ECHA PROPOSES RESTRICTION ON TERPHENYL, HYDROGENATED[1]

Summary

The proposed restriction would prevent the manufacturing, use and placing on the placing on the market of terphenyl, hydrogenated in concentrations greater than 0.1 % by weight.

Terphenyl hydrogenated is a synthetic substance, mainly used as a heat transfer fluid (HTF). It was identified by ECHA as a Substance of Very High Concern (SVHC) in 2021 because of its very persistent and very bioaccumulative (vPvB) properties. The substance terphenyl, hydrogenated is a UVCB substance including a multitude of constituents. The vPvB properties are related to the presence of specific constituents in the substance. At least o-terphenyl fulfils both vP and vB criteria[2]. As o-terphenyl occurs in significant concentrations in the UVCB substance (> 0.1% w/w), terphenyl hydrogenated is considered to fulfil the vPvB criteria.

Terphenyl, hydrogenated is imported into the EU as a substance, in mixtures and in articles. There is no manufacture of Terphenyl hydrogenated within the EU. According to REACH registration, terphenyl, hydrogenated, is used as HTF and as a plasticiser in polymer applications, adhesives and sealants, coatings, fillers, putties and plasters. Furthermore, a stakeholder survey, in preparation of the restriction proposal indicated that the main use of terphenyl hydrogenated is as HTF (around 90% of the tonnage range), the use of the substance as a plasticiser is the second relevant use (around 10% of the tonnage range. The final coatings, sealants/adhesives can be used in a variety of sectors, e.g. the aerospace industry. Additionally, plasticisers are also used in the cable industry.

The proposed restriction aims at preventing releases of terphenyl hydrogenated into the environment from the uses that cause most concern, in plasticisers and during the waste lifecycle stage of articles. The Dossier Submitter proposes derogations for uses in situations where emission can be controlled, i.e. heat transfer fluids and uses with higher socio-economic impacts, such as the substance's use as plasticiser in the production of aircraft and their spare parts.

RESTRICTION REPORT CONSULTATION

The consultation on this proposed restriction will start on 20/06/2022 and end on 20/12/2022.

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the evaluation of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

[1] The information note has been prepared based on the Annex XV report prepared by Italy.
[2] Information taken from SVHC support document (2018)

In addition, initial reactions to the proposed restriction may be submitted by the early comments deadline of 20/07/2022. In early comments respondents may outline when they plan to submit subsequent comments and on which topics. This information can assist the Rapporteurs of the committees to plan their evaluation.

	Committee	
Plenary meeting (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after start of consultation)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after start of the consultation)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months after start of the consultation)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal are likely to make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

How to submit a comment in the consultation on the proposed restriction

Firstly, please read the consultation guidance that describes the relevant information that should be submitted. It is available here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socio-economic analysis.
- Section 4: Non-confidential attachments can be added here.
- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot or printed copy for your future reference.

Specific information requests

In addition to the general comments, outlined above, 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?

The final opinions of both Committees are scheduled to be available by 31/07/2023. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.