossier Submitter did neither consider the use of HTF in articles.
- RAC is of the opinion that the lack of information regarding non-HTF uses brings major uncertainties in the risk assessment of terphenyl, hydrogenated.
- RAC concludes that all identified information gaps, unrealistic assumptions and a number of uncertainties in the emission and exposure assessment of terphenyl, hydrogenated bring significant uncertainty in its risk assessment.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.1.3.

3.2. JUSTIFICATION THAT ACTION IS REQUIRED ON A UNION WIDE BASIS

Summary of Dossier Submitter's assessment:

The Dossier Submitter concluded that action is required on a Union-wide level based on the following considerations':

1. The overall aim for vPvB substances such as terphenyl, hydrogenated is to minimise the exposures and emissions to humans and the environment (REACH Regulation, Annex I, section 6.5). Measures to reduce the ongoing emissions are therefore regarded as mandatory. For these substances, for which it is not possible to establish a safe level of exposure, risk management measures should always be taken to minimise exposure and emissions, as far as technically and practically possible (recital

70 of the REACH Regulation).

2. The uses of terphenyl, hydrogenated are broad and the main use as HTF as well as the use of terphenyl, hydrogenated as plasticiser and as other uses containing terphenyl, hydrogenated are imported into the EU and are placed on the market in all EU member states.

3. Potential national regulatory actions are not considered adequate to manage the risks, in particular the risk on the plasticiser uses. Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to actions undertaken by individual Member States.

RAC conclusion(s):

Based on the key principle of ensuring a high level of protection across the Union and of maintaining the free movement of goods within the Union, RAC supports the view that any necessary action to address risks associated with terphenyl, hydrogenated should be implemented in all Member States.

Key elements underpinning the RAC conclusion(s):

According to the data obtained from stakeholders, the total number of closed loop manufacturing systems using terphenyl, hydrogenated as HTF in the EU is close to 1 300 systems, which are installed in 24 of the 27 EU Member States. Moreover, an increasing trend of terphenyl, hydrogenated volumes used in the EU in the future is assumed. The results of the monitoring program at industrial sites clearly shows that releases of terphenyl, hydrogenated from HTF could be relatively frequent (i.e. 15% of the monitored HTF systems).

The Dossier Submitter considers that long-range transport of terphenyl, hydrogenated is unlikely based on its semi to non-volatile profile (estimated by a boiling point of 342 °C at 1013 hPa) not meeting the key pre-conditions for long-range transport chemicals. RAC notes that the boiling point alone is not sufficient to assess the volatility of a substance and considers that long-range transport can also occurs via migratory species based on the Stockholm convention criteria. The screening programme results performed in Norway (NILU, 2018 and COWI AS, 2020) shows that hydrogenated terphenyl congeners are found in house dust, sewage water and sludge, landfill, marine sediments, marine fish and freshwater benthic biota. It is also the case for terphenyls, including o-terphenyl, and they have also been detected in surface water. The sources of emissions have not been identified but the detection in surface water, marine sediment and biota show the potential for transfer to a receiving environment. Additionally, Moh et al. (2002) describe accidental contamination of food items with terphenyl, hydrogenated, and Sturaro et al. (1995) detected the substance as contaminant in food cardboard packages made from recycled material containing carbonless copy paper. Based on these monitoring results, RAC considers that properties of persistence and, bioaccumulation, combined with adsorption to soil and sediment and its detection in various environmental matrices are of sufficient concern in their own right.

RAC concludes that the current risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk and that action is required on a Union-wide basis.

SEAC conclusion(s):

Based on the key principle of maintaining the free movement of goods within the Union, SEAC concludes that any necessary action to address risks associated with terphenyl, hydrogenated should be implemented in a harmonised manner across all MSs, and action is therefore required on a Union-wide basis.

Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter considers that potential national regulatory actions are not adequate to manage the risks, vis-à-vis the management of risks related to the use as a plasticiser. The Dossier Submitter proposes union-wide action to avoid trade and competition distortions, thereby ensuring a level playing field in the internal market as compared to actions undertaken by individual Member States. SEAC concurs with the Dossier Submitter's reasoning that those eventual national measures are not adequate to address the risks at hand and that an EU-wide measure is more suitable and appropriate in targeting the risks at hand, whilst at the same time ensuring a level playing field in the internal market.

- The Dossier Submitter states that there are REACH registrants in 4 different member states, thus the use is not limited to one member state.

SEAC considers that the fact that there are REACH registrants in several member states, indicates that action on a union wide basis is the most appropriate measure.

The Dossier Submitter checked (in 2021) the SCIP[7] -database and found that in total more than 12 000 entries containing terphenyl, hydrogenated were notified, in December 2022 the number of entries is almost 25000. The Dossier Submitter concluded that 85 % of the use of terphenyl, hydrogenated in articles is related to the use of the substance as a plasticiser. A more recent search on the SCIP database has shown that there are also an important number of articles containing terphenyl, hydrogenated for HTF use. However, information from the SCIP database needs to be used with caution. The database can be valuable to identify specific uses, but the number of notifications might be misleading, as the notification system and updating is not set up for counting articles. Despite the limitations of the use of data of the SCIP database and the caution required on the use of exact numbers from the SCIP dataset, SEAC considers that the order of magnitude of the numbers and variety of articles and uses notified, indicates that action on a Union-wide basis is necessary to ensure the free movement of goods within the Union.

- The Dossier Submitter also presents information on the number of HTF systems (1300 to 1500), and this shows that in 24 of the member states installations are present where terphenyl, hydrogenated is used as HTF.

SEAC considers that the widespread use in a large fraction of the Member States indicates that action on Union-wide basis is the most appropriate measure.

SEAC considers that the points raised above demonstrate that the conclusion of the dossier submitter on the need for Union-wide action is based on well-developed arguments accompanied with clear evidence and SEAC considers the conclusion of the Dossier Submitter therefore as robust.

[7] https://echa.europa.eu/scip

3.3. ANALYSIS OF ALTERNATIVES

3.3.1. Approach to the analysis of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter has performed an analysis regarding the advantages and disadvantages of different alternatives to terphenyl, hydrogenated. The Dossier Submitter states that alternatives would need to be technically and economically feasible, but also have a favourable hazard profile to avoid regrettable substitution and subsequent regulatory action on the alternative.

Considering these conditions, the Dossier Submitter process of identifying alternatives has been divided into three general steps:

- Screening of information sources
- Assessment on the technical suitability of the alternatives, considering the different uses of terphenyl, hydrogenated.
- Assessment of the hazard profile of the alternatives

After the first step of the identification process (screening of information sources) an initial list of potential alternatives to terphenyl, hydrogenated was defined.

The uses are independent from each other and as such, some alternatives may be suitable replacements for some uses, but not for others. For this reason, an analysis of the risk reduction, technical and economic feasibility, and availability of these potential alternatives to terphenyl, hydrogenated has been done (see detailed information in Annex E.2.3.).

SEAC conclusion(s):

The search for alternatives is not comprehensive (especially for uses other than HTF), and the list of alternatives presented is neither complete nor properly justified.

The technical criteria used to shortlist alternatives are not specific to each of the uses in scope, and the choice of alternatives appears therefore not well justified.

Key elements underpinning the SEAC conclusion(s):

Regarding the search for alternatives:

The Dossier Submitter has presented several alternatives based on literature, information from stakeholders, responses to SEA questionnaires and information received in the consultation on the Annex XV report. The questionnaires are: Lead Registrant SEA questionnaire (2018), EU Commission SEA questionnaire (2020), Consultation on ECHA's Draft 10th Recommendation (2020), and Dossier Submitter questionnaire (2021). Ninety-six responses were received in total (removing duplicates). A further 57 comments were received in the consultation on the Annex XV report.

The Annex XV report however lacks bibliographic references related to alternatives and there is no evidence of the information received from stakeholders in the Annex XV Dossier. The proposed list of alternatives is derived from responses to SEA questionnaires and the consultation on the Annex XV report, and it should be noted that, according to the Dossier Submitter, the responses to the SEA questionnaires on potential alternatives have been very scarce and poor (especially for uses other than HTF). SEAC has scrutinised the comments on ECHA's Draft 10th Recommendation and all of them are related to the use as HTF. Something similar derives from the comments received; no available alternatives have been proposed.

Even for the HTF use, where the analysis of alternatives is more comprehensive, some alternatives have not been considered, such as diisopropyl-1 1'-biphenyl. In Paratherm (2022), this substance is compared with Therminol 66 (main commercial HTF fluid containing terphenyl, hydrogenated).

Due to the lack of information, the Dossier Submitter identifies alternatives for uses other than HTF based on whether the substance is registered (in REACH) for that use. The only exception is for the use in sealants in the aerospace industry; for that specific use three alternatives are presented (chlorinated paraffins, phthalates and dibenzoates) based on a comment by the Aerospace Industry Association and literature research (see BD section 2.2, pp 48) and one alternative, Diethylene glycol bis(3-aminopropyl) ether, is presented as this alternative is used by a company selling to the aviation industry (according to their website) in formulations substituting of terphenyl, hydrogenated. However, no further evidence is presented. Additionally, a distinction is made between different phthalates in the Background Document, ortophtalates on one side and iso- and terephtalates on the other. There is no further justification or evidence indicating that the last group is specifically used as a substitute of the substance of concern. The main reason for splitting phthalates in two groups is that ortophtalates is a substance of concern while iso- and terephtalates seem have a less hazardous profile.

3.3.2. Availability and technical and economic feasibility of alternatives

Summary of Dossier Submitter's assessment:

The Dossier Submitter concluded that there is not a universal alternative to terphenyl, hydrogenated that covers all the identified uses of this substance.

The Dossier Submitter states that a suitable alternative to terphenyl, hydrogenated that covers all the identified uses of this substance has not been found when used as HTF, plasticiser, adhesive and sealants, paints and coatings, and ink and toners (because most of them could lead to a regrettable substitution).

Only one potential alternative, commercially available in the required quantities, has been found for the use as solvent or process medium (biphenyl), mainly as textile dyestuff carrier. It is worth noting that the Lead Registrant of this substance, which is also the Lead Registrant of terphenyl, hydrogenated, is placing on the market biphenyl as process media or solvent in many industries, including chemicals and petrochemicals (Eastman, 2022b). However, the company does not recommend or market terphenyl, hydrogenated as solvent or process medium (Eastman, 2022c). This is an indication that both substances are not substitutable in this use.

The Dossier Submitter states that it lacked the required information to assess technical and economic suitability of this alternative with certainty because in stakeholder surveys specific technical and economic data related to the potential alternatives have not been provided by the impacted actors. Despite the absence of more precise information on technical and economic feasibility, the Dossier Submitter assumed that this assessment of alternatives for the functions of terphenyl, hydrogenated and its conclusions are still valid.

SEAC conclusion(s):

The criteria to shortlist and further discard alternatives are limited and are not specific enough for the different uses and types of industries that were described in the assessment. The assessment of the Dossier Submitter does not include sufficient specific technical and economic data to evaluate alternatives in terms of their economic and technical feasibility.

Because of the shortcomings in the description of technical criteria defined by the Dossier Submitter and their limited assessment of the alternatives identified, SEAC finds that the

technical feasibility of alternative substances for all the other uses apart from HTF can therefore not be properly evaluated and SEAC cannot conclude whether the Dossier Submitter's conclusion that the alternatives are not suitable is warranted. In the case of the use of the substance as an HTF all identified alternatives would lead to regrettable substitution.

Biphenyl is the only substance available that can potentially be a standalone alternative for some of the uses (as solvent or laboratory chemical) although technical and economic information is needed to assess its feasibility and to evaluate whether this alternative would be used in practice (biphenyl is confirmed to be manufactured as a coproduct with terphenyl, hydrogenated, so a ban on the latter would have an important impact in the production of the former that has not been assessed by the Dossier Submitter). Cyclohexylbenzene could also be an alternative for the same uses as biphenyl, although it cannot be the only alternative, as the low registered quantities would not, most likely, be enough to satisfy the demand for those uses. Another alternative Diethylene glycol bis(3-aminopropyl) ether has been identified as a potential substitute in some uses in aviation, but there is no further assessment of the substance. Finally, phthalates have been split into orthophthalates and iso and terephthalates, the iso- and terephtalates are not considered hazardous and the Background Document indicates that they could be used in some applications in the aerospace industry although neither additional information nor evidence is provided. For all the other uses alternatives have been identified that lead or could potentially lead to a regrettable substitution if confirmed as SVHC (they are under assessment as PBT or CMR). Besides, for all of the mentioned alternatives, further technical and/or economic information is needed to assess their feasibility (which is not present in the Background Document presented by the Dossier Submitter).

Key elements underpinning the SEAC conclusion(s):

After the screening of alternatives, the Dossier Submitter proposes an initial list with 17 elements. From this list, eight alternatives have been shortlisted for further assessment.

Shortlisting by the Dossier Submitter was based on technical and hazard considerations. Alternatives have been discarded for their use as HTF using the boiling point as technical requirement. Alternatives identified for one particular use that are not registered for other uses were rejected for those uses.

Table 2 shows the alternatives that were considered; the technical feasibility column shows if the alternative fulfils the technical criteria. This means the boiling point for HTF. For all the other uses there are no technical criteria; all that the Dossier Submitter required for an alternative to be considered technically feasible is being registered for that use. When the alternative is not registered for a use, it appears in grey in the table. Green indicates that the alternative is technically feasible, according to the Dossier Submitter. All the technically feasible alternatives are evaluated taking into account the hazard profile. If the substance has a proved hazardous profile (being PBT or CMR) it is discarded (in red in the table), if the substance is under assessment, it is not discarded, but the concern is shown in the table (in yellow).

Table 6: Summary of alternatives and its assessment using technical and risk criteria

		Technical feasibility						Hazard classification	Shortlisted
	Alternatives: Chemical name	HTF	P	S	Lab	A (c,p,i)	A(s,a)		
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene							PBT?	Yes
2	Dibenzylbenzene, ar-methyl derivative							CMR (self-PBT[1])	No
3	Benzene, ethylenated, by-products from							N/A	No
4	Reaction mass of diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl							CMR	No
5	Reaction mass of m-terphenyl and o-terphenyl							PBT	No
6	Diphenyl ether							CMR?	Yes
7	Biphenyl								Yes
8	Cyclohexylbenzene								Yes
9	Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues							PBT?	Yes
10	Benzyltoluene							N/A	No
11	Ditolyl ether							N/A	No
12	Mineral fluids							N/A	No
13	Dibenzoates							Repr?	Yes
14	Orthophtalates							PBT-vPvB	No
15	Chlorinated paraffins							CMR, PBT?	No
16	Iso- and Terephthalates							N/A	Yes
17	Diethylene glycol bis(3-aminopropyl) ether							N/A	Yes

Where:
HTF: Heat transfer fluid, P: plasticizer, S:solvent, Lab: Laboratory chemical, A(c,p,i): additive coatings, paint and inks, A(s,a): additive sealants and adhesives

[1] according to comments received in the public consultatio

The uses considered as most important are as HTF (because of the volume used) and as plasticiser and additive in coatings, plastics, inks, sealants and adhesives (because of the emissions and the industry used in, aerospace). All of the alternatives are under assessment as SVHC substances, except for the ones for uses as solvent and laboratory chemicals.

The shortlisted alternatives were assessed by the Dossier Submitter considering the availability, hazard profile, technical feasibility, and economic feasibility. Regarding technical and economic feasibility there is no information that can allow an assessment of the substances.

Alternative 1 (1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene): technically feasible for its use as HTF (based on its boiling point as technical requirement). There is uncertainty about its availability (the REACH registration tonnage is confidential, according to the Dossier Submitter; referring to information on the ECHA website, the tonnage could be around 100-1000t/y. The substance is considered High Production Volume by OECD) and about the economic impact (which is barely estimated). Concerns about being a regrettable substitution (under assessment as PBT).

Alternative 2 (Diphenyl ether): Registered uses as a solvent and laboratory chemical. The substance is available in the market. Technical and economic feasibility cannot be assessed as there is no information available. Concerns about being a regrettable substitution (under assessment as CMR).

Alternative 3 (Biphenyl): Registered uses as a solvent and laboratory chemical. The substance is available in the market. Technical and economic feasibility cannot be assessed as there is no information available.

Alternative 4 (Cyclohexylbenzene): Registered uses as a solvent and laboratory chemical. The substance is not available in the market in the quantities needed. There is a preliminary technical evaluation (based on the bromine index of the substance that is related to its function as a solvent) indicating that it is does not perform as well as a solvent as terphenyl,

hydrogenated. The Dossier Submitter concludes that it is not technically feasible without further justification. Economic feasibility cannot be assessed as there is no information available.

Alternative 5 (Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues): Registered uses as plasticiser, solvent, laboratory chemical and additive (for sealants, adhesives, coatings, paints and inks). The substance is available in the market. Technical and economic feasibility cannot be assessed as there is no information available. Concerns about being a regrettable substitution (under assessment as PBT).

Alternative 6 (Dibenzoates): There is no information about availability, technical and economic feasibility. Concerns about regrettable substitution (some of the substances in this group have reproductive toxicity properties Cat. 1b).

Alternative 7 (Iso- and Terephthalates): There is no information about availability, technical and economic feasibility.

Alternative 8 (Diethylene glycol bis(3-aminopropyl) ether): There is no information about technical and economic feasibility.

Table 7 shows a summary of the assessment of the shortlisted alternatives (in yellow substances under assessment for being SVHC):

Table 7: Assessment of shortlisted alternatives

		Technical feasibility								
	Alternatives: Chemical name	HTF	P	S	Lab	A (c,p,i)	A(s,a)	Availability (t/y)[1]	Economic	Technical
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene							Confidential	120 000 - 300 000 +[2]	Ok
6	Diphenyl ether							1 000 - 10 000	No info	No info
7	Biphenyl							1 000 - 10 000	No info	No info
8	Cyclohexylbenzene							100 - 1 000	No info	??[3]
9	Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues							10 000 - 100 000	No info	No info
13	Dibenzoates							No info	No info	No info
16	Iso- and Terephthalates							No info	No info	No info
17	Diethylene glycol bis(3-aminopropyl) ether							100 - 1 000	No info	No info

HTF: Heat transfer fluid, P: plasticizer, S:solvent, Lab: Laboratory chemical, A(c,p,i): coatings, paint and inks, A(s,a): sealants and adhesives

1 REACH registration tonnage

2 €/company, plus other costs related to downtime and disposal

3 Indicates technically not feasible, but no evidence

Alternatives for HTF use.

The alternatives considered as substitutes for HTF all belong to the category of synthetic fluids. The other categories (for heat transfer fluid uses), mineral-based oils and silicones, have been discarded without further evidence.

Silicon fluids have been discarded due to performance related issues as well as high costs, even though there is some evidence that they can be used on some of the industrial uses presented by the Dossier Submitter such as e.g. Concentrated Solar Power (CSP) (Helisol XLP, 2022a) (Helisol XLP, 2022b). In (Giaconia et al., 2021) an assessment of heat transfer fluids for CSP applications is presented, where they compare thermal (synthetic and mineral) oils and molten salt mixtures for CSP. The authors conclude that in CSP installations molten salts could replace synthetic oils, although with higher costs and a more difficult management of the installation. Two comments have been received (#3676,#3706) indicating problems associated with the use of silicones. One comment (#3676) underlines the high viscosity of

the substance (which has an impact on pumping: costs and maintenance) and the other (#3706) is related to the formation of by-products that can foul the heat exchanger decreasing its performance and highlighting that this substance has a lower heat transfer coefficient, resulting in a less efficient process.

Mineral oils have been discarded for technical reasons, indicating that they cannot be used at temperatures above 315-320ºC (based on an outdated reference from 1998)). More information is needed to eliminate this alternative as there is some evidence of mineral fluids that can operate above 320ºC (Oliterm 30, 2022). There are comments received (#3663, #3676, #3680, #3693 and #3706) that indicate the unsuitability of this alternative. There are issues related to the formation of low boiling substances (can cause pump cavitation and increase the risk because of their flammability), high boiling substances (can form deposits and sludges) the reduced lifespan of the substance and the impossibility to use mineral oils above 300ºC.

SEAC considers that there are currently no suitable alternatives for the use of terphenyl, hydrogenated as an HTF. Although this situation is not foreseen to change in the future (due to the inherent properties needed by the substance to operate in the high temperature range), the availability of suitable alternatives or technologies that do not pose a risk of regrettable substitution should be monitored. This is further discussed in section 3.4.4.4

Alternatives for aerospace and defence industry

There are some alternatives for the use as additive in adhesive and sealants in the aerospace industry, but a substantial underpinning as to their suitability as alternatives is missing. The alternatives are dibenzoates, phthalates (ortho- iso and tere-) and chlorinated paraffins and Diethylene glycol bis(3-aminopropyl) ether. Orthophtalates and chlorinated paraffins are discarded because of their hazard properties and environmental behaviour. These alternatives are already used in the aerospace industry as indicated in Thioplast™ G (a liquid polysulfide polymer) brochure, where is says: "*Phthalates, Phosphates, and Benzoates have replaced since years the more toxic chlorinated Di-phenyls or hydrogenated terphenyls as plasticisers in Thioplast™ G based sealants*" (Thioplast, 2022). Diethylene glycol bis(3-aminopropyl) ether is also indicated to be sold to the aerospace industry according to the website of the manufacturer. It is recognised by the aerospace industry (comments #3655, #3707 in the consultation on the Annex XV report) that there are some formulations on the market that do not contain terphenyl, hydrogenated but they also indicate that they are only certified for some companies and some uses.

Alternatives for other uses

There is no additional information for other uses and the identification of alternatives is based on whether these substances are registered for those uses.

Regarding the function of the substance:

Establishing the requirements for the different uses to be fulfilled by the substance is important to identify and assess potential alternatives. Without such information, SEAC cannot evaluate whether alternatives are going to be used in place of the Annex XIV substance and SEAC is hampered in the evaluation of the impacts a restriction would have.

The function of the substance is described (E.2.1) for its use as a HTF but it is not described for any other of the uses. This means that there is not a description of technical requirements to compare alternatives with. The identification of alternative substances or technologies fulfilling the function for these uses cannot be addressed, and the technical feasibility of an alternative substance for all the other uses but HTF cannot be properly demonstrated or compared. In comments #3655, #3707 the aerospace industry provides a long list of properties and performance requirements that formulations containing terphenyl, hydrogenated have and that should be fulfilled by alternative formulations.

The required properties of the substance for its use as HTF ar indicated, but the requirements are only described qualitatively (low viscosity, high heat capacity, etc..). The lack of quantitative indicators or metrics (and standards -ISO or DIN- to measure them) makes it difficult to assess if an alternative fulfils the requirements.

The only quantitative property of the substance (that is used to shortlist alternatives) is the boiling point (342ºC at 1atm). But due to the possible wide variety in industrial uses, it is not clear if this temperature is a requirement for all of the industries considered or if the required temperature varies depending on the type of industrial process at hand. One of the main properties indicated in many comments received (#3658,#3669, #3672, #3675, #3693, #3698, #3701, #3710) is the thermal stability of the molecule which allows for a long lifecycle. This means that even for a process where another substance could be used terphenyl, hydrogenated would be preferred for economic reasons.

The screening of SCIP database shows that terphenyl, hydrogenated is also used as HTF in domestic appliances (like ovens or gas stoves). This equipment uses temperatures below 300ºC. This implies that some alternatives that are discarded for the use as HTF in industrial sites could be suitable for the use as HTF in domestic articles.

Consequently, the assessment of the dossier submitter lacks a clear set of technical requirements of the substance that would facilitate a comparison with other substances to assess their technical suitability. SEAC notes that some additional information was submitted in the consultation on the Annex XV report, but the information was not sufficient to resolve the issues. SEAC therefore finds that the technical feasibility of an alternative substance for all the other uses apart from HTF cannot be properly evaluated.

3.3.3. Risk of Alternatives

Summary of Dossier Submitter's assessment:

Since terphenyl, hydrogenated has been identified as a vPvB substance, quantitative risk characterisation is not appropriate nor meaningful. Therefore, it is not feasible to carry out a risk comparison between terphenyl, hydrogenated and its potential alternatives. Instead, a comparison of hazard properties has been used as an indicator of potential regrettable substitutions. Short-listed alternatives were assessed qualitatively based on a comparison of available information on hazard profile, including consideration of:

- Hazard classifications notified under CLP
- On-going regulatory assessments

In summarising, an alternative to terphenyl, hydrogenated that covers the uses of this substance has not been found when used as HTF, plasticiser, adhesive and sealants, paints and coatings, and ink and toners (because most of them could lead to a regrettable substitution), and only one potential alternative has been found for the use as solvent or process medium (biphenyl), although there is some uncertainty as to whether this alternative would be technically and economically suitable for this application.

As stated in Annex E.2.3.3., biphenyl could be a potential alternative to terphenyl, hydrogenated for its use as solvent or process medium, mainly as textile dyestuff carrier. The Lead Registrant of this substance, which is also the Lead Registrant of terphenyl, hydrogenated, is placing on the market biphenyl as process media or solvent in many industries, including chemicals and petrochemicals (Eastman, 2022a). However, the company does not recommend or market terphenyl, hydrogenated as solvent or process medium (Eastman, 2022b). This is an indication that both substances are not substitutable in this use.

RAC conclusion(s):

Based on the data presented in the Background Document by the Dossier Submitter, RAC understands that no suitable alternatives to terphenyl, hydrogenated were found by the dossier submitter for HTF, because they considered that candidates had similar or worse hazard properties, mainly PBT or CMR.

Based on the data presented in the Background Document by the Dossier Submitter, RAC notes that no information is available on the alternatives to terphenyl, hydrogenated used in articles. This represents a significant uncertainty regarding the proposed restriction, considering the wide variety of the article uses and hence potential high number of alternatives.

RAC considers that alternative with a better hazard profile compared to terphenyl, hydrogenated might exist for adhesives uses for aerospace industry sector, pending further evaluation.

Key elements underpinning the RAC conclusion(s):

The main alternatives to terphenyl, hydrogenated in HTF (based on technical documentation on specifications for plant construction and the RMOA conducted by the Finnish Safety and Chemicals Agency (Tukes, 2020)) are 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene (CAS 63231-51-6; EC 400-370-7), and dibenzyl¬benzene, ar-methyl derivative (CAS 53585-53-8; EC 258-649-2). 1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene is identified by the Dossier Submitter as the unique potential alternative of terphenyl, hydrogenated for the HTF use. Nevertheless, this substance is under PBT assessment and the substitution of terphenyl, hydrogenated by this alternative when used as HTF in non-pressurised liquid phase systems could result in regrettable substitution.

RAC noted that the reaction mass of m- and o-terphenyl (CAS 904-797-4) is quoted in Table 20 in the background document as potential alternatives to terphenyl, hydrogenated for HTF uses. In the last step of the identification process, this substance had been discarded by the dossier submitter due to its PBT properties. In the RMOA conducted by Finland (Tukes 2020) this substance "reaction mass of m-and o-terphenyl" was not considered as potential alternative because it contains o-terphenyl as a constituent. In case of a time-limited derogation for HTF uses, other substances can be used as alternatives to terphenyl, hydrogenated in low temperature (<250-350°C), non-pressurised heat transfer systems. However, these alternatives have not been assessed in above mentioned FI RMOA as they cannot be considered direct alternatives in high temperature, non-pressurised heat transfer systems.

Most of the respondents of the consultation on the Annex XV report claimed the absence of reliable alternatives for this use (#3637, #3659, #3666, #3669, #3672, #3679, #3687, #3689, #3690, #3693, #3697, #3698, #3701, #3706, #3709, #3710, #3714, #3716, #3717, #3720). Some respondents also indicate that alternatives with other parameters and potentially with lower environmental concern cannot provide the same heat exchange and resistance capability and will lead to a significant redesign of the installation (#3658; #3675, #3676, #36791, #3695). Furthermore, it is not known in how many industrial installations terphenyl, hydrogenated is used in low temperature (<250-350 °C) conditions.

RAC notes that no information is available on the alternatives to terphenyl, hydrogenated used in articles in the background document or submitted during the consultation on the Annex XV dossier. This represents a significant uncertainty regarding the proposed restriction.

For aerospace industry uses, the aerospace industry (#3655, #3662, #3707) claims, that no direct replacement is possible, and the alternatives need to contain terphenyl, hydrogenated.

The Dossier Submitter notes that a comparison of the formulations via the old[8] and the new[9] safety data sheet of one of the adhesives reveals, that terphenyl, hydrogenated has been replaced by diethylene glycol bis(3-aminopropyl) ether (CAS-No. 4246-51-9). According to ECHA's website[10], no harmonised classification exists for this substance, but data submitters broadly recognised this substance as a skin sensitiser. According to the website of the company, they are selling this alternative not only to the aviation industry[11,12] but to other sectors as well. RAC took note of this data and considers that diethylene glycol bis(3-aminopropyl) ether might be an alternative of terphenyl, hydrogenated for adhesives use with a better hazard profile. Diethylene glycol bis(3-aminopropyl) ether is neither classified as CMR Cat 1 nor as a PBT/vPvB substance or meets the equivalent level of concern criteria, so would not be eligible for SVHC classification.

For uses other than aerospace industry and HTF, the Dossier Submitter identified and presented a list of alternative substances in Table 22 of the Background Document. RAC notes that several listed alternatives could result in regrettable substitution for these uses, including:

- Diphenyl ether as a potential alternative to terphenyl, hydrogenated for the use as solvent or process medium, and laboratory chemicals but its CMR status is under assessment.

- Benzene, Mono-C10-13, Alkyl Derivatives, Distillation Residues has been assessed as a potential alternative to terphenyl, hydrogenated for the uses as plasticiser, adhesive and sealants, paints and coatings, ink and toners, solvent or process medium, and laboratory chemical. However, the PBT status of this substance is under assessment.

- Cyclohexylbenzene classification is notified under CLP regulation as Aquatic Acute 1, H400 and Aquatic Chronic 1 H410 and could be considered compatible for solvent and laboratory chemical uses, but the Dossier Submitter concluded that it cannot be considered a suitable alternative for terphenyl, hydrogenated as on the basis of its hazard classification. However, RAC noted that the hazard profile of this substance is more favourable than that of terphenyl, hydrogenated. A conclusion regarding the relevance of this substitution can only be reached through a risk assessment requiring knowledge of the processes and the quantities involved to estimate a potential release. Since these data were not presented by the Dossier Submitter, the RAC cannot conclude on the environmental risk that this substitution would represent.

- The Dossier Submitter considers that biphenyl could be compatible for its use as solvent or process medium, mainly as a textile dyestuff carrier, and as laboratory chemical. This substance is registered under the REACH Regulation for solvent and laboratory chemical uses and classified under CLP \regulation as Aquatic Acute 1 H400. A conclusion regarding the relevance of this substitution can only be reached through a risk assessment requiring knowledge of the processes and the quantities involved to estimate a potential release. Since these data were not presented by the Dossier Submitter, RAC cannot conclude on the environmental risk that this substitution would represent. However, RAC noted that the hazard profile of this substance is more favourable than that of terphenyl, hydrogenated.

- Dibenzoates could be potential substitutes of terphenyl, hydrogenated as plasticiser and additive in adhesive and sealants from the technical point of view, however, some of the substances in this group have reprotoxic properties and are classified as Rep

[8] Safety Data Sheet is available to the Dossier Submitter.
[9] ResinLab EP1290 Clear Epoxy Adhesive.
[10] Brief Profile - ECHA (europa.eu) (20/02/2023)

[11] ResinLab - The Leading Resin Manufacturer.
[12] How to Choose a Static Mixer - ResinLab.

cat 1b, leading to potential regrettable substitution.

- The iso- and terephtalates- are not considered hazardous by the Dossier Submitter and it is indicated that they could be used as plasticizer, additive sealants and adhesives in the aerospace industry although neither additional information nor evidence is provided.

3.3.4. Conclusion on analysis of alternatives (SEAC).

SEAC conclusion(s):

There is insufficient evidence in the Background Document to conclude whether there are suitable alternatives for some of the uses or for some applications (like some processes in the use as HTF). According to the comments received in the consultation on the Annex XV report, it can be concluded that for the use of the substance as an HTF there is no suitable alternative.

Comments received in the consultation on the annex XV report also indicate that there could be some alternatives for some uses in the aerospace industry, but these alternatives would require additional time to be developed and would not be suitable for all the applications of terphenyl, hydrogenated in the aerospace and defence sector. For all other uses only biphenyl and cyclohexylbenzene could be alternatives for the uses as solvent and laboratory chemical.

All the identified alternatives (except for those identified for some minor uses indicated above) lead to regrettable substitution.

Key elements underpinning the SEAC conclusion(s):

The assessed alternatives were identified on the basis of stakeholder information gathered during the dossier development stage as well information submitted via comments received during the consultation on the Annex XV report Most of the information however is related to one of the uses (HTF), some of the alternatives have been discarded by the Dossier Submitter without sufficient justification. The Dossier Submitter has identified several alternatives, although the analysis is not comprehensive.

The Dossier Submitter has assessed the alternatives based on the risk they pose for human health and the environment but lacked the required information to assess economic and technical feasibility of the alternatives. There is no clear description of technical requirements that the alternatives have to fulfil to compare its performance against the substance of concern. The Dossier Submitter only considers one key performance requirement (the boiling point) and this applies only for one of the uses (HTF).

None of the presented alternatives is considered suitable to substitute terphenyl, hydrogenated for all its applications. Only biphenyl (and partially cyclohexylbenzene) could be considered as a substitute for the use of terphenyl, hydrogenated as a solvent or laboratory chemicals, and iso- and terephthalates and Diethylene glycol bis(3-aminopropyl) ether as constituents in formulations for some uses in the aerospace industry but no information was available to assess their economic and technical feasibility.

In a recent RMOA undertaken by the Finnish authorities the risk of regrettable substitution with substances similar to terphenyl, hydrogenated is considered to be high. The two foremost alternatives (EC-No 258-649-2 and EC-No. 400-370-7) to terphenyl, hydrogenated (CAS 61788-32-7) have been grouped together into a "technical functional group" (Tukes, 2020) due to their use as Heat Transfer Fluid (HTF) and the potential PBT properties of the two alternatives. In this respect SEAC notes that with the current targeting and scope of the proposal, focussing on terphenyl, hydrogenated, there is a risk of regrettable substitution as actors could potentially use one of the substances from this functional group as a substitute.

This could lead to situation of regrettable substitution with actors merely using another PBT (or likely to be PBT) substance instead of terphenyl, hydrogenated. Without the key information to assess economic and technical feasibility, SEAC cannot evaluate whether the potential suitable alternatives are fulfilling or replacing the function of terphenyl, hydrogenated for some uses.

3.4. JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Summary of the proposed restriction

The aim of the proposed restriction is to minimise the emissions of terphenyl, hydrogenated in Europe.

Various regulatory risk management options have been assessed to identify the options that are most appropriate to terphenyl, hydrogenated. Discarded Ros as well as other union-wide measures are set out in **Annex E.1.2** and **Annex E.1.3** respectively, whilst the Ros included in the SEAs are set out below.

All considered Ros, defined in Annex E.1.1, restrict, use and placing on the market of terphenyl, hydrogenated as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months. Whilst the strictest RO (RO3) does not include any derogations, RO1 and RO2 include derogations of varying scope and length for uses as HTF and as plasticiser in the production of aircrafts. A summary of the considered derogations is provided in Table 8.

Table 8: Summary of considered derogations

	RO1	**RO2**	**RO3**
A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months.			
Derogation for the use and placing on the market for industrial sites as HTF.	Implementation of strictly controlled closed systems with technical containment measures to minimise environmental emissions.	Implementation of strictly controlled closed systems with technical containment measures to minimise environmental emissions.	None
Derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts.	EiF + 5 years	None	None

The analysis in **Annex E.8** shows that RO3 (the most stringent RO) has the highest emission reduction potential but comes at much higher costs than the other risk management options. RO2 has a higher emission reduction capacity than RO1 but a higher cost per kg of emissions prevented. RO1 has a high cost per kg of emissions prevented coupled with a high emission (risk) reduction capacity.

The Dossier Submitter considered RO1 the most appropriate risk management option because

they consider that it is effective and reduces potential risks to what the Dossier Submitter considers is an acceptable level (however, not defining what an acceptable level is) within a reasonable period of time, while this RO is considered to be proportionate as it proposed derogations in situations where the substance is considered to be used in a closed system or allow extra time for industry to find alternatives in sectors that are particularly impacted by this restriction.

3.4.1. Targeting of the proposed restriction

Summary of Dossier Submitter's assessment:

The proposed restriction (RO1) is targeted to the exposure that is of most concern, e.g., the use of terphenyl, hydrogenated as a plasticiser. It is assumed to impose low costs to reduce a potential risk and that the measures are proportionate to the risk. The restriction is practical because it is implementable, enforceable, and manageable, as the proposed restriction is easy to understand and communicate down the supply chain.

The aim of the proposed restriction is to minimise the emissions of terphenyl, hydrogenated in the EU.

Various regulatory risk management options have been assessed to identify the options that are most appropriate to terphenyl, hydrogenated. Discarded ROs as well as other Union-wide measures are set out in Annex E.1.2 and Annex E.1.3 respectively, whilst the ROs included in the SEAs are set out below.

All considered ROs restrict the manufacture, use and placing on the market of terphenyl, hydrogenated as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months. Whilst the strictest RO (RO3) does not include any derogations, RO1 and RO2 include derogations of varying scope and length for uses as HTF and as plasticiser in the production of aircrafts. A summary of the considered derogations is provided in Table 9:

Table 9 Overview of restriction options considered by the Dossier Submitter

	RO1	**RO2**	**RO3**
A restriction on the use and placing on the market as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months.			
Derogation for the use and placing on the market for industrial sites as HTF.	Implementation of strictly controlled closed systems with technical containment and organisational measures to minimise environmental emissions.	Implementation of strictly controlled closed systems with technical containment and organisational measures measures to minimise environmental emissions.	None
Derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts, maintenance and repair.	EiF + 5 years	None	None
Derogation for the use and placing on		None	None

the market in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats, as long as these applications are covered by the WEEE Directive (2012/19/EU).			

The analysis in Annex E.8 shows that RO3 (the most stringent RO) has the highest emission reduction potential but at much higher costs than the other risk management options. RO2 has a higher emission reduction capacity than RO1 but a lower C/E. RO1 has a high C/E coupled with a high emission (risk) reduction capacity.

RO1 and RO2 include a derogation that shall apply for the use and placing on the market of terphenyl, hydrogenated for industrial sites as a HTF, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions. The conditions and requirements that a HTF installation shall comply with to be considered as a strictly controlled closed system are defined in Appendix 5 of the Annexes to this restriction report. Compliance with Appendix 5 should be mandatory for all current and future heat transfer systems using terphenyl, hydrogenated as HTF to comply with the derogation conditions of the HTF use in this restriction.

The Dossier Submitter considered RO1 the most appropriate risk management option because it is effective and minimises the risks within a reasonable period of time.

RAC conclusion(s):

- RAC agrees that a broad EU-wide restriction is the most appropriate measure to reduce the risks of terphenyl, hydrogenated. RAC notes that the potential risks resulting from the use of additional substances containing o-terphenyl have not being assessed by the Dossier Submitter and are not included in the scope of the restriction proposal and that this may need to be assessed in the future.

- RAC supports derogations which would not affect the effectiveness of the proposed restriction but is not in favour of unlimited derogation for the use as HTF at industrial sites which would impair the substitution of SVHCs substances targeted by REACH. RAC is of the opinion that for such vPvB substances as terphenyl, hydrogenated, the time period should be as short as possible to guarantee the smallest possible releases during the derogation.

- RAC supports time limited derogations for the use of HTF in industrial sites, provided that such sites have implemented strictly controlled, closed systems. The implementation of the strictly controlled systems shall be monitored by a representative program to assess the environmental emissions.

  RAC does not support a time limited derogation for the use in aerospace and defence applications. RAC considers the aerospace and defence applications as a wide-dispersive use due to the professional use of various formulations. RAC notes that

there is not enough information on the risks at relevant life cycle stages to ensure minimisation of emissions of terphenyl, hydrogenated from all formulations used in the aerospace and defence sector.

RAC does not support a derogation for electromechanical control of ovens and stoves. RAC considers that the proper treatment of HTF by waste holders is unclear and in the absence of any further information on current practices in the Member States cannot conclude on the environmental release at waste disposal from ovens and stoves. Moreover, RAC notes that the Dossier Submitter's derogation also include electrical capillary thermostats for which no information at all was provided. RAC therefore supports a restriction for the use of terphenyl, hydrogenated in thermostats.

Further evaluation of the use/sector-specific derogations is integrated into the subsequent section of this opinion on the section 3.4.3 'Effectiveness in reducing the identified risks'.

Key elements underpinning the RAC conclusion:

The Dossier Submitter has targeted the restriction proposal to terphenyl, hydrogenated based on the assumption that the constituents of terphenyl, hydrogenated are not present in other substances or exist as substances as such. RAC does not agree with this assumption taking into account that the substance "reaction mass of m-terphenyl and o-terphenyl "(EC 904-797-4) is registered under REACH and o-terphenyl (EC 201-517-6) and terphenyl (EC 247-477-3) are notified under the CLP regulation. RAC notes that the potential risks resulting from the use of these substances containing o-terphenyl have not being assessed by the Dossier Submitter and are not included in the scope of the restriction proposal. This leads to uncertainties regarding the baseline calculations and the effectiveness of the restriction proposal.

Emissions of terphenyl, hydrogenated occur from all uses based on RAC's qualitative assessment detailed in section 3.4.3. Considering the broad use of the substances in many sectors, a broad restriction covering all uses, articles, and mixtures, with carefully selected and justified derogations where emissions are confirmed to be managed using appropriate operational conditions and risk management measures, is RAC's view from a risk perspective an effective measure. A broad restriction would also cover potential future uses. Articles, specifically imported ones, cannot be efficiently targeted by a risk management option under REACH other than a restriction. However, RAC does not agree that all the proposed restricted uses and derogations have been justified by the Dossier Submitter.

The Dossier Submitter proposed to target the restriction of the use of terphenyl, hydrogenated as a plasticiser since they considered that the largest source of terphenyl, hydrogenated emission to the environment in the EU is attributed to the use in adhesives/sealants and the "Service life of articles produced from use as plasticiser". Nevertheless, RAC notes that the uncertainty linked to the estimation of the releases and their sources does not permit to conclude on the relevance of the targeted use and sector.

For RAC to conclude that a proposed derogation would not affect the effectiveness of the proposed restriction, emissions from the use should be either negligible or the operational conditions and risk management measures must have been justified to be appropriate and effective to minimise residual emissions as low as possible. However, the exposure assessment (section 3.1.2) show that releases are not minimised by OCs/ RMMS currently in place for the use of terphenyl, hydrogenated as HTF in industrial installations proposed to be derogated. RAC notes that derogation for this use shall only be granted for the sites complying with minimum OCs/RMMs described in Appendix 5 of the Annexes to the Background Document. Those are expected to minimise the environmental releases. However, RAC is of the opinion that the appropriateness and effectiveness of the technical measures and

operational conditions cannot be confirmed before a representative monitoring program of environmental releases would be conducted at industrial sites. Additionally, as pointed out in response to a comment received in the consultation on the Annex XV report (#3719), derogations without a time limit would hamper the aim to promote a progressive substitution when suitable alternatives become available. Further evaluation of the use/sector-specific derogations is integrated into the subsequent section of this opinion on the section 3.4.3 'effectiveness in reducing the identified risks'.

SEAC conclusion(s):

The restriction targets all uses of terphenyl, hydrogenated and proposes derogations for the use of terphenyl, hydrogenated as an HTF and in applications for the aviation and defence sector.

According to the Dossier Submitter, the aerospace industry is responsible for almost half of the emissions. The aerospace industry has indicated in the consultation on the Annex XV report that the implications of a ban of the substance without having a certified substitute would lead to the closure of EEA-based facilities. The rest of the releases come from other uses. SEAC finds that there is a lack of information on how the industries that manufacture the products for these other uses are going to react, and more important if there are safer alternatives for these applications (as for the moment, no safer alternatives have been presented). SEAC lacks information on the realistic substitution.

The Dossier Submitter has, defined strictly controlled closed system (SCCS) conditions that would lead to the minimisation of emissions and exposure for the use of terphenyl, hydrogenated as HTF in industrial installations. RAC has concluded that if applied, these conditions would minimise emissions. Considering the uses and their related emissions and taking as granted the application of the SCCS conditions in case of derogations RO1 and RO2, SEAC considers that the restriction targeting is appropriate and well justified and that the derogation conditions are well defined.

SEAC concludes that the use of terphenyl, hydrogenated as a HTF should be limited to a temperature range of 250°C- 350 °C, to better align with the intended use of the substance (high temperature heat transfer fluid) for which no non-regrettable substitutes are available.

SEAC also considers that although the targeting is appropriate, other possibilities could also have been chosen, such as targeting the restriction to the substance that is PBT/vPvB (o-terphenyl) or grouping substances with similar function. Given the results of a recent RMOA undertaken by the Finnish authorities, SEAC recommends that further regulatory action should be considered for the two substances identified there as the two foremost alternatives, to lower the risk of regrettable substitution.

Key elements underpinning the SEAC conclusion:

The Dossier Submitter states that terphenyl, hydrogenated is mostly used as HTF (90% of the annual tonnage) but the emissions are mainly due to its use as plasticiser (almost 10% of the annual tonnage, and 85% share of the emissions). Besides, the use of the substance as a HTF, comes with requirements of a closed system, which means that (if adequately controlled) emissions are very low.

When the substance is used as a plasticiser, the substance is incorporated into the article, where emissions are difficult to control, and the correct disposal and waste management at the end of service life is problematic, due to the presence of PBTs. These arguments support targeting the use as plasticizer, as it causes most concern. However, the assumptions underlying those arguments are uncertain, as RAC considers that the exposure assessment is not reliable.

The analysis of alternatives indicates that all the alternatives identified by the Dossier

Submitter would lead to a regrettable, or potentially regrettable substitution, except for the use as solvent and laboratory chemical. These uses are small (less than 1% of tonnage used and less than 5% of the releases).

HTF

HTF is used in a closed system where emissions are almost negligible if they are adequately controlled. Releases due to the use as HTF account for 9% of the total emissions.

For the use of terphenyl, hydrogenated as HTF, the Dossier Submitter launched a questionnaire in 2021 (getting 30 responses out of 250 questionnaires). Responses indicate that most of the respondents (from different industrial sectors) would switch to an alternative in case of a ban on the use of the substance. The responses are not known to SEAC, and SEAC therefore finds the conclusions based on the questionnaire uncertain. Since, as explained in section 3.3, SEAC has concluded based on the comments received in the consultation on the Annex XV report, that there are currently no safer alternatives, this means that users are likely to switch to a commercial alternative resulting in regrettable substitution. However, based on the comments received during the consultation on the Annex XV report SEAC considers that a more plausible scenario, for parts of the industry, in case of full ban would be the closure of production or relocation due to the high costs associated with the retrofit, modification of the installation and downtime of production.

There are some uncertainties regarding the completeness and thoroughness of the analysis of alternatives. There could for example be alternatives for some industrial sectors (like concentrated solar power plants) or for some of the uses of HTF (that do not require so high temperatures). However, the Dossier Submitter has set one single technical criterion (boiling temperature at 342ºC at 1atm for the whole use of the substance as HTF without any consideration on whether this single criterion is applicable to all HTF installations (industrial and non-industrial). In case the alternatives for some applications would be clearly identified and they were safer and technically and economically feasible, the derogation could be modified to exclude these particular applications. The comments submitted in the consultation on the Annex XV report however indicate that an alternative is required to not only fulfil the high temperature criteria but also needs to be thermally stable and thus having a long service life, the latter implies that applications for which suitable alternatives could be available are very rare and they constitute only a very small part of the total of the sites. Strictly controlled conditions for closed systems have been specifically described by the Dossier Submitter. RAC has evaluated these conditions and concluded that they would be effective and appropriate in minimising emissions and that they are monitorable and enforceable.

Comments from the consultation and further input from stakeholders would suggest that the intended use of the substance is in a temperature range of 250˚C- 350 ˚C. The range 250 – 350 degrees is determined based on comments #3676 and #3685, which mark respectively the lowest and highest temperatures that were mentioned in comments as being within the relevant operating range. SEAC proposes to limit the use of the substance to this temperature range to better align with the intended use of the substance (high temperature heat transfer fluid) for which no non-regrettable substitutes are available.

Aerospace & Defence (A&D)

Products used in the aerospace industry are subject to strict safety and performance requirements and any change in the elements or applications used in the production of aircrafts requires extensive testing, validation, (re-)qualification and (re-)certification before these products can be commercially implemented. This is a complex process that takes many years to complete.

Comment # 3655 from two associations (Aerospace and Defence Industries -ASD- and Aerospace Industries Association -AIA-) representing more than three thousand aerospace and defence industries states that the industry will have to cease its activities in the EEA if

terphenyl, hydrogenated is restricted before suitable alternatives are available. This contrasts with information from the Dossier Submitter that one respondent from the aerospace industry indicated that they would switch to an alternative, but is not necessarily in contradiction, as there are many companies producing for different aerospace applications and different alternatives may appear for different applications. In comment # 3655 and #3707 it is emphasized that the industry must fulfil stringent safety requirements and comply with certification and approval through EASA (European Union Aviation Safety Agency), which means that substitution takes time, even after suitable alternatives are found. The challenges in substituting substances in the aerospace in general are explained in a publication of the EASA on the authorisation process (ECHA-EASA, 2014).

Comments # 3655 and # 3707 also question the scope of the derogation, as they find the term "plasticiser" to be unclear. They consider the term 'plasticiser' unclear in scope (it is not clear if some uses like dispersant or carrier would be included in the plasticiser definition), and they also consider that it is necessary to include more than aircrafts; they suggest using the term "aerospace and defence applications". Moreover, these comments provide evidence that a derogation for legacy parts as well and present evidence supporting a derogation of 10 years instead of five, this is further elaborated in section 3.4.7 of this opinion.

Other uses

One final remark: the restriction aims to reduce emissions mainly by targeting the use of the substance as a plasticiser. There is a lack of information on how the different industries reliant on terphenyl, hydrogenated are going to react, and more importantly, if there are safer alternatives for these applications (as for the moment no safer alternatives have been presented). The Dossier Submitter observes that there were no comments related to other uses (that are not HTF uses in industrial installations or uses in the aerospace industry) neither in previous surveys nor in the consultation on the Annex XV report and assumes that this is an indication that there is substitution in place or that the substitution can take place without major consequences. SEAC concurs that this is a likely scenario although there is uncertainty regarding whether the substitution would be regrettable or not.

Based on the provided evidence SEAC considers it plausible that under any of the restriction options proposed, some regrettable substitution would occur. This would be a worst case scenario where similar emissions of equal concerns would occur that would not be controlled..

General

SEAC furthermore notes that the current restriction only targets terphenyl, hydrogenated, whereas in a recent RMOA undertaken by the Finnish authorities the risk of regrettable substitution with substances similar to terphenyl, hydrogenated is considered to be high. The two foremost alternatives (EC-No 258-649-2 and EC-No. 400-370-7) to terphenyl, hydrogenated (CAS 61788-32-7) have been grouped together into a "technical functional group" (Tukes, 2020) due to their use as Heat Transfer Fluid (HTF) and the potential PBT properties of the two alternatives. In this respect SEAC notes that with the current targeting and scope of the proposal which is focused on terphenyl, hydrogenated, there is a risk of regrettable substitution as actors could potentially use one of the substances from this functional group as a substitute. Based on this potential for regrettable substitution, SEAC recommends that further regulatory action should be considered that would address these two substances as well, and with that lower the risk of regrettable substitution by lowering the risk that any of these two alternative substances can be used in uncontrolled environments.

SEAC takes note of the observation of RAC which points out that o-terphenyl (the constituent of terphenyl, hydrogenated that drives the restriction proposal due to its vPvB properties) may be present as constituent of other substances in addition to terphenyl, hydrogenated.

SEAC further takes note of the observation of RAC that this restriction proposal is focused on terphenyl, hydrogenated, because of its content of o-terphenyl. However, RAC points out that a wider restriction proposal focused on o-terphenyl and all other uses of o-terphenyl (in other substances) could have been more effective.

3.4.2. Other regulatory risk management options

Summary of Dossier Submitter's assessment:

The Dossier Submitter considered national regulatory actions not to be adequate to manage the risk of terphenyl, hydrogenated. Union-wide action is proposed by the Dossier Submitter to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States (Annex XV restriction report, section 1.3).

A short description of different Union-wide legislative options that may have the potential to influence emissions of terphenyl, hydrogenated to the environment is presented in Annex E.1.3 to the Annex XV report. These legislative options concern Waste Framework Directive, REACH authorisation, Water Framework Directive, RoHS Directive and Industrial Emissions Directive.

However, the Dossier Submitter concludes that these presented options are not considered to have the potential to minimise the emission of terphenyl, hydrogenated, as they are currently not considered to be feasible, are not considered as an appropriate risk management option, or not effective in reducing the risk.

Concerning other REACH instruments, the analysis of Authorisation as RMO – against the restriction route demonstrates that the Restriction route would be the most appropriate option to deal with the potential risks derived from the manufacture and use of terphenyl, hydrogenated in the EU. In contrast, authorisation would be a disproportionate, less practical, and less effective provision due to the lack of suitable alternatives for the vast majority of the volume used; and therefore, it should not be selected as a RMO for this substance (see section E.1 of the Annex).

RAC conclusion(s):

RAC considers that the data in the Background Document on emissions, despite major uncertainties, and the environmental monitoring data available demonstrate that existing regulatory risk management instruments are not sufficient to address the risk.

RAC concludes that current obligations under the CLP regulation, the Water framework directive, the Industrial Emissions Directive, and the Waste Framework Directive do not directly lead to a reduction of emissions of terphenyl, hydrogenated.

RAC is of the opinion that a REACH authorisation would be less effective to control the risk due to the continuation of emissions considering the time required for the process and the non-inclusion of imported articles.

Key elements underpinning the RAC conclusion(s):

The available data on emissions and exposure as well as data from environmental monitoring show that current regulatory risk management measures applying for part of the uses are not sufficient to minimise the releases, exposures and the risk resulting from the use of terphenyl, hydrogenated.

RAC notes that terphenyl, hydrogenated is currently neither included in Annex VI of the CLP

regulation nor identified as priority substances or priority hazardous substances under EU Water framework directive (WFD). The manufacture and some uses of terphenyl, hydrogenated are covered by the Industrial Emissions Directive (IED) based on best available techniques (BAT) reference documents however, not all uses are included. Under the Waste Framework Directive, suppliers of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA (SCIP notification obligation) to ensure that the information on articles containing SVHC is available throughout the whole lifecycle of products and materials, including at the waste stage. However, these obligations do not directly lead to a reduction of emissions. Pursuing the authorisation regime route would result in the continuation of emissions as long as the applications are under assessment. A large number of applications for authorisation would be expected to be received due to the very high number of the sites using HTF, so this period could be long.

A REACH authorisation would be less effective to control the risk due to the continuation of emissions considering the time required for the process of the inclusion of the substance into the Annex XIV to REACH and the subsequent application process for authorization of the 1300 different industrial sites using HTF. Additionally, an authorization obligation would not cover the import of articles containing terphenyl, hydrogenated, which seems significant based on the SCIP database. A restriction of those uses could only follow based on a restriction proposal by ECHA according to Article 69(2) of REACH once the substance is added to Annex XIV. Therefore, further time would be required, meaning more environmental release of terphenyl, hydrogenated, before the risk from articles is controlled. RAC acknowledges that a REACH authorization would lead to information on environmental emissions at industrial sites however the mandatory monitoring program included in the RAC opinion is proposed to provide a similar level of information.

All these elements underpin the conclusion that a REACH restriction is the most appropriate EU wide measure to address the identified risk from the uses of terphenyl, hydrogenated.

RAC notes, however, that the Dossier Submitter did not propose a restriction and neither assessed the risks for other substances containing o-terphenyl (see section 3.1.1). It is unknown to RAC how effective the proposed restriction is compared to a restriction proposal which would have covered all substances containing o-terphenyl.

SEAC conclusion(s):

SEAC agrees with the Dossier Submitter that there are no other regulatory risk management options other than a restriction that are sufficient and efficient to address the risk. A restriction under REACH is the most appropriate risk management option.

Key elements underpinning the SEAC conclusion(s):

Terphenyl, hydrogenated is a substance that is not included in the CLP regulation as its PBT/vPvB properties are not established within the CLP regulation. The Water Framework Directive does not include the substance as a priority substance or as priority hazardous substance. The Waste Framework Directive prescribes that supplier of articles containing SVHCs on the Candidate List in a concentration above 0.1% w/w must submit information to ECHA (SCIP database) but it does not directly address the reduction of emissions. The Industrial Emissions Directive follows an integrated approach considering the whole environmental performance of the plant and it is based on the application of Best Available Techniques to grant permits for different industries. It covers some of the uses, but it is not sufficient to address the whole risk of the substance.

Pursuing the REACH authorisation route would be less proportionate, effective and practical due to the number of industries across the EU using terphenyl, hydrogenated, the different uses of the substance, its incorporation in articles and the possibility to import articles containing the substance. Authorisation would, however, provide further information on the specific uses and the possibilities to require specific risk management options.

Several other points speak in favour of a restriction as the most appropriate measure:

- Pursuing the authorisation route would result in the continuation of emissions as long as the applications are under assessment. A large number of applications for authorisation would be expected to be received, so this period could be long. Besides, if the authorisation is granted emissions would occur during that period.

- As some of the identified uses concern the use of the substance in articles, REACH Authorisation would not initially be a very effective measure (as articles could continue to be imported) until ECHA prepares a REACH Article 69(2) restriction.

- The Authorisation process would focus on the substances, rather than on the constituents, whereas the risks associated with the use of terphenyl, hydrogenated are caused by the presence of its constituent, o-terphenyl. Pursuing a restriction based on constituents (as is done in the Chloroalkanes and PAH restriction) would allow for more targeted regulatory actions.

- On the other hand, as there are possibilities for regrettable substitution, authorisation would be less effective as a measure than restriction. As highlighted in section 3.4.1, terphenyl, hydrogenated (CAS 61788-32-7) and the two existing proven alternatives (EC-No 258-649-2 and EC-No. 400-370-7) have been grouped together into a "technical functional group" by the Finnish authorities, listing on Annex XIV would lead to a substance-by-substance approach (as only substances and not groups are included in annex XIV) resulting in a high risk of regrettable substitution taking place.

All these elements underpin the conclusion stating that there are no other regulatory risk management options that can sufficiently address the risk.

3.4.3. Effectiveness in reducing the identified risk(s)

Summary of Dossier Submitter's assessment:

In 2018, terphenyl, hydrogenated was identified as a substance meeting the criteria of Article 57(e) as a substance which is vPvB, in accordance with the criteria and provisions set out in Annex XIII to REACH.

Terphenyl, hydrogenated is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**). Quantification of risks is currently not possible for PBT or vPvB substances, which makes quantification of benefits challenging. Moreover, for these substances a full cost-benefit assessment is usually not feasible due to their specific properties. The potential benefits will be linked to the environmental stock and therefore also the reduction in emissions. SEAC is advising the use of emission reductions, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, as a proxy for potential future benefits (ECHA, 2008).

The continued use of terphenyl, hydrogenated is described in the baseline scenario of terphenyl, hydrogenated in Annex D.3. It should be noted that emissions prior to 2025 were not considered. Furthermore, the model assumes that emissions ceases when the use of terphenyl, hydrogenated is banned for a certain use. A significant share of the emissions occurs at the end-of-life stage. Furthermore, if the use as terphenyl, hydrogenated is banned, it has to be taken into account that due to required emptying and disposal of the currently installed base (approximately 25 000 tonnes in approximately 1 500 plants in the EU), there is a significant potential for additional releases that have not been taken into account in this analysis. Therefore, the reduction in emissions compared to the baseline will in reality be

spread over the entire analysis period (2025-2044).

RAC conclusion(s):

- RAC agrees that following from the RAC conclusion on the quantitative emissions assessment, the baseline scenario with/without the restrictions reported in the Background Document (i.e., the basis of the estimated quantitative effectiveness) are not considered to be robust enough to draw any quantitative conclusion.

- Instead, RAC qualitatively evaluated the effectiveness of the proposed restriction from the point of view of the overall objective to minimise the releases and exposures.

- RAC concludes that overall, the proposed restriction is effective in minimising the risks resulting from the use of terphenyl, hydrogenated (see Table 10 below).

Table 10: Use specific conclusions of the qualitative emission assessment of RAC

Sector	Subsector	Alternatives available	RAC conclusion on uses, release, and emission minimisation	Derogation/longer/TP / higher concentration limit supported
Heat Transfer fluid	Industrial sites	Yes, but are suspected to be PBT, (Finnish RMOA)	Main use (90%) of terphenyl, hydrogenated Environmental releases are likely based on available information presenting inconsistency probably due to different level OC/RMMs in the industrial sites using HTF. RAC concludes that the compliance of industrial sites with the OC and RMM requirements described in the Appendix 5 of Annex XV report Annexes is appropriated to reduce the environmental releases and the risk.	RAC supports a derogation for HTF provided that the industrial sites implement, strictly controlled closed systems with technical containment measures, as outlined in Appendix 5 of the Annexes to the Background Document, to prevent environmental emissions. RAC concludes that the sites must also implement a representative monitoring program to confirm the effectiveness of the OC and RMM to reduce environmental releases as much as technically and practically feasible. RAC supports a time-limit derogation to promote the development of safer alternatives. The time-limit shall be as short as possible.
	Thermostats (consumer use)	There is no information available to conclude whether there are suitable alternatives.	Wide-dispersive use (consumer use). Environmental releases are assumed at all life cycle stages and especially during the waste life cycle. No robust information on existing RMMs in the sector. Based on the available information, RAC cannot conclude on environmental emissions for this use.	No

			RAC therefore, supports a restriction for HTF incorporated in articles.	
Plasticiser	All uses including Formulation Industrial and professional uses (including articles production) Incorporation in articles	There is no information available to conclude whether there are suitable alternatives.	Wide-dispersive use (industrial and professional use) with environmental release assumed at all life cycle stages and especially during the waste life cycle of articles. SPERCs described for the formulation, industrial and professional uses of adhesives /sealants (FEICA/EFCC) and coatings/inks (CEPE) confirm the releases to water, air, soil and solid waste considering specific OCs and RMMs applied in the sector. RAC considers that environmental emissions would be inevitable due to the limited potential for containment of releases at the waste/recycling life-cycle stage. RAC therefore, supports a restriction for plasticiser uses.	No
	Aerospace and Defence applications	Three alternatives for the use as additive in adhesive and sealants: dibenzoates, phthalates and chlorinated paraffins. Nevertheless, regarding the hazard properties of these alternatives, RAC cannot exclude regrettable substitutions.	RAC assumes a wide-dispersive use due to professional uses and in the absence of further information. Environmental releases are assumed at all life cycle stages (except for the polysulfide sealant formulations containing also octylphenol ethoxylate which are subject to REACH Authorisation) and especially during service life cycle of the articles containing terphenyl, hydrogenated at concentration ≥ 0.1% w/w.	No

			No robust information on existing OC/RMMs in the sector (except for the polysulfide sealant formulations containing also octylphenol ethoxylate which are subject to REACH Authorisation). RAC therefore, supports a restriction for aerospace and defence applications.	
Solvent/process medium	Industrial use		RAC cannot conclude if it is a local or wide-dispersive use based on the available information. Environmental releases are assumed by default and specific release factors. No information to conclude on the application of the SpERC conditions of use for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions RAC therefore, supports a restriction for solvent/process medium.	No
Laboratory chemical	Professional uses		RAC assumes a wide-dispersive use due to the use by professionals and in the absence of further information. Environmental releases are assumed by default release factors and information provided by the users. No information to conclude on the application of the SpERC conditions of use for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions	No

			RAC therefore, supports a restriction for the use as laboratory chemical by professionals.	

Key elements underpinning the RAC conclusion(s):

The quantitative assessment of the effectiveness of the proposed restriction reported by the Dossier Submitter cannot be considered to be robust based on the RAC conclusion on the emissions assessments detailed in section 3.1.3. Therefore, RAC qualitatively evaluated the effectiveness of the proposed restriction from the point of view of the overall objective to minimise the releases and exposures.

Qualitative assessment

- HTF industrial use

In the background document, the use of terphenyl, hydrogenated as HTF in industrial sites is reported to represent approximately 90% of the total imported tonnage in the EU (appr. 6700 t/y in 2020). According to the data obtained from the stakeholders, the total number of closed loop manufacturing systems using terphenyl, hydrogenated, is estimated by the Dossier Submitter to be close to 1300 systems installed in 24 EU Member States.

Sectors using terphenyl, hydrogenated as HTF representing an installed base volume in EU of 25 000 t, are Chemicals, specialities and petrochemicals (48%), Renewable energy (Organic Ranking Cycle, Concentrated Solar Power) (22%) Polymers and plastics (20%), oil and gas processing (5%), Process equipment heating (5%) (Table 4 of the background document).

During the consultation on the Annex XV report and in the Background Document, use of terphenyl, hydrogenated as an HTF is described as being constantly contained within a closed loop system with limited discharges. However, exposure to the environment cannot be disregarded as demonstrated in Annex B.9. (Exposure Assessment). During operation, special attention needs to be paid to the interfaces of the closed system to the atmosphere, such as closed draining, separation points (joints, mechanical seals, flanges, valves, etc.) and rotary transmission equipment (pumps, etc.).

Potential emissions to the environment are prevented by the implementation of stringent containment measures and controls during the design stage of the closed system. Other exposure and emission sources of terphenyl, hydrogenated when used as HTF are related to transport, loading and refilling operations, replacement or topping-up of the HTF, industrial cleaning operations, and disposal of the HTF. The Dossier Submitter considers that 5% of the imported tonnage were used for top-up and refill. A respondent to consultation on the Annex XV report indicated that 3% of the total quantity used is dedicated to top-up and refill (#3679). Approximately 35% of that volume (2 275 tonnes) was used for complete replacements in existing plants, at the end of the HTF service life. The service life is considered to be 20 years. 60% (approximately 3 900 tonnes) account for filling new installed plants in the EU.

To estimate the emission, RAC notes that in Table 26 of Annex B.9.3.3., the Dossier Submitter reports measurements from 13 sites, although no specific information about the heat transfer systems has been received from Site S-09 (basic chemicals producer). The remaining 12 sites include 17 heat transfer systems installed with a total volume of 2 356 tonnes (2 336 m3) of terphenyl, hydrogenated. RAC noticed that this represents 1% of the sites and 9.8% of the volume of terphenyl, hydrogenated installed (according to the data included in Table 6 of Annex A.2.) and considers this percentage not high enough to be representative.

The Dossier Submitter proposes a derogation, provided that sites using HTF, implement strictly controlled closed systems with technical containment and organisational measures to prevent environmental emissions. Appendix 5 in the Annex to the Background Document describes how to reach strictly controlled closed systems conditions in heat transfer systems using terphenyl, hydrogenated as HTF. This appendix intends to be a guidance based on existing EU legislation or guidance documents and cover all expected conditions of use in industrial installations using HTF. RAC is of the opinion that overall, the OCs and RMMs

described in the Appendix 5 are adequate to minimise the risk resulting from environmental releases of terphenyl, hydrogenated.
However, RAC notes that the proposed OC/RMMs are only optional and cannot be assessed for each HTF user. Therefore, RAC considers that the only way to ensure the effectiveness of the strictly controlled conditions described by the DS is to implement a representative monitoring program covering the different conditions of use of the HTF system. Provision of the representative monitoring results to the enforcement authorities would allow for better evaluation of the situation at the industrial sites and would confirm further or not the appropriateness and effectiveness of OCs and RMMs in place.

- Non HTF industrial/professional use

The Dossier Submitter assumes that the non-HTF uses represent approximately 10% of the total EU imported volume (appr. 771 t/y) based on stakeholders' consultation. RAC notes that it is not specified if HTF use relates only to industrial and professional uses or if it also includes HTF mixtures incorporated in articles. The split of volumes per use based on information provided by stakeholders is presented in Table 2 of the Background Document. Plasticiser uses in sealants, adhesives, castings, and coating make up for ca. 95% of the non-HTF uses, while the remaining ca. 5% are used as processing solvents, 0.5% as part of corrosion inhibitor oils and 0.2% as laboratory chemicals (i.e., analytical standards and microscope immersion oils).

In December 2022, the SCIP Database had a total number of almost 25 000 database entries[13] and the received stakeholder information indicates that some of the registrants are importing mixtures from non-EU countries into the EU. An internet search by the Dossier submitter led to the finding of 66 Safety Data Sheets (SDSs) in EU and USA format for non-HTF products, mainly plasticiser formulations. The concentration levels of terphenyl, hydrogenated within these mixtures are ranging from < 1% to up to 60%.

- HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats (consumer use)

The use of terphenyl, hydrogenated in these cases is as HTF in the electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats. Widespread release is assumed due to the consumer use of these articles. RAC notes that there is currently no information on sector specific RMMs and OCs or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from this use during article production and service life. RAC assumes no relevant release of terphenyl, hydrogenated during service life of the ovens/stoves since HTF is contained in a closed vessel however spills from thermostats and accidental releases cannot be disregarded without further information.

At the end of life, RAC acknowledges that household ovens and hydrocarbons are in the scope of the WEEE Directive (2012/19/EU) which requires the Member States to ensure proper treatment i.e., removal of all fluids and a selective treatment in accordance with Annex VII. For HTF use in ovens, waste holders are required to treat the fluid as hazardous waste based on its classification. If no harmonised classification is available, the waste holder should employ its best efforts to assign a classification, based on the published self-classifications in the C&L inventory and taking particular notice of the classification transmitted via the SDS of the operator generating the waste. RAC notes that there is no harmonised classification for terphenyl, hydrogenated and various self-classification for aquatic chronic 4 (569 notifiers), aquatic chronic 2 (48 notifiers), aquatic acute 1/chronic 1 (4 notifiers) and aquatic chronic 1 (1 notifier) and not classified (15 notifiers) are available. Therefore, RAC considers that the proper treatment of HTF by waste holders is unclear and in the absence of any further

[13] This number corresponds to the number of entries disseminated on ECHA website (SCIP dissemination portal) and includes double counting as it includes entries based on "referencing".

information on current practices in the Member States cannot conclude on the environmental release at waste disposal from ovens and stoves. Moreover, RAC notes that the Dossier Submitter's derogation also include electrical capillary thermostats for which no information at all was provided. RAC therefore supports a restriction for the use of terphenyl, hydrogenated in thermostats.

- Plasticiser

RAC notes that limited information regarding the use of terphenyl, hydrogenated as a plasticiser is provided by the Dossier Submitter. In the Background Document, the use of the substance as a plasticiser is described as the second most relevant use, involving around 10% of the imported tonnage range (730 T/y). Terphenyl, hydrogenated is used as a plasticiser mainly for the formulation of sealants/adhesives, coatings/ paints/ inks, construction products as well as additives in plastics and polymer preparations which are incorporated in articles used in a wide variety of sectors. Among those categories, adhesives/sealants is the main mixture category incorporated in articles notified to the SCIP database followed by inks, polymer and paints/coatings. The main category of articles incorporating those mixtures is "Vehicles, aircraft, vessels and associated transport equipment" followed by "Electrical machinery and equipment and components thereof", "Products of the chemical or allied industries" and "Machinery and mechanical appliances".

The Dossier Submitter assumes that articles notified to the SCIP database are small and components of very complex products such as vehicles (e.g., cars, trains, planes), electrical and electronic equipment (e.g., for the protection of joints of buried high voltage cables), construction and building components, or furnishings. Downstream sectors (Gifas and the Aerospace Industries Association) confirmed the use of the substance in their sector in sealants in the Draft background document for terphenyl, hydrogenated (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020) and the Annex XV public consultation (see the Aerospace and Defence comment #3655). One individual company commented on its use of terphenyl, hydrogenated as ingredient in formulation of a bitumen-based polyurethane used for expansion joints in concrete constructions and filling compound for underground high voltage joints up to 550 kV (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020).

The use of terphenyl, hydrogenated as plasticiser is wide-dispersive and its supply chain can be characterised by the following actors: formulators, users at industrial sites (including articles producers), professional workers and users of articles. No precise and up-to-date information is available on the total number of industrial sites where the substance is currently used. However, this number was expected to be well above 100 in the Draft background document for terphenyl, hydrogenated (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020). Consumer uses (as additive in sealant and adhesive applications, in plastic applications and in coatings, paints and inks) were previously reported in registrations dossiers but are not supported anymore in the current active registrations (ECHA, 2019).

Environmental releases of terphenyl, hydrogenated are assumed to occur during all life-cycle stages of the use of the substance as a plasticizer (ECHA, Draft background document for terphenyl, hydrogenated, Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV, 2020). Similar default release factors in water, wastewater and soil, are assumed by the Dossier submitter for the formulation (ERC 2), industrial uses (ERC 5), professional uses (ERC 8f) and articles service-life (ERC 10a) of sealants/adhesives and coatings/inks. Specific Environmental Release Categories (SPERCs), described in the Background document for the formulation, industrial and professional uses of adhesives /sealants (FEICA/EFCC) and coatings/inks (CEPE) confirm the releases to water, air, soil and solid waste considering specific operational conditions and

RMMs applied in the sector (even if they are generally reduced compared to the default release factors).

RAC notes that there is currently no information on sector specific RMMS and OCs or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from plasticizer uses including from articles during waste life cycle. RAC is aware that the waste stage is the source of highest emissions of all the life-cycle-stages of produced articles based on the previous restriction cases on PBT/vPvB substances (e.g. Dechlorane Plus).

Described articles are complex products which are composed of multiple components for which separation and properly management of terphenyl, hydrogenated containing parts in the waste phase seems unrealistic. In addition, high recycling rates required for different waste streams (e.g., end-of-life vehicles, waste EEE recycling) in the EU and as well the Circular Economy prohibit large-scale incineration. RAC therefore supports a restriction for plasticiser uses.

- Plasticiser use in Aerospace and Defence applications

Terphenyl, hydrogenated is used in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations. During the consultation of the Annex XV report, a comment on these applications was received (comment # 3655) from the Aerospace and Defence industries association of Europe (ASD) and the Aerospace Industries Association (AIA).

ASD and AIA explained that their members still rely on the use of terphenyl, hydrogenated in formulations used in the EEA for both production and repair of aerospace and defence (A&D) products. ASD and AIA members also import articles containing terphenyl, hydrogenated (≥0,1%) into the EEA. The following (non-exhaustive) A&D uses of terphenyl, hydrogenated in sealants/adhesives are described where, terphenyl, hydrogenated is used to manufacture, repair and maintain A&D products:

• as encapsulants
• around rivets/fasteners
• in jet engine compressors
• for smoothing/levelling
• to seal fuel tanks
• to seal pressurised aircraft cabins, military aircraft cockpits
• for electrical and thermal potting
• in repair schemes for aircraft that are expected to be in service for decades
• in specific confidential uses in defence and security programs and uses for the manufacture and repair of other safety-critical parts.

Terphenyl, hydrogenated is present as a constituent of sealant/adhesive formulations used by the A&D sector in concentrations up to 50% in one half of a two-part component system. It remains in the finished articles, within the cured sealants/adhesives. Uses of terphenyl, hydrogenated are also required in some finish paints/topcoats used by the A&D sector. Industrial and professional users of formulations containing terphenyl, hydrogenated are trained workers following the information on the SDS and local laws. The affected sealant/adhesive formulations are not water-miscible and as such no release of hardener or sealant to wastewater from the facility during sealant mixing, and related cleaning and maintenance activities are expected.

RAC notes that some of these formulations, i.e. polysulfide sealants, are subject to current

REACH Authorisation (application number 0203_02[14]) where they also contain(ed) Octylphenol ethoxylate (OPE). As demonstrated in the dossier for the formulation of the polysulfide sealants, there is no release to air due to the volatility of OPE, no release to water due to the absence of water use nor liquid waste generated, no direct or indirect release to soil and all wastes are discarded as hazardous waste i.e., collected and disposed via licensed waste contractors. RAC considers the RMMs and OCs for the formulation of polysulfide sealants also effective to control the release of terphenyl, hydrogenated in the environment. However, it is worth to note that they will only apply until OPE will be substituted (the review period is 24/12/2024) and they do not cover the application of the sealants and the service-life of articles incorporating such formulations. In the REACH authorisation, the release of OPE during maintenance (service life) is assumed to be controlled by the collection and disposal as hazardous waste of the removed sealant and RAC is of the opinion that it is also applicable to terphenyl, hydrogenated release. On the other hand, during service life, release by migration into water is assumed for OPE but it is expected to be low due to its interaction with the cross-linked matrix and its encapsulation in the article. RAC considers that it is unknown whether these assumptions are also applicable to terphenyl, hydrogenated and notes that finish paints/topcoats formulations also used by the aerospace and defence sector will be more exposed to raining water and leaching. RAC also notes that it is more volatile than OPE and its concentration in articles is higher (i.e. > 0.1% w/w when OPE concentration is < 0.1 % w/w) which could potentially led to increased environmental releases. As already noted, the waste disposal of the articles is expected to be the major source of releases for these uses. However, RAC notes that the authorisation specifies, that at end of life all A&D products must, as part of aviation requirement to avoid being used as suspect unapproved parts, be destroyed to avoid reuse as counterfeit parts. At the end of life, parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to EU and national requirements. RAC is of the opinion that these rules are applicable for the entire aerospace and defence sector and therefore no release is expected from waste at the end of life.

Overall, RAC considers the aerospace and defence applications as a wide-dispersive use due to the professional use of various formulations. RAC notes that even if the volume of the substance related to aerospace and defence applications is not known with precision, it represents <10% of the imported tonnage range estimated at approximately 730 T/y. However, there is not enough information to ensure minimisation of emissions of terphenyl, hydrogenated from all formulations used in the aerospace and defence sector. RAC concludes that a general derogation for the use of terphenyl, hydrogenated in aerospace and defence applications cannot be supported.

- Solvent/process medium

This use is reported in the Background Document at industrial sites, but no information is available on the number of sites in the EU to conclude on a local or wide dispersive use.

In the Background Document, default release factors (ERC 4) and Specific Environmental Release Categories (ESVOC SpERC 4.1.z.v2) assume releases in air, wastewater, soil, and solid waste even if the conditions of uses considered in the SpERCs allow to reduce significantly some emissions (by a factor of 100 000 for air and wastewater and a factor of 500 for soil).

RAC notes that there is currently no information to conclude on the application of the conditions of use assumed in the SpERC for this specific use sector or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from this

[14] See also: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/52405/del/200/col/synonymDynamicField_1512/type/asc/pre/2/view.

use. RAC therefore supports a restriction for solvent/process medium use.

- Laboratory chemical

This use is reported in the Background Document at industrial and professional sites. Use for laboratory analysis of HTF samples are related to the use as HTF at industrial sites and its qualitative assessment is included in the generic scenario for this use.

Terphenyl, hydrogenated is also used as laboratory chemical (e.g., as microscope immersion oils) by professionals. Wide-dispersive use is assumed due to the use by professionals in the absence of information on the number of users.

In the Background Document, default release factors at industrial sites (ERC 6b) assume releases in air, wastewater and soil and releases only in air and wastewater at professional sites (ERC 9b). The LR SEA questionnaire (2018) indicates that no release to wastewater occurs at industrial sites, but it confirms that release occurs in air and soil.

RAC notes that there is currently no information on RMMs and OCs for the use of laboratory chemicals by professionals or EU level regulatory measures in place to ensure minimisation of emissions of terphenyl, hydrogenated from laboratory chemical uses. RAC therefore supports a restriction for laboratory chemical uses. However, RAC supports a derogation for the laboratory analysis of HTF samples if the restriction includes strict controlled conditions to minimise environmental emissions at industrial and professional sites using HTF.

3.4.4. Socioeconomic analysis

3.4.4.1. Costs

Summary of Dossier Submitter's assessment:

Economic impacts concern costs or cost savings comparing the "proposed restriction" scenario with the "baseline" scenario.

The costs of the three ROs (RO1, RO2 and RO3) are estimated based on the behavioural assumptions set out in Annex E.3. and the responses received from the different stakeholder consultations, plus information obtained via literature searches. Due to the assumptions made and the uncertainty related to them, the investment costs have not been presented as equivalent annual costs (EAC[15]), using a discount rate.

The estimated total costs for RO3 (most stringent RO) are in the range of € 13.3 billion consisting of substitution costs, investment costs, profit losses as well as enforcement costs[16]. Around 93% of these costs are allocated to the use as HTF, followed by about 6.4% by the plasticiser use in aviation. The costs on the non-aviation plasticiser uses and the remaining uses (e.g., solvents) are contributing insignificantly with below 0.5%. Table 25 of the Annex to this restriction provides a summary of the costs.

The difference between RO3 and RO2 is, that there is a derogation proposed for all HTF uses. Consequently, the costs for all non-HTF uses remain the same, since these applications will be prohibited as of 18 months after entry into force. Most of the costs of the HTF use assessed in RO3 are not considered, except for enforcement costs and costs related to structural and

[15] EAC is a process whereby non-recurrent (e.g., capital, plant down-time) costs of a measure are equalised over its lifetime using the relevant discount rate.

[16] The exact procedure and all details on costs and economic impacts considered for all RO's are described and explained in Annex E.5.

organisational (e.g., training) improvements of the plants, as needed. The derogation will apply, provided that such sites implement strictly controlled closed systems with technical containment measures to minimise environmental emissions.

In comparison to RO3, the total costs of RO2 consisting of substitution costs, investment costs, profit losses as well as enforcement costs are reduced significantly to an amount of about € **919 million**. The cost contribution of HTF uses is about 4.5% and the majority of the costs is carried by the Aviation plasticiser use (>90%). The remaining uses carry about 3% of the costs.

Regarding RO1 (the least stringent option), the costs consisting of substitution costs, investment costs, profit losses as well as enforcement costs for the HTF use and the "Non-Aviation Plasticiser" and "Other Uses" remain the same as compared to RO2. Because in this RO a 5-year derogation (2025-2029) is considered for the aviation plasticiser use the loss in sales of terphenyl, hydrogenated from terphenyl, hydrogenated manufacturers and importers to formulators of sealants and adhesives will be reduced to 15 years. The profit loss by the importers and manufacturers of terphenyl, hydrogenated in the aviation industry accounts for € **12.9 million** (430 tonnes per year x € 8 000 € x 15 x 0.25). A Similar reduction in of loss of profits applies to the aviation industry due to a shortened restriction timeline.

A profit loss of € 615 million was taken into account (€ 41 million per year x 15 years) for the aviation supply chain. The Dossier Submitter believes that this is a worst-case consideration and potentially an overestimation, because the 5 years derogation (after EIF) should have provided most actors in this industry sufficient time to substitute the use of terphenyl, hydrogenated as plasticiser in the aviation sector. Terphenyl, hydrogenated was included in the Candidate List in June 2018[17], thus providing more than 10 years of time for reformulation and re-certification (Supplemental Type Certificates).

Summary of derogations proposed in the Annex XV report.

All considered ROs, defined in Annex E.1.1, restrict the, use and placing on the market of terphenyl, hydrogenated as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months. Whilst the strictest RO (RO3) does not include any derogations, RO1 and RO2 include derogations of varying scope and length for uses as HTF and as plasticiser in the production of aircrafts.

A summary of the considered derogations is provided in the background Document which is presented below in 9.

Table 11: Restriction options and scope and length of derogations

	RO1	**RO2**	**RO3**
A restriction on the, use and placing on the market as a substance, in mixtures or in articles in concentrations of ≥ 0.1% w/w from EiF + 18 months.			
Derogation for the use and placing on the market for industrial sites as HTF.	Implementation of strictly controlled closed systems with technical containment measures to minimise environmental emissions.	Implementation of strictly controlled closed systems with technical containment measures to minimise environmental emissions.	None

[17] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

Derogation for the use and placing on the market in plasticisers use for the production of aircrafts and their spare parts.	EiF + 5 years	None	None
Derogation for the use of HTF in thermostats of ovens and stoves			

SEAC conclusion(s):

SEAC finds that there are large uncertainties in the cost estimations provided in the Background Document.

SEAC finds that the behavioural assumptions used by the Dossier Submitter are not sufficiently justified; these assumptions define which costs are relevant and which costs are therefore important for the cost estimations.

SEAC questions the behavioural assumptions for the Aerospace and Defence (A&D) sector as there was information from the consultation on the Annex XV report from two industry associations which indicate that a larger fraction of companies would cease their activity than estimated by the Dossier Submitter. Based on the evidence provided, SEAC finds that this implies that the possibilities for substitution before EiF or EiF+5 years are significantly lower than assumed by the Dossier Submitter. On that basis, SEAC finds that for the A&D sector the costs presented in the Background Document, related to a full ban (RO 2 and 3) or a derogation for 5 years after EiF (RO 1), are likely to be significantly underestimated. Both the behavioural assumptions (discussed further below) and information from the consultation on the Annex XV report from two industry associations, referring to an Application for Authorisation for OPE in the Aerospace and Defence sector, justify SEAC's view.

SEAC also questions the behavioural assumptions for the HTF use, as there is new information in the consultation on the Annex XV report, indicating that substitution implies costs, and that the costs could be a financial constraint for parts of the industry, which could imply that the possibilities for substitution are lower than assumed by the Dossier Submitter. If substitution would take place, it is likely to be regrettable. On that basis, SEAC finds that the costs presented in the Background Document, related to a full ban on the HTF use (RO 3) are likely underestimated, justified by the behavioural assumptions mentioned above.

SEAC finds that the (implied) costs estimated for implementing the strictly controlled closed system (SCCS) for the HTF use are justified, and that the costs are not substantial, as it is likely that only minor changes in installations and training of personnel is needed.

SEAC notes that the Background Document did not contain information on the socio-economic impacts related to a derogation for the use of terphenyl, hydrogenated in thermostats in ovens and stoves.

SEAC finds that the costs estimated for the other sectors, use as plasticiser and other uses are low, but uncertain, as the justification is scarce.

Key elements underpinning the SEAC conclusion(s):

HTF

SEAC finds that the Dossier Submitter has underestimated the total costs for the HTF use in RO3. According to the comments from the stakeholder consultation of the Annex XV restriction

report, several respondents are claiming that they will cease or relocate activities and a large fraction of the comments state that there is a risk for regrettable substitution.

SEAC therefore finds it likely that the behavioural responses to RO3 would be either ceasing or relocating activities or substituting with substances of an equal level of concern, which could lead to regrettable substitution. This implies that the total costs as assessed by the Dossier Submitter could be underestimated, as it is likely that the degree of substitution will be lower than assumed and that the degree of ceasing or relocating will be higher.

Finally, both the Dossier Submitter and several comments from the consultation on the Annex XV dossier, provide information regarding wider economic interests related to the use of terphenyl, hydrogenated in certain key renewable energy technologies. A total ban could therefore undermine the EU green Deal activities related to clean energy and climate change. The wider economic impacts have not been quantified. But there are reasons to assume that they are substantial.

SEAC finds that the costs in RO 1 and 2, related to fulfilling the requirements for the strictly controlled closed systems are justified by information from stakeholders. The relevant costs are linked to improvements of plants, organizing of procedures, training, and inspections. Therefore, the costs for monitoring as RAC recommends are included in these costs. The Dossier Submitter estimated these costs to be € 20 000 per site and with 1 500 sites it will amount to € 30 million. The Dossier Submitter indicates that these costs could be overestimated, as several plants already currently would comply with the SCCS and perform monitoring.

Aerospace and Defence

Comments to the stakeholder consultation from two industry association (ASD and AIA # 3655 and # 3707) provide evidence that a five-year transition period, as proposed by the Dossier Submitter, is not sufficient to substitute to less hazardous chemicals. The major reason is that the sector needs the possibility to operate under harsh conditions, which means that sealants, adhesives etc need to fulfil specific quality requirements. The other major reason is that materials and processes need to meet stringent safety requirements that are subject to independent certification and approval through EASA (European Union Aviation Safety Agency). Every application must be individually assessed to determine that requirements are met, and details are provided regarding what these approvals involve. SEAC notes that this is consistent with information from applications for authorisation in the aerospace sector already assessed by the Committee.

The consequence of the strict requirements and need for certification and approval is that it is likely that there will be no substitution if a suitable alternative is not available nor certified.

To reach its conclusions regarding the time that would be needed for substitution in the A&D sector (and therefore, to avoid the consequences of a ban), SEAC has scrutinised the following information:

1. The document: "An elaboration of key aspects of the authorisation process in the context of aviation industry" (ECHA 2014)[18]
2. AfA 203 The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part sealants
3. Comment #3655 (Aerospace and Defence Industries Association of Europe, Aerospace Industries Association)
4. Comment #3707 ((Aerospace and Defence Industries Association of Europe,

[18] See: https://www.easa.europa.eu/en/document-library/general-publications/echa-easa-elaboration-key-aspects-authorisation-process

Aerospace Industries Association)
5. The document: Aerospace & Defence Qualification Process Impacts on Ability to Substitute Cr(VI) Substances paper (Global Chromates Consortium for Aerospace)[19]
6. Other relevant AfAs related to the A&D sector, IDs: 0096,0098,0099,0116,0117
7. The document: "Setting the Review Period when RAC and SEAC give opinions on an Application for Authorization" (ECHA,2013)

SEAC notes the following elements that impact on the time needed for substitution (the numbers noted refer to source of the information in the documents above):

- The supply chain for the A&D industry is a long and complex one, starting from the formulator (the one concerned in this case) it goes downstream:

  formulator -> processor -> component manufacturer -> OEM -> MRO shop -> customer [1,2]

- The inherent characteristics of this sector require that all materials and processes have to meet demanding and stringent safety requirements (comply with airworthiness regulations). This means that the alternatives have to go through the following process:

  development of alternatives -> qualification -> validation -> certification -> industrialization [1,2,3,4,5]

- Long lifecycle of aircraft products exceeding decades (from production to end of life it can take more than 50 years).[1]

- Very high costs in the non-use scenario in the range of billions of euros and significant impacts to society as indicated in [2,4,6]

- The large number of uses and products where the alternatives have to be implemented [3,4].

- The implementation of an alternative does not mean to find another substance and to use it in place of terphenyl, hydrogenated, it consists of developing new formulations. Many different formulations have to be developed for different products, parts and OEMs.[3,4]

- The long supply chain implies testing in several phases, testing all the new formulations in parallel is challenging because of the available resources of formulators [4]

- There is some substitution in place, and the A&D sector is working on finding new formulations and the use of terphenyl, hydrogenated is expected to be decreasing in the coming years.[3,4]

- In previous related cases, like Applications for Authorization for chromates substances the applicants asked for 12 years and SEAC recommended (and the Commission granted) 7 years. These applications are focused on very specific uses and products with much limited scope than the current uses and applications where terphenyl,

[19]See:
https://ramboll.com/-/media/files/reh/GCCAAerospaceDefenceQualificationProcessImpactsonAbilitytoSubstituteCrVISubstanceswhitepaper

hydrogenated is used.[6]

- The criteria and considerations that lead for a long review period in Applications for Authorization[7]

Based on the evidence described above, SEAC finds it justified that it would take more than 5 years to fully substitute, and that it is likely that these activities will cease if suitable alternatives are not available, which means that it is likely that the activity will cease under all the proposed restriction options.

As mentioned above, these submitted comments indicate that the profits at risk for the A&D sector are significantly underestimated. SEAC notes, however, that these estimates are based on qualitative arguments, not any estimates per se.

The comments provide information that the profits at risk affect not only the aerospace and defence companies but extend to the entire supply chain and third-party facilities (maintenance, repair, and overhaul). SEAC considers that it is likely that cease in delivery of A&D products and spare parts to the EEA will lead to an inability to service and repair existing A&D products, aircrafts could be grounded, and defence fleets immobilised. According to the information received in the comments, because of this, airplanes will lose their airworthiness certification and will need to be grounded if no suitable alternative is found to replace terphenyl, hydrogenated on time.

The assumptions regarding behavioural responses will affect the cost estimations, as they define which costs to include. SEAC finds it reasonable to take the qualitative assessment provided by ASD/AIA as reliable. SEAC recognises that the Dossier Submitter has not updated the cost estimates or qualitative assessment of costs for the aviation sector. The order of magnitude of costs can be corroborated with information from one application for Authorisation on 4-tert-OPnEO, as referred to in comment #3655 and # 3707. The comments refer to an application concerning the use of 4 in sealants the aviation industry. 4-tert-OPnEOhas a similar use as terphenyl, hydrogenated in sealants. ASD/AIA states that the cost estimate done in this application can be used to give a better understanding of the costs, although the use and extent is not perfectly similar. Members of Ethoxylates in Aerospace Authorisation consortium estimated the cost to be € 5940 –25 940 million (annualized). The comment states that for terphenyl, hydrogenated, the monetized impact is likely significantly higher, as A&D relies on many other sealants/adhesives containing terphenyl, hydrogenated that do not also contain 4-tert-OPnEO.

SEAC finds that the cost estimate from the application is significantly higher than the Dossier Submitter’s estimate. SEAC also finds that the estimate from the application is only for the members of EEAC and thus should be multiplied by an unknown number to represent the whole sector. SEAC does not know this consortium's share of the total market, but as SEAC knows that it does not represent the whole market, it is likely that the costs estimated in the AfA is an underestimation of the costs for the A&D sector. SEAC finds that the costs for all the restriction options proposed by the Dossier Submitter could be underestimated. The reasoning is that the profit loss is likely underestimated. The further costs associated with grounding of planes and ceasing of activity are not estimated at all. These costs could be substantial as they include costs related to ceasing of activity in the supply chains for maintenance, repair, and overhaul.

Ovens and Stoves

The background Document did not contain information on any costs and benefits related to a derogation for the use of terphenyl, hydrogenated in thermostats for ovens and stoves. No comments were received asking for a derogation for this use in the consultation on the Annex XV report.

Other sectors and all uses

The Dossier Submitter states that for the non-aviation plasticisers and the other uses, there was no information from the stakeholders. The Dossier Submitter has thus assumed the same cost range as for the aviation industry, excluding the aviation industry's re-approval costs. SEAC acknowledges that only one comment has been received during the consultation regarding the use as plasticiser and no comments related to the use as solvent/process medium, use as a laboratory chemical or miscellaneous use. SEAC also acknowledges that there are no comments from previous surveys (conducted by different actors like ECHA or the Dossier Submitter). SEAC finds that the estimation is uncertain, as it is based on scarce information, but the limited information available indicates that the costs are negligible for the users.

3.4.4.2. Benefits

Summary of Dossier Submitter's assessment:

In 2018 terphenyl, hydrogenated was identified as a substance meeting the criteria of Article 57(e) as a substance which is vPvB, in accordance with the criteria and provisions set out in Annex XIII of REACH.

Terphenyl, hydrogenated is chemically stable in various environmental compartments with minimal or no abiotic degradation (see **Annex B.4.1**) and is very bioaccumulative, which means that the concentrations in the environment may increase over time (see **Annex B.4.3**). Quantification of risks is currently not possible for PBT or vPvB substances, which makes quantification of benefits challenging. Moreover, for these substances a full cost-benefit assessment is usually not feasible due to their specific properties. The potential benefits will be linked to the environmental stock and therefore also reduction in emissions. SEAC is advising the use of emission reductions, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, as a proxy for potential future benefits (ECHA, 2008). (Also described under section 3.4.3 – summary of Dossier submitter's assessment)

SEAC conclusion(s):

In SEAC's view, the approach taken by the Dossier Submitter is in general a reasonable way to assess the benefits of the proposed restriction. In 2018, terphenyl, hydrogenated was identified as a substance meeting the criteria of Article 57(e) as a substance which is vPvB, in accordance with the criteria and provisions set out in Annex XIII of REACH. Terphenyl, hydrogenated is chemically stable in various environmental compartments with minimal or no abiotic degradation and is very bio accumulative, which means that the concentrations in the environment may increase over time.

The Dossier Submitter refers to the ECHA Guidance for PBT/vPvB assessment (ECHA, 2017), which states: "Experience with PBT/vPvB substances has shown that they can give rise to specific concerns that may arise due to their potential to accumulate in parts of the environment and

- that the effects of such accumulation are unpredictable in the long-term.
- such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in substance concentration".

The current level of understanding of effects in the environment and on human health is limited. No safe level of exposure can be established. Furthermore, once in the environment, the substances are almost impossible to remove, i.e. any respective contamination is irreversible. Therefore, prevention of emissions is, in SEAC's view, a reasonable approach,

because it is the only viable option to reduce or stop the increase of terphenyl, hydrogenated in the environment.

However, even though the approach is considered appropriate in general, SEAC notes that RAC concludes that the methodologies used to assess environmental releases of terphenyl, hydrogenated are not robust enough to draw quantitative conclusions on emissions and emission reduction, due to insufficient justification provided, various inconsistencies in reporting between different sections of the Background Document and significant data gaps for some use scenarios.

Based on a qualitative evaluation of the available information (section 3.4.3), RAC concludes that releases to the environment from all uses within the scope of the proposed restriction are expected (i.e., current information specifying operational conditions and risk management measures cannot guarantee that releases are controlled under the conditions of use.)

In conclusion, SEAC considers that even though benefits are to be expected due to a restriction, these cannot be expressed via a standard quantified risk assessment as quantification of risks is not possible for these substances. SEAC therefore follows a qualitative approach similar to the approach used in the PFHxA restriction. SEAC considers that the uncertainties in the emission reduction estimates do not allow to use them as a proxy for risk as has been the practice in restriction proposals for similar substances. Therefore, **SEAC cannot draw a conclusion on the magnitude of the restriction related benefits.** Still, **SEAC notes RAC's conclusion that due to the wide-dispersive use of the substance in numerous sectors, substantial emissions to the environment are expected to occur.** Due to the vPvB properties of terphenyl, hydrogenated these emissions will lead to an increasing environmental stock, and any potential impacts and damages arising from this stock will last over decades if not centuries. **RAC's qualitative conclusion serves SEAC as a basis for further sector-specific discussions on proportionality and derogations.**

SEAC considers that RAC's conclusions add to the uncertainties on the benefits already arising from the possibility for regrettable substitution. In conclusion, SEAC finds that the magnitude of the benefits of the different restriction options are highly uncertain but expects that benefits will occur in the form of minimising emissions.

Key elements underpinning the SEAC conclusion(s):

SEAC's conclusion on benefits is based on the following points:

- **Concern:** SEAC notes that RAC confirmed the high **persistence** of terphenyl, hydrogenated. Any emissions will stay in the environment practically eternally, gathering up constantly, meaning that the environmental stock will always be increasing leading to an irreversible and continuing contamination. RAC further concluded that the resulting exposures may lead to unpredictable long-term adverse effects on the environment and human health, the seriousness of which may increase with increasing exposures. Therefore, prevention of the build-up of further stock is, in SEAC's view, a reasonable approach.

  More information on substance properties and RAC's conclusion on risks as well as the risk reduction effectiveness of the proposed restriction can be found in the relevant RAC sections of this opinion.

- **Emission reduction used as a proxy for risk reduction/benefits assessment:** SEAC notes that the Dossier Submitter has based the benefits assessment on quantified release estimates and qualitative supportive information. SEAC in general agrees with the use of this approach that is in line with SEAC's guidance "*Evaluation*

of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC".[20] The approach was supported by both Committees, RAC and SEAC. However, SEAC notes RAC's concern with the Dossier Submitter's specific assessment, E.g. the assessment is not robust enough to draw quantitative conclusions on emissions and emission reduction, due to insufficient justification provided, various inconsistencies in reporting between different sections of the Background Document and significant data gaps for some use scenarios. SEAC therefore notes that no quantified information on emission reduction is available to assess the benefits of the proposed restriction and the proportionality and derogations respectively.

- **Benefits estimation:** due to the above-mentioned shortcomings in the Dossier Submitter's assessment, RAC could not establish neither quantitative emission estimates, nor any respective ranges, as there is insufficient scientific data to conclude with certainty on the use volumes, source, and scale of emissions. RAC provides a qualitative discussion on a per-sector basis. Even though some of the Dossier Submitter's assumptions are, according to RAC, unrealistic worst-case and generally the emission estimates are not robust enough for a quantitative assessment, the use areas of highest concern when it comes to potential EU emissions of terphenyl, hydrogenated are the use as a plasticiser in sealants and adhesives (further information is provided in the respective RAC sections of this opinion). SEAC notes RAC's conclusion that measured data in various environmental matrices convincingly demonstrate that emissions to the environment do occur.

  SEAC notes that overall, RAC is able to draw one of the two conclusions below for each of the different sectors/uses (further information on which conclusion was reached for each sector/use is provided in table x of the RAC opinion as well as the proportionality section of the SEAC opinion):

  - **RAC concludes that emissions cannot be minimised by means other than a ban on use, (e.g. uses which are wide-dispersive, and where there is no information on the risk management measures in place).**
  - **RAC concludes that emissions can be minimised by means other than a ban (e.g. through site-/use-specific RMMs) and therefore supports a derogation for uses where appropriate RMMs can be implemented.**

  No additional quantitative information is available to SEAC as regards the benefits of a restriction.

- **(Regrettable) Substitution:** SEAC highlights that some **alternatives** are associated with risks, especially for the HTF uses. Different risk profiles may be difficult to weigh against each other, and as far as the risks of alternatives are not fully elucidated (or perhaps it is not even known yet which alternatives would be adopted in each use) careful consideration is necessary when phasing out substances allowing time for the industry to find out suitable less risky alternatives for the different uses. SEAC finds that using emissions as a proxy for risk, and then therefore using the reduction in emissions as a proxy for the benefits, has shortcomings if the substitution that takes place mostly is regrettable substitution. Emissions as a proxy for risk will give an indication of how efficient the proposed restriction is in reducing emissions from terphenyl, hydrogenated, but it will fail in being a proxy for the benefit to the society

[20] https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3

of a restriction where substitution is likely to occur with other PBT or vPvB substances.

In this respect SEAC notes specifically the trade-off made between RO1, RO2 and RO3. Given that in RO3 a full ban for terphenyl, hydrogenated is proposed, the risk of regrettable substitution is higher than in the situation with RO1 and RO2, which aim at emission control via appropriate OCs and RMMs for the HTF uses.

Information from the consultation on the Annex XV report supports that there is a large risk for regrettable substitution for the use as HTF under RO3. The information further indicates that for the A&D sector, substitution could be possible, but it will take time caused by the requirements for certification and approvals etc. When it comes to the other sectors and uses as plasticisers and other uses, there is scarce information, there could be a risk for regrettable substitution, but it is uncertain.

3.4.4.3. Other relevant impacts

Summary of Dossier Submitter's assessment:

Societal impacts are impacts that may affect workers, consumers, and the general public that are not covered under health, environmental or economic impacts (ECHA, 2008), including employment, working conditions, job satisfaction, and education of workers and social security. Depending on the RO selected for terphenyl, hydrogenated , societal impacts may vary significantly. A complete restriction leading to a practical ban of all uses of terphenyl, hydrogenated (RO3) would have a significant impact down the supply chain, particularly related to potential job losses in many industries that rely on terphenyl, hydrogenated as an HTF. In contrast, RO1 would allow the continued use of terphenyl, hydrogenated in this application (provided operations are undertaken under certain containment measures) and therefore the impact would be limited.

In many cases, it will be difficult to obtain quantitative information on employment impacts, especially on specific issues such as different occupational groups (in particular without direct consultation with industry representatives and trade associations).

Impacts on EU employment are closely linked to the extent to which there might be any potential production stops or any permanent closure of production and relocation of production outside the EU under each restriction scenario. Via the stakeholder consultation process, some numbers were provided by the HTF industry, which allows at least a qualitative/semi-quantitative assessment to calculate lost jobs. In total, 4 147 potential jobs at risk were reported. As described under **Annex E.4.1.1.** (Substitution and Investment Costs under RO3) it is assumed, that 25% of the HTF users (375 sites) would relocate to non-EU and another 25% (375 sites) would abandon business in the EU.

Assuming, that 50% of the 4 147 jobs at risk would be lost, the **lost jobs** in the EU's **HTF industry** using terphenyl, hydrogenated would be **2 074**. The Dossier Submitter assumes, that for the terphenyl, hydrogenated use as plasticiser in the **aviation industry** due to its complex value chain, approximately **1 500 jobs could be lost** for a total terphenyl, hydrogenated ban in this industry. Putting the lost revenues of the "**non-aviation plasticiser and other uses**" into perspective with the aviation plasticiser use, the percentage is approximately 1.6%. This would result in approximately **24 lost jobs**. For RO1 it is assume, that 50% of the formulators in the aviation plasticiser industry will be able to reformulate until the restrictions enter into force, so that the lost jobs will be reduced to half, which means 750 lost jobs would occur.

According to the SEA guidance (ECHA, 2008), the total societal value of a job loss is "around 2.7 times the annual pre-displacement wages". Since the number of jobs at risk in the various Member States is not known, the average annual gross salary in the EU is reported at

€ 24 700[21] for 2018. Therefore, an average annual gross salary of € 25 000 was used. The resulting average annual jobs at risk and their net present value over the analytical period (2025 – 2044) are shown in table 29 (see Annex). The Societal Loss was calculated by the number of lost jobs, multiplied by 2.7 and 20 years, respectively 15 years for aviation plasticiser use under RO1.

SEAC conclusion(s):

SEAC finds it plausible to include the consequences of unemployment for the fraction of the industries that would choose to relocate or cease their production. The methodology for estimating the value of the job losses is in line with SEAC's note on the social cost of unemployment[22].

The costs related to unemployment and wider economic impacts are highly dependent on the behavioural assumptions. As noted under the cost section, SEAC considers that the risk for ceasing activity or relocating for both HTF and the A&D sector is likely underestimated by the Dossier Submitter, which could imply that the number of jobs at risk are underestimated.

SEAC also finds that the underlying assumptions for estimating jobs at risk for the HTF use is partly justified but uncertain, and that the assumptions for estimating jobs at risk for the plasticisers is not well justified.

Key elements underpinning the SEAC conclusion(s):

Unemployment

The Dossier Submitter states that some numbers were provided by the HTF industry, and in total 4 147 potential jobs at risk were reported. According to the behavioural assumptions, the Dossier Submitter assumes that 50 % of the industry would close or relocate and thus 2074 jobs are at risk for the HTF use.

SEAC finds this uncertain as the risk for ceasing or relocation is likely underestimated, it would also imply that the value of the lost jobs is underestimated.

The Dossier Submitter states that for the use of terphenyl, hydrogenated in the A&D sector, the jobs at risk would be 1 500. The justification is related to the estimation of job losses in the aviation sector for the proposed restriction on Dechlorane Plus. SEAC finds that it is not well justified why the jobs at risk would be the same for terphenyl, hydrogenated.

Comment # 3655 and # 3707 to the public consultation provided evidence that the whole aviation sector reliant on terphenyl, hydrogenated will cease operations, and that it will have further consequences for different businesses reliant on transport by air. SEAC finds that this indicates that the estimation of 1500 jobs at risk might be significantly underestimated.

The Dossier Submitter has also estimated that there would be 24 jobs lost in the other plasticiser industries. SEAC does not find this plausible either, as the behavioural assumption was that 100 % of the industry would switch to an alternative.

The Dossier Submitter has used the default factor of 2.7 times the annual pre-displacement wages, as recommended in SEAC's note. The Dossier Submitter has used an average gross

[21] The average gross salary was estimated based on an average EU gross earning of € 13.7 per hour uplifted to 2020 (Eurostat), 40.3 hours work weeks (Eurostat, 2018b) and 33 holidays per year (European Data Portal, 2016).

[22] See: https://echa.europa.eu/documents/10162/17086/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25?t=1549885930050

salary of € 25 000 for the EU, as it is not known where the lost jobs are. SEAC finds this approach in line with the SEAC note and its accompanying report[23].

Table 12: Number of jobs at risk and their value

Sector	RO1		RO2		RO3	
	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €	Lost Jobs	Societal Value Million €
HTF	0.00	0.00	0.00	0.00	2 074	140.00
Plasticiser Aviation	750	50.63	1 500	101.25	1 500	101.25
Plasticiser non-Aviation and Other Uses	24	1.62	24	1.62	24	1.62
Total per RO	**774**	**52.25**	**1 524**	**102.87**	**3 598**	**242.87**

The value of the jobs at risk is presented in Table 12. SEAC finds that the estimated number of jobs at risk is likely underestimated and thus the value will be underestimated, although the Dossier Submitter has used the methodology recommended by SEAC.

Wider economic impacts

The Dossier Submitter states that the proposed restriction is not expected to affect competition between EU and non-EU actors placing products on the EU market significantly, due to the proposed derogation for the HTF uses and the time limited derogation for plasticiser uses in the A&D industry.

The Dossier Submitter also states that in contrast, implementation of RO3 would create distortion and unfair competition, since many products could be produced outside the EU, using terphenyl, hydrogenated. The Dossier submitter states that a full ban will play against the objective of a sustainable and self-sufficient EU chemical industry, and that in addition, terphenyl, hydrogenated is used in certain key renewable energy technologies and thus that a ban could undermine the EU Green Deal.

The wider economic impacts have not been quantified. But SEAC finds reasons to assume that they are substantial.

A full ban will also have significant impacts for customers and businesses who rely on the services provided by the A&D industry. Grounding of planes could have large consequences for passenger traffic and air freight. SEAC finds that these wider impacts are potentially substantial.

SEAC finds this qualitative approach to the possible wider economic impacts reliable.

[23] See: https://echa.europa.eu/documents/10162/17086/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554?t=1476111468417

3.4.4.4. Proportionality

Summary of Dossier Submitter's assessment:

As highlighted in **Annex E.5**, the risks and thereby the benefits of preventing emissions of PBT and vPvB substances cannot be quantified, and in the case of vPvBs, the Dossier Submitter considers that there are no known impacts. This prohibits the use of a traditional cost-benefit analysis to assess proportionality. To evaluate the acceptability of regulatory options despite the lack of quantitative information on benefits, SEAC recommends using C/E values and if available "a comparator or a "benchmark" on the level of costs that are deemed to be worthwhile taking when reducing emissions" (ECHA, 2014). The total cost of introducing a restriction on terphenyl, hydrogenated is higher for the more stringent ROs (RO2 and RO3) and the largest cost component by far is the potential loss of profits due to not having a feasible alternative to switch to in case of a full ban (RO3), mainly related to the use of the substance as HTF. Equally, the more stringent restriction scenario would lead to the highest emission reductions and, by proxy, higher potential environmental benefits. The Dossier Submitter considers that the main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of terphenyl, hydrogenated vs. the cost to industry and society from potential investment costs and profit and job losses, as well as to supply disruptions for products that may be difficult to produce without access to terphenyl, hydrogenated. Based on the lack of feasible alternatives, it is difficult to evaluate substitution costs and R&D activities in detail.

Table 13 shows the Dossier Submitters C/E estimates for each RO. The proposed RO1 has a high C/E (90 €/kg terphenyl, hydrogenated emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1.

Table 13: Cost Effectiveness of all ROs.

	Total Economic Impact (€)	**Total Emissions** (tonnes)	**Total Emissions** (kg)	**Terphenyl, hydrogenated Reduced against Baseline** (kg)	**C/E** (€ per kg terphenyl, hydrogenated)
Baseline		19 584	19 584 000	-	-
RO1	1 489 000 000	3 006	3 006 000	16 578 000	**90**
RO2	2 976 000 000	686	686 000	18 898 000	**157**
RO3	18 172 000 000	0	0	19 584 000	**928**

The Dossier Submitter notes that the C/E ratios fall within the benchmark zone of other restrictions that have previously been regarded as proportionate.

RO2 has, with 96.5%, a higher emission reduction capacity but a lower C/E with a factor of 1.7 (157 €/kg terphenyl, hydrogenated emissions avoided) compared to RO1. RO3 as the most stringent RO has the highest emission reduction potential but at much higher costs (928 €/kg terphenyl, hydrogenated emissions avoided), which are a factor of 10 compared to RO1.

The proposed RO1 has a high C/E coupled with an acceptable emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1 in order to respect the

proportionality principle.

The main trade-off on a societal level is the potential environmental benefits associated with reducing emissions of terphenyl, hydrogenated vs. the cost to industry and society from potential investment costs and profit and job losses, as well as to supply disruption for products that may be difficult to produce without access to terphenyl, hydrogenated.

SEAC conclusion(s):

SEAC notes that the approach of the Dossier Submitter to assess the proportionality of the proposed restriction is a cost-effectiveness analysis (CEA) for sectors where robust cost estimates are available. SEAC agrees that in the absence of a standard quantified risk assessment approach, e.g., as for PBT substances, a CEA is an appropriate way forward to assess proportionality. However, SEAC notes RAC conclusion on the lack of robustness of the Dossier submitter's emission estimation and takes note of RAC's qualitative approach. SEAC notes that the lack of reliable emission data makes a meaningful CEA for the overall restriction proposal impossible. The following aspects are considered further by SEAC when discussing proportionality:

- The qualitative analysis of RAC on whether the identified risks are best mitigated with a restriction or with OC and RMM
- The availability of alternatives before the entry into force
- The cost estimation made by the Dossier submitter.
- Any comments from the consultation

Despite the described uncertainties in the Dossier Submitter's cost assessment, SEAC can conclude on proportionality in a qualitative manner for the different uses/sectors covered. SEAC stresses that there are arguments in favour of proportionality; first and foremost, the irreversibility related to accumulating stocks of terphenyl, hydrogenated in the environment due to continued emissions and the persistence of the substance.

SEAC will discuss proportionality in a qualitative manner, sector by sector, as there are different qualitative aspects to consider for the different sectors.

SEAC points out that this analysis is based on the available, overall qualitative information in the restriction dossier, information provided during the consultation on the Annex XV report as well as RAC's conclusion on uses and emission minimisation as far as technical and practically possible In this respect, SEAC recognises that there are large uncertainties on the exact magnitude of the socio-economic impacts of the restriction and of the emissions for specific sectors. Therefore, SEAC acknowledges that more accurate and representative information on emissions and costs could change the outcome of the sectoral analysis, for example concerning the need for a derogation or the proposed length of the transition period.

SEAC finds that a change in restriction option 1, with a prolonging of the derogation for the A&D sector from 5 to 10 years will likely be proportionate. The justification for this prolongation is in the information submitted in the consultation on the Annex XV report, providing evidence that the Aerospace and Defence sector would need a derogation for 10 years, to avoid grounding of planes.

For the HTF use, RAC finds that the specified requirements for strictly controlled closed systems with technical containment measures, as outlined in Appendix 5 of the Annexes to the Background Document, will minimise environmental emissions. RAC concludes that the sites must also implement a representative monitoring program to confirm the effectiveness of the OC and RMM to minimise emissions. SEAC takes note of RAC's conclusion, and as the costs of implementing these conditions are expected to be small, the derogation for HTF use

in RO1 and RO2 is likely proportionate.

SEAC takes note of RAC's recommendation to set a time limit to the derogation for the use of terphenyl, hydrogenated as a HTF to provide an incentive to substitution. SEAC has asked a specific question on the topic on the consultation on its draft opinion. Several comments on the consultation on the draft opinion state that the consequences of a time-limited derogation of 20-years are not assessed and that such a time-limit would not be proportionate and provided evidence on the potential impacts this would have. On the basis of the evidence and arguments provided in the comments in the consultation on the SEAC draft opinion, SEAC concludes that a time-limited derogation would not be proportionate and that no time-limit should be set on the derogation to use terphenyl, hydrogenated.

SEAC takes note of RAC's conclusion that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the requirements of the WEEE Directive (respectively the national transpositions) are sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided. Observing the lack of socio-economic data to support a derogation, SEAC cannot support a derogation for the consumer use of terphenyl, hydrogenated ovens and thermostats. A specific question on this topic was asked in the consultation on the SEAC draft opinion, but despite reaching out to relevant actors in the supply chain, no comments with information relevant to this point have been submitted. SEAC takes this as an indication that it is both technically and economically feasible to substitute away from terphenyl, hydrogenated for this use, and thus that a ban is proportionate.

SEAC finds that a ban for the use as plasticiser and other uses in other sectors, is likely proportionate as there will be a substantial reduction in emissions and the lack of information on the potential costs indicates that the costs are low.

Key elements underpinning the SEAC conclusion(s):

The following elements underpin SEAC's conclusions on proportionality:

- SEAC stresses that it is the magnitude of **environmental benefits of the emission reduction** achieved that is uncertain (due to large uncertainties and data gaps, no quantitative conclusions on releases and a respective release reduction through a restriction are drawn by RAC and available to SEAC). SEAC considers that the **irreversibility of emissions** is a key argument in the discussion of proportionality. The pollution stock is permanent, i.e., not possible to remove from the environment with the available remediation methods.

- SEAC notes that the Dossier Submitter did try to use emissions as a proxy for risk in its assessment, which is the current standard approach applied also by SEAC in its evaluation of restrictions and authorisation applications for substances for which no standard quantitative risk assessment is possible (following ECHA's guidance on the evaluation of restrictions and authorisation applications for PBT and vPvB substances in SEAC[24]).

HTF

The Dossier Submitter has presented criteria for strictly controlled closed systems (SCCS). According to RAC, these criteria will be effective and appropriate to minimise releases

[24] See: evaluation_pbt_vpvb_substances_seac_en.pdf (europa.eu)

provided they're accompanied with a mandatory monitoring requirement.

SEAC's qualitative judgement is that the conditional derogation for HTF in RO1 and RO2 is likely proportionate, as the emissions are minimized with the criteria for SCCS and the costs of implementing measures to ensure SCCS in the small proportion of plants which would not currently comply with the conditions of the derogation are low. The relevant costs are linked to improvements of plants, organizing of procedures, training, and inspections. Thus, the costs for monitoring as RAC recommends are included in these costs. The Dossier Submitter estimated these costs to be € 20 000 per site and with 1 500 sites it will make € 30 million.

SEAC's qualitative judgement is that RO3 is likely not proportionate. Several comments to the stakeholder consultation support the concern that there is a large risk for regrettable substitution. Thus, SEAC finds that the benefits are uncertain, but likely worse even if a full ban for terphenyl, hydrogenated were put in place. Substitution to alternatives that are regrettable, and for which no requirements for the implementation of strictly controlled closed systems have been defined will lead to further emissions of SVHC-substances.

SEAC finds that the Dossier Submitter has underestimated the total costs for the HTF use in RO3. According to the comments from the stakeholder consultation, there is information that a substantial proportion of companies would cease the use or relocate, and a large fraction of the comments state that there is a risk for regrettable substitution. SEAC thus finds it likely that the behavioural responses to a full ban for HTF would be ceasing the use, relocating or regrettable substitution. This implies that the total costs could be underestimated, but that within that total, the substitution costs could be overestimated as it is likely that the degree of substitution will be lower than assumed and that the degree of ceasing or relocating will be higher. SEAC also finds that the costs related to unemployment could be underestimated, both because of the distribution of the behavioural assumptions and as it seems that the number of jobs at risk per site is small. Finally, both the Dossier Submitter and several comments to the stakeholder consultation state that there are wider economic impacts related to the use of terphenyl, hydrogenated in certain key renewable energy technologies, a total ban could therefor undermine the EU green Deal activities related to clean energy and climate change. The wider economic impacts have not been quantified. However, there are reasons to assume that they are substantial.

As the benefits are uncertain and the costs significant (and significantly higher than for RO 1 and RO 2), SEAC finds that for HTF, RO3 is the least proportionate option, and is likely not proportionate at all.

Time-limited derogation for the use as HTF

SEAC takes note of RAC's recommendation to set a time limit to the derogation for the use of terphenyl, hydrogenated as a HTF to provide an incentive to substitution.

SEAC notes that no such time limit was proposed by the dossier submitter and that the submitted Annex XV dossier does not contain information which is relevant and specific enough for SEAC to consider the appropriateness of such a time limit and/or to recommend any specific length of a time limited derogation. SEAC therefore raised this as a question in the consultation on the SEAC draft opinion, asking for feedback on the impacts of a time limit based on the expected operating life of the relevant installations (as any premature substitution would require costly retrofitting) and proposing that this could be 20 years.

A total of 24 comments have been received that supplied SEAC with enough specific information to formulate an opinion on the proportionality of such a time-limited derogation and its possible length.

Summary of Comments received

A majority of the comments to the consultation on the draft SEAC opinion raise concerns

about proposing a time-limited derogation of 20 years, or any time limited derogation. One point raised is that this derogation has not been proposed by the Dossier Submitter, thus not assessed, and it has not been possible for stakeholders to comment on it until now. The comments argue that a time-limited derogation will not be proportionate, as it would result in overall more emissions from similar SVHCs (the alternative SVHCs does not need to operate in installations that have requirements of SCCS, this would be the case for installations that would be set-up during the time limit of the derogation, which would be expected to choose one of the substitutes instead of terphenyl, hydrogenated and to which the SCCS would not strictly apply the SCCS. Given the expected increase in the use of HTF for green and renewable energy installations as well recycling installation, SEAC finds his scenario plausible.

The major arguments for stating that a time-limited derogation of 20 years, or any time-limited derogation is likely not proportionate are listed below.

Lifetimes of industrial sites go long beyond 20 years. Although the submitted comments would indicate that there would be sites with expected reduced lifetime (30 years), for larger establishments the useful time can be more than 50 years (all petrochemicals, such as e.g. PET manufacturers are in this segment). Some examples of existing sites and since when they are running are given in table 8.

Table 14: Examples of sites using terphenyl, hydrogenated as an HTF and their date of construction

	Location	Product	Year of construction
Exxonmobile	Fife, UK	Ethylene plant	1981
	Fawley, UK	Refinery	1951
Borealis	Schwechat, AT	Polypropylene	1961
INEOS	Antwerp	Polypropylene, PET	1992
		Petrochemical complex	1970
	Koln (cologne)	Polyethylene	1957
	Rafnes (Norway)	Polyethylene	1975
Dow	Stade (Germany)	Polyethylene	1972
	Terneuzen (Netherl	Polyethylene	1965
REPSOL	Tarragona	Petrochemical complex	1976
	Puertollano	Petrochemical complex	1965

Other examples of plants running more than 20 years have been provided in some of the comments (#1174, #1185, #1199, #1201, #1217).

- **It is not foreseeable that a new, safe substance will be found**. The very nature of what makes the substance useful (thermal stability and boiling point), requires persistency properties that would make it likely that any substitute in the same heat range with the same performance would be identified as PBT. In fact, two alternatives were included in the RMOA conducted by Tukes, one is suspected to be PBT (1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene) and the other one (dibenzylbenzene, ar-methyl derivative) is self-classified as PBT (comment #1171)**.** Terphenyl, hydrogenated has an expected service life of more than 20 years, as indicated in several comments (#1171, #1177, #1186, #1193, #1199, #1201). Comment #1171 states that >40% of the analysed HTF is older than 20 years.

- **A time-limited derogation does not imply that the manufacturers will spend resources searching for an alternative**. There are two main reasons supporting this: the argument presented previously and the possibility to switch to another existing alternative (which means regrettable substitution) or relocate outside the EU.

- **A time-limited derogation will hamper new investments** in sites using terphenyl, hydrogenated as HTF in the EU **or the new sites will use an alternative substance (regrettable substitution).** As the lifetime of the industrial sites is longer than a time-limited derogation of 20 years, all investment decisions will take the potential upcoming ban into account, and it will thus affect all investments, leading to either regrettable substitution or investments locating outside the EU. Both outcomes (no investments or regrettable substitution) would have additional negative consequences for the EU.

  A time-limited derogation will have an adverse effect on achieving the goals of the EU Green Deal. The substance is used in plants producing renewable energy (like combined heat and power plants -CHP-, organic Rankine cycle plants -ORC-, solar power plants, biofuel plants or waste oil energy plants). These plants have an important impact on decarbonization and climate change. Besides terphenyl, hydrogenated is used in plants that improve sustainability and circular economy like the mentioned waste oil plant or plastic recycling plants (in fact, there is a 1bn $ project to build a facility for material-to-material molecular recycling for hard to recycle plastics in France, the plant is expected to be operational in 2025).
- **A time limited derogation will stop new investments in existing plants** (as indicated in the first item, the lifetime of an establishment is not determined and it can be extended by retrofitting those parts that are outdated or get damaged. In fact, there are currently investments in the EU of billions of euros in existing plants manufacturing plastics/petrochemicals). Closure, relocation, or regrettable substitution are the potential scenarios.

- A **time-unlimited derogation can always be changed in the future**. If the situation changes (new technologies or new substances) it can be reviewed and cancelled.

SEAC's evaluation of the submitted comments.

SEAC assumed as a premise that the time-limited derogation should be set based on the expected average lifetime of installations, to avoid that any premature substitution would result in regrettable substitution and require costly retrofitting in installations that normally have a long lifetime. The comments received (for example, comments #1171, 1174, 1175, 1177, 1178, 1184, 1190, 1193, 1194, 1199, 1206, 1216, 1217 and 1218) provide evidence that this premise is not fulfilled with the initially proposed 20 years, as the lifetime of installations can be significantly longer.

SEAC considers that a time-limited derogation of 20 years, or any length of a time-limited derogation, will lead to a situation with potential regrettable substitution or investments being relocated to outside the EU. It is important to remember that the current restriction only targets terphenyl, hydrogenated, whereas in a recent RMOA of the Finnish authorities, it was concluded that the risk of regrettable substitution with substances similar to terphenyl, hydrogenated is considered to be high. The two foremost alternatives (EC-No 258-649-2 and EC-No. 400-370-7) to terphenyl, hydrogenated (CAS 61788-32-7) have therefore been considered together for further regulatory action as a "technical functional group" (Tukes, 2020) due to their use as Heat Transfer Fluid (HTF) within the same temperature range and the potential PBT properties of the two alternatives.

In this respect, SEAC notes that with the current targeting and scope of the proposal, focussing on terphenyl, hydrogenated, there is a risk of regrettable substitution as actors could potentially use one of the substances from this functional group as a substitute. This could lead to situation of regrettable substitution with actors merely using another PBT (or likely to be PBT) substance instead of terphenyl, hydrogenated. SEAC is recommending that regulatory action be considered for the two potential regrettable substitutes identified;

however, such action taking place at some point in the future cannot be assumed in SEAC's analysis, and SEAC needs to take the current situation as the baseline.

It is clear from the evidence presented in the comments that, despite the recommendation for a review before the end of the time-limit set on the derogation, industry would operate as assuming the time-limit as fixed (considering the possibility that a review would extend the time-limit if no sustainable alternatives are available to be too uncertain). Therefore, in practice, SEAC foresees the following scenarios for existing and new plants, assuming a baseline in which no regulatory action will take place on the rest of the functional group, or other potential alternatives, if there is a time-limit set on the derogation.

Existing plants

Would adjust the OCs and RMMs to comply with the SCCS conditions and ensure minimisation, and then continue using terphenyl, hydrogenated until the expiration of the time limited derogation, or until major maintenance is needed, and there is need for an investment decision. After that, SEAC considers that it is likely that the following possible scenarios may occur:

A) a retrofit would be performed to ensure that the installation would be capable of using one of the close substitutes, which could then be used without controlled conditions since OCs and RMMs would have to be readjusted to comply with SCCS conditions
B) Closure
C) Relocation

Numerous comments (#1175, #1176, #1177, #1178, #1180, #1182, #1185, #1186, #1188, #1194, #1199, #1201, #1206, #1215, #1218) indicate that relocation is the most plausible scenario.

SEAC considers that all these scenarios would incur very high costs, and scenario A would also have the potential of higher emissions than continuing to use terphenyl, hydrogenated while complying with the conditions.

New plants

Would not use terphenyl, hydrogenated. Instead, they would either:

A) use one of the close alternatives which could be used in a non-controlled manner without the assurance (via e.g. monitoring) that emissions of a PBT-like substance would be minimised

B) make the investment outside of the EU instead.

Comments received (see above) indicate that the investment being made outside of the EU is the most plausible scenario.

SEAC considers that scenario A is highly likely to result in higher emissions than using use terphenyl, hydrogenated while complying with the conditions. Scenario B would have high costs to the EU.

In the current situation where only terphenyl, hydrogenated is restricted, substitution to one of the other substances has a high potential to lead to higher emissions of an SVHC, as the rest of the functional group, or other potential alternatives, do not currently have requirements for the implementation of strictly controlled closed systems. Additionally, the lifetime of these alternatives is shorter, which implies that they have to be replaced more often, leading to more potential for emissions. In addition, (confidential) comments to the SEAC draft opinion #1173 and # 1177 indicate that the use of any of the other substances in

the functional group would be less optimal from a technical and economical perspective for the installations. In conclusion, substitution with these alternatives would thus lead to higher emissions and higher investment and operational costs. A situation with higher emissions and higher costs is clearly not proportionate.

Last, but not least, the current restriction, not taking into account the functional group, or other potential alternatives, will not ensure a level playing field between similar substances for similar uses and might lead to investments using heat transfer fluids that are not the best option from neither a technical, nor an economical view, and at the same time lead to further emissions. Several comments, especially # 1180 and # 1216 highlight that there has been no real assessment of the substitution costs, not taking into account indications that the performance of the alternatives is less preferable and less safe and potentially more costly (# 1171, # 1186) in investment and operation. Some comments, especially # 1177 also emphasize that there is no reliable assessment of the behavioural responses regarding the fraction that would relocate and the fraction that would substitute, and thus no reliable estimation of the costs to the society of a ban or a time-limited derogation. This also implies that there is no reliable assessment of the potential consequences for the society if a large fraction of these industries will relocate outside the EU.

SEAC is aware that a reliable assessment of these costs is lacking. SEAC is also aware that the costs presented by the Dossier Submitter for RO3 are likely significantly underestimated and SEAC finds that the content of the comments on the draft opinion justifies that it is likely that the costs for RO3 are significantly underestimated, although the comments have not given reliable estimations of the potential costs for the society.

SEAC thus finds that RO3, with a time-unlimited derogation is likely proportionate. The major arguments are that strictly controlled closed systems will ensure minimisation of emissions. This means that a restriction has clear benefits, although they are not quantified. Potential substitution will be regrettable, and the potential alternatives are not subject to requirements of SCCS, which means substitution will thus lead to more emissions of PBT/SVHC substances than a time-unlimited derogation. On the cost side it is clear that both the costs for substitution and the costs for society if a large fraction of these industries relocate are significantly underestimated.

SEAC takes notes of the conditions set by RAC which set up a requirement to monitor emissions and to review a site's existing OC and RMM on a yearly basis until minimisation can be confirmed. These conditions would assure that sites indeed do comply with the strictly controlled closed systems requirements.

SEAC considers that a review should be undertaken should new information on alternatives that would not pose a risk of regrettable substitution become available.

A&D

The Dossier Submitter has proposed RO1, which includes a derogation for five years after EiF for production and maintenance in the A&D sector.

Comments to the stakeholder consultation from two industry association (ASD and AIA) provide evidence that five years is not sufficient to substitute to less hazardous chemicals. The major reasons are that the sector need the possibility to operate under harsh conditions, which means that sealants, adhesives etc need to fulfil specific quality requirements. The other major reason is that materials and processes need to meet stringent safety requirements that are subject to independent certification and approval through EASA (European Union Aviation Safety Agency). Every application must be individually assessed to determine that requirements are met, and this is consistent with information from applications for authorisation in the aerospace sector.

The strict requirements and need for certification and approval imply that it is likely that there

will be no substitution if a suitable alternative is not available and certified. Based on the information provided, SEAC finds that it would take more than 5 years to fully substitute, and that it is likely that the activities will cease if suitable alternatives are not available, which means that it is likely that the activity will cease under all the proposed restriction options.

SEAC finds that the costs for all the restriction options proposed by the Dossier Submitter could be underestimated. The reasoning is that the profit loss is likely underestimated, the further costs associated with grounding of planes and ceasing of activity are not estimated at all. These costs could be substantial as they include costs related to ceasing of activity in the supply chains for maintenance, repair, and overhaul. And there are wider economic impacts related to the consequences of reduced flights and thus reduced air freight.

Because of the substantial costs related to ceasing of activity in the A&D sector, SEAC finds that it is likely proportionate to suggest a prolonging of the derogation for the A&D industry from five to ten years.

Consumer use as HTF in thermostats in electromechanical temperature controls of ovens and stoves:

RAC concluded that there is no information in the Background Document related to the RMMs and OCs applied by companies that are using terphenyl, hydrogenated as HTF in thermostats of ovens and stoves. The Dossier Submitter assumed that at the end of their service life, ovens and stoves are disposed of according to the WEEE Directive (2012/19/EU) and that any risk is covered. RAC is of the opinion that it is not possible to conclude, based on the limited information provided by the Dossier Submitter, if the WEEE requirements (respectively the national transpositions) are sufficient to ensure that releases of terphenyl, hydrogenated from ovens and stoves are avoided. SEAC observes that no socio-economic data was provided by the Dossier Submitter nor in the consultation that would support this derogation and will ask a specific question on this topic on the consultation on the SEAC draft opinion.

Other sectors, use as plasticisers and other uses.

SEAC finds that the proposed restriction for use as plasticiser and other uses outside the A&D sector is likely proportionate.

The estimated costs are not likely to be substantial, although SEAC finds them uncertain.

The conclusion is supported by the fact that there has been only one comment in the stakeholder consultation, and this indicates that it is likely that a ban will not pose significant problems.

3.4.5. Practicality, including enforceability

Summary of Dossier Submitter's assessment:

The Dossier Submitter considers the proposed restriction to be practical because it is affordable, implementable, enforceable and manageable.

Regarding enforceability, the Dossier Submitter considers that enforcement authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. They consider that analytical methods can be easily adapted from the methods to analyse o-terphenyl. Given that such methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

RAC conclusion(s):

RAC concludes that overall, the restriction is implementable, enforceable, and manageable.

RAC agrees with the Forum advice regarding the derogation for terphenyl, hydrogenated used as HTF in industrial installations to define in more detail in the legal text strictly controlled closed systems and the obligations of the end user.

RAC is of the opinion that a representative monitoring program to assess environmental releases in air, water and soil is implementable by industrial users of terphenyl, hydrogenated as HTF and enforceable by the enforcement authorities for a better evaluation of the appropriateness and effectiveness of RMMs and OCs.

RAC agrees with the Forum opinion on monitorability that the sampling of products on the market should be feasible but that a standard analytical method is required. RAC notes that they are some uncertainties related to the standard analytical method development.

Key elements underpinning the RAC conclusion(s):

The Forum considered the enforcement of the proposed restriction as generally practicable but noted that inspections may vary a lot depending on the personal involved (e.g., non-professional personal of the end user, competent technical bodies, additional experts) and the documentation available (e.g., manual of the manufacturer). RAC agrees with the Forum that, as a consequence, the derogations in Paragraph 2 and 3 of the proposed restriction entry by the Dossier Submitter would require further elaboration in order to provide sufficient basis for the enforcement of the requirements. The Dossier Submitter has provided a definition of strictly controlled closed systems, recommended technical measures and points of inspection and training for enforceability in Appendix 5 of the Annex XV Annexes. However, RAC noted that the different criteria described in the Appendix 5 are only optional and their implementation would differ between the industrial installations using HTF. Therefore, RAC is of the opinion that the strictly controlled closed systems should be confirmed by monitoring environmental releases which shall be checked by the inspectors. These conditions should be added in the restriction entry in order to make the derogation possible.

RAC is of the opinion that the industrial installations must implement a yearly representative monitoring program with the samples taken at relevant points of the circuit to assess the environmental releases in air, water, and soil, under normal conditions and at each intervention on the circuit. Additionally, all solid waste which had been in contact with terphenyl, hydrogenated shall be collected and disposed of as hazardous waste in line with applicable regulations. The information from the monitoring program (including waste management), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken, shall be documented, maintained, and be made available by the industrial sites, upon request, to the competent national authority of the Member State where the site is located.

The industrial sites may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that release to the environment has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific condition of use function appropriately.

Where the frequency of a monitoring programme has been reduced, any subsequent changes to the operational conditions or risk management measures that may affect the release to the environment at each of the sites where the use takes place shall be documented. The industrial sites shall assess the impact of such changes by monitoring to demonstrate that exposure of the environment continues to be reduced to as low a level as technically and practically possible.

There is currently no specific analytical method for the determination of terphenyl, hydrogenated but a reference analytical method by GC-MS for o-terphenyl in air (NIOSH method 5021) as reported in the background document. For enforcement of the restriction, the Dossier Submitter recommends to monitor o-terphenyl and estimates indirectly the

concentration of terphenyl, hydrogenated assuming a concentration of 7.1% of o-terphenyl based on the highest concentration provided in the REACH registration dossier. RAC is of the opinion that this approach could bring significant uncertainties in the identification and quantification of terphenyl, hydrogenated and recommends to develop analytical methods which could differentiate o-terphenyl from other terphenyl isomers present in the UVCB and guarantee the distinction between o-terphenyl and terphenyl, hydrogenated or from other sources. RAC notes that NILU NIVA (NILU, 2018) has developed non-standardised GC-MS analytical methods to monitor different hydrogenated terphenyls and terphenyls congeners (including o-terphenyl, m-terphenyl and p-terphenyl) in air, water, biota and solid (sediment, sludge and dust) samples. In scarcity of any available standards for the broad group of congeners of hydrogenated terphenyls, a synthesis of 13C6-dicyclohexylbenzene was undertaken. The major congener, $^{13}C_6$-sH12pTP was extracted and purified by crystallization. to serve as standard solution for spiking samples prior to extraction and quantify all hydrogenated terphenyls congeners. Two other publications which are not referred to in the Background Document report further monitoring studies. The screening programme 2019 (COWI AS, 2020) analysed terphenyl, hydrogenated in wastewaters, sludge, passive samplers, sand trap, sediment, fish and house dust in various locations in Norway by GC-MS/MS (triple quad) along with other semi-volatile compounds but no details on the methodology are provided. The other report refers to an accidental release of Therminol 66, with terphenyl, hydrogenated as main component, in a Norwich fjord (NIVA, 2012 in Norwegian). Samples of mussels were analysed by a commercial laboratory. A known amount of sample of the soft parts was added to isopropanol, cyclohexane and internal standard (d10-phenatrene) and then treated with ultrasound, shaking and centrifugation. The organic phase was extracted and washed with saline solution, before removal of polar components with Bond Elute. The extract was run on GC-MS in SIM/Scan mode. To determine the uncertainty of the analysis, a so-called "spiking" test was carried out in which a known amount of Therminol oil was added to a "reference sample" and analysed. The detection limit of 0.1 mg/kg was calculated from the spiked reference sample. Therminol oil was also found in the reference sample without addition leading to higher detection limit and uncertainty than expected if Therminol-free material had been used in the spiking tests. A sample of the oil was analysed to determine retention times and ion ratios. From the probable fragmentation pattern, five different peaks were identified by the author to be the different isomers of the terphenyl, hydrogenated compound.

Based on the information on available analytical methods, RAC assumes that it should be feasible to develop standardised analytical methods for the enforcement of this restriction.

RAC recognizes the relevance of the concentration limit of 0.1% w/w of terphenyl, hydrogenated proposed by the Dossier Submitter because it triggers the information requirement under REACH Article 31 for substances and mixtures and Article 33 for articles. However, RAC agrees with the Forum that a standardised analytical method with a limit of detection below 0.1% w/w shall be elaborated in order to sampling of liquid mixtures and articles for the uniform enforcement of the restriction. The limit of detection for o-terphenyl are 2 µg/sample of air in the reference analytical method dated 1994 and 1 µg/m3 for air in the monitoring program at industrial sites reported in the Background Document annexes. Limit of detections are not reported in the NILU report from 2018 but concentrations of 1/0.1 ng/m3 of air, 3/1.8 ng/L of water and 1/0.3 ng/g of sediment were measured for hydrogenated terphenyls/ terphenyls, respectively. The method was able to differentiate o-, m- and p-terphenyls and had LoDs in the range of ng (ng/m3, ng/g or ng/L depending on the relevant sample types). However, as raised by the Forum, it is uncertain whether these limits of quantifications are applicable to sampling of liquid mixtures or articles under the scope of this restriction.

RAC agrees with the Forum that a sample preparation for articles would need to be elaborated as well.

SEAC conclusion(s):

SEAC agrees that the proposed restriction is in general enforceable. This is based on the information provided in the Background Document and Forum's advice. SEAC notes Forum's opinion that the restriction can be regarded as enforceable, as long as reliable normative test methods are defined.

Key elements underpinning the SEAC conclusion(s):

The scope of the proposed restriction is clear for the different sectors

The definition of strictly controlled closed systems allows the inspection by competent technical bodies in the case of use as heat transfer fluid.

The existing analytical methods allow to measure the substance in the concentration limits proposed, although a standardised protocol is missing and should be developed.

3.4.6. Monitorability

Summary of Dossier Submitter's assessment:

The Dossier Submitter considers the proposed restriction to be monitorable.

Analytical methods for quantitative determination of terphenyl, hydrogenated are available. The analytical method used has been the NIOSH 5021 for o-terphenyl using a PTFE filter and analysis by GC/MS. The sampling and analysis have been carried out on a best effort basis using this method, with semi-quantitative analysis by GC/MS using o-terphenyl as a calibration standard. In this way, it has been possible to identify any terphenyl peaks present and quantify them as o-terphenyl.

RAC conclusion(s)

RAC notes that the tonnage band declared in the REACH registration or imported on industrial sites, (information in SDS), could be used for monitoring the use of terphenyl, hydrogenated.

RAC is of the opinion that standard analytical methods needs to be develop in liquid mixtures, articles and environmental samples to assess the effectiveness of the restriction.

RAC notes that monitoring is based on o-terphenyl and concludes that the standard analytical methods should be able to differentiate o-terphenyl from terphenyl, hydrogenated or from other substances containing o-terphenyl. Therefore, there is a need for the users of the latter substances to indicate they do not use terphenyl, hydrogenated.

RAC is of the opinion that the implementation of a representative monitoring program is necessary for the enforcement authorities to assess the appropriateness and effectiveness of RMMs and OCs to minimise environmental releases at industrial sites using terphenyl, hydrogenated as HTF.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.4.1.

The analytical method used has been the NIOSH 5021 for o-terphenyl using a PTFE filter and analysis by GC/MS. The sampling and analysis by the dossier submitter in its monitoring campaign have been carried out on a best effort basis using this method, with semi-quantitative analysis by GC/MS using o-terphenyl as a calibration standard. In this way, it

has been possible to identify any terphenyl peaks present and quantify them as o-terphenyl. The reporting limits are 0.4 µg for air samples and 1.0 µg for soil samples. No determination of o-terphenyl in liquid samples was performed during the exposure measurements.

The DS recommends assuming the highest concentration of o-terphenyl (7.1%, detected by GC/MS analysis) provided in the REACH registration dossier of terphenyl, hydrogenated (ECHA, 2021b) to calculate the concentration of terphenyl, hydrogenated from the results obtained for o-terphenyl. This is not a direct method for the identification and quantification of terphenyl, hydrogenated, since this substance is a UVCB.

The Dossier Submitter did not address the presence of o-terphenyl in other substances (as e.g., a constituent), the Dossier Submitter considered that o-terphenyl (CAS 84-15-1) is not a chemical product itself and is not marketed as an individual substance globally.

RAC has reservations on this statement (see section 3.4.1) as the proposed method would capture o-terphenyl where it may be present as a constituent of other terphenyl substances that are not in scope of the proposed restriction.

RAC therefore considers that during the enforcement for example, the declaration of the quantity and the identity of the substance containing terphenyl should be verified to examine compliance with the proposed restriction. Furthermore, RAC highlights that the main issue of the proposed restriction (RO1) is the lack of monitoring requirements in the guidance on strictly controlled closed systems for HTF derogation. Although the Dossier Submitter considered that o-terphenyl (CAS 84-15-1) is not a chemical product itself and is not marketed as an individual substance globally, RAC notes that on the ECHA website o-terphenyl can be found as such or included in other substances and that other substances may be commercially available in the EU, even though no registration dossiers are available, when they are manufactured or imported at a tonnage below 1 t/y per legal entity.

RAC notes that the reaction mass of o-terphenyl and m-terphenyl is registered in the tonnage band 10-100 tonnes per year and that this quantity could interfere with the global volumes marketed for terphenyl, hydrogenated. Therefore, RAC notes that during the enforcement for example, the declaration of the quantity and the identity of the substance containing o-terphenyl should be verified to exclude the substance that are out of the scope of the suggested restriction.

SEAC conclusion(s):

Based on the information provided in the restriction dossier, SEAC agrees that the restriction is monitorable.

Key elements underpinning the SEAC conclusion(s):

SEAC agrees that as regards contents in articles, monitoring of the proposed restriction can be conducted through regular enforcement activities.

Time trend monitoring could be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring. Long range transport, and persistence of the chemicals restricted would however complicate such monitoring. Monitoring based on verification of emission reductions should also be considered.

Further to that, monitoring can be performed based on regular enforcement activities. These activities can also keep track of the number of sites in compliance with the SCCS and hence any increasing compliance with these conditions can be tracked over time.

3.4.7. Conclusion whether the suggested restriction is the most appropriate EU-wide measure

RAC conclusion(s):

RAC concludes that the proposed restriction is with some modifications the most appropriate EU wide measure.

The revised proposed restriction with some modifications is effective in minimising the risk.

A time limited derogation on the use as a HTF in industrial installations is supported provided that strictly controlled closed systems are implemented and the requirement to implement a representative monitoring program is foreseen as part of the restriction.

The restriction is generally practicable, enforceable and monitorable. Further development of the analytical methods is recommended.

RAC points out that o-terphenyl (the constituent of terphenyl, hydrogenated that drives the restriction proposal due to its vPvB properties) may be present as constituent of other substances in addition to terphenyl, hydrogenated. RAC recommends that the risks posed by o-terphenyl resulting from the use of these substances should be further investigated and addressed if confirmed.

Key elements underpinning the RAC conclusion(s):

RAC concludes for the reasons set out in section 3.1.1 that the scope of the restriction is not optimal.

Due to significant uncertainties on the emission estimates and the uses of terphenyl, hydrogenated, RAC cannot give a robust view on the effectiveness of the restriction on a quantitative basis. However, the qualitative analysis performed by RAC demonstrates that emissions can be expected for all the identified uses (see section 3.4.3) and the overall need for action given the vPvB properties of the substance.

Other regulatory risk management options have been disregarded in section 3.4.2 because they do not address terphenyl, hydrogenated or, all its uses or, they would delay the minimisation of environmental releases compared to a broad restriction. RAC concludes that a restriction is the preferred regulatory measure compared to other, REACH and non-REACH, actions.

RAC considers that the use of HTF in industrial installations can be derogated if the sites are compliant with specific OCs and RMMs described in Appendix 5 of the Annex to the Annex XV Dossier. The derogation will be valid a minimum length of years after the entry into force of the restriction in order to allow the development of safer alternatives.

In section 3.4.1, RAC concludes that the restriction is implementable, enforceable and manageable. RAC is of the opinion that the industrial installations using terphenyl, hydrogenated must implement a representative monitoring program to assess the environmental releases without delay. Provision of the results of the representative monitoring results to the enforcement authorities will allow for a better evaluation of the situation at the industrial sites and inform further the appropriateness and effectiveness of RMMs and OCs.

RAC notes that analytical methods are limited and need more development for the enforcement of the restriction proposal.

SEAC conclusion(s):

SEAC acknowledges the uncertainties of the proposed restriction but considers the suggested restriction, including SEACs modification, the most appropriate EU-wide measure. This takes into account the proportionality of its socio-economic benefits to its socio-economic costs.

Key elements underpinning the SEAC conclusion(s):

Despite the uncertainties in the assessment, SEAC considers that the proposed restriction is still effective and proportionate, if the conditions are changed as reflected upon in this opinion.

SEAC considers the restriction is likely to be effective, considering the qualitative analysis made by RAC which clearly highlights the need for restriction for wide-dispersive use as well the possibility to mitigate risks in situations where OCs and RMMs are considered to be effective and appropriate in mitigating any risk associated with the use of terphenyl, hydrogenated.

In that sense SEAC considers in particular the statements of RAC that the modified SCCS are appropriate and effective in minimising emissions of terphenyl, hydrogenated, SEAC notes these RMM are available at low cost. Considering RAC's conclusion and the associated cost, the proposed derogation is likely to be proportionate

SEAC considers that the proposed derogation for the aerospace and defence centre is likely to be proportionate, provided the length of the derogation is extended from 5 to 10 years. *SEAC takes note of RAC's discussion regarding additional OC and RMM to be required to reduce emissions].*

Given the overall considerations SEAC considers the modified proposal as proportionate and effective and hence considers it to be the most appropriate union wide measure.

SEAC takes notes of RAC's recommendations on o-terphenyl and on any grouping (albeit with suitable alternatives or with other terphenyls)

3.5. SUMMARY OF UNCERTAINTIES

3.5.1. Uncertainties evaluated by RAC

Summary of Dossier Submitter's assessment:

A number of uncertainties have been identified and described by the Dossier Submitter in the Background Document (section 3 and Annex F). The Dossier Submitter considered the input parameters on volumes and uses (Annex A) as well as the number of sites using terphenyl, hydrogenated to be quite accurate, since consistent data was provided from industry during the stakeholder consultations and direct interviews with the concerned parties

Owing to a lack of site-specific exposure information for the EU, a generic approach closely aligned with ECHA Guidance R16 has been used for the exposure assessment. The approach involves a number of assumptions and, where appropriate, a realistic worst-case approach has been chosen in line with ECHA Guidance R16. Uncertainties in the use factors, for the plasticiser use, is a driving factor for the results of the exposure assessment. The limited information on volumes for certain uses combined with the lack of information on fractions of terphenyl, hydrogenated released to air, water, and soil from the various processes using terphenyl, hydrogenated and lifecycle stages, creates uncertainties in the exposure assessment.

The share of the total emissions was evaluated based on the market sector. The analysis showed that the HTF use has by far the largest share of the total emission in the high emission scenario. All other uses have a share of a few percent, each. However, the Dossier Submitter considered the result of the high emission scenario as not reliable since the actual emission associated with the industrial use of terphenyl, hydrogenated is unrealistic and overestimates

the actual emission.

A differentiation between plasticizer (non-aviation) and plasticizers for use in aviation was not made and the expected releases are just based on the volumes used in these sectors.

RAC conclusion(s):

RAC estimates that inconsistent information related to the total use volume, operational conditions and environmental release factors for the use of HTF in industrial installations constitute significant uncertainties in the risk assessment of terphenyl, hydrogenated.

RAC is of the opinion that the lack of information regarding non-HTF uses brings major uncertainties in the risk assessment of terphenyl, hydrogenated.

RAC concludes that all identified information gaps, unrealistic assumptions and uncertainties in the emission assessment of terphenyl, hydrogenated add uncertainty to the effectiveness of this proposed restriction.

RAC is of the opinion that there is uncertainty on the effectiveness of this proposed restriction in minimizing releases to the environment of o-terphenyl, the vPvB constituent of terphenyl, hydrogenated, as it could also be present in other substances outside the scope of this restriction.

RAC notes that analytical methods are limited and need more development, making the monitorability of the restriction uncertain.

RAC concludes that overall, given the vPvB properties of terphenyl, hydrogenated couples with the wide dispersive uses, the identified uncertainties would not impact the effectiveness and enforceability of the restriction as proposed by RAC.

Key elements underpinning the RAC conclusion(s):

Key elements underpinning the RAC conclusions are presented in section 3.1.1, 3.1.3.; 3.4.1; 3.4.2.

Despite the uncertainties identified, the qualitative assessment outcome clearly shows that a restriction is needed, whereas for other uses operation conditions and risk management measures can be proposed that are appropriate and effective in limiting the risk for as far as technically possible.

RAC proposes some modifications to the restriction proposed by the Dossier Submitter in order to reduce the uncertainties related to the risk of terphenyl, hydrogenated used in aerospace and defence applications and as HTF in industrial installations and concludes that overall, the identified uncertainties would not impact the effectiveness and enforceability of the restriction as proposed by RAC.

3.5.2. Uncertainties evaluated by SEAC

Summary of Dossier Submitter's assessment:

The estimated costs for the ROs are associated with some degree of uncertainty. Information received from individual actors during the stakeholder consultation were extrapolated to entire industries. This poses uncertainty, as the exact data for non-responding companies are unknown. Moreover, the accuracy of the collected data and the robustness of the adopted methodology introduce uncertainty.

This methodology has been described in detail in **the Background Document** (Economic

Impacts). In particular, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling sites, may be subject to uncertainty. Assumptions made on behavioural responses are intrinsically uncertain. The C/E calculations incorporate both, emissions, and costs, thus, the same uncertainties described before will apply to the C/E estimates as well. It is hardly possible to reduce these uncertainties any further without more information from stakeholders. Therefore, the conclusions of this dossier should be verified in the stakeholder consultation of this Annex XV dossier.

There are uncertainties associated with some of the input factors and consequently results of the analysis. The key uncertainties are considered to be profit losses, estimations of market growth rates, estimation of total market size (in the plasticiser value chain) as well as not declared margins, turnovers, and costs for closing and dismantling of sites. **Error! Reference source not found.** Table 15 shows in a simple manner the sensitivity of key outcomes of the Impact Analysis. The arrows indicate the impact of the uncertainty of some key parameters on the outcomes of the SEA. **"↓"** means, that the assumption lowers the estimate and **"↑"** means that the assumption increases the estimate.

Table 15: Sensitivity of key uncertainties as assessed by the Dossier Submitter

Parameter tested	**Impact on Emissions**	**Impact on Costs**	**Impact on C-/E-Ratio**
Market growth rate underestimated	↑	None	↑
Market growth rate overestimated	↓	None	↓
Cost overestimation	None	↓	↓
Cost underestimation	None	↑	↑

SEAC conclusion(s):

Identified uncertainties:

- The existence of suitable alternatives for some uses
- The reduction of the emissions of the different uses due to the lack of quantitative reliable data
- The costs and benefits of the restriction (see previously described uncertainties)

Key elements underpinning the SEAC conclusion(s):

SEAC's conclusion on uncertainty aspects of the assessment and the corresponding justification is given in the respective sections of this opinion and its Annex. In summary, SEAC notes the following:

- **Availability of data:** SEAC notes that for most sectors and uses affected by the restriction the availability of robust and representative data is limited. Even though numerous stakeholders provided information during the consultation on the Annex XV report, this information is often product-/use- and/or company-specific and does not allow SEAC to extrapolate it for the assessment of an overall sector; specifically, as the assessment of this information done by the Dossier Submitter is somewhat

limited.

- **Costs** of the proposed restriction: SEAC notes that the Dossier Submitter changed their approach during the opinion making process of SEAC from a partly quantitative to an overall qualitative cost assessment. This is mainly due to lack of robust input data. An overall qualitative cost assessment approach makes it difficult for SEAC to compare costs to the potential benefits of a restriction, specifically if any respective benefits information is scarce and uncertain as well (see bullet point below). SEAC notes that overall, the qualitative cost assessment is surrounded by numerous uncertainties, specifically as substitution-related costs (their likelihood, magnitude) are concerned.

- **Benefits** of the proposed restriction: the Dossier Submitter initially followed the agreed approach for assessing the benefits of a restriction for PBT-like substances, i.e. emissions serving as a proxy for risk. Furthermore, SEAC notes that overall, RAC was not able to verify the Dossier Submitter's emission calculations, which resulted in only general qualitative conclusions of RAC (no figures provided, not even ranges).

- **Proportionality** of the proposed restriction: SEAC notes that due to the above stated data gaps and uncertainties, an evaluation and conclusion on whether or not the restriction is overall proportionate is not possible based on socio-economic considerations. SEAC approached its evaluation and conclusion therefore differently, as pointed out in the proportionality section above. Even though any such alternative approach does not allow SEAC to draw an overall conclusion on scientific grounds, it at least allows a sector-based discussion of relevant factors surrounding the proportionality issue.

4. Annex 1

Detailed assessment of the costs

Key elements underpinning the SEAC conclusions on the assessment of the Dossier Submitters estimation of the costs:

The Dossier Submitter has identified several restriction scenarios, that are defined by the anticipated behaviour of the affected actors, in response to the different ROs. All actors will not necessarily react the same way when faced with a restriction, but they will choose among the available options.

The behavioural options that the Dossier Submitter deems most plausible are:

1. Switch to an alternative substance.
   This option is only available for the uses for which an alternative is available from EiF + allowed transition period.
2. Business relocation outside EEA.
3. Company would abandon business related to terphenyl, hydrogenated (globally).

SEAC finds these behavioural options reasonable and plausible; however, SEAC observes that the Dossier Submitter has not included a behavioural assumption for the HTF users, in the situation of a derogation with requirements to have strictly controlled closed systems. It seems as if the Dossier Submitter has an underlying assumption that the plausible response is to install the SCCS.

HTF

The Dossier Submitter states that close to two-thirds of the respondents that are using terphenyl, hydrogenated as HTF answered that they would switch to an alternative substance in case of RO3. The Dossier Submitter states that this result contrasts with the conclusion obtained in the assessment of alternatives, in which the response was that an alternative to terphenyl, hydrogenated as HTF is not currently available. The Dossier Submitter presents different explanations for these contrasting results: the respondents could switch to a similar substance (regrettable substitution), or the respondents could rely on their suppliers coming up with an alternative before the transition period runs out.

The Dossier Submitter highlights that it is likely that those who have replied in the consultation (during dossier development) that they would switch to an alternative, probably will consider other commercially available products, which have similar properties as terphenyl, hydrogenated (vPvB or PBT). The Dossier Submitter therefore assumes that 25 % of sites using terphenyl, hydrogenated would cease business, that 25 % would relocate and that 50 % would switch to alternative substances or technologies. The Dossier Submitter also assumes that 25 % of those switching would switch to substances that do not have the required thermal stability and therefore needs replacement every 2-4 years, due to the high degradation rate (instead of 20 years for terphenyl, hydrogenated). The Dossier Submitter assumes that the other 25 % would switch to an alternative heating system, which would carry very high investment costs.

SEAC finds that the Dossier Submitter's assumptions regarding these behavioural responses are not in accordance with the results from the questionnaire, and there is no explanation of why this is the case. Additionally, the questionnaire has few respondents, so it is unclear how representative the answers are. The Dossier Submitter has not given any other justification for the assumptions made. Therefore, SEAC finds that this is not well justified and that the basis for the cost calculations is uncertain.

40 comments regarding potential alternatives to terphenyl, hydrogenated when used as HTF have been received (#3589, #3591, #3637, #3658, #3659, #3660, #3661, #3663, #3664,

#3665, #3666, #3669, #3671, #3672, #3674, #3675, #3676, #3679, #3680, #3683, #3684, #3685, #3687, #3689, #3690, #3691, #3693, #3695, #3697, #3698, #3700, #3701, #3705, #3706, #3709, #3710, #3713, #3716, #3717, and #3720). The respondents are unaware of any alternative with the same properties and performance to be considered drop-in substitutes. Other potential alternatives will need time and economic efforts (extra costs related to design and R&D activities) to be evaluated. The properties of the alternatives and their compatibility with the materials and equipment of the current installations could lead to a change in the design of the HTF system (complete or massive). This could be economically not feasible (high cost) and could compromise the business. Also, these adaptations will increase the disposal of materials (fluid and equipment).

SEAC acknowledges the comments received in the consultation but highlights that these comments do not further clarify the behavioural assumptions for the use as HTF. What SEAC takes forward from these comments is that the Dossier Submitter's estimation that 50 % of industry would substitute could be an overestimation, as it is unlikely that the industry will have time and financial capacity to substitute to safer alternatives before EiF, and that substitution will take place with equally hazardous alternatives leading to regrettable substitution.

Use of terphenyl, hydrogenated as plasticiser in production and maintenance of aircrafts (A&D sector)

RO1 includes a derogation for the use of terphenyl, hydrogenated as a plasticiser in the production of aircrafts, with a transition period of 5 years. RO2 and RO3 does not include a derogation for this use and have the general transition period of 18 months.

The Dossier Submitter has different assumptions on the behavioural assumptions for the aerospace sector. The assumptions are based on scarce information from stakeholders. The Dossier Submitter assumes that 50 % of the market actors would substitute and that the other 50 % will cease their production. SEAC considers that the justification for the assumptions for the expected behavioural response are unclear, as are the assumptions themselves.

Comment # 3655, # 3662 and # 3707 from an industry association for aerospace and defence and a supplier to the A&D sector states that the industry reliant on terphenyl, hydrogenated will cease under RO3. The justification is the technical requirements, certification, and approval requirements.

The Dossier Submitter has not changed its opinion on the behavioural assumptions for the A&D sector after receiving the comments.

SEAC considers that the Dossier Submitter's justification for the expected behavioural responses is unclear.

SEAC considers the information from the industry submitted during the consultation on the Annex XV report to be more reliable than the evidence on which the Dossier Submitter based its assessment and would find it reasonable that a larger fraction of the industry will need to cease operations under all restriction options. However, SEAC does not have detailed information on exactly how large this fraction could be, nor the potential timelines for grounding airplanes and ceasing activity.

With a ban on the use of terphenyl, hydrogenated, manufacturing, maintenance, repair, and imports of A&D equipment will not be possible, and it means that affected aircraft and defence equipment will be grounded.

SEAC finds that the Dossier submitter's behavioural assumption on the reaction of aerospace and defence industry to a ban on terphenyl, hydrogenated are not realistic and that, based on comments submitted in the consultation, the impacts of such a ban on cessation of

activities that rely on terphenyl, hydrogenated in the A&D sector is underestimated by the dossier Submitter.

Other uses of terphenyl, hydrogenated

The Dossier Submitter notes that none of the respondents have indicated that a restriction would pose a problem for uses than other than HTF and as the use of the substance as plasticiser in production of aircrafts. The Dossier Submitter has therefore not suggested derogations for other uses in any of the restriction options 1,2 or 3.

The Dossier Submitter uses this information to conclude that all other uses will be able to switch to an alternative before the transition period has run out.

One response from a manufacturer (#3662) of components for the A&D industry using terphenyl, hydrogenated mixtures in their components was received. In this comment it was pointed out that terphenyl, hydrogenated, in addition to its use in the A&D industry, is also used in some medical, scientific, and industrial applications in formulations of catalysts, adhesives, encapsulants and paints.

No responses from the end-application users in the medical, scientific and process industry were received during the consultation on the Annex XV report. The Dossier Submitter in their response to comments states that this supports the view that the application of terphenyl, hydrogenated as plasticiser in other uses and applications has been replaced already or will be substituted shortly.

SEAC acknowledges that only one comment has been received during the consultation. SEAC also acknowledges that there are no comments from previous surveys (conducted by different actors like ECHA or the Dossier Submitter). SEAC agrees with the conclusion that this uses probably have been replaced or substituted, but in the comment received it is stated that there are no suitable alternatives to terphenyl, hydrogenated identified. SEAC has no information if regrettable substitution has already taken place, or if it is likely that regrettable substitution will take place as a consequence of the proposed restriction.

Economic impacts of RO3

Substitution and investment costs

Type of cost	**Plasticiser in aviation (in million €)**	**Other plasticiser use (in million €)**	**HTF (in million€)**
Chemical cost	0	0	50
R&D costs	1	1	3.75
Re-approval costs	1	0	0
Disposal costs	0	0	6.25
Cleaning and rinsing	0	0	0.75
Downtime during retrofitting	0	0	1 875
Refill	0	0	25

Investment and retrofitting	1	1	375
Investment: Installation of new technologies	0	0	3 750
Investment: installations of new plants outside EU	0	0	3 750
Decommissioning and disposal	0	0	187.5
Loss in efficiency and yield	0	0	9.37
Subtotal	3	2	10 032.62
Total	€ 10 037.62		

Plasticisers in the aviation industry:

The Dossier Submitter states that the Aviation industry commented, during the development of the dossier, that the wide range of applications and parts that are used within the aerospace and defence industry is significant The Dossier Submitter informs that one stakeholder provided a cost estimate of R&D costs of € 100 000 per company, and the DS used this to make an estimate of € 1 000 000 for the whole industry. The Dossier Submitter has also estimated, based on assumptions, a total investment cost of € 1 million, based on own assumption. The Dossier Submitter has not estimated additional operational costs due to a lack of information. The Dossier Submitter has also estimated a cost of € 1 million for re-approvals in the aviation sector, based on their own assumptions. This sums up to € 3 million for the A&D sector.

SEAC notes that the distinction between the restriction scenarios needs to be clear and justified, as it is crucial for estimating the costs.

The Dossier Submitter has no information on potential alternative substances. The Dossier Submitter has checked online services for chemical prices and find that it is reasonable to assume a cost of € 6 – 10 per kg, with an average value of € 8 per kg. The Dossier Submitter assumes that there are no additional costs for the chemical substitutes and due to lack of information the Dossier Submitter assumes that load levels and performance for alternatives are comparable.

SEAC finds that the estimated numbers are very uncertain, as the justification for the behavioural assumptions are unclear and that there is scarce justification, especially for the investment costs and the re-approval costs.

Comment # 3655 and # 3707 from an industry association representing aerospace and defence gives a qualitative description of the potential costs associated with all the restriction scenarios. They claim that the costs would be substantial, as the companies relying on terphenyl, hydrogenated would cease their production. This implies that the substitution costs, as estimated by the Dossier Submitter could be overestimated, as a consequence of less substitution and more cessation of activities. The potential loss of producer and consumer surplus will be discussed in the section on costs of loss in profits and reduced EU production below.

Other uses as plasticisers and other uses:

The Dossier Submitter states that for the non-aviation plasticisers and the other uses, there was no information from the stakeholders. The Dossier Submitter has thus assumed the same cost range as for the aviation industry, excluding the aviation industry's re-approval costs.

SEAC acknowledges that only one comment has been received during the consultation regarding the use as plasticiser and no comments related to the use as solvent/process medium, use as a laboratory chemical or miscellaneous use. SEAC also acknowledges that there are no comments from previous surveys (conducted by different actors like the ECHA or the Dossier Submitter).
SEAC finds that the estimation is uncertain, as it is based on scarce information.

HTF:

The Dossier Submitter has estimated the substitution costs for the HTF use by using information from the stakeholder consultation and by using literature sources.

In Annex A, the Dossier Submitter states that there are approximately 1 300 sites in EU, and in the impact assessment, the Dossier Submitter states that there are approximately 1 500 sites in the EU. 1 500 sites are used in the estimation of the substitution costs.

The Dossier Submitter has assumed that 50 % of the sites will substitute, and that 25 % of these will substitute to mineral oils which are less efficient and that the other 25 % will switch to high pressure vapour systems. This complete change of equipment would require significant capital investments to modify the installed equipment.

28 comments from HTF-users (#3589, #3637, #3658, #3659, #3660, #3661, #3664, #3665, #3666, #3669, #3672, #3675, #3676, #3680, #3683, #3687, #3690, #3691, #3693, #3695, #3696, #3703, #3705, #3709, #3710, #3716, #3717, and #3720) are related to the socio-economic impact of the restriction to terphenyl, hydrogenated. In general, the cost of the substitution of terphenyl, hydrogenated when used as HTF by a potential alternative is expected to be very high (up to € 9 million according to response #3710). These costs are related to the evaluation of alternatives (R&D costs), retrofit of the installation (design costs), emptying and cleaning of the system, disposal of waste (fluid and equipment), modification/construction of the installation, and downtime of production. In some cases, these costs make the business unviable, leading to the closure of production (or relocation outside the EU) and the consequent loss of jobs.

The few comments that have come up with quantified costs are on the same line as the costs estimated by the Dossier Submitter.

The Dossier Submitter has included costs related to business relocation out of the EU. SEAC does not concur with including these costs, as it could lead to an overestimation of the costs, although SEAC sees that a recalculation will have a minor impact on the overall costs.

SEAC finds that uncertainty about the behavioural assumptions could imply that the substitution costs are underestimated as a consequence of less substitution and more cessation. The potential loss of producer and consumer surplus will be discussed in the section on costs of loss in profits and reduced EU production below. The Dossier Submitter has not given any response to the comments mentioned above that indicate that the costs of substitution could be so substantial that they would lead to closure or production or relocation. SEAC finds that this indicates that the fraction of the industry that actually will substitute might be overestimated.

Cost of loss in profits and reduced EU production

If companies must reduce their EU production and sales of products temporarily or permanently, there will be associated profit losses, which are considered as costs to the society. The "sales at risk" are represented by substances and products for which a reduction in sales due to a restriction on terphenyl, hydrogenated is most likely.

Upstream profit loss

The Dossier Submitter estimates a profit loss for the (manufacturers and) importers of terphenyl, hydrogenated of € 268 million for the HTF market, a profit loss of € 17.2 million for plasticisers in aviation and a profit loss of € 13.62 million for other uses, using the tonnages, a tonnage price of € 8000 per tonne and a common gross margin of 25 %.

First, according to SEAC, only the fraction of the industry that would cease production or relocate, has profits at risk in this scenario. The Dossier submitter has included the whole volume for HTF and plasticisers, which leads to an overestimation.

The reason for not including the fraction of the industry where the assumption is that they switch to an alternative substance with the same price, is that the lost profits from the sale of terphenyl will be outbalanced by the increased profits from the sales of the alternatives. Terphenyl, hydrogenated is not manufactured in the EU, and there would be no issues with EU production being relocated to outside of the EU.

SEAC would first suggest that the values for the HTF and A&D sector should be halved, according to the assumption that 50 % would cease their production. This implies that the Dossier Submitters estimate is likely overestimated. Secondly SEAC will question the length of the analytical period for calculating the profit loss. The Dossier Submitter has not given an explanation. The last point implies that SEAC does not know all the assumptions behind the estimation and can thus not conclude if it is reliable or not.

Downstream profit loss

A&D sector

The Dossier Submitter has estimated a profit loss of € 164 million for downstream use of plasticisers in the aviation industry.

SEAC finds it difficult to understand what this profit loss is representing. € 41 million is the estimate for yearly profits at risk in the A&D sector, in the restriction proposal for Dechlorane Plus. The Dossier Submitter has not justified why this estimate could be used for terphenyl, hydrogenated in the aviation sector, except stating that the uses are similar. It is not justified if the volumes and values are similar.

As mentioned above, comment # 3655 and # 3707 to the public consultation indicates that the profits at risk for the A&D sector are significantly underestimated, but they have only provided qualitative arguments, not any estimates per se.

The comments state that the profits at risk affect not only the aerospace and defence companies but their supply chain and third-part facilities (maintenance, repair and overhaul). Cease in delivery of A&D products and spare parts to the EEA will lead to inability to service and repair existing A&D products, aircrafts could be grounded, and defence fleets immobilised.

The comments stats that the airplanes will lose their airworthiness certification and will need to be grounded if no suitable alternative is found to replace terphenyl, hydrogenated on time.

The behavioural assumptions will affect the cost estimations, as it is defining which costs to include. SEAC finds it reasonable to take the qualitative assessment provided by ASD/AIA as reliable. SEAC recognises that the Dossier Submitter has not updated the cost estimates or qualitative assessment of costs for the aviation sector.

The order of magnitude of costs can be corroborated with information from one application for Authorisation on OPE, as referred to in comment #3655 and # 3707. The comments refer to an AfA, concerning the use of OPE in sealants the aviation industry. OPE has a similar use as terphenyl, hydrogenated in sealants. ASD/AIA states that the cost estimate done in this AfA can be used to give a better understanding of the costs, although the use and extent is not perfectly similar. Members of Ethoxylates in Aerospace Authorisation consortium estimated the cost in the AfA is € 5 940 –25 940M (annualized). The comment states that for terphenyl, hydrogenated, the monetized impact is likely significantly higher, as A&D relies on many other sealants/adhesives containing terphenyl, hydrogenated that do not also contain OPE.

SEAC finds that the cost estimate from the AfA is significantly higher than the Dossier Submitters estimate. SEAC also finds that the estimate from the AfA is only for the members of EEAC and thus should be multiplied by an unknown number to represent the whole sector. SEAC does not know this consortium's share of the total market, but as SEAC knows that it does not represent the whole market, it is likely that the costs estimated in the AfA is an underestimation of the costs for the A&D sector.

SEAC considers the Dossier Submitters cost estimate as significantly underestimated.

HTF

The Dossier Submitter has estimated a revenue loss of € 53,12 million € per year for the PET market and thus a revenue loss of € 106,25 million per year for all downstream use of HTF. The estimation is based on an estimation of the profits at risk in the PET market, and an assumption that all other HTF uses will have a similar loss.

SEAC find the estimations for the PET market partly well justified and finds that the assumption that all other uses have a similar profit loss is not well justified. Although SEAC sees that the estimation gives an indication of the possible cost level.

Other uses

The Dossier Submitter considers that the other uses don't have profits at risk, as it is assumed that the uses have substituted to alternatives before the end of the transition period. SEAC finds this reasonable.

Table 16: Lost profits per sector (source, Background document)

Type of lost profits	Aviation (in million €)	Other (in million €)	HTF (in million €)
Sale of terphenyl, hydrogenated by manufacturers and importers	1,72	0	26,8
Downstream user sales	164	0	425
subtotal	165,72	0	451,8
total	617,52		

Enforcement costs

The Dossier Submitter has based the estimation of the enforcement costs on the average administrative cost of enforcing a restriction estimated by ECHA, of € 55 000 € per year.

The Dossier Submitter finds that the enforcement costs for all EEA 30 over 20 years will be € 1,1 million and have distributed these evenly over the three different uses, resulting in a cost of € 0,37 million for each use.

SEAC agrees with this estimation.

Summary of costs for RO3

Table 17: Summary of costs for RO3

Type of cost	Aviation (in million €)	Other (in million €)	HTF (in million €)
Substitution and investment	3	2	10 032.62
Profit loss	165,72	0	451,80
Enforcement costs	0,37	0,37	0,37
subtotals	169,09	2,37	10 484,79
% Of total costs			
Total sum	€ 10 656,25		

Economic impacts of RO2

The difference between RO3 and RO2 is that there is a derogation in place for all HTF uses. Consequently, the costs for all non-HTF uses remain the same as in RO3.

Most of the costs related to HTF uses will not be incurred, except for enforcement costs and costs related to structural and organisational improvements of the plants, as needed to fulfil the requirements for strictly controlled closed loop.

During the stakeholder consultation, costs for those improvements were communicated to be € 10 000 – 30 000. The Dossier Submitter assumes an average cost of € 20 000. With 1 500 sites, this sums up to € 30 million. The on-site measurements conducted in several HTF plants demonstrated that most had these strictly controlled closed systems in place and potentially only training is needed. This could indicate that the costs are overestimated.

Table 18: Total costs for RO2

Type of cost	Aviation (in million €)	Other (in million €)	HTF (in million €)
Substitution and investment	3	2	30
Profit loss	165,72	0	0

Enforcement costs	0,37	0,37	0,37
subtotals	169,09	2,37	30,37
% of total costs	83,68	1,17	15,05
Total sum	201.82		

Economic impacts of RO1

Regarding RO1, the costs for HTF use and the "other" plasticiser use remain the same as for RO2.

The Dossier Submitter has estimated a profit loss for the A&D sector of € 83 million. The Dossier Submitter believes that this is a worst-case consideration and potentially an overestimation. The Dossier Submitter considers that the 5-year derogation (after EiF) should provide most actors in the industry time to substitute to a less hazardous substance.

SEAC finds that the Dossier Submitter has not clearly explained how they came up with the estimation of € 83 million.

Comment # 3655 and # 3707 to the public consultation provided evidence that 5 years is not sufficient for the aviation sector and that they would need between 4,5 and 13 years to substitute and re-certificate to be in compliance with the specific requirements for aviation. The comments are not clear about the costs related to a 5-year derogation.

SEAC finds that the fraction of substitution and cessation is crucial to define the profits at risk in the A&D sector in RO1. It seems like the Dossier Submitter assumes a drop-in substitute, but they have not specified if it is 100 % or not. SEAC finds that if there is a drop-in alternative available after EiF + 5 years, it is reasonable that there are no profits at risk.

On the other hand, if SEAC takes into account the comments from the A&D sector, there might not be any substitution after 5 years, and the profits at risk are thus the same as for RO 2 and RO 3.

SEAC finds that zero could be a lower bound for the profits at risk in RO1 and that € 170 million, as in RO 2 and RO3 could be a higher bound. Although the higher bound is highly uncertain as SEAC has found it likely to be significantly underestimated.

Table 19: Total costs for RO1 (consisting of substitution costs, investment costs, profit losses as well as enforcement costs)

Type of cost	Aviation (in million €)	Other (in million €)	HTF (in million €)
Substitution and investment	3	2	30
Profit loss	82,86	0	0
Enforcement costs	0,37	0,37	0,37
subtotals	86,23	2,37	30,37
% Of total costs	72,48	1,99	25,53

Total sum	118,96

Table 20: Comparison of total costs for RO1-RO3

Type of cost	RO1 (in million €)	RO2 (in million €)	RO3 (in million €)
Substitution	35	35	10 037,62
Profit losses	82,86	165,72	617,52
Enforcement costs	1,1	1,1	1,1
total	118,96	201,82	10656,24

The Dossier submitter states that RO3 shows the highest costs, since it is the most severe RO.

SEAC finds the differences between the costs for the different ROs reasonable, as the differences reflect the costs for HTF and aviation.

5. Annex 2

How to reach the Strictly Controlled Closed System (SCCS) condition in heat transfer systems using Terphenyl, hydrogenated as HTF

Executive Summary

The REACH restriction on Terphenyl, hydrogenated outlines two options (RO1 and RO2) which derogate heat transfer fluid (HTF) uses at industrial sites if such sites implement strictly controlled closed systems (SCCS). This document aims to ensure an adequate level of technical preparation and design of a plant to guarantee an elevated level of protection against environmental releases. The document can be applied to other organic HTFs similar to Terphenyl, hydrogenated if REACH Restrictions are introduced for other HTFs.

As the term SCCS is not defined yet, this document aims to establish clear instructions for downstream users to ensure continued safe use of the substance and enable authorities to be able to verify compliance with these conditions during inspections. The document aims to develop the SCCS condition by taking references and combining criteria from existing EU Legislation or official EU Guidance Documents, including:

- Strictly Controlled Conditions (SCCs)
  - ECHA Practical Guide 16 (ECHA, 2014)
  - REACH Article 18
- CMR Directive (Article 5) on the prevention and reduction of exposure via closed systems
- The IPPC Directive, including Best Available Techniques (BAT), as outlined in the BAT Reference Document (BREF) on i.e., Production of Polymers (COM, 2007)
- Seveso Directive
- European Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (Pressure Equipment Directive – PED)
- German Standard DIN 4754-1 (DIN, 2015), 'Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test'
- US Standard NFPA 87 (Standard for Fluid Heaters)
- References and documents on HTF Systems from the Employers Mutual Insurance Association (Berufsgenossenschaft Rohstoffe und Chemische Industrie), the German Legal Accident Insurance (DGUV) and the Risk Engineering Guideline from Insurer HDI
- Operational procedures from existing restrictions (e.g., Isocyanates) or the Guideline for industrial users of 1-methyl-2-pyrrolidone (NMP) to help them comply with the substance's restriction requirements (ECHA 2020; ECHA, 2019)

This document covers:

- Design and construction
- Fill & Start-Up (unloading & loading)
- Operation & Maintenance (incl. storage)
- Dismantling/Decommissioning & Waste
- Inspections & Training

The document contains in an Annex an Inspection Check List to enable control of the Heat Transfer Systems designed to achieve the SCCS condition and the enforceability of the criteria.

1. Introduction

1.1. For whom is this document written?

This document is addressed to HTF downstream users (DUs) of Terphenyl, hydrogenated in order to provide practical advice and assist users in complying with their obligations under the HTF Derogation of Terphenyl, hydrogenated within the Terphenyl, hydrogenated Restriction. It is furthermore addressed to enforcement authorities in order to verify compliance during inspections. The attached inspection checklist will be an extremely useful tool to audit compliance on-site.

The basic concept of this document, particularly related to the case of HTF, is to demonstrate enclosure, avoidance of leakages and releases to the environment. An adequate level of technical preparation and design of a plant to guarantee elevated level of protection against environmental releases is lacking under the SCC descriptions. Therefore, this document intends to combine the different elements in one document.

This document applies to heat transfer installations in which Terphenyl, hydrogenated is used as a Heat Transfer Fluid, heated to temperatures below or above its initial boiling point at atmospheric pressure. The installations shall be designed and constructed (new installations), adapted (existing installations), and operated according to the technical requirements and operational procedures as outlined in this document in order to assure their technically tightness and that they remain technically tight.

The operator of each HTF plant shall ensure that the equipment is provided and operated in such a way that they safely withstand the mechanical, chemical, and thermal stresses to be expected due to the intended mode of operation in order to avoid any releases and exposure.

Compliance with this document will be mandatory for all current and future installations to comply with the derogation conditions of the HTF use in the Terphenyl, hydrogenated restriction.

The general approach described in this document can be applied to other organic HTFs, alike to Terphenyl, hydrogenated, if similar REACH Restrictions are introduced for other HTFs.

1.2. The restriction proposal

Restriction Options RO1 and RO2 include a derogation that shall apply for the use of Terphenyl, hydrogenated as HTF at industrial sites, provided that such sites implement strictly controlled closed systems with technical containment and other measures, to minimise environmental emissions.

However, as the term **Strictly Controlled Closed Systems (SCCS)** is not defined yet, it will be difficult for plant operators and enforcement authorities to verify compliance with these conditions.

The term "*Strictly Controlled Closed System*" was introduced into REACH via the Restriction of the Siloxanes (D4, D5, D6)[25] as outlined below:

"*The use of D5 is under Restriction Condition 6.a derogated from the restriction in strictly controlled closed dry-cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated and are only permitted when strict operational conditions and risk management measures are adopted (e.g., use of closed systems).*"

According to the Final BD of the Siloxanes Restriction[26], the wording proposed should be interpreted by analogy to:

(i) the concept of Strictly Controlled Conditions (SCC) for Intermediates under REACH[27], and

(ii) from a derogation included in existing restriction entry forty-six in Annex XVII (on the use of nonylphenol for industrial washing and cleaning) (e.g., "*closed*" processes).[28]

The derogations in Entry 46 of REACH Annex XVII reads as follows:

…."controlled closed systems where the washing liquid is recycled or incinerated."

Unfortunately, no further technical description and process safety measures are provided.

1.3. The Guide on strictly controlled conditions

ECHA Practical Guide 16[29] (ECHA, 2014) sets out the requirements to verify whether a substance is used as an intermediate under Strictly Controlled Conditions (SCCs). The legal background is related to intermediates and their reduced information requirements, if managed under SCC.

As the use of Terphenyl, hydrogenated as HTF in heat transfer systems is not considered intermediate, this Guide cannot be considered completely appropriate to describe this use. However, it could be a good starting point for the definition of SCCS.

SCC are addressed in the law under REACH Article 18, as summarized below:

- the substance is rigorously contained by technical means during its whole life cycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

- procedural and control technologies shall be used that minimise emission and any resulting exposure;

[25] Registry of restriction intentions until outcome - ECHA (europa.eu)

[26] Microsoft Word - REST_D4D5D6_FinalBD.docx (europa.eu)

[27] 291b6e50-5598-42d3-8a2b-d63d50a68104 (europa.eu)

[28] e5842a1e-e9f9-6096-2829-72f71c00eaab (europa.eu)

[29] 291b6e50-5598-42d3-8a2b-d63d50a68104 (europa.eu)

- only trained and authorised personnel manage the substance;
- in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
- substance-handling procedures are well documented and strictly supervised by the site operator.

SCCs under REACH are described as "*a combination of technical measures that are underpinned by operating procedures and management systems*" Those measures include:

- Rigorous containment of the substance by technical means, supported by procedural and control technologies in place, used to minimize emissions and resulting exposure (including during sampling, cleaning, and maintenance).
- Management systems in place, specifying that handling of the substance must be performed by trained, authorised, and supervised personnel in accordance with well documented procedures.
- Special procedures in place for cleaning and maintenance.
- Procedural and/or control technologies in place to deal with accidents, waste management and, in a more generic way, to minimise emissions and exposure.

The Guide on SCCs puts specific emphasis on the following additional items:

- Systems need to be designed with the objective of minimising exposure, including in loading and unloading operations. A number of options for this are provided, focused on enclosure and isolation.
- Ancillary equipment (pipelines, pumps) must be designed and installed in a way that will ensure containment at all times.
- Special procedures are expected for activities not directly related to the use of the substance, e.g., cleaning and maintenance and associated technical requirements (purging, washing). Also control of wastewater or air emissions from those activities have to be treated / collected in order to minimise eventual releases of the substance to the environment. Moreover, permit-to-work procedures need to be in place for these activities, in order to ensure that workers will always be aware of potential safety requirements of the operations.
- Although PPE can be used as "*good practice*" procedures, it has to be underlined that rigorous containment should be achieved without taking into account the use of PPE.
- The implementation of RMMs to control releases to the environment below threshold values (e.g., local PNEC) is not sufficient to justify SCCs. Technical measures have to be in place in addition to the regular emissions reduction measures in order to demonstrate that emissions are effectively minimised.
- Waste handling and management (including wastewater treatment plants – WWTP) is subject to the same requirements as handling of the substance under normal operations. Some specific indications related to waste collection are:
    - Collection of waste in sealed drums in a dedicated filling station, equipped with glove box and an integrated LEV.

- Collection of liquid waste in road tankers. Loading and unloading of truck tanks taking place in dedicated stations. Tanks to be provided with vapour recovery systems, connection of tanks to loading system through flexible hoses, using dry-break couplings. Hoses to be drained and purged before they are connected and/or disconnected. Systems are provided with integrated LEV or other air-dynamic barriers.

- Monitoring of the process for the presence of emissions and releases and measuring of the exposure of workers and/or the environment is one option to confirm the integrity and effectiveness of the rigorous containment methods that are implemented. In this regard, measurement of the (potential) releases of the substance to different environmental compartments may be required to demonstrate compliance with environmental legislation such as the IED Directive (Directive 2010/75/EU replacing the IPPC Directive)[30], water discharge permits and so on. Other adequate procedures are acceptable too.
- Suppliers of a substance that is intended to be used under SCCs has to recommend the relevant Risk Management Measures (RMMs) to its downstream users. In the case of terphenyl hydrogenated, it is clear that it would be for the user to apply SCCs or any equivalent level of protection. It would be recommendable for the user of terphenyl hydrogenated to confirm in writing to the permitting authority of the HTF plant that they abide to the relevant RMMs and the requirements in this document.

1.4. Other reference documents

Moreover, there is other EU Legislation or official EU Guidance Documents which were used as valuable references for the definition of SCCS.

For example, the EU's **CMR Directive**[31] is addressing in Article 5 the prevention and reduction of exposure via closed systems. Unfortunately, this term is not included in the definitions.

The **IPPC Directive**[32], which in essence is about minimising pollution from various industrial sources throughout the European Union, was consulted too. The IPPC Directive is based on several principles, including Best Available Techniques (BAT), as outlined in the BAT Reference Document (BREF) on i.e., Production of Polymers (COM, 2007)[33] and is applicable to operators of industrial installations.

In addition, the **Seveso Directive**[34] (Directive 2012/18/EU) was used as a reference, which was enacted to prevent major accidents and to ensure appropriate preparedness and response should such accidents nevertheless happen.

[30] The Industrial Emissions Directive - Environment - European Commission (europa.eu)

[31] EUR-Lex - 02004L0037-20220405 - EN - EUR-Lex (europa.eu)

[32] EUR-Lex - 32010L0075 - EN - EUR-Lex (europa.eu)

[33] Production of Polymers | Eippcb (europa.eu)

[34] EUR-Lex - 32012L0018 - EN - EUR-Lex (europa.eu)

Furthermore, the European Directive 2014/68/EU[35] on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (**Pressure Equipment Directive – PED**) was used as a reference. PED is applicable to Terphenyl, hydrogenated because for most of the systems the maximum allowable temperature of the HTF installations (325-350°C) exceeds the flashpoint of the substance (170°C), according to Point 1(a) of Article 13 to PED.

Besides, the **German Standard DIN 4754-1** (DIN, 2015)[36], 'Heat transfer installations working with organic HTFs - Part 1: Safety requirements, test', was used. This standard applies to heat transfer appliances in which organic HTFs are being heated with atmospheric pressure to reach a temperature above or below their initial boiling point.

The document applies to heating appliances only as far as the pipes of the heater contain the HTFs. The document has the purpose of satisfying protection targets for the production and supply, in particular those specified in the PED.

The **US Standard NFPA 87**[37] (Standard for Fluid Heaters) was considered as well. It provides safety guidance for fluid heaters and related equipment to minimize fire and explosion hazards that can endanger the fluid heater, the building, or personnel to avoid leakages and thus emissions.

Moreover, references and documents on HTF Systems from the **Employers Mutual Insurance Association** (Berufsgenossenschaft Rohstoffe und Chemische Industrie)[38], the **German Legal Accident Insurance** (DGUV)[39] and the Risk Engineering Guideline from **Insurer HDI**[40] were consulted.

Finally, **operational procedures** from existing restrictions (e.g., **Isocyanates**[41]) or the **Guideline** for industrial users of 1-methyl-2-pyrrolidone (**NMP**) to help them comply with the substance's restriction requirements (ECHA 2020; ECHA, 2019)[42].

These legislations, guidelines, and standards shall be used as a basic requirement when designing, building, and operating new systems. In addition, existing systems must be assessed on a regular basis using the most up-to-date standards and to improve the structural and organisational matters if applicable.

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[35] EUR-Lex - 32014L0068 - EN - EUR-Lex (europa.eu)

[36] DIN 4754-1 - 2015-03 - Beuth.de

[37] NFPA 87: Standard for Fluid Heaters

[38] DGUV Regel 100-500 Betreiben von Arbeitsmitteln | DGUV Publikationen

[39] Microsoft Word - V_3.11 Sicherheitsbetrachtungen beim Betreiben von WÃ¤rmeÃ¼bertragungsanlagen mit organischen WÃ¤rmetrÃ¤gern.docx (bgrci.de)

[40] 20190305_403-HRC-REG130GB__heat_transfer_oil_systems.pdf (hdi.global)

[41] Registry of restriction intentions until outcome - ECHA (europa.eu)

[42] All news - ECHA (europa.eu)

2. Design and construction

The installations using Terphenyl, hydrogenated as HTF shall be designed and constructed (new installations) and adapted (existing installations) according to technical requirements and operational procedures as outlined in this document.

The installations shall comply with all of the applicable legislation in force, at the European, national, regional, and local levels, related to the design and construction of heat transfer systems, in order to assure that during operation the protection of human health and the environment is guaranteed. Specifically, the main European legislation to consider is the Pressure Equipment Directive – PED.

According to PED, the heat transfer system shall be designed, constructed, and equipped in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.

Furthermore, in order to achieve the SCCS condition, the complete heat transfer system installation (it means, all of the equipment involved in the process) shall be designed, constructed, and adapted to ensure rigorous containment of Terphenyl, hydrogenated, in order to minimise releases and, consequently, the possibility of exposure to the environment (ECHA, 2014). In fact, ECHA Guidance on intermediates (ECHA, 2010)[43] states that rigorous containment can be only achieved by the technical design of the equipment which aims at preventing releases. This design will consider the physico-chemical properties of Terphenyl, hydrogenated and the process conditions, and the release of Terphenyl, hydrogenated will be prevented through containment systems. In addition, plant components shall be considered to be technically leak tight if they are designed such that they remain technically leak tight due to their construction (BAUA, 2022).

All of the components of the heat transfer system, including heat exchangers, piping, insulation, pumps, valves, gaskets, seals, relief devices, and instrumentation, must be selected during the design process for compatibility with Terphenyl, hydrogenated and the intended system temperature and pressure. Any component not specifically suitable for Terphenyl, hydrogenated shall be used with extreme caution. In addition, the components of the system must accommodate all expected temperature extreme. Thermal growth in heat transfer systems operated with organic fluids requires careful study because they can experience larger temperature variations (GAP, 2013).

Therefore, it is important that, during the designing and building of the heat transfer system, the system designer and the Terphenyl, hydrogenated manufacturer are consulted for advice on the choice of, e.g., the gasketing material (for joints) and the packing material (for valves and pumps) that will provide the best leak-free service for Terphenyl, hydrogenated at the intended operating temperatures and pressures, and considering the operating environment, both internal and external (FM Global, 2022).

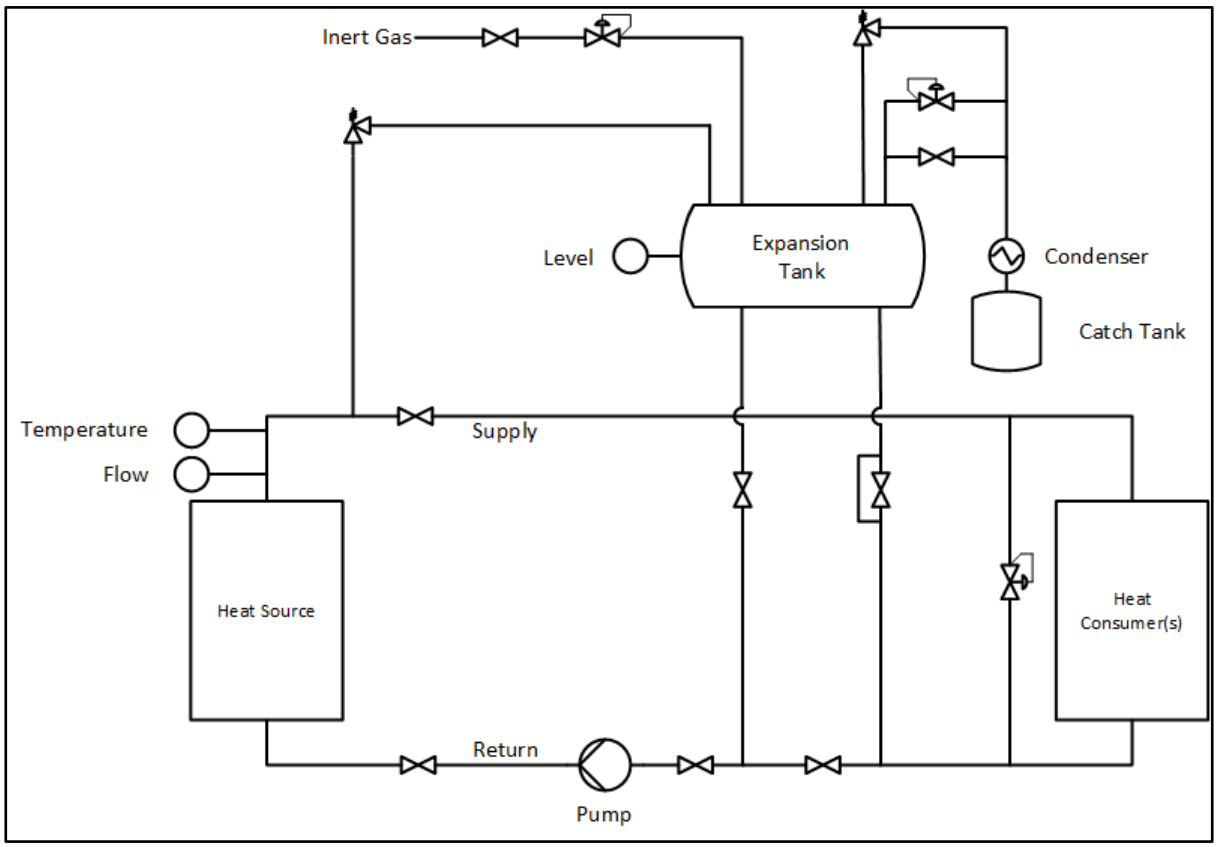
Although Terphenyl, hydrogenated is used in a wide number of sectors and settings, the heat transfer system installations are similar across industry sectors. For this reason, it is possible

[43] https://echa.europa.eu/documents/10162/2324906/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641

to establish general and common risk management measures through the design process (ECHA, 2019).

There are many technical means that can be considered during the design of the heat transfer system installations to prevent emissions by containment. Due to this fact, all of the reference texts considered in this document do not define any exhaustive list of equipment or technical requirements. As stated in German Standard DIN 4754-1 (DIN, 2015), deviations from its requirements are possible if it can be demonstrated that the safety standard of that standard is met in another way. In addition, the same standard provides that other requirements can be observed, as the specified in valid statutory regulations and regulations, as well as regulations of accident insurance institutions. Due to this, the technical means and equipment named in this section, and also in the other sections of this document, shall be considered exclusively as examples.
Non-pressurized HTF systems are operating below the boiling point of the fluid (like systems using Terphenyl, hydrogenated) but are still working under a system pressure which is greater than the atmospheric one. The pressure is typical a few bars. Therefore, they can only operate reliably and efficient if the plant is tight.

Figure 1: Schematic Heat Transfer Fluid System.



2.1. Heat transfer system area

The construction of the heat transfer system shall be conducted on an impermeable surface (e.g., concrete) to avoid soil contamination in case of potential emission, and to facilitate the cleaning and containment of the leakage.

The area under the system shall be coupled with sloped floors, and curbs, dikes, and controlled drainage systems must be designed to divert potential leakage and runoff to a safe location, to prevent a potential Terphenyl, hydrogenated spill from flowing into adjacent production areas, storage areas, or floors below (FM Global, 2022). Drainage to a waste treatment facility would be the ideal protection measure. However, at a minimum a dike at the thermal heater or boiler to contain Terphenyl, hydrogenated in this area is critical (GAP, 2013). In any case, the drainage of contaminated effluents must be stored in closed systems (COM, 2007).

2.2. Vessels and tanks

According to the generic BAT for equipment design described in the BREF for polymers (COM, 2007), the process vessels shall be equipped with vents to prevent pressure build up by inert gases. This is also a requirement of the PED in order to avoid harmful effects, such as water hammer, vacuum collapse, corrosion, and uncontrolled chemical reactions, and to permit cleaning, inspection, and maintenance in a safe manner. These vents are also used to depressurise and flush equipment during emergencies and prior to maintenance. The best option is that venting and expansion lines are routed into collection systems (BAUA, 2022) and connected to air pollution control equipment.

To prevent leaks from relief vents, rupture disks can be used in combination with safety valves. The pressure between the rupture disc and the safety valve is monitored to detect any leaks. If the safety valves are connected to an incinerator, rupture disks may not be necessary (COM, 2007).

An effective BAT is to design and construct calamity basins/tanks to control potential accidents during the processes involving high volumes of Terphenyl, hydrogenated that are out of the usual operational conditions (filling and drain). These tanks, used for the safe storage of escaping Terphenyl, hydrogenated, may be of metallic materials or other material, such as concrete with oil-repellent coating (DIN, 2015).

2.3. Piping and piping parts

The piping installation must be designed with appropriate and resistant materials to prevent breakages that could lead to environmental pollution (COM, 2007). Welded construction must be used whenever possible (GAP, 2013; DIN, 2015).

In addition, the thermal expansion must be taken into account by the appropriate routing of the piping or by installing suitable expansion joints (DIN, 2015). The number of flanges (connectors) must be minimised to avoid potential leaking points and to accommodate only fundamental/essential major equipment isolation and/or removal, and the gaskets must be effective (COM, 2007).

In order to prevent the escape of large quantities of Terphenyl, hydrogenated, stop valves in the flow and return pipes are to be installed. This is especially important in systems containing more than five tonnes of Terphenyl, hydrogenated. These stop valves are to be actuated from a

safe position. The stop valves shall be of proven suitability, or their suitability shall be documented by providing the results of testing from the valve manufacturer or an accredited expert (DIN, 2015).

2.4. Pumps

In order to prevent and minimise emissions, the use of magnetically driven or canned motor pumps, or pumps with double seals and/or a liquid barrier is recommended (COM, 2007).

The pump housings must be designed to withstand at least a maximum pressure of 16 bar. The shaft seals must be of proven suitability, or their suitability must be demonstrated, e.g., by submitting test results from the pump manufacturer or an accredited expert (DIN, 2015).

It must be ensured that potential heat transfer fluid leaks from the shaft seal are safely diverted and collected (DIN, 2015). Therefore, it is recommended that pumps are surrounded by curbs (FM Global, 2022).

2.5. Thermal insulation

At points where there is a risk of Terphenyl, hydrogenated leaking (e.g., at flange connections and fittings), the thermal insulation shall be designed in such a way that potential leaks can be detected with the lowest response timing (DIN, 2015).

2.6. Sampling points

In order to prevent and minimise emissions, special equipment shall be used at sampling points to ensure that only small quantities of Terphenyl, hydrogenated can escape (BAUA, 2022).

2.7. Other technically leak-tight plant components

Other components that can be included in the design and construction of heat transfer systems operating with Terphenyl, hydrogenated as HTF in order to prevent and minimise emissions to the environment are the following (COM, 2007; BAUA, 2022; DIN 2015):

- valves with bellow
- valves with double packing seals
- valves with sealing of the spindle feedthrough by means of bellows and safety stuffing box
- flanges with weld lip gaskets
- flanges with flat faces
- flanges with raised faces
- flanges with tongue and groove faces
- flanges with protrusion and recess
- flanges with V-grooves and V-groove gaskets
- flanges with smooth sealing faces and special gaskets (e.g., soft gaskets up to twenty-five bar, gaskets with metal inner rim, grooved gaskets, corrugated gaskets, or metal jacketed gaskets, if a mathematical check shows sufficient safety against the yield point when using standard flanges)
- flanges with smooth sealing strip and no special design requirements for the seal
- cutting and clamping ring connections
- shaft seals with double-acting mechanical seal

- shaft seals based on simple operating principles (e.g., single-acting mechanical seals or stuffing boxes)
- metal-sealed connections

In case this kind of components, or any of the other components listed in this section (e.g., pumps), cannot be considered during the design and construction stages of the heat transfer system using Terphenyl, hydrogenated as HTF, and standard components are used instead, containment devices shall be installed beneath them.

2.8. Control equipment and safety devices

The instrumentation, the control equipment, and the safety devices (e.g., Terphenyl, hydrogenated level monitors) shall be designed to ensure that the heat transfer system and the process remain safe (GAP, 2013)

3. Fill & Start-Up (unloading & loading)

The processes of filling, start-up, shutdown, and drain of the heat transfer system are out of the usual operational conditions of the installation. In the processes of filling and drain of the HTF, that can occur before the start-up and after the shutdown (respectively) of the installation, Terphenyl, hydrogenated is managed out of the heat transfer system. Therefore, these processes are potential emission sources of Terphenyl, hydrogenated and, for this reason, special containment measures shall be taken for their performance.

According to PED, the heat transfer system shall be provided with accessories to ensure safe filling and drain (discharge), in particular with respect to the following risks:

- On filling: overfilling or over pressurisation
- On drain: uncontrolled release of the fluid
- On filling or drain: unsafe connection and disconnection

A generic BAT in order to avoid potential emissions to the environment related to these processes is to minimise plant start-ups and shutdowns. This can be achieved through improved operation stability (assisted by monitoring and control systems) and equipment reliability. Emergency stops can be avoided by timely identification of deviating conditions followed by the application of a controlled shutdown process (COM, 2007).

The renewal of the Terphenyl, hydrogenated in the heat transfer system is required because the substance begins after many years in service to age (in some cases until 20-30 years), resulting in degradation products, an increase in viscosity, and solids may begin to form. Once the Terphenyl, hydrogenated quality has been analysed and found to be compromised, corrective actions have to be performed (e.g., partial or complete drain).

After the fluid has been cooled to a safe level, it can safely be drained via pumps, following appropriate written procedures, from the system into storage tanks for disposal. The removal of the fluid from the system as well as the fill with new Terphenyl, hydrogenated takes place in sealed and contained areas.

Filling and drain processes of Terphenyl, hydrogenated shall only be undertaken by qualified personnel (DIN, 2015).

During the period in which the installation is filled and started up, it is necessary to continuously monitor all connections, heat transfer system components, and pipes for leakages. Likewise, the pipeline network shall be controlled (e.g., the fixed and sliding supports) to ensure that it is correctly installed (VDI, 1995).

To ensure that the heat transfer system will be leak-free when filled and started up with Terphenyl, hydrogenated, it is recommended to conduct special leakage testing in addition to a general hydrostatic test. It has to be noted that a pipeline may pass a hydrostatic test and yet have leaks when the heat transfer fluid is used. The details of leakage testing procedures can be obtained from the system designer and manufacturer of Terphenyl, hydrogenated (FM Global, 2022). The most common and reliable leakage testing is the detection of leakages by painting joints (flanged or welded connections, etc.) with suitable wetting agents, e.g., soap solutions (VDI, 1995). This leakage detection testing can be performed by the procedures defined in the German standard DIN 4754 (DIN, 2015).

In order to facilitate the detection of leakages during filling and start up, thermal insulation shall not be applied in the potential leak points until after an operating period of about 30 to 50 hours has exposed and after the installation has been exposed to one or more heating/cooling cycles (VDI, 1995).

After each filling and start-up processes, the heat transfer system must be checked visually for leakages (VDI, 1995).

The control and testing procedures during shutdown and drain processes are equivalent to those set out above for filling and start-up processes.

4. Operation & Maintenance (incl. storage)

4.1. Operation

The heat transfer systems using Terphenyl, hydrogenated as HTF shall be operated according to technical requirements and operational procedures as outlined in the operational manual of the system designer and this document.

According to PED, the method of operation specified for the heat transfer system shall be such as to preclude any reasonably foreseeable risk in the operation of the equipment. In order to ensure that the heat transfer system and the process remain safe during operation, operating limits for temperature, pressure, Terphenyl, hydrogenated level, flow rates, and chemical composition of Terphenyl, hydrogenated shall be established for the heat transfer system and the process it serves (GAP, 2013).

The technical measures introduced during the design and construction stages, such as control engineering safety devices, aim at fully enclosing the system and avoiding emissions to the environment during operation. For their part, the organisational measures, such as written methods (operating procedures, working instructions, permits to work, etc.), aim to maintain the process conditions achieved by the technical measures.

Detailed written methods (procedures, instructions, and permits) for all normal and emergency operations shall be provided. These written procedures shall be supplemented

with formal operator training programs for initial qualification and periodic refresher training (GAP, 2013). The existence of written procedures and instructions is also a requirement of some of the conformity assessment procedures applicable to pressure equipment according to PED.

The adoption and implementation of these written procedures, instructions, and permits for safe operation, constitutes the operation control of the heat transfer system. As stated in the Seveso Directive, the operational control includes:

- maintenance, of plant, processes, and equipment
- alarm management and temporary stoppages
- consideration of the available information on best practices for monitoring and control, with a view to reducing the risk of system failure
- management and control of the risks associated with ageing equipment installed in the establishment and corrosion
- inventory of the equipment, strategy, and methodology for monitoring and control of the condition of the equipment
- appropriate follow-up actions and any necessary countermeasures;

As defined in the Seveso Directive, storage means the presence of a quantity of substances for the purposes of containment , depositing in safe custody, or keeping in stock. In the case of the heat transfer systems operated as SCCSs (fully enclosed), the system itself acts as a warehouse for the Terphenyl, hydrogenated. Consequently, the technical and organisational measures implemented at the operational level guarantee that there are no potential emissions during storage.

4.2. Maintenance

The heat transfer systems using Terphenyl, hydrogenated as HTF shall be maintained according to technical requirements and operational procedures as outlined in the operational manual of the system designer and this document.

The plant components of a heat transfer system operated with Terphenyl, hydrogenated as HTF shall be considered to be technically leak tight if their technical leak tightness is continuously ensured by maintenance and monitoring (BAUA, 2022). This means that, in addition to the purely design, constructive, and technical measures, the organisational measures can also lead to a technically tight plant. These measures include the appropriate preventive maintenance program and the control of the installation through regular leak tightness checks on components (seals, flanges, pumps, etc.).

The scope and frequency of the measures to be taken in the course of preventive maintenance shall depend in detail on the type of design, mode of operation, stresses and strains, as well as the condition of Terphenyl, hydrogenated. These measures shall ensure technical tightness of the heat transfer system (BAUA, 2022). Care must be taken to ensure that the scope and frequency of the measures are specified in written documents (e.g., in operating instructions or in the maintenance program).

Control and safety devices must be checked for their effectiveness (DIN, 2015). Furthermore, the complete heat transfer system must be checked visually for leakages, within the recommended inspection intervals (VDI, 1995).

The technically leak-tight plant components shall be checked for leak tightness, either as a whole or in affected sections, after any repair work. The appropriate procedure shall be determined in dependence on the application (BAUA, 2022). Repairs to the components of the heat transfer system may only be conducted by personnel with appropriate technical training (DIN, 2015).

The operator of the heat transfer system shall ensure that (FM Global, 2022):

- any and all system leaks are corrected promptly, regardless of how small they may be, making corrections of a permanent nature (e.g., repacking valve stems, replacing leaky gaskets, etc.), as applicable
- any fluid spilled from a leak shall be cleaned up immediately.
- any pipe or equipment insulation that is discovered to be oil-soaked is promptly removed and replaced with clean, oil-free insulation, and the cause of the leak is corrected.
- any openings in pipes or equipment (e.g., maintenance holes, instrument ports, inspection ports, etc.), are on the same inspection and maintenance schedule as all system equipment, seals, flanges, and other known potential leak points.

Periodic sampling of Terphenyl, hydrogenated is necessary to control and evaluate the quality of the Terphenyl, hydrogenated installed in the heat transfer system, in order to avoid any loss of efficiency in the overall heat transfer performance of the system. This process is performed a minimum of once a year (DIN, 2015).

The sampling of Terphenyl, hydrogenated from the heat transfer system, through the special equipment designed for this purpose, may only be conducted by persons with appropriate technical training (DIN, 2015). Specific operating instructions for taking samples of Terphenyl, hydrogenated from the heat transfer system have to be developed by the system operator in order to avoid the emission of the substance.

4.3. Top-up

The top-up (or refill) process is part of the general maintenance process. During the top-up process a Terphenyl, hydrogenated volume is managed out of the heat transfer system and, therefore, it is a potential emission source of Terphenyl, hydrogenated. For this reason, special containment measures shall be taken for the performance of this process.

The top-up demand is driven by the degradation rate of Terphenyl, hydrogenated, which partially decompose at elevated temperature, and the separated low-boiling degradation products. For this reason, a periodical collection of the decomposition products and a consequent refill with new Terphenyl, hydrogenated is needed. It has to be noted that the top-up process is not related to emission of Terphenyl, hydrogenated into the environment but to thermal degradation of the HTF.

Refilling of Terphenyl, hydrogenated to the heat transfer system may only be conducted by persons with appropriate technical training (DIN, 2015). Specific operating instructions for this process have to be developed by the system operator in order to avoid the emission of the substance

The refilling operation shall be conducted in a way remarkably similar to the filling operation (see **Section 3** of this document), taking into account that the volume of Terphenyl,

hydrogenated involved in this process will be much smaller than in the case of filling. This means that the equipment and the technical and organisational measures during refilling will be the same as during filling. However, some additional care is needed (e.g., avoid adding wet fluid into the hot system). These specificities shall be included in the operating instruction of this process.

The degradation products of Terphenyl, hydrogenated (mainly low boiling fractions) must be separated from the heat transfer system, e.g., by venting, condensation, and collection for disposal, or by incineration via the flare system.

5. Dismantling/Decommissioning & Waste

The processes of dismantling, decommissioning, waste disposal, and cleaning of the heat transfer system are out of the usual operational conditions of the installation. In these processes Terphenyl, hydrogenated and Terphenyl, hydrogenated containing materials are managed out of the heat transfer system. Therefore, these processes are potential emission sources of Terphenyl, hydrogenated and, for this reason, special containment measures shall be taken for their performance.

The disposed Terphenyl, hydrogenated and Terphenyl, hydrogenated containing materials come from diverse sources:

- Periodical collection of degradation/decomposition products
- Complete drain of the heat transfer system
- Sampling of Terphenyl, hydrogenated for periodic quality control
- Spills and leakages
- Dismantling of the heat transfer system

The degradation/decomposition products (mainly low boiling fractions) formed as breakdown products of Terphenyl, hydrogenated at elevated temperatures, must be separated from the system. They can be treated in two diverse ways:

- They are collected into a vent line, condensed, and sent to a dedicated collection vessel or drum. In this case, these degraded products are low boiling components, which may contain fractions of Terphenyl, hydrogenated, that are disposed of externally through an authorized external company.
- They are vented in closed loops to be internally incinerated (through the furnaces, steam boilers, flares, etc., installed in the sites). In this case they are internally disposed of.

In case of complete drain of the heat transfer system, the used Terphenyl, hydrogenated shall be collected (e.g., in drain tanks) prior to be sent to an external waste operator.

The Terphenyl, hydrogenated amounts generated during the sampling process are collected in little containers.

The spills and leakages of Terphenyl, hydrogenated shall be removed by using absorbent material, such as mats or loose media. Once any remaining fluid has been absorbed, this material is removed for appropriate disposal.

In case a heat transfer system plant has to be dismantled, the whole heat-transfer system needs to be emptied, flushed, rinsed, and cleaned prior to dismantling. The solvent-water mixture containing Terphenyl, hydrogenated is disposed of through an external waste operator.

The technical measures introduced during the design and construction stages, together with the organisational measures, aim at fully enclosing the system and avoiding emissions to the environment during dismantling/decommissioning and disposal processes. Specific operating instructions for these processes have to be developed by the system operator in order to avoid the emission of the substance.

All of the above-mentioned materials (water fraction/emulsion with Terphenyl, hydrogenated, drained and sampled Terphenyl, hydrogenated, absorbent materials, water fraction/emulsion with Terphenyl, hydrogenated, and solvent-water mixture containing Terphenyl, hydrogenated) must be disposed in accordance with legislation applicable to waste oil (VDI, 1995). The aim is to recycle waste oil containing Terphenyl, hydrogenated in form of new materials or as energy (by burning in an authorized incinerator).

The owner of the waste oil is responsible by law for ensuring that its disposal is in accordance with the pertinent legislation. He may release the waste oil only to those refuse collectors who have been officially authorized for the purpose and must ensure that they hold a license for its collection and transportation (VDI, 1995).

The disposed products are transported directly inside the collection tanks, after drumming into barrels, or by truck. Piping and hoses of the trucks, collection tanks, and barrels are cleaned in the same disposal companies and the solvent-water mixture is disposed together with the received product.

It must also be ensured that the vehicles used for transport meet the requirements laid down in the regulations on transportation of dangerous goods by road (VDI, 1995).

Once a charge of Terphenyl, hydrogenated has been approved for disposal, it would be expedient to have it removed direct from the heat transfer system. If intermediate storage is necessary for logistic reasons, all the relevant legal provisions must be observed. This storage can be performed in tanks that conform to regulations on public transport (trucks tank) if the duration of storage is shorter than 24 hours or less, or until the next working day (VDI, 1995).

6. Inspections & Training

In addition to the purely constructive and design measures, technical combined with organizational measures can also lead to a permanently technically tight plant. Apart from the human and technological factors, the organizational structure for safety measures also plays a key role when it comes to plant safety. The following elements needs integration into an appropriate organizational structure:

- responsibility;
- actions;
- procedures;
- processes;
- resources.

Such organizational structures are required to promote the high quality in terms of establishment, operation, change, maintenance, monitoring, emergency planning, accident prevention and limiting the negative effects of accident.

Inspections and training play a vital role in the organisational measures for plant safety.

6.1. Inspections

Heat transfer systems with organic heat transfer fluids are in general plants which require special supervision, including monitoring. From a legal point of view, they are "working equipment" and are therefore subject to the local safety regulations (HDI, 2016).

According to PED, most of the heat transfer systems with organic HTFs are requiring external inspections by third party accredited inspectors prior to commissioning and during operations. In the following, only the internal inspections (self-inspections) conducted by the trained and instructed site personnel are outlined.

The top priority of any inspection is to assist in eliminating or significantly reduce the risk of releases of Terphenyl, hydrogenated from any HTF plant into the environment. Inspections allow to see whether relevant regulations, standards and practices are being met, whether safety management systems are in place and function appropriately (with respect to technical, organisational, and human factor issues), and whether safety documentation is valid. The aim of the periodic inspection is to provide a statement that the system is in proper condition and that there are no safety concerns about the continued operation of the system against the continued operation of the system.

In general, all system parts which are relevant for the tightness of the plant, including valves, pumps, trace heating, electric equipment and special equipment are subject to obligatory regular inspections. The type, scope and frequency of inspections can be taken from the plant permit, legal and authority regulations, from technical rules and the operating instructions and manuals of the manufacturers of the system parts (HDI, 2016).

The entire system must be visually inspected by an instructed worker at regular intervals, but at least once a week. During system operation, hints pointing to defects shall always be observed, like (HDI, 2016):

- liquid pools or traces of HTF,
- accumulated incrustations,
- deformations,
- discolourations,

- unusual noises and smells,
- unusual smoke colours and
- smoke or vapour escaping from component joints or vents.

However, some workplaces might have higher risk areas that need to be inspected on a more frequent basis. The inspection strategy needs to be worked out depending on the level of risk.

The primary objective of the inspection is to identify potential causative factors for releases or potential releases of Terphenyl, hydrogenated into the environment. This would include the following:

- Infrastructure components such as surface sealing, loading docks, storage areas dewatering and drainage;
- HTF system parts such as piping, valves, pumps, trace heating, flanges;
- Handling and storage of materials in and around the workplace;
- Worker's behaviour;
- Faulty procedures that are ineffective or can cause releases;
- Newly introduced procedures and processes (MoC);
- Previously identified hazards that have not been addressed.

By maintaining a detailed record (see attached "Inspection Checklist"), the inspection can be documented and identified observations and deficiencies recorded and addressed. The inspection results shall contain the following information:

- Sections of the HTF plant that were inspected;
- System parts that were inspected;
- Processes that were inspected, e.g., top-up or refilling procedure;
- Time and date of inspection;
- Participating members of the inspection;
- Areas, processes, machinery, and other items that were found to be of potential risk for Terphenyl, hydrogenated release;
- Recommendations to address the issues.

Based on the site-specific conditions, the permits, the local regulations, applicable technical rules and the operating instructions and manuals of the manufacturers of the system parts, a plant specific inspection plan, including internal and external inspections, has to be compiled and kept up to date. **Table 1** is showing an example of an inspection plan template.

Table 1: Example of an inspection plan template.

Type of Inspection	Frequency	Inspection by	March 2023
Top-Up Procedure	when occurring	Maintenance	
Sampling Procedure	annually	Laboratory	
Piping, Valves, Pumps	weekly	Maintenance	
Terphenyl, hydrogenated Waste Storage	monthly	EHS	
……	……	……	
……	……	……	
……	……	……	

6.2. Training

Under the REACH Restriction of Terphenyl, hydrogenated, the primary duty for the Terphenyl, hydrogenated downstream user in a HTF plant is to ensure that the substance is not released into the environment.

Organisational measures cannot substitute design and control engineering safety devices but are absolutely necessary in order to maintain the safety of a heat transfer oil system permanently, e.g., by correct operation (incl. training) and suitable maintenance. Thus, organisational measures are a complementary module for plant and process safety.

When instructing the workers, the employer shall take the necessary precautions to ensure that employees are provided with adequate information, in particular on the hazards arising from the work equipment in their immediate working environment, even if they do not use the equipment themselves. Where necessary, operating and work instructions for the equipment used at work have to be supplied in a form and language they can understand. During instruction, the employer must take the necessary precautions to ensure that (BG RCI, 2022):

- the workers who use the work equipment receive appropriate instructions in particular about the hazards associated with the use of the equipment;
- those responsible for conducting repair, maintenance, conversion, cleaning, and other work, receive appropriate special instruction.

The contents of the instruction must be adequate and recorded. Participants confirm by signature their participation in the instruction (BG RCI, 2022). In general, workers must (to the best of their ability) support all measures to prevent hazards and to follow the relevant instructions of the employer. They must use the equipment provided and must not follow instructions that are contrary to safety requirements.

There are inherent dangers and complexities within chemical and process facilities, so companies must verify that employees have the knowledge to perform their duties safely and efficiently. Chemical safety training for operators, maintenance workers, EHS and inspection teams is intended to ensure that chemical facilities have trained workers needed to handle the chemicals and processes they manage and that they are knowledgeable about the chemical processes involved. Chemical safety training has therefore many benefits. It improves knowledge and adherence to safer practices, reduces exposure to chemicals and is

essential for protecting human health and the environment and to ensure safety from potential hazards posed by chemicals, in manufacturing or other industries.

The **training needs** of such personnel and the provision of the suitable training has to be identified via a worker's specific analysis.

This could be relevant for subcontracted personnel working in the facility too. Therefore, appropriate measures shall be taken by the employer to ensure that workers in the Terphenyl, hydrogenated HTF plant receive sufficient and appropriate training and to raise awareness, in particular in the form of information and instructions, concerning:

- Potential risks of Terphenyl, hydrogenated exposure and environmental releases;
- Precautions to be taken to prevent exposure and incidents, incl. waste handling;
- Steps to be taken in case of spills and incidents;
- Process safety requirements and tasks to adequately control the risks.

The personnel managing the HTF plant and the Terphenyl, hydrogenated (e.g., in top-up and disposal) have to be appropriately trained and supervised. Training and supervision shall be a documented part of a systematic programme (not an isolated event). The identified training needs shall be documented by the site operator in a workers and plant specific training plan.

A training plan is the working document that contains information regarding how, when and where training has to be conducted. It also spells out the core details of a training program including its goals and objectives, duration, and assessment methods for certification. Having a training plan is important for an efficient training process and acts as a roadmap for instructions, sets realistic expectations for participants and keeps the instructor accountable. The employer shall document the successful completion of the training, which shall be renewed at least every five years. **Table 2** is illustrating an example of workers specific training plan template.

Table 2: Example of a workers specific training plan template.

Employee Name: John Schmitt Department: Maintenance Role: Maintenance Engineer					
Training Topic	Mode of Training	Training Hours	Expected Completion Date	Status	Recurring Training
Hazard Training on Terphenyl, hydrogenated used as the HTF	Online	4	Q4, 2022	completed	No
Spill & Emergency Procedures	Classroom	2	Q1, 2023	in progress	Yes
General System & Process Safety	Classroom	6	Q2, 2023	not started	Yes
Waste Management of Terphenyl, hydrogenated containing Waste	Classroom	4	Q1,2023	In progress	Yes
…….	…….	…….	…….	…….	…….

The training shall be:

- adapted to take account of new or changed risks;
- repeated periodically to relevant workers;
- documented to demonstrate that workers have successfully completed the training prior to working in the plant;
- conducted by a competent trainer/expert.

Training elements included, but not limited to, are:

- Hazard Training on Terphenyl, hydrogenated;
- general system & process safety;
- cleaning, leakages, maintenance, sampling;
- waste management of Terphenyl, hydrogenated containing waste;
- identification of critical handling stages;
- behaviour-based safety;
- management of change (MoC);
- evaluation of existing safety and working instructions.

The training shall comply with the provisions set by the Member State in which the industrial or professional user(s) operate. Member States may implement or continue to apply their own national requirements, as long as the above-mentioned minimum requirements are met.

The restriction of isocyanates[44] (ECHA, 2020) can serve as a good reference, where new minimum training requirements[45] for workers which are managing diisocyanates and mixtures containing diisocyanates were introduced[46].

[44] Registry of restriction intentions until outcome - ECHA (europa.eu)

[45] 503ac424-3bcb-137b-9247-09e41eb6dd5a (europa.eu)

[46] The EU introduces mandatory training of diisocyanates workers in new REACH Restriction - FSK - Fachverband Schaumkunststoffe und Polyurethane e.V. (fsk-vsv.de)

Annex 1: Inspection Checklist Template

Inspection Check List for Heat Transfer Systems designed to achieve the SCCS Condition

Requirements	Response		Remarks
	OK	Action required	
A. Installation and equipment			
Is the whole heat transfer system installed on a concrete (or equivalent) surface?			
Is the area under the heat transfer system designed to divert potential leakage and runoff to a safe location?			
Suitable equipment has been installed for this purpose (sloped floors, curbs, dikes, drainage systems, etc.)?			
Is potential leakage and runoff diverted to a closed containment system?			
Is potential leakage and runoff diverted to a waste treatment facility?			
Are vessels and tanks equipped with vents and/or expansion lines?			
Are vents and/or expansion lines routed into collection systems?			
Are vents and/or expansion lines connected to air pollution control equipment?			
Does the installation have calamity basin/tanks to control large accidental spills of Terphenyl, hydrogenated?			
Has the number of flanges in the piping lines been minimized to minimum technical requirements?			
Are there stop valves installed in the flow and return pipes?			
Has the suitability of the stop valves been proved (by manufacturer tests or an accredited expert)?			
Are the installed pumps prepared to contain leakages by themselves (magnetically driven, canned motor, double seals, liquid barrier, etc.)?			
If not, is it guaranteed that any leakage from the pumps will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Have the pump housings designed to withstand at least a maximum pressure of 16 bar?			
Has the suitability of the shaft seals been proved (by manufacturer tests or an accredited expert)?			
Is thermal insulation installed in such a way that leaks can be detected?			
Is the equipment for sampling points of Terphenyl, hydrogenated specially designed to contain leakages?			
Are all the other installed components (valves, flanges, seals, connections, etc.) prepared to contain leakages by themselves?			
If not, is it guaranteed that any leakage from them will be diverted and collected (curbs, dikes, containment devices beneath them, etc.)?			
Are there control equipment and safety devices in place to ensure the safety of the system and the process?			

Requirements	Response		Remarks
	OK	Action Required	
B. Filling, start-up, shutdown, and drain of Terphenyl, hydrogenated			
Has the heat transfer system been provided with accessories to ensure the safe performance of these operations?			
Have start-ups and shutdowns been minimized according to the site-specific operations?			
Please, provide the number of start-ups and shutdowns from the last inspection.			
Are there operating instructions for start-up and shutdown?			
Are start-up and shutdown performed by qualified persons?			
Has the Terphenyl, hydrogenated completely drained (due to degradation) and filled from the last inspection?			
If so, were all the components (pumps, piping, connections, etc.) of the heat transfer system continuously monitored for leakages during these operations?			
Are there operating instructions for the complete drain and filling of Terphenyl, hydrogenated?			
Is the complete drain and filling of Terphenyl, hydrogenated performed by qualified persons?			
C. Operation of the heat transfer system			
Has an operating limit for pressure been established?			
Has any deviation from the pressure limit been detected since the last inspection?			
If yes, please specify how many pressure limit deviations have been detected and which values were reached.			
Has an operating limit for temperature been established?			
Has any deviation from the temperature limit been detected since the last inspection?			
If yes, please specify how many temperature limit deviations have been detected and which values were reached.			
Has an operating limit for Terphenyl, hydrogenated level been established?			
Has any deviation from the Terphenyl, hydrogenated level limit been detected since the last inspection?			
If yes, please specify how many Terphenyl, hydrogenated level limit deviations have been detected and which values were reached.			
Has an operating limit for flow rate been established?			
Has any deviation from the flow rate limit been detected since the last inspection?			
If yes, please specify how many flow rate limit deviations have been detected and which values were reached.			
Is there an operating manual for the heat transfer system?			
Are there operating instructions for the heat transfer system?			
Are there operating instructions for handling Terphenyl, hydrogenated?			
Are operating manual and operating instructions always available to the workers in a form and language they can understand?			

Requirements	Response		Remarks
	OK	Action Required	
D. Maintenance of the heat transfer system			
Is there a preventive maintenance plan in place?			
Are there operating instructions for maintenance and repair work?			
Is maintenance performed by qualified persons?			
Are control and safety devices checked for their effectiveness?			
Are all the openings in the installation (e.g., maintenance holes, instrument ports, etc.) included in the maintenance plan?			
Is the heat transfer system or parts of it tested for leakage detection?			
How is the heat transfer system or parts of it tested for leakage detection? Which tests are conducted (e.g., use of foaming agents, acoustic test, etc.)?			
Installation area			
Heater			
Vessels and tanks			
Vents and relief devices			
Piping and piping parts			
Pumps			
Thermal insulation			
Sampling points			
Valves			
Flanges			
Seals			
Connections			
Control equipment			
Safety devices			
Is the heat transfer system or parts of it checked visually during operation for leakage detection?			
Are these tests performed according to the procedures defined by the manufacturer or other accepted standards?			
If so, which ones are used?			
What are the time intervals of the tests for leakage detection?			
Is there a test book or written records about these tests?			
Is the heat transfer system or parts of it tested for leakage detection before the start-up, during the filling and drain of Terphenyl, hydrogenated, and after the shutdown of the operation?			
Is the heat transfer system or parts of it checked visually during these activities to detect leakages?			
Is the painting with wetting agents test (e.g., soap solution) performed during these activities to detect leakages?			
Is thermal insulation removed during these activities to facilitate the detection of leakages?			
Is the plant or parts of the plant tested for leakage detection after adaptations, maintenance, and repair?			
Are there operating instructions for the detection of leakages?			
Requirements	**Response**		**Remarks**
	OK	**Action Required**	
E. Maintenance of the heat transfer system (cont.)			
Are tests for leakage detection performed by qualified persons?			

Are leakages corrected promptly (regardless of how small they may be)?			
Are the leakages corrections of a permanent nature?			
Are leakages cleaned up immediately?			
Are there operating instructions for the elimination and cleaning of leakages?			
Is the elimination and cleaning of leakages performed by qualified persons?			
Is the oil-soaked thermal insulation promptly replaced and the cause of the leak corrected?			
Is Terphenyl, hydrogenated sampled and its quality controlled a minimum of once a year?			
Are there operating instructions for sampling of Terphenyl, hydrogenated?			
Is Terphenyl, hydrogenated sampling performed by qualified persons?			
Are there operating instructions for top-up of Terphenyl, hydrogenated?			
Is top-up of Terphenyl, hydrogenated performed by qualified persons?			
F. Dismantling/decommissioning and waste disposal			
How are the low boiling fractions disposed of?			
Vented, condensed, collected, and externally disposed of.			
Vented and internally incinerated.			
Is the drained Terphenyl, hydrogenated from the heat transfer fluid collected (vessels/tanks)?			
Is the sampled Terphenyl, hydrogenated collected (little containers)?			
Are spills removed using absorbent material?			
Has the heat transfer system or parts of it been dismantled after the last inspection?			
If so, was the heat transfer system emptied, flushed, rinsed, and cleaned prior to dismantling?			
Are the above-mentioned materials disposed of internally?			
If so, is the company officially authorized, holding a license for waste collection?			
Are the above-mentioned materials recycled as energy by internal incineration?			
Are the above-mentioned materials disposed of by external companies?			
If so, are these external companies officially authorized, holding a license for waste collection and transportation?			
Do the vehicles used for transportation meet the requirements laid down in ADR?			
Are the above-mentioned materials recycled as energy by authorized external incinerators?			
Is intermediate waste storage necessary?			
If so, are all the relevant legal provisions observed?			
Are there operating instructions for dismantling and waste disposal?			
Are dismantling and waste disposal performed by qualified persons?			

Requirements	Response		Remarks
	OK	Action Required	
G. Training			
Is there a general training plan in place?			
Are there specific training plans per job position/activity?			
Are the training needs of each job position evaluated and documented?			
Does the content of each specific training include adequate information about the hazards associated with the use of Terphenyl, hydrogenated?			
Does the content of each specific training include adequate information about the hazards associated with the use of the equipment?			
Does the content of each specific training include adequate information to avoid the release of Terphenyl, hydrogenated into the environment?			
Does each specific training comply with the provisions set by all the Legislation applicable to the job position/activity?			
Are the contents of each specific training recorded?			
Do the participants confirm by signature their participation in each specific training?			
Is the completion of each specific training documented?			
Is the effectiveness of each specific training evaluated?			
Has the periodicity of each specific training been defined?			
Has the training level of the subcontractors been evaluated?			
H. Inspection			
Has an inspection plan been defined for the heat transfer system?			
Are external inspections by third-party accredited inspectors required prior to start-up of the heat transfer system or parts of it?			
Are external inspections by third-party accredited inspectors required during operation of the heat transfer system or parts of it?			
If so, how often are these inspections conducted?			
Are internal inspections by trained and instructed site personnel performed on the heat transfer system or parts of it?			
If so, how often are these inspections conducted?			
Are the results of these inspections documented?			
Are the identified observations and deficiencies recorded and addressed?			
Result of the inspection			
After this inspection, can be considered the heat transfer system permanently technically tight (system achieving SCCS condition)?			
Members of the inspection team			
Date of the inspection			

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