



**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-000007224-79-01/F**

**ECHA/SEAC/[reference code to be added after the adoption of the  
SEAC opinion]**

**Agreed**

**10 March 2023**

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON  
TERPHENYL, HYDROGENATED

**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 agreed by SEAC and the Committee's justification for their opinion. 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 March 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** of all members having the right to vote.

**ADOPTION OF THE OPINION OF SEAC**

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

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**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

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 March. Interested parties **[were invited]** to submit comments and contributions by 15 May.

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 **[date of adoption of the opinion]**. **[The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by [number of days] by the ECHA decision [number and date]]**<sup>1</sup>.

**[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]<sup>5</sup> 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and]<sup>3</sup> 71(1)]**<sup>6</sup>.

The opinion of SEAC was adopted **by [consensus.] [a simple majority]** of all members having the right to vote. **[The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]**<sup>6</sup>.

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<sup>1</sup> Delete the unnecessary part(s)

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## 1. OPINION OF RAC AND SEAC<sup>2</sup>

The restriction proposed by the Dossier Submitter is:

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.

The restriction proposed by the Dossier Submitter is:

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	<ol style="list-style-type: none"><li>1. Shall not be placed on the market from [18 months after entry into force]:<ol style="list-style-type: none"><li>a) As a substance on its own.</li><li>b) As a constituent of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w.</li><li>c) In articles or any parts thereof containing terphenyl, hydrogenated in concentrations equal or greater than 0.1% w/w.</li></ol></li><li>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 (SCCS) with technical containment and organisational measures to prevent environmental emissions.</li><li>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).</li></ol>

<sup>2</sup> Do not delete any of the headings in this document under any circumstances. This is important to keep in mind for the combination of the RAC and SEAC opinion towards the end of the opinion-making process.

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	<p>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.</p>
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### 1.1. THE OPINION OF RAC

See RAC Opinion

### 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, taking into account 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 1: Restriction proposed by SEAC

Column 1	Column 2
Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
<p>Terphenyl, hydrogenated</p> <p>CAS No: 61788-32-7</p> <p>EC No: 262-967-7</p>	<p>1. Shall not be placed on the market, or used, from [18 months after entry into force]:</p> <ul style="list-style-type: none"> <li>a) as a substance on its own.</li> <li>b) in other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w.</li> <li>c) in articles or any parts thereof in a concentration equal or greater than 0.1% w/w.</li> </ul> <p>2. By way of derogation, Paragraph 1 shall not apply to the use and the placing on the market for use as a</p>

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	<p>heat transfer fluid 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. This derogation shall end by [20 year(s) after entry into force of the restriction].</p> <p>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].</p> <p>[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].]</p> <p>[5. Paragraph 2 shall be reviewed before the expiration of the derogation to evaluate the achieved emission reduction as well as the availability of suitable alternatives that do not pose concerns for regrettable substitutions.</p>
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**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.

[Column 2, paragraph 2: SEAC concluded that this derogation should be time-limited, and that the time limit should be based on the expected operating life of the relevant installations. SEAC proposes that a time-limit of 20 years could be appropriate. Further information to support the decision on what would be the most appropriate time limit will be asked in the consultation in the SEAC draft opinion.

*Column 2, paragraph 5; SEAC proposes a review clause in the derogation to verify, before the date of expiration of the derogation whether further minimisation of emissions is possible, and whether suitable alternatives that do not a pose risk of regrettable substitution have become available.*

SEAC recommends to the Commission that the need for further regulatory action on two



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potential alternatives for terphenyl, hydrogenated (dibenzylbenzene, ar-methyl derivative and 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene) identified as such by Finland in a Risk Management Options Analysis (RMOA)<sup>3</sup> is further assessed. This is further discussed in section 3.4.1.

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<sup>3</sup> <https://echa.europa.eu/documents/10162/2248ee6d-9304-4e2b-677b-9d2782f8afc4>

## 2. SUMMARY OF PROPOSAL AND OPINION

### 2.1. Summary of proposal

The restriction aims at reducing risks to human health and the environment from the use of terphenyl, hydrogenated. Terphenyl, hydrogenated was identified by ECHA as a Substance of Very High Concern (SVHC) in 2018 because of its very persistent and very bioaccumulative properties (vPvB). Terphenyl, hydrogenated is a substance with an unknown or variable composition, complex reaction products or biological materials (UVCB substance) and was assessed by evaluating the properties of different relevant constituents present in the substance. At least one of these constituents (ortho-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 mainly used as a Heat Transfer Fluid (HTF) for industrial use at high temperatures range of 325-350°C in various industry sectors. Other uses include applications as processing solvent and as plasticiser.

Terphenyl hydrogenated is not manufactured in the European Union (EU) and the imported volume (based on 2020 data) is estimated to be 7 500 tonnes. The main use, representing approximately 90% of the annual volume of use, is as an HTF. Although the use of the substance as a HTF is taking place in closed loop systems, environmental emissions are still possible. Moreover, for all non-HTF uses, such as uses as processing solvents and plasticisers, an unacceptable risk for the environment and human health has been identified. No suitable alternatives for the use of terphenyl, hydrogenated as HTF seem to be currently available without creating a situation of regrettable substitution. There is limited information available on the alternatives of terphenyl, hydrogenated for the other uses, i.e., as processing solvent and as plasticiser, due to the lack of information on the specific uses and the technical function of the substance regarding this use.

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 environmental emissions could be sufficient to demonstrate a risk. REACH Restriction was identified as the most relevant and proportionate Regulatory Management Option (RMO).

No suitable alternatives for terphenyl, hydrogenated are currently available, without creating a situation of regrettable substitution except for some minor uses.

Three restriction options (RO1, RO2, RO3) are analysed in the impact assessment. All restriction options restrict, use and placing on the market of terphenyl, hydrogenated as such of in concentrations equal to or greater than 0.1% w/w in mixtures or articles by the end of a transition period of 18 months.

Whereas the strictest restriction option (RO3) does not include any derogations, RO1 and RO2 include a derogation of varying scope and length for uses as HTF and RO1 is the least stringent including an additional derogation for the use and placing on the market in aerospace and defence applications as well as a derogation of for the use of the substance in thermostats in ovens and stoves.

Based on the available information on alternatives, costs and benefits for society as a whole, the analysis of the effectiveness, proportionality, practicality and monitorability of RO1, RO2 and RO3 and the impact assessment performed, RO1 (the least stringent with two derogations, i.e. at industrial sites as HTF and in plasticisers use for the production in aircraft and their spare parts) has been proposed by the Dossier Submitter to be the most appropriate risk management option. This RO is considered by the Dossier Submitter to be proportionate,

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as it proposes derogations in situations where the substance is used as a heat transfer fluid in strictly controlled closed systems and allows extra time for industry to find alternatives in sectors (specifically the aviation sector) that are particularly impacted by this restriction.

The proposed restriction is assumed to impose low costs to reduce a potential risk, with the measures being proportionate to the risk. The restriction is practical because it is implementable, enforceable and manageable.

Furthermore, the proposed Restriction has a cost-effectiveness ratio of € 90/kg Terphenyl, hydrogenated emissions avoided, which the Dossier Submitter considers to be high, coupled with a high emission (risk) reduction capacity of 85%. The total costs have been estimated to be approximately € 1.5 billion, assuming a 5-year transitional period for use of the substance as a in the production of aircrafts and their spare parts.

### 2.2. Summary of opinion

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 under 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 cost and job loss 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

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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 like 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 substitution.

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, but that emissions can be minimised via the definition of SCCS as provided by the Dossier Submitter. 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-month 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, RAC finds 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. SEAC concluded that this derogation should be time-limited, and that the time limit should be based on the expected operating life of the relevant installations. SEAC proposes that a time limit of 20 years could be appropriate. SEAC concludes this derogation should be reviewed to a) establish whether further minimisation would be possible and b) evaluate the availability of suitable alternatives that do not pose a risk of regrettable substitution. 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.

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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.

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## 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 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 reduces potential risks to an acceptable level within a reasonable period of time.

Terphenyl hydrogenated is a UVCB- substance. Terphenyl, hydrogenated 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 (ortho-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.

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.

#### 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.

The hazardous properties have been summarised in the Support Document related to the SVHC identification (ECHA, 2018a) leading to the identification of terphenyl, hydrogenated as an SVHC due to its vPvB properties based on a weight of evidence approach of the available data.

From the available data, ECHA concluded that at least o-terphenyl, one of the constituents of terphenyl hydrogenated, fulfils both vP and vB criteria. As o-terphenyl occurs in significant concentrations in terphenyl hydrogenated (> 0.1% w/w), this substance meets the criteria to be considered as 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 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):

See RAC opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

**3.1.3. Emissions and exposures**

**Summary of Dossier Submitter's assessment:**

Terphenyl hydrogenated is widely used in the EU and is imported to the EU 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 (see Annex A.1).

Based on information the DS received from stakeholders, the global volume of terphenyl, hydrogenated manufactured in 2020 is approximately 32 000 tonnes per year, and the total volume imported in 2020 into the EU is in the order of 7 500 tonnes per year. The EU volume of 7500 tonnes per year includes as well estimates of imports in articles and formulations, which is in the order of 100 tonnes per year (see section 1.1 of the background document and Annex A).

The main use of Terphenyl, hydrogenated is as a high-temperature Heat Transfer Fluid (HTF) (which represents approximately 90% of the total use volume according to stakeholder feedback). A HTF is a recirculating fluid that transfers heat through heat exchangers to cold streams and returns to the heat source (heater). 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. Synthetic HTFs like terphenyl hydrogenated do not require pressurizing at temperatures up to 350°C which represents an advantage in terms of operational costs. Another advantage of using a mineral or synthetic fluid, as opposed to water, is that it generally has a lower freezing point. Lastly, HTFs also tend to be less reactive and corrosive to pipes and other parts of the system than water (see section 1.1 of the background document (BD)).

The use of the substance as a plasticiser is the second relevant use, involving around 10% of the use volume. Plasticisers are additives that increase the plasticity or decrease the viscosity of a material. Terphenyl, hydrogenated is used as a plasticiser primarily in 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) as well as in coatings and inks.

The remaining registered uses (both industrial and professional) represent less than 1% of the amount of substance imported into the EU. According to feedback of 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 information provided in the SCIP database was used to confirm and identify uses. The SCIP database confirms that Terphenyl, hydrogenated is used in articles, which are used in complex objects, such as vehicles (cars, trains, planes), Electrical and Electronic Equipment (EEE), construction and building components, or furnishings.

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 has not been widely found in the environment so far. The Dossier Submitter considers that this should not be interpreted as the substance not yet having entered the environment, but that it has previously not been measured in environmental

samples.

**RAC conclusion(s):**

See RAC opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **3.1.4. Risk characterisation**

**Summary of Dossier Submitter's assessment:**

The Dossier Submitter states under section 1.2.6 of the Annex XV restriction report 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 (REACH Annex I, section 6.5).

**RAC conclusion(s):**

See RAC opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **3.1.5. Existing risk management measures and operational conditions**

**Summary of Dossier Submitter's assessment:**

The Dossier Submitter considered that use of the terphenyl hydrogenated as HTF takes place in closed loop systems. appendix 5 of the BD explains the definition of strictly controlled conditions

When used as a plasticiser terphenyl, hydrogenated will be incorporated into/onto an article. At the end of the service life, the article must be disposed of. During the disposal at a waste treatment plant terphenyl, hydrogenated may be released into the environment. Consequently, the end of the article's service life leads to the generation of waste containing the substance and the final disposal may lead to additional releases to the environment. The Dossier Submitter assumes, that current OC's and RMMs are not sufficient to address the concern at the waste-stage.

**RAC conclusion(s):**

See RAC opinion.



**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

**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 BD). 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).

The lack of information on fractions released to air, water, and soil from the various processes during terphenyl, hydrogenated' lifecycle creates significant uncertainties in the exposure assessment. The approach used is generic and uncertainties arise in the modelled outputs. Moreover, it is to be noticed that the number of articles containing terphenyl, hydrogenated imported into the EU and exported from the EU is not known with any certainty. In addition, it is an uncertainty if a restriction of imported articles with terphenyl, hydrogenated content of greater than 0.1% w/w is considered sufficient to adequately address the concerns or if the restriction should cover concentrations as well < 0.1%, since REACH Article 7(2) on "Notification Requirements", Article 33 on "Supply Chain Communication" and the "SCIP Notifications" do not apply. This is an uncertainty since it is not clear, how many articles with concentration levels < 0.1% of Terphenyl hydrogenated are being imported and if those imported articles would pose a risk of environmental exposure.

**RAC conclusion(s):**

See RAC opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

**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)

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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, and in particular the risk arising from the use of the substance as a plasticiser. Union-wide action is therefore 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):**

See RAC opinion.

### **Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **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<sup>4</sup> -database and found that in total more than 12 000 entries containing terphenyl, hydrogenated were notified, in December 2022

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<sup>4</sup> <https://echa.europa.eu/fi/scip>

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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.

### 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 approach of the Dossier Submitter in 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 Dossier Submitter highlights that 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):

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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 10<sup>th</sup> 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 10<sup>th</sup> 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, orthophtalates 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 orthophtalates is a substance of concern while iso- and terephtalates seem to 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 identified because most of them could lead to a regrettable substitution.

Only one potential alternative, commercially available in the required quantities, has been

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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 biphenyl on the market as a 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 considered to be a suitable for 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 terephthalates 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

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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 considering 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 2: Summary of alternatives and its assessment using technical and risk criteria

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

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 a 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

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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 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.

Following is the number of alternatives shortlisted per use:

HTF: 1,

- Plasticiser: 4,
- Solvent: 4,
- Laboratory chemical: 4.
- Additive in coatings, paints and inks: 2,
- Additive in sealants and adhesives: 4

Table 3 shows a summary of the assessment of the shortlisted alternatives (in yellow substances under assessment for being SVHC):

Following is the number of alternatives shortlisted per use:

- HTF: 1,
- Plasticiser: 4,
- Solvent: 4,

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- Laboratory chemical: 4.
- Additive in coatings, paints and inks: 2,
- Additive in sealants and adhesives: 4

Table 3 Assessment of shortlisted alternatives

	Alternatives: Chemical name	Technical feasibility						Availability (t/y) <sup>1</sup>	Economic	Technical
		HTF	P	S	Lab	A (c,p,i)	A(s,a)			
1	1,2,3,4-Tetrahydro-5-(1-phenylethyl)naphthalene							Confidential	120 000 - 300 000 + <sup>2</sup>	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	?? <sup>3</sup>
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

<sup>1</sup> REACH registration tonnage      <sup>2</sup> € /company, plus other costs related to downtime and disposal

<sup>3</sup> 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 heat transfer that coefficient is lower, resulting in a less efficient process.

Mineral oils have been discarded for technical reasons, indicating that they cannot be used at temperatures above 315-320°C (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 320°C (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 300°C.

SEAC considers that there are currently no suitable alternatives for the use of terphenyl,



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hydrogenated but that this situation may change in the future, the availability of suitable alternatives that do not pose a risk of regrettable substitution should therefore be verified in due time. 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. Orthophthalates 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 it 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 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 function of the substance for its use as HTF is 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 (342°C, at 1atm). But due to the possible wide variety in industrial uses, it is not clear if this temperature is a requirement for all 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

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300°C. 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, a 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):

See RAC opinion.

#### Key elements underpinning the RAC conclusion(s):

See RAC opinion.

### 3.3.4. Conclusion on analysis of alternatives

#### RAC conclusion(s):

See RAC opinion.

#### Key elements underpinning the RAC conclusion(s):

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See RAC opinion.

### **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 based on 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 must 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 no information was available to assess their economic and technical feasibility.

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.

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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 4:

Table 4 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.			
<u>Derogation</u> 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
<u>Derogation</u> 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 Dossier Submitter states that 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 the proposed measures are considered to

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be 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.

**RO1** is considered by the Dossier Submitter to be the RO with the most balanced scenario between socio-economic impacts and the potential for emission reduction (kg avoided emissions of terphenyl, hydrogenated). Under RO1 there is a general derogation for HTF use, provided that such sites implement strictly controlled closed systems with technical containment measures to prevent environmental emissions (described in appendix 5 to the annexes of the Background Document). Under RO1, use and placing on the market of the substance for its use as a plasticiser for the production of aircrafts and their spare parts is proposed to be derogated for five years after entry into force of the restriction

Exposure measurements on facilities using terphenyl, hydrogenated as HTF formed the basis of the Dossier Submitter's assessment that concluded that emissions from HTF plants are negligible (see **Annex B.9.**: Exposure Assessment) if certain design standards are met.

Terphenyl, hydrogenated is critical to many industrial processes and suitable alternatives do not exist for high temperature, non-pressurised HTF applications. The most common alternative substances are expected to have similar vPvB/PBT properties; therefore, replacement would result in significant costs and likely regrettable substitution. Since substitution is not feasible, a ban of terphenyl, hydrogenated is assumed to lead to significant negative socio-economic impacts, potentially resulting in relocation outside of the EU of some industrial users of terphenyl, hydrogenated.

Furthermore, RO1 includes a derogation for the use of terphenyl, hydrogenated in plasticisers in the production of aircrafts and their spare parts from Eif + 5 years. Terphenyl, hydrogenated is used in the aerospace industry as a key ingredient in several critical sealant/adhesive/coating formulations for which it was reported that there are currently no alternatives available. Terphenyl, hydrogenated is used due to its 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 aerospace industry needs time to develop alternative formulations, to test them against performance requirements, and to qualify and validate their use. This process can take several years. It was therefore deemed to be appropriate by the Dossier Submitter to provide a derogation for 5 years after Eif. Considering the date of inclusion in the Candidate List in June 2018 and timeline of the restriction process, the overall timeframe for reformulation was longer than 10 years.

RO1 is still expected to reduce most of the emissions of terphenyl, hydrogenated, as the proposed derogation on plasticiser use in the aviation sector is time limited. According to the Dossier Submitter, the analysis and comparison of the ROs in **Annex E.8.** "Proportionality" shows that RO1 is the most proportionate and cost-effective option and shows, that the need for derogations for both uses is justified.

Under **RO 2** there is a general derogation for HTF use, provided that such sites implement strictly controlled closed systems with technical containment measures to prevent environmental emissions. Under RO2, a restriction on use and placing on the market of the substance as a plasticiser to produce aircrafts and their spare parts will enter into force immediately.

The socio-economic impact on society would be higher and proportionality is lower compared to RO1. As outlined under RO1, the aviation sector is subject to strict regulations, where some parts need rigorous testing and compliance demonstrations to be certified for use. New materials or design changes can only be introduced on the aircraft if testing and compliance demonstrations has been approved. Therefore, the Practicality (implementability, enforceability, manageability) of this option was considered worse to the proposed option RO1, the transitional period (Eif + 18 months) would be considered not to be long enough for the aviation industry to reformulate, test and recertify .

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In addition, it needs to be considered, that aerospace supply chains are complex with many actors involved at different levels involving a significant number of SMEs, which increases complexity and timing for substitution.

The monitorability of the restriction is expected to be similar to the proposed restriction RO1. This option **RO2 was overall discarded** as it would be less net beneficial to society than the proposed restriction.

**RO3** is the RO with the highest risk reduction potential and thus the option that would give over long time the highest environmental benefits related to reduced emissions associated with the use of terphenyl, hydrogenated. Under this RO, no derogations would be granted which would mean that all uses of terphenyl, hydrogenated must cease by the end of the transition period (EiF + 18 months).

The impact on the aviation industry is the same as under RO2. The impact on the HTF sector is considered by the Dossier Submitter to be significant. All ca. 1,300 existing systems using terphenyl, hydrogenated as HTF in the EU would need to either shut down their plants or retrofit their plants for using alternative HTF (potentially leading to regrettable substitution) or alternative technologies. The Dossier Submitter considers that this would not only result in much higher costs and socio-economic impacts but could as well result in higher emissions, since all plants would need to be emptied and the terphenyl, hydrogenated waste would need to be disposed of. The installed volume of about 25 000 t in the EU would become hazardous waste that would be needed to be adequately disposed of.

Therefore, RO3 was discarded as disproportionate. The practicality (implementability, enforceability, manageability) of this option is the worst of all ROs. Monitorability of the restriction is expected to be worse too, compared to the proposed restriction. It will be difficult to monitor at closed HTF systems, if terphenyl, hydrogenated has been replaced.

Actors or sectors that would be heavily impacted by a restriction have a vested interest in putting forward evidence that a derogation for their use is needed. Since few stakeholders outside the HTF and Aviation sector provided such information, this would indicate that a restriction on terphenyl, hydrogenated would not result in disproportionate costs for their uses/sectors.

Therefore, it is concluded that derogations are not needed in any other sectors. ROs with derogations for uses outside the HTF and Aerospace sectors have therefore not been considered. It remains a risk that there are actors with critical uses of terphenyl, hydrogenated, who did not respond to the stakeholder consultations, but in the absence of any such evidence, the Dossier Submitter considers that increasing the risk to the environment by choosing a more lenient RO is not justified

### **RAC conclusion(s):**

See RAC opinion.

### **Key elements underpinning the RAC conclusion:**

See RAC opinion.

### **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

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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 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.

### **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

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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 342°C at 1atm for the whole use of the substance as HTF without any consideration on whether this single criterion is actually 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.

### *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.

One final remark: the restriction aims to reduce emissions mainly by targeting the use of the substance as 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 or use 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



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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 a regrettable substitution would occur. This would be a worst-case scenario where similar emissions of equal concerns would occur that would not be controlled and a non-level playing field is arrived at), then extending the Eif for all the uses as it would take more time to ban the substances that the users switched to.

It is also a plausible scenario that the A&D industry dependent on terphenyl, hydrogenated would have to cease its activities under RO3 and RO2 and maybe under RO1 (because 5 years could be not long enough to get new suitable alternatives approved). Comments submitted by companies using Terphenyl, hydrogenated as HTF claim that they will shut down under RO3 (full ban). This indicates that there can be both regrettable substitution and plant shutdowns under all restriction scenarios.

SEAC furthermore notes that the current restriction only targets Terphenyl hydrogenated, whereas in a recent RMOA of the Finnish authorities the risk of regrettable substitution with substance 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 direct 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. 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.

### 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, 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,

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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).

The main use of terphenyl, hydrogenated in the EU (approximately 90% of the volume) is as a high temperature, non-pressurised HTF. This use takes place in closed systems from which low emissions are, in principle expected. However, situations may arise in which releases could be possible (e.g., top-up, sampling, transport, cleaning and maintenance or final disposal). Because of the properties of terphenyl, hydrogenated as a vPvB substance, those situations could lead to an unacceptable risk of terphenyl, hydrogenated reaching environmental compartments. Furthermore, it is not clear whether industry is currently using the best available technologies to guarantee that emissions during normal operations are adequately controlled. For this reason, a restriction could be based around introducing technical requirements to ensure that terphenyl, hydrogenated is used and handled at industrial settings in an appropriate manner, e.g., via establishing specific technical requirements aimed at granting tight engineering controls on the equipment where terphenyl, hydrogenated is used.

### **RAC conclusion(s):**

See RAC opinion.

### **Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **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, 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:

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- 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, 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 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. The Dossier Submitter consider that their assessment follows SEAC’s advice to use of emission reductions as a starting point for the assessment of potential future benefits, in combination with factors of concern, including the level of persistence and bioaccumulation, long-range transport potential and uncertainty, is 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 (2025-204)

**RAC conclusion(s):**

See RAC opinion.

**Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

**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<sup>5</sup>), 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<sup>6</sup>. 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 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-

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<sup>5</sup> 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.

<sup>6</sup> The exact procedure and all details on costs and economic impacts considered for all RO's are described and explained in Annex E.5.

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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<sup>7</sup>, 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 5: 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.			
<u>Derogation</u> 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
<u>Derogation</u> 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
<u>Derogation</u> for the use of HTF in thermostats of ovens and stoves			

<sup>7</sup> [Candidate List of substances of very high concern for Authorisation - ECHA \(europa.eu\)](https://echa.europa.eu)

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### **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. SEAC also finds that the costs related to unemployment could be underestimated, both because of the distribution of the behavioural assumptions and, because it seems that the number of jobs at

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risk per site is small.

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 M €. 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)<sup>8</sup>
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, Aerospace Industries Association)
5. The document: Aerospace & Defence Qualification Process Impacts on Ability to Substitute Cr(VI) Substances paper (Global Chromates Consortium for Aerospace)<sup>9</sup>

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<sup>8</sup> See: <https://www.easa.europa.eu/en/document-library/general-publications/echa-easa-elaboration-key-aspects-authorisation-process>

<sup>9</sup>See: <https://ramboll.com/-/media/files/reh/GCCAAerospaceDefenceQualificationProcessImpactsonAbilitytoSubstituteCrVISubstanceswhitepaper>

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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, 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.



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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 four in sealants the aviation industry. 4-tert-OPnEO has 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 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 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

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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

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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*

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in SEAC".<sup>10</sup> 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 is provided in table 8 of the RAC opinion as well as the proportionality section of the SEAC opinion):

- o **RAC concludes that emissions cannot be minimised by means other than a ban on use, e.g., due to wide-dispersive uses.**
- o **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 these 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 of a restriction where substitution is likely to occur with other PBT or vPvB substances.

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<sup>10</sup> [https://echa.europa.eu/documents/10162/13580/evaluation\\_pbt\\_vpvb\\_substances\\_seac\\_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3](https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf/af4a7207-f7ad-4ef3-ac68-685f70ab2db3)

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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 assumed, 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

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€ 24 700<sup>11</sup> 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<sup>12</sup>.

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 down or relocate and thus 2 074 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.

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<sup>11</sup> 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).

<sup>12</sup> See: [https://echa.europa.eu/documents/10162/17086/seac\\_unemployment\\_evaluation\\_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25?t=1549885930050](https://echa.europa.eu/documents/10162/17086/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25?t=1549885930050)

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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 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<sup>13</sup>.

Table 6: 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
<b>Total per RO</b>	<b>774</b>	<b>52.25</b>	<b>1 524</b>	<b>102.87</b>	<b>3 598</b>	<b>242.87</b>

The value of the jobs at risk is presented in Table 6. 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.

<sup>13</sup> See: [https://echa.europa.eu/documents/10162/17086/unemployment\\_report\\_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554?t=1476111468417](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 7** shows the Dossier Submitters C/E estimates for each RO. The proposed RO1 has a high C/E (90 €/kg PHT emissions avoided) coupled with a high emission (risk) reduction capacity of 85%. That is why the Dossier Submitter is proposing RO1.

Table 7. Cost Effectiveness of all ROs.

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

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 PHT emissions avoided) compared to RO1. RO3 as the most stringent RO has the highest emission reduction potential but at much higher costs (928 €/kg PHT 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 PHT 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



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produce without access to PHT.

### **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 (noting that that minimisation would not imply complete elimination of emissions). 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 prolonging is in the information submitted in the 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 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 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 proposes a

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20-year time limit and will ask a specific question on the topic on the consultation on its draft opinion.

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, and will ask a specific question on the topic on the consultation on its draft opinion.

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., n 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<sup>14</sup>).

*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 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

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<sup>14</sup> See: [evaluation\\_pbt\\_vpvb\\_substances\\_seac\\_en.pdf \(europa.eu\)](#)

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estimated these costs to be 20 000 € per site and with 1 500 sites it will make 30 M €

SEAC's qualitative judgement is that RO3 is likely not proportionate. Several comments to the stakeholder consultation support the concern that there is a risk for regrettable substitution. Thus, SEAC finds that the benefits are uncertain, even if a full ban for terphenyl, hydrogenated were put in place.

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 therefore 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.

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. As SEAC considers that any premature substitution would result in regrettable substitution and require costly retrofitting in installations that normally have a long lifetime, a time limit would therefore be set based on the expected average lifetime of installations in which terphenyl hydrogenated is used as HTF. SEAC further notes the difficulty in finding alternatives for the use as HTF, given the required properties of any alternative substance.

SEAC also considers that a review should be undertaken before the derogation comes to an end to confirm if alternatives that do not pose a risk of regrettable substitution have become or are close to becoming available. The review should also consider if emissions can be minimised further.

*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 associations (ASD and AIA) provide evidence that five years is not sufficient to substitute to less hazardous chemicals. The major reasons are 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 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

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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.

As a consequence 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.

The Dossier Submitter considers to be **enforceable**; a restriction needs to have a clear scope so that it is obvious to enforcement authorities which products are within the scope of the

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restriction and which ones are not. Moreover, the restriction needs a concentration limit value that can be subject to supervision mechanism. The proposed RO1 provides these prerequisites. The monitoring of the proposed restriction is expected to be done through enforcement. Enforcement activities under RO1 should focus on two actions; firstly, authorities should verify that downstream users of Terphenyl, hydrogenated as a HTF adapt their installations - if needed - to introduce appropriate means of containment to minimise releases and ensure adequate collection of any potential release of the substance. This could be developed via identification of the relevant actors using Terphenyl, hydrogenated in this sector and implementation of inspections by the relevant Member States. The second action would be related to the import of Terphenyl, hydrogenated into the EU, as such, in mixtures or in articles, and the production of articles in the EU. For articles placed on the market, authorities could check the documentation from the supply chain confirming that articles do not contain Terphenyl, hydrogenated.

### **RAC conclusion(s):**

See RAC opinion.

### **Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **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<sup>15</sup>.

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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.

This method has been applied to air samples (PTFE filters for the sampling of inhalable dust) and soil samples (bulk). The methodology used for the collection of these samples is described in **Annex B.9.3.3**. 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, although the method used in the analysis of liquid samples would be the same.

There are limitations with this method, as it is possible to report what terphenyls are found but cannot guarantee that all terphenyls present in the air will be trapped on the filter. Therefore, there may be other compounds present in the air that can be not detected.

There are no standard analytical methods for the identification of the other main individual components of terphenyl, hydrogenated, as m-terphenyl or p-terphenyl. In fact, the NIOSH pocket guides to chemical hazards for o-terphenyl, m-terphenyl and p-terphenyl (CDC, 2019) refer to the NIOSH 5021 analytical method for o-terphenyl as common measurement method.

For this reason, the Dossier Submitter 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. Although this is not a direct method for the identification and quantification of terphenyl, hydrogenated, it can give an idea of the concentration of terphenyl, hydrogenated in the samples.

### **RAC conclusion(s):**

See RAC opinion.

### **Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

### **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

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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):**

See RAC opinion.

#### **Key elements underpinning the RAC conclusion(s):**

See RAC opinion.

#### **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 operational conditions and risk management measures 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 sectors is likely to be proportionate, provided the length of the derogation is extended from 5 to 10 years. SEAC takes note of RAC's conclusions regarding the lack of information on the OC and RMM in place in these sectors of use 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 to further investigate the potential risks from the use of substances containing o-terphenyl.

### 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 Dossier Submitter therefore used a combination of relevant release factors from OECD Emission Scenario Documents (ESD), industry Specific Environmental Release Categories (SPERCs) and default release factors from ECHA Guidance R16. In 2018 an Exposure & Release Questionnaire was sent out to users of Terphenyl, hydrogenated. Information obtained from this questionnaire is also used in the exposure assessment. It is uncertain though whether the used information is applicable to all sites where Terphenyl, hydrogenated is used in the same way.

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. Consequently, the high share of the total of the high emission scenario and the share of the individual use needs to be interpreted with caution.

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):

See RAC opinion.

##### Key elements underpinning the RAC conclusion(s):

See RAC opinion.

#### 3.5.2. Uncertainties evaluated by SEAC

##### Summary of Dossier Submitter's assessment:



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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. 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 8: 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,

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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

### 4.1. 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,

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#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 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

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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 other than HTF and for the use of substance as a 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 the 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

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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 M € 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.

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### *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 M€ 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 produced quantified cost estimates 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.

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### 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 M 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.



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The comments state 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 5940 –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 Submitter's 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 9 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	164	0	425

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sales			
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 M € for each use.

SEAC agrees with this estimation.

### Summary of costs for RO3

Table 10 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.

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Table 11 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 M €. 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 M €.

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 M €, 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 12: 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 €)

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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 13: 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.

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