Response to comments (RCOM) on the Annex XV dossier proposing restrictions on:

Terphenyl, hydrogenated

EC number:	CAS number:
262-967-7	61788-32-7

Annex XV report: Third Party Consultation

Timing: From 20/06/2022 to 20/12/2022

Specific information requests:

In addition to the general comments, the consultation includes several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

Use as high temperature Heat Transfer Fluid (HTF)

1. Any robust, representative data on the Operational Conditions and Risk Management Measures that are in place in heat transfer systems where terphenyl, hydrogenated is used?

2. The Dossier Submitter states that Directive 2014/68/EU - the Pressure Equipment Directive (PED) - would apply to heat transfer systems containing terphenyl hydrogenated and that as such this already sets requirements to these installation in terms of safety. What robust representative evidence is there that these OC and RMM are appropriate and effective in containing the substance and avoiding emissions?

3. The Dossier Submitter states (Section E.3.4 of the Annexes to the terphenyl, hydrogenated Restriction report) that the following measures must be in place to contain the substance: general leakage collection systems, containment devices installed beneath flanges and pumps, retention systems in pumps and valves to ensure that any leakage of terphenyl, hydrogenated through the seals is safely drained off and collected in a contained space, terphenyl, hydrogenated level monitoring. Do you have robust representative data on the extent that these measures in place throughout the sector? What are the costs of installing and operating these OCs and RMMs if not already available?

4. The top-up or refill demand in heat transfer systems is driven by the degradation rate of the HTF and the separated low-boiling and high boiling degradation products. Do you have any information on releases of these degradation products and on the presence of o-terphenyl in the degradation products? How are releases to the environment avoided when e.g. fluids are replaced or topped-up, when accidental spills occur or when installations are decommissioned at the end of service life. Do you have robust, representative information on the likelihood and severity of accidental releases of terphenyl, hydrogenated including accidental spills, disposals, decommissioned installations? Do you have any robust representative data on how wastes are managed in heat transfer systems?

5. The Dossier Submitter has identified (Section E.A.1 of the Annexes to the terphenyl, hydrogenated Restriction report) that the heat transfer systems play a role in the further development of renewable energy sources (in e.g. solar panels) and that as such the use of terphenyl-h in these applications is assumed to grow. What is the expected Compound Annual Growth Rate for HTF? Would a restriction on terphenyl-hydrogenated be an impediment to the further development of renewable energy sources?

6. Considering the use of terphenyl, hydrogenated, as a heat transfer fluid, the Dossier Submitter discards some alternatives based on boiling point. However, the boiling point depends on the type of process in which the HTF fluid is used. Could other alternatives for HTF like biphenyl, (hybrid organic) silicones or mineral oil be used for some processes (for example Concentrated Solar Panels (CSP) or Organic Rankine Cycle (ORC) or some chemical plant)? Could you provide justification, to support a derogation or why alternatives to terphenyl, hydrogenated are not suitable? We would particularly welcome information on any specific technical criteria relevant to specific uses that could not be fulfilled by alternatives.

Other uses

7. Any robust, representative information on uses of terphenyl, hydrogenated as a plasticiser in coatings, sealants, adhesives, polymers, cables and inks? Although the above uses have been identified by the Dossier Submitter, very limited information is reported. Is terphenyl, hydrogenated used in processes and articles other than those mentioned in the restriction proposal? What is the function of terphenyl, hydrogenated in articles, in what type of articles is it applied and at what is the concentration of terphenyl, hydrogenated in the articles that is needed in order to achieve this function? How are the markets for the articles including terphenyl, hydrogenated? Is there competition from alternatives? Which markets are expected to grow, and which are not?

8. Any further robust representative information on specific uses of terphenyl, hydrogenated in the aerospace applications to justify the proposed derogation by the Dossier Submitter? Relevant information for these uses (i.e. articles and aerospace applications) could include, amounts currently used, site-specific emission data (associated with manufacture, service-life or end-of-life (management at waste stage)), and any impacts (costs and benefits to society) of the proposed restriction on these uses (in line with the elements of a socio-economic analysis (SEA) as outlined Annex XVI of REACH.

9. Information on analytical method(s): which analytical methods are available to quantify terphenyl, hydrogenated (or its constituents such as o-terphenyl) in substances, mixtures and articles (apart from NIOSH 5021 “o-Terphenyl”) and what is the applicability of these analytical methods at EU level?

10. Any further information on actual concentration of Terphenyl, hydrogenated in recycled materials (or as impurity in substances and mixtures) and information on how the proposed restriction could potentially affect the concentration of terphenyl hydrogenated in recycling (especially of plastic materials)

11. As terphenyl, hydrogenated and biphenyl are produced together in the same process as coproducts, if terphenyl, hydrogenated would be banned, how would it affect to the biphenyl final cost? In case of maintaining biphenyl production how would terphenyl, hydrogenated be disposed of?

12. In which other substances, mixtures and articles is ortho-terphenyl present? What are the associated uses? What would have been the consequences of this restriction, in terms of avoided emissions and compliance, if the scope would have been on ortho-terphenyl instead of terphenyl, hydrogenated?

Overview of comments received

In total 61 comments were received, 51 of them from companies (#3589, #3591, #3637, #3656, #3658, #3659, #3661, #3662, #3663, #3664, #3666, #3669, #3670, #3671, #3672, #3673, #3674, #3675, #3676, #3677, #3679, #3680, #3681, #3683, #3684, #3685, #3686, #3687, #3689, #3690, #3691, #3693, #3695, #3696, #3697, #3698, #3699, #3700, #3701, #3702, #3703, #3704, #3705, #3706, #3709, #3710, #3713, #3715, #3716, #3717, and #3720), 5 from individuals (#3660, #3665, #3678, #3692, and #3694), 3 from industry or trade associations (#3655, #3707, and #3711), and 2 comments were submitted by Member States (#3712, #3719). No comments were received from NGOs.

4 comments received from companies (#3677 and #3681) and from individuals(#3692 and #3694) were empty and without any information. Therefore, these comments have not been considered and the total number of valid comments have been set at 57.

Figure 1 gives an overview of the comments per type of submitter:

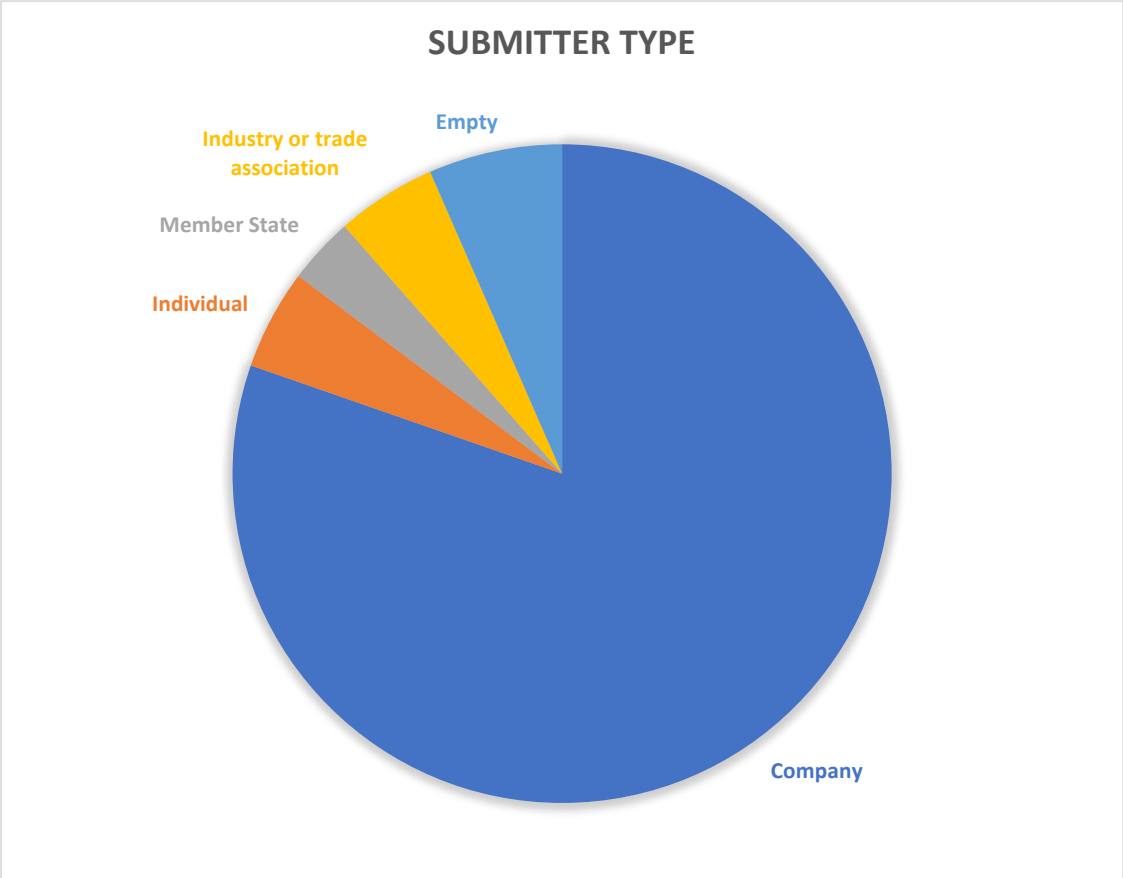

Figure 1: Overview of comments per type of submitter

Out of the 57 comments 52 (91%) were received on the use of Terphenyl, hydrogenated as Heat Transfer Fluid (HTF). 3 comments (from 2 organisations and 1 company) were received on Terphenyl, hydrogenated use in the aviation and defence industry (#3655, #3662, #3707).

The number of comments per country were as follows:

- Austria (3)
- Belgium (4)
- Czech (1)
- Estonia (1)

- Finland (1)
- Germany (3)
- Greece (2)
- Hungary (1)
- Italy (16)
- Latvia (1)
- Lithuania (2)
- Luxemburg (1)
- Netherlands (7)
- Poland (6)
- Romania (1)
- Slovakia (1)
- Spain (2)
- Sweden (2)
- Switzerland (1)
- UK (1)

An overview of the origin of comments that were submitted per Member State is presented given in Figure 2:

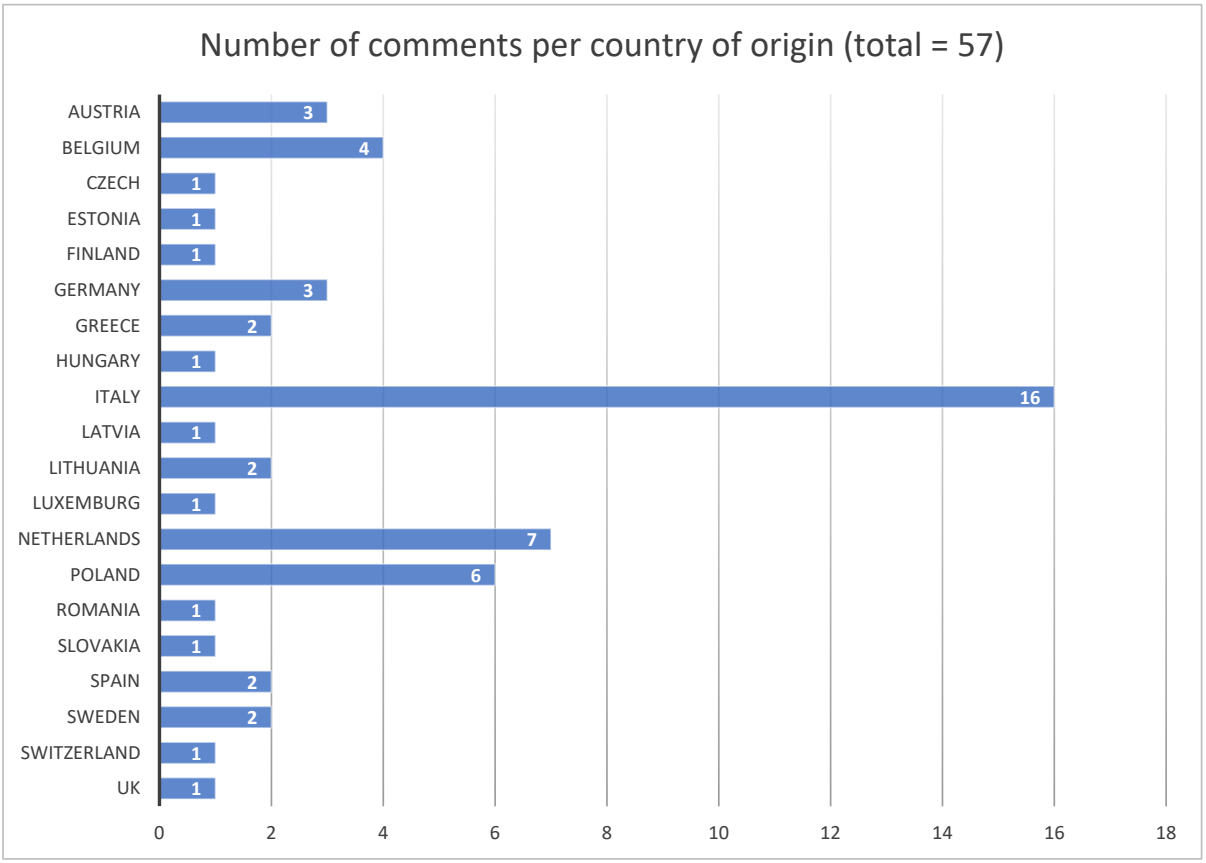

Figure 2: Overview of comments per country of origin

In total, comments from stakeholders in 18 EU Member States were received and 2 from non-EU countries (UK and Switzerland). Most comments (28%) were submitted by Italian stakeholders, 12% by stakeholders from the Netherlands, 11% by stakeholders from Poland, followed by Belgium (7%), and Austria and Germany (each 5%).

An overview of the areas of interest is presented given in Figure 3:

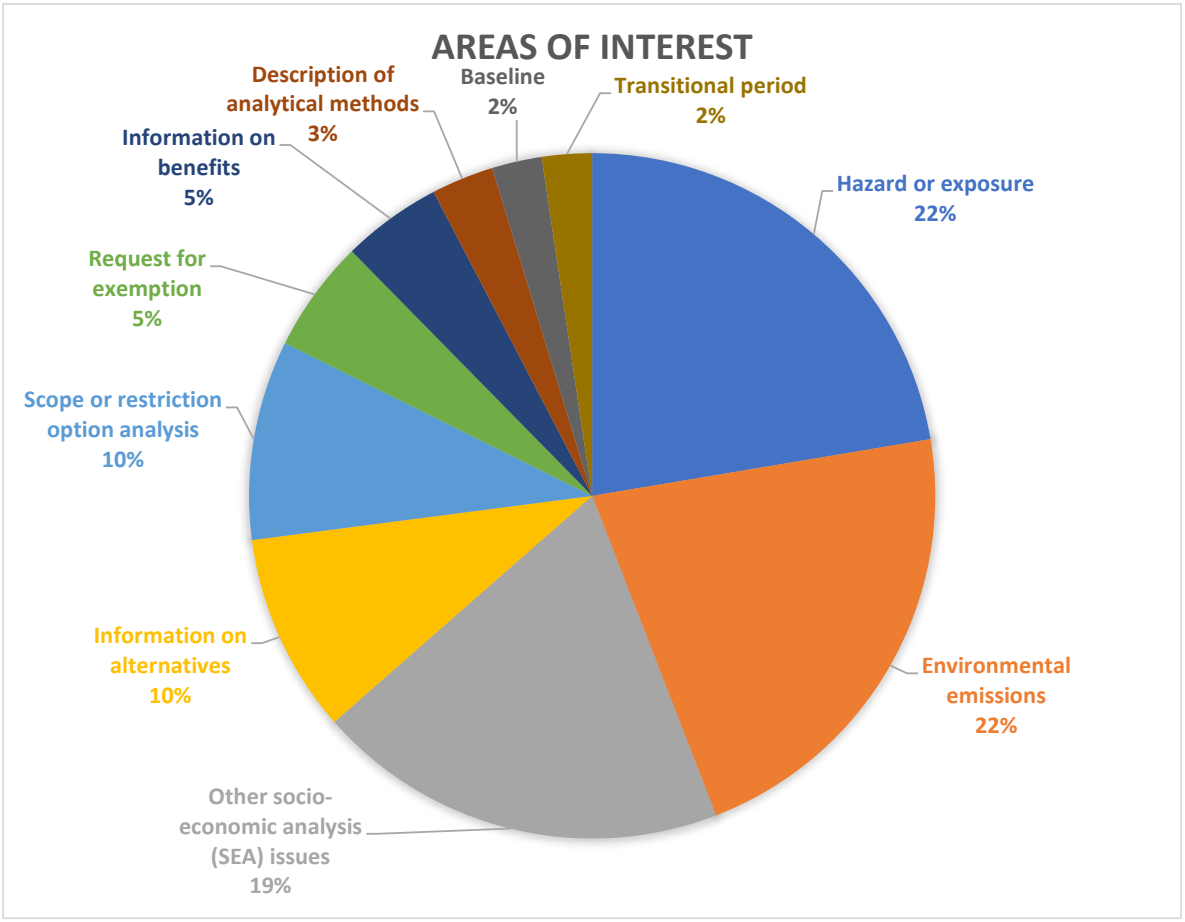

Figure 3: Overview of the areas of interest

The main areas of interest in the consultation are related to the hazard and exposure, environmental emissions, and other socio-economic analysis (SEA) issues. The structure of this document responding to comments (RCOM) is organised around the main items and issues raised in the consultation.

Response to comments by Dossier Submitter

The Dossier Submitter would like to thank all interested parties that submitted comments and information to the Annex XV consultation. The Dossier Submitter notes that many of the comments received were similar in nature and could be grouped into topics.

To improve the clarity of the responses, the Dossier Submitter has prepared a set of general responses to common topics addressing multiple individual comments followed, when appropriate, by specific responses to individual comments.

These general responses summarise the nature of the comments received and describe, in general terms, how the Dossier Submitter has responded to them, typically by revising specific parts of the Background Document. As such, detailed responses to the comments are often only contained in the Background Document. Where appropriate, for example where there is no update to the Background Document in response to comments on a particular topic, a more elaborated response is provided in this RCOM.

To assist stakeholders to understand how their comments were assessed, the Dossier Submitter has provided an indicative list of comment numbers that are associated with a specific topic(s). Nevertheless, whilst the Dossier Submitter has made best efforts to report these lists for each topic, these lists are not meant to be exhaustive. Therefore, unless a comment has been responded to specifically and individually or within a general response, it should be understood that the Dossier Submitter has considered all of the comments received in the consultation when

preparing these general responses. In some cases, the Dossier Submitter has responded to comments by revising the wording of the "conditions of the restriction" (e.g. the use of Terphenyl, hydrogenated in the aviation and defence industry). Commenters should note that the wording of the conditions of the restriction in the Background Document is only intended to express the intention of the Dossier Submitter in a form which is a concise as possible and is not a proposal for legal text in Annex XVII. The European Commission will decide on the legal wording used to update Annex XVII of REACH if a restriction is adopted.

The comments received have been grouped into the following topics:

- Use as Heat Transfer Fluid
- Use as a Plasticiser
- All uses in Aviation and Defence
- Use as Solvent/process medium
- Use as Laboratory chemical
- Miscellaneous

1. Use as Heat Transfer Fluid

1.1. General Comments

As mentioned above, 91% of the responses are related to the use of Terphenyl, hydrogenated as HTF (#3589, #3591, #3637, #3656, #3658, #3659, #3660, #3661, #3663, #3664, #3665, #3666, #3669, #3670, #3671, #3672, #3673, #3674, #3675, #3676, #3678, #3679, #3680, #3683, #3684, #3685, #3686, #3687, #3689, #3690, #3691, #3693, #3695, #3696, #3697, #3698, #3699, #3700, #3701, #3702, #3703, #3704, #3705, #3706, #3709, #3710, #3711, #3713, #3715, #3716, #3717, and #3720). In general, the comments on the HTF uses did not result in any additional information that would have required an update of the Background Document. On the contrary, the comments received fully support and underline the information provided in the Annex XV Restriction Dossier and the Background Document. Hence, the Dossier Submitter does not see any reasons to update the Background Document regarding the use of the substance as a HTF use since no information was submitted during the consultation on the Annex XV Dossier that contradicted the Dossier Submitter's conclusions.

1.2. Operational Conditions (OCs) and Risk Management Measures (RMMs)

44 out of 52 responses from the HTF-users responded, that OCs and RMMs are in place and that the heat transfer systems are applying strictly controlled closed systems (#3589, #3591, #3637, #3656, #3658, #3659, #3660, #3661, #3663, #3664, #3665, #3666, #3669, #3670, #3672, #3673, #3674, #3675, #3676, #3679, #3684, #3685, #3686, #3687, #3690, #3691, #3693, #3695, #3696, #3697, #3698, #3700, #3701, #3702, #3704, #3705, #3709, #3710, #3711, #3713, #3715, #3716, #3717, and #3720). In addition it was confirmed by 43 respondents that releases are highly unlikely and if they occur, they are accidental (#3589, #3591, #3637, #3656, #3658, #3659, #3660, #3661, #3663, #3664, #3665, #3666, #3669, #3670, #3671, #3672, #3674, #3675, #3676, #3679, #3680, #3683, #3684, #3685, #3686, #3687, #3690, #3691, #3693, #3695, #3696, #3698, #3700, #3701, #3703, #3704, #3709, #3710, #3711, #3713, #3716, #3717, and #3720).

This information has been used by the Dossier Submitter in the definition of Strictly Controlled Closed Systems (SCCS) and related OCs and RMMs, that are already in the Background Document (see Section 2.3.1 and Appendix 5).

1.3. Role in Renewable Energy Sources

13 respondents (> 23% of all responses) agree with the Dossier Submitter that Terphenyl hydrogenated is important for innovative technologies in the sector of renewable energy sources. 11 companies who participated are operating Organic Rankine Cycle (ORC) biomass facilities (#3661, #3669, #3671, #3672, #3673, #3674, #3675, #3683, #3691, #3702, #3716) and one company operating in the Concentrated Solar Power (CSP) sector (#3666) highlighted the role of terphenyl, hydrogenated in its operations. This is in line with the information of the Dossier Submitter as reflected in the Restriction Proposal.

Based on an assumed increase in the use of renewable energy sources, the Dossier Submitter assumed that the number of HTF installations containing Terphenyl, hydrogenated will increase in the coming years. Based on the comments received, the Dossier Submitter does not see the need to update the Background Document, the responses underline the findings of the Restriction Proposal fully.

1.4. Alternatives

40 comments regarding potential alternatives to Terphenyl, hydrogenated when used as HTF have been received (#3589, #3591, #3637, #3658, #3659, #3660, #3661, #3663, #3664, #3665, #3666, #3669, #3671, #3672, #3674, #3675, #3676, #3679, #3680, #3683, #3684, #3685, #3687, #3689, #3690, #3691, #3693, #3695, #3697, #3698, #3700, #3701, #3705, #3706, #3709, #3710, #3713, #3716, #3717, and #3720).

The respondents are unaware of any alternative with the same properties and performance to be considered as drop-in substitutes. Other potential alternatives should be evaluated accurately, and this will take time and economical efforts (extra costs related to design and R&D activities). 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 (resulting either significant, costly adaptations or in a complete redesign of the installation). 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).

Regarding mineral oils, 5 respondents (#3663, #3676, #3680, #3693, and #3706) state that there are some technical issues related to their use as a HTF: they cannot be used at high temperatures (over 280-300°C), and tend to form sludge and deposits in the heat exchanger during overheating, their lifespan is lower when compared to Terphenyl, hydrogenated, etc. Therefore, in the case of substitution, they must be replaced more frequently, and the system must be cleaned each time, increasing maintenance costs and disposal waste (and its associated higher cost).

2 respondents (#3676 and #3706) indicate that silicon fluids are not suitable alternatives due to their high viscosity (pumping issues in the current installations) and the tendency to create silicon-based by-products (which may precipitate or increase the fouling).

Regarding Biphenyl, 1 comment (#3676) states that this substance cannot be considered as an alternative because it has a very low flash point, not suitable for their heat transfer system. Another 2 comments (#3705 and #3706) inform that, to use this substance as an alternative, the system has to be pressurised (retrofit of the installation at a high cost).

Finally, 7 respondents indicate that some of the potential alternatives show the same PBT properties (#3679, #3684, #3689, #3690, #3693, #3697, and #3698) For this reason, the use of these substances leads to the same potential environmental problems of the Terphenyl, hydrogenated and, therefore, the substitution should be considered regrettable. This information is in line with the comment from the Finnish Competent Authority (#3712).

All the information received is in line with the analysis of alternatives to Terphenyl, hydrogenated when used as HTF and, therefore, the Dossier Submitter does not see the need to update the Background document.

1.5. Socio-Economic Impact

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.

Considering that Terphenyl, hydrogenated is used in some very important industries, this impact would be felt by consumers, who would find it difficult (low supply and/or high prices) to access items that are key to modern living standards.

The Dossier Submitter consider that these comments do not result in any additional information that would have required an update of the Background Document.

1.6. RAC Rapporteurs Comments

RAC acknowledged the number of submitted comments, which are very uniform in describing the use of HTF in closed systems and reporting only accidental releases of Terphenyl, hydrogenated in line with the information provided in the Background Document.

However, RAC notes the absence of monitoring data provided by the responding companies to support this statement and identifies that some companies mention accidental releases directed to their wastewater treatment plants (#3637, #3665) and accidental leakages, which is collected in an oily water storage tank for pre-treatment prior to sending to the wastewater treatment plant and/or managed via the national rule on waste management (#3637, #3661, #3665, #3666, #3695)

RAC is of the opinion that, overall, the OCs and RMMs described by the Dossier Submitter in the Appendix 5 of the Background Document are effective and appropriate to minimise the risk resulting from environmental releases of terphenyl, hydrogenated. However, RAC notes that the proposed OC/RMMs are only optional and cannot be assessed for each HTF user. Therefore, RAC considers that the only way to ensure the effectiveness of the strictly controlled conditions described by the Dossier Submitter is to implement a representative monitoring program covering the different conditions of use of the HTF system. Such monitoring would allow for better evaluation of the situation at the industrial sites and would confirm the appropriateness and effectiveness of OCs and RMMs in place. Such monitoring results would also allow enforcement authorities to verify compliance with the restriction.

RAC acknowledged the number of submitted comments related to the absence of reliable alternatives for the industrial use of HTF (#3637, #3659, #3666, #3669, #3672, #3679, #3687, #3689, #3690, #3693, #3697, #3698, #3701, #3706, #3709, #3710, #3714, #3716, #3717, #3720). Some respondents also indicate that alternatives with other parameters and potentially with lower environmental concern cannot provide the same heat exchange and resistance capability and will lead to a significant redesign of the installation (#3658; #3675, #3676, #36791, #3695). Furthermore, it is not known in how many industrial installations terphenyl, hydrogenated is used in low temperature (<300-325 °C) conditions.

RAC acknowledged the comment that an unlimited derogation of the use of terphenyl, hydrogenated, identified as SVHC, as a HTF in industrial use would hamper the aim to promote a progressive substitution when suitable alternatives become available (#3719). The Dossier Submitter has not given a response to this comment. RAC is of the opinion that a time limit is required for the derogation of HTF use at industrial sites in order to promote the development of safer alternatives, RAC, emphasizes the shortest possible time limit to minimise environmental emission as far as possible but considers that the length of the time-limit would to be elaborated by SEAC.

11 companies who participated are operating Organic Rankine Cycle (ORC) biomass facilities (#3661, #3669, #3671, #3672, #3673, #3674, #3675, #3683, #3691, #3702, #3716) and one company is from the Concentrated Solar Power (CSP) sector (#3666) highlighting that Terphenyl hydrogenated is important for innovative technologies in the sector of renewable energy sources. This is in line with the information of the Dossier Submitter as reflected in the Restriction Proposal. RAC agrees with the Dossier Submitter that the number of HTF installations containing Terphenyl, hydrogenated is assumed to increase in the coming years in parallel with this sector.

1.7. SEAC Rapporteurs Comments

SEAC acknowledges the number of submitted comments related to renewable energy installations (biomass ORC and CSP) that provide more information on the use of terphenyl, hydrogenated. Although the information is not necessarily an indication of the market growth per se, SEAC recognises that there is a great potential for the use of terphenyl, hydrogenated in the conversion of low and medium temperature heat, in green energy systems such as solar energy systems, biomass combustion or waste heat sources. Within the context of renewable energy sources, the Organic Rankine Cycle (ORC) is an important technology for exploiting these

low to medium temperature-based systems and SEAC can therefore concur with the potential increase in need for terphenyl, hydrogenated and the market growth foreseen for this substance indicated by the Dossier Submitter in the annex XV dossier.

SEAC acknowledges that there are no comments indicating that there exists an available alternative (that is not PBT) and that substitution would be considered regrettable.

Based on the information submitted in the consultation on the Annex XV report, The Dossier Submitter did not see any reason to update the cost estimates, as the few comments that have come up with quantified cost estimates do not, according to the dossier submitter, change the costs estimates that were already provided in the submitted Annex XV dossier. SEAC acknowledges that it is not necessary to update the cost estimates for HTF and takes the cost estimation already submitted by the Dossier submitter forwards in its evaluation of the impacts of the proposed restriction.

SEAC recognises that Terphenyl, hydrogenated is used in several renewable energy installations and that there is a potential for a consumer loss, both according to consumers preferences in the energy market, energy prices and potential consequences for climate change. These costs are not quantified, these costs are however considered qualitatively in SEAC's opinion.

Based on the long lifecycle of HTF installations, the risk of regrettable substitution and the significant wider impacts associated with a premature replacement of the substance and or a full stop of the use of terphenyl, hydrogenated in HTF installation SEAC finds on the one hand that there is reason to consider that that if the risk is adequately controlled the timeless derogation could be justified. On the other hand, should a time limited derogation be proposed then this should be linked with expected operating life of the relevant installations. SEAC proposes that a time limit of 20 years could be appropriate but will seek more evidence on the advantages and disadvantages of such a time-limited derogation in the SEAC draft consultation.

2. Uses in Aerospace and Defence

In total 3 responses (#3655, #3662, #3707) were received on uses of Terphenyl, hydrogenated in aviation and defence industry and new information was provided. One joint response from the Aerospace and Defence Association of Europe (ASD) and the Aerospace Industrial Association (AIA) was succeeded by a follow-up submission. The other response was from a downstream user of Terphenyl in formulations in different formulations for the aerospace and defence (A&D) industry.

Terphenyl, hydrogenated is used as an ingredient in formulations for catalysts, adhesives, encapsulants and varnishes, but not only in the aerospace and defence industry. The manufacturing takes place outside of the EU, final articles are exported to the EU. It was reported that for all use applications, no viable Terphenyl, hydrogenated-free alternatives have yet been identified.

ASD/AIA responded that the primary ongoing use in this sector is found in sealants and adhesives, but as well in top-coat formulations and in resin catalyst mixtures, which is confirming basically the findings of the Dossier Submitter. The technical function of Terphenyl, hydrogenated seems not to be clear, but the understanding of the Dossier Submitter is that the technical functionality is predominantly as a plasticiser, but ASD/AIA is not sure that this is the only functionality provided by the substance. The supply chain has reported in addition to this use also other uses, such as a dispersant or a carrier.

A long list of properties and performance requirements needed for Terphenyl, hydrogenated containing sealants/adhesive was provided. However, these properties need to be met by the mixtures and not Terphenyl, hydrogenated itself.

In addition, ASD/AIA made clear, that the sectorial use is broader than for aircrafts only but should be applied for all applications in the A&D industry.

Based on the provided information, the Dossier Submitter has modified the derogation scope to go beyond just aircraft applications and supports the derogation of all applications in the aerospace and defence industry.

Due to the unclear functionalities of Terphenyl, hydrogenated in formulations for applications in the A&D industry, the derogation scope was modified too in this respect. The Dossier Submitter proposes to derogate the use and placing on the market in aerospace and defence applications and their spare parts to consider the unclear functionalities.

Moreover, the Dossier Submitter broadened the derogation by including “maintenance and repairs”, as requested by ASD/AIA. Furthermore, ASD/AIA is anticipating that it takes 10 years or more to substitute Terphenyl, hydrogenated due to the complexity of the alternatives development.

Regarding the request to extend the derogation timeline to 10 years after entry into force, the Dossier Submitter disagrees for the following reasons:

- SVHC Substances are by definition subject to risk management measures. It is therefore not surprising that risk management measures are now being implemented for the substance. Terphenyl, hydrogenated was included in the SVHC List in early 2018. A realistic Entry into Force (EiF) for a REACH restriction is considered earliest in 2025. 5 years after Entry into Force of the Restriction the derogation of the use in the A&D industry should cease, which is assumed to be 2030. In total this has provided industry at least 13 years for finding alternatives for reformulation and certification.

- The Dossier Submitter has evidence, that alternatives for its use as a plasticiser do exist:

    - Via internet research it was found that substitution of Terphenyl, hydrogenated in epoxy-based adhesives is taking place already. Product literature from an adhesives company does demonstrate, that the substance was removed from

their products to address global regulatory concerns regarding its vPvB properties.

- A further in-depth analysis on plasticisers revealed that there are classes of phthalates, different from orthophthalates, which are in general less hazardous, such as Isophthalates and Terephthalates. There is an ECHA document on the Assessment of Regulatory Needs (ECHA 2021) that reports information on this group of phthalates. While for some substances the need for further studies is highlighted, for others the results indicate that, due to the unlikely hazard of these substances, there is currently no need for further EU regulatory risk management measures.

- No quantitative data on costs were provided so far. The Dossier Submitter invited the A&D industry in 2021 to participate and provide comments for the Restriction Proposal preparation via its Socio-Economic-Analysis Questionnaire. Unfortunately, no comments were received at this time.

2.1. RAC Rapporteurs Comments

RAC acknowledges the three responses on uses of Terphenyl, hydrogenated in the aerospace and defence sector. One joint response (#3655) from the Aerospace and Defence Association of Europe (ASD) and the Aerospace Industrial Association (AIA) was succeeded by a follow-up submission (#3707). The other response was from a downstream user of Terphenyl, hydrogenated (#3662) in different formulations for the aerospace and defence (A&D) sector (among other sectors).

ASD and AIA explained that their members still rely on the use of Terphenyl, hydrogenated in formulations used for both production and repair of aerospace and defence (A&D) products. ASD and AIA members also import articles containing PHT (>0,1%). In addition, ASD/AIA made clear, that the sectorial use is broader than for aircrafts only but should be applied for all applications in the A&D industry. ASD/AIA responded that the primary ongoing use in this sector is found in sealants and adhesives, but as well in top-coat formulations and in resin catalyst mixtures. Further general information on RMMs and OCs at factory/industrial settings including repairs at airports is given, which includes trained workers, compliance with SDS, no expected wastewater releases for sealant/adhesive formulations which are not water-miscible, waste management during formulation and repair/maintenance procedures. Formulation and mixing of polysulfide sealants/adhesives also containing octylphenol ethoxylate (OPE) are managed according to the RMMs and OCs of the REACH authorisation (AfA 0203-02).

Concerning the REACH authorisation, RAC notes, as OPE is only present at <0.1% in the sealants, it is not further subject to authorisation and information on the service life is sparse. As already noted, the waste disposal of the articles is expected to be the major source of releases for these uses. RAC also notes that environmental release of OPE during service life is assumed to be low due to its interaction with the matrix and that no re-use and hazardous waste treatment at the end of the service life are performed as part of aviation requirement. However, there is not sufficient information to assume that the RMM/OCs in place for the polysulfide sealants can be extrapolated to all formulations used in the A&D sector that include not only sealants/adhesives but also finished paints and topcoats. Moreover, terphenyl hydrogenated is more volatile and used at far higher concentration than OPE in the formulations which could potentially lead to an increased environmental release. Overall, RAC considers the aerospace and defence applications as a wide-dispersive use due to the professional use of various formulations. RAC notes that even if the volume of the substance related to aerospace and defence applications is not known with precision, it represents <10% of the imported tonnage range estimated at approximately 730 T/y. However, there is not enough information to ensure minimisation of emissions of terphenyl, hydrogenated from all formulations used in the aerospace and defence sector. RAC concludes that a general derogation for the use of Terphenyl, hydrogenated in aerospace and defence applications cannot be supported.

Evaluation of proportionality and cost/benefit for restricting as well as derogating uses will be performed by SEAC.

2.2. SEAC Rapporteurs Comments

Taking into considerations the comments received and the Forum advice, SEAC agrees with the Dossier Submitter on the need to change (widen) the scope of the derogation for the aerospace industry.

SEAC takes note of the Forum advice, which highlighted that use 'as a plasticiser' would require enforcement authorities (NEAs) to determine if Terphenyl hydrogenated is indeed added as a plasticiser or for other purposes which is something the Forum saw as problematic for enforcement. To facilitate enforcement Forum had suggested to take away 'use as a plasticiser' and focus merely on the presence of the substance rather then it's intended use in an article.

SEAC takes note of the evidence provided by the Aerospace aviation and Defence sector on the need for a longer period for a derogation. SEAC discusses this further in its opinion but notices that on several occasion in the process of applying for authorisation, long phase-out periods have been granted based on the strict safety requirements set in the aviation sector and the long re-qualification periods that are required to meet these strict safety requirements.

SEAC does not agree with the Dossier Submitter considerations that a five-year transition period is sufficient and considers that the internet search and the findings on substitution on some epoxy-based adhesives is not enough evidence to claim that suitable alternatives are available in general. On the contrary, the comments received indicate that, as of today, most of the uses neither are substituted nor that there is an alternative identified.

SEAC acknowledges that the timelines for substitution depend on both finding a formulation and passing the certification requirements.

SEAC agrees that there is no quantitative estimation of the consequences of not having an alternative in time but also recognises the important consequences for the industry and the society if there is no alternative in place.

The Dossier Submitter has not given any response to the comments on behavioural assumptions. These comments states that the airplanes need to be grounded if they do not fulfil all the requirements and have the correct certification. The behavioural assumptions will affect the cost estimations, as it is defining which costs to include. SEAC notes that the Dossier Submitter has not updated the cost estimates or qualitative assessment of costs for the aviation sector. SEAC finds that the submitted evidence would have constituted enough evidence to do so.

SEAC finds it reasonable to take the qualitative assessment provided by ASD/AIA as reliable and to consider a longer transition period of the use of terphenyl, hydrogenated in the aviation and defence sector. Further reasoning on this is provided in SEAC's draft opinion.

3. Use as a Plasticiser in non-aviation uses

One response from a manufacturer (#3662) of components mainly for the A&D industry using Terphenyl, hydrogenated mixtures in their components was received. It was pointed out in this comment 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 details on costs were provided, no suitable PHT-free solutions have been identified so far.

No responses from the end-application users in the medical, scientific and process industry were received during the consultation on the Annex XV dossier. This actually supports the Dossier Submitters view, that the application of Terphenyl, hydrogenated as plasticiser in non-aviation applications has been replaced already or will be substituted shortly, as outlined in the Restriction Proposal and the Background Document. Recent evidence of substitution by industry players was found via literature search. This new information on substitution was included in the Background Document (see Section 2.2 and Annex E.2.2). Besides, further potential alternative plasticisers were identified via a literature search and included in the updated dossier too (see Section 2.2 and Annex E.2.2).

3.1. RAC Rapporteurs Comments

RAC acknowledges the information provided 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. RAC notes that, based on the notifications to the SCIP database, the origin of articles containing terphenyl, hydrogenate and whether they are imported into the EU or exported to third countries is highly uncertain. The concentration ranges of terphenyl, hydrogenated applied in articles to retain its function is not known in most cases. RAC concludes that overall, the lack of information regarding the articles brings a significant uncertainty in the release and risk assessment of terphenyl, hydrogenated. RAC supports a ban on the placing on the market and use as a plasticiser in non-aviation uses to address the identified risks.

3.2. SEAC Rapporteurs Comments

SEAC acknowledges that only one comment has been received during the consultation on the Annex XV dossier on this use. 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 of the Dossier Submitter that this use has been replaced or substituted or that it is easy to substitute however SEAC has concerns about potential regrettable substitution having taken place.

4. Use as Solvent / Process Medium

No responses were received during the consultation on the Annex XV dossier on this use. This supports the Dossier Submitters view, that the application of Terphenyl, hydrogenated as solvent or process medium have been replaced already or will be substituted shortly, as outlined in the Restriction Proposal and the Background Document. Therefore, the Dossier Submitter did not identify a need to update the Background Document.

4.1. RAC Rapporteurs Comments

RAC acknowledges that no comments have been received during the consultation on the Annex XV dossier on this use. RAC notes that 'miscellaneous uses' represent 1% of all uses of Terphenyl, hydrogenated and includes solvent/process medium and laboratory chemical.

In the absence of information on RMMs for those uses, the Dossier Submitter concludes that formulation, industrial use as solvent/process medium and use as laboratory chemical by professionals can generate releases into the environment.

4.2. SEAC Rapporteurs Comments

SEAC acknowledges that no comments have been received during the consultation on the Annex XV dossier on this use. 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 use has been replaced or substituted or that it is easy to substitute but SEAC has concerns about potential regrettable substitution having taken place.

5. Use as a Laboratory Chemical

There was no response related to the use of Terphenyl, hydrogenated as a laboratory chemical.

However, related to the use as HTF, 19 respondents mention (#3589, #3591, #3656, #3658, #3659, #3661, #3663, #3669, #3675, #3679, #3685, #3690, #3691, #3693, #3695, #3698, #3701, #3709, #3710) that analysis of the HTF is done at intervals to keep track of the HTF quality and the presence of low-boiling and high-boiling degradation products. These analyses are taking place as quality control measures in laboratories for the monitoring of the HTF degradation status. Therefore, this use is related to the use of Terphenyl, hydrogenated as HTF and described in the Exposure Assessment of the Background Document and is part of the Strictly Controlled Closed System conditions as described in Appendix 5 of the BD. According to the dossier submitter interpretation, the sampling and quality analysis is already covered by the HTF-use derogation. Consequently, the Dossier Submitter does not identify a need to update update the Background Document.

5.1. RAC Rapporteurs Comments

RAC acknowledges that no comments have been received during the consultation on the Annex XV dossier on this use. RAC is of the opinion that the lack of information does not allow the assessment of the environmental releases for these uses. RAC supports a ban on the placing on the market and use as laboratory chemical uses (professional use) to address the identified risks.

5.2. SEAC Rapporteurs Comments

SEAC acknowledges that no comments have been received during the consultation on the Annex XV dossier on this use. 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 use has been replaced or substituted

6. Miscellaneous

6.1. Co-Production of Terphenyl, hydrogenated and Biphenyl

The response from #3589 confirmed that Terphenyl, hydrogenated and Biphenyl are manufactured as accompanying products, as outlined in the Restriction Dossier. If a decision is taken to ban Terphenyl, hydrogenated completely (e.g. via Restriction Option 3), it will then be impossible to produce Biphenyl and production of that product would cease also. Biphenyl has a wide range of uses including as a critical component in some products that are used widely in the CSP market. Withdrawal of these products would have a severe impact on the global Concentrating Solar-thermal Power (CSP) industry. The Dossier Submitter wants to note, that the scenario on a potential ceasing of Biphenyl manufacturing was not taken into account in the Socio-Economic Impacts of RO 3, since relevant information was and is currently not available for a robust Socio-Economic Analysis. Consequently, the Economic Impacts on RO3 are currently underestimated.

6.2. Restriction vs Authorisation

The comment received from the Swedish Competent Authority (SE CA) – KEMI (#3719) raises the possibility that Restriction may not be the best Regulatory Management Option (RMO) to address the risk related to the use of Terphenyl, hydrogenated as HTF. This comment states that the proposed derogation without time limit is in fact no suggestion for the Restriction of this use. KEMI proposes a targeted restriction for the uses where an unacceptable risk can be clearly identified and fulfil the aims of REACH to progressively substitute SVHCs by adding Terphenyl, hydrogenated to annex XIV followed by Authorisation.

The Dossier Submitter wants to point that both RMOs (Restriction and Authorisation) were evaluated in a previous RMOA performed on this substance and the outcome of this process was

Restriction as the best RMO. The details of this evaluation can be found in the document that has been shared with all of the National CAs.

Furthermore, the result of the analysis of alternatives included in the Background Document (that has been supported by the Finnish CA, according to comment #3712, and by many of the comments submitted by the industrial respondents), states that there are currently no viable alternatives for the substitution of Terphenyl, hydrogenated when used as HTF, and that some of the potential alternatives could came into a regrettable substitution, as their PBT properties are similar. This means that, at this moment, the Authorisation would also not lead to the substitution of the substance neither to the reduction of the risk.

However, as the use of the substance as HTF has been directly linked to the compliance with the strictly controlled closed system (SCCS) condition through the derogation included in the Restriction proposal, the risk can be easily controlled by enforcement, without any time limit.

6.3. RAC Rapporteurs Comments

RAC acknowledges the comment received from the Swedish Competent Authority (SE CA) – KEMI (#3719).

RAC acknowledges that a REACH authorization would lead to information on environmental emissions at industrial sites, however RAC is of the opinion that a REACH authorisation would be less effective to control the risk due to the continuation of emissions considering the time required for the process of the inclusion of the substance into the Annex XIV to REACH, the subsequent application process for authorization of the 1300 different industrial sites using HTF and the lack of alternatives for the vast majority of the volume used and also the non-inclusion of the articles containing terphenyl hydrogenated.

6.4. SEAC Rapporteurs Comments

Regarding biphenyl, SEACs acknowledges as indicated in the opinion that biphenyl and terphenyl are coproducts in the existing manufacturing process and that a ban on terphenyl would seriously affect (or even impede) biphenyl production. SEAC agrees that this would imply an economic impact (not quantified by the Dossier Submitter) and that the costs would be higher than those indicated in the Background Document.

Regarding the comment by the Swedish Competent Authority SEACs points to the explanation in the Opinion about why a Restriction is the best Regulatory Management Option.