

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

Terphenyl, hydrogenated

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

SEAC draft opinion: Third Party Consultation

Timing: From 15/03/2023 to 15/05/2023

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:

1. The proposal includes a derogation for the use of terphenyl, hydrogenated as a heat transfer fluid for use in industrial sites within strictly controlled closed systems. 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. Please provide evidence regarding whether this is the case.
2. What impact would a time limited derogation for the use of terphenyl, hydrogenated as a heat transfer fluid for use in industrial sites (as described in question 1) have on the profitability of installations where heat transfer fluids are used and on investment decisions? What would be the impact if the time limit were shorter than 20 years?
3. What would be the impact of not granting a derogation for the use of terphenyl, hydrogenated in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats?
4. What would be the impact of a restriction of uses other than industrial HTF uses, uses in electromechanical temperature controls of ovens and stoves or in electrical capillary thermostats and uses in the aerospace and defence sector?

Overview of comments received

In total 28 comments were received, 24 of them from companies (##1171, #1173, #1174, #1175, #1176, #1177, #1178, #1180, #1182, #1184, #1185, #1186, #1187, #1188, #1190, #1193, #1194, #1199, #1206, #1207, #1215, #1216, #1217, #1218, 2 from industry or trade associations (#1201, #1212) and one comments was received from a Member State (#1203) and one from and individual (#1198). No comments were received from NGOs.

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

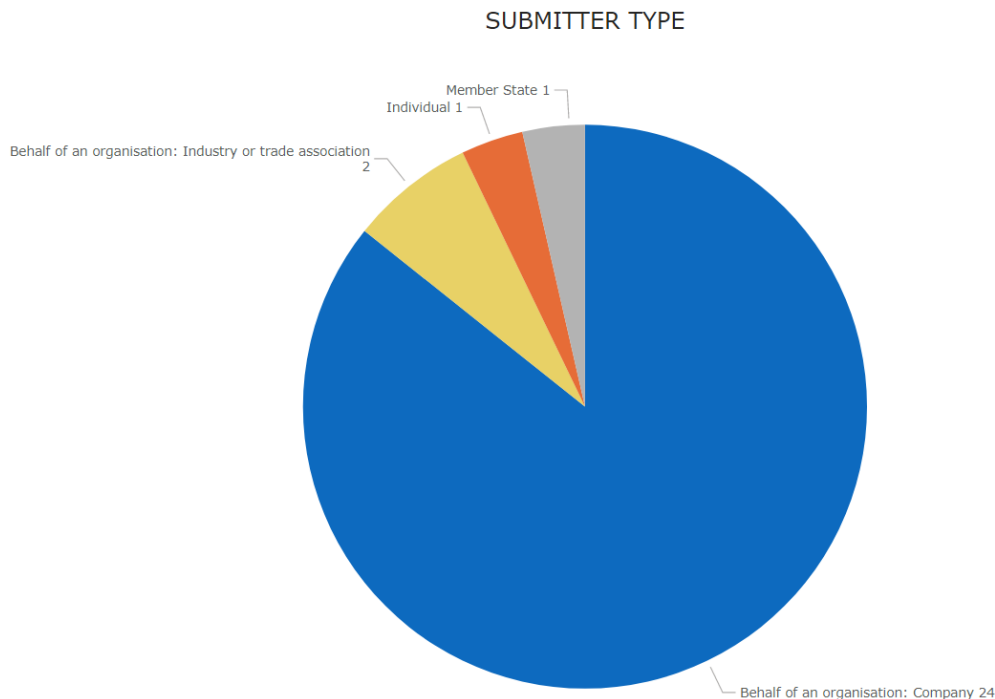


Figure 1: Overview of comments per type of submitter

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:

- Italy (17)
- Netherlands (4)
- Germany (3)
- Austria (1)
- Belgium(1)
- Spain(1)
- Sweden(1)

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

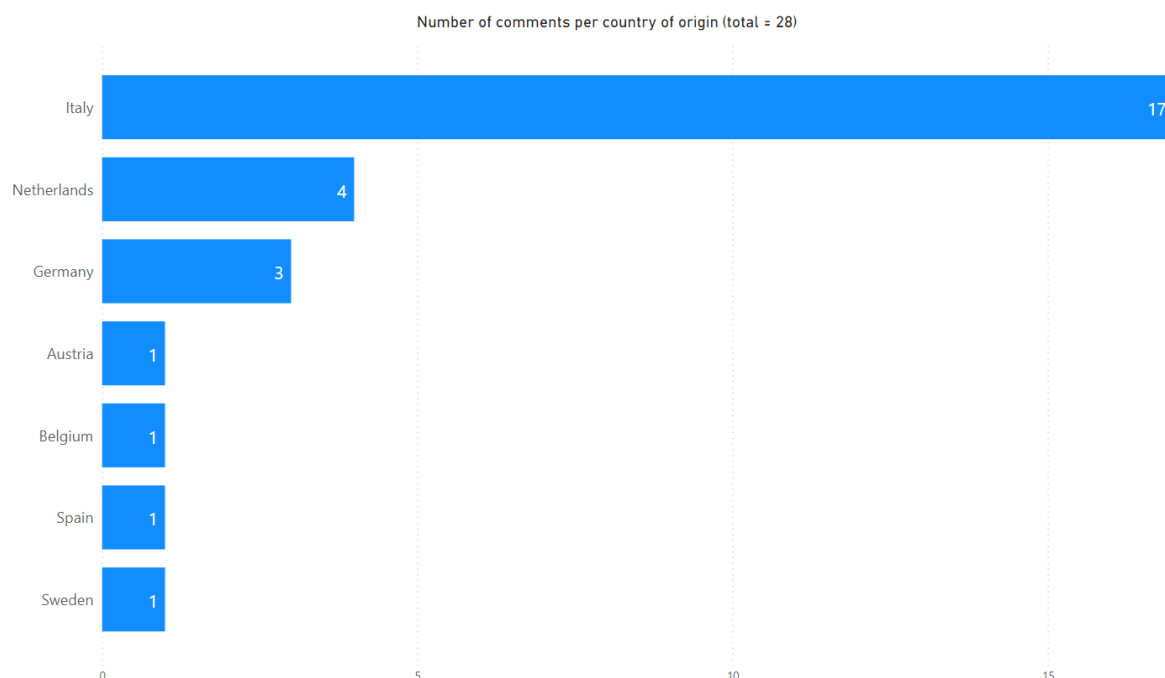


Figure 2: Overview of comments per country of origin

Response to comments by SEAC

SEAC would like to thank all interested parties that submitted comments and information to the draft opinion. SEAC notes that many of the comments received were similar in nature and could be grouped into topics.

Given the number of comments received, and to improve the clarity of the responses, the SEAC 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 SEAC has responded to them, typically by revising specific parts of the draft opinion.

To assist stakeholders to understand how their comments were assessed, SEAC has provided an indicative list of comment numbers that are associated with a specific topic(s). Nevertheless, whilst SEAC 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 SEAC has considered all of the comments received in the consultation when preparing these general responses. In some cases, SEAC has responded to comments by revising the wording of the "conditions of the restriction". Commenters should note that the wording of the conditions of the restriction in the Opinion is only intended to express the intention of SEAC in a concise a form 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 following the questions SEAC posed in the consultation note¹ (See specific information requests.

1.1 Appropriateness of time limit to the derogation for HTF use

Question: The proposal includes a derogation for the use of terphenyl, hydrogenated as a heat transfer fluid for use in industrial sites within strictly controlled closed systems. 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. Please provide evidence regarding whether this is the case.

Comments received

Comments #1171, #1173, #1174, #1175, #1176, #1177, #1178, #1180, #1182, #1184, #1185, #1186, #1187, #1188, #1190, #1193, #1194, #1198, #1199, #1201 #1203, #1206, #1207, #1215, #1216, #1217, #1218,

A majority of the comments received during the consultation on the draft SEAC opinion concerns the proposed time-limited derogation of 20 years (or any other time-limit). One point raised is that this derogation has not been proposed by the Dossier Submitter, thus not assessed, and it has not been possible for stakeholders to comment on it until now. The comments state that a time-limited derogation will not be proportionate, as it would result in overall more emissions from substances with similar properties² (the alternatives are not subject to the same requirements to operate under SCCS) and at the same time cause higher costs for industry with a risk that part of the industry would relocate.

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

- **Lifetimes of industrial sites go long beyond 20 years.** Although the submitted comments would indicate that there would be sites with an expected reduced service life (30 years), for larger establishments the lifetime is often more than 50 years (all petrochemicals, such as e.g. PET manufacturers are in this segment). Some examples of existing sites and since when they are running are given in Table 1.

Table 1: Examples of sites using Terphenyl Hydrogenated as an HTF and their date of construction (source: comments)

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

- **It is not foreseeable that a safer, suitable alternative will be found.** The very nature of what makes the substance useful (thermal stability and boiling

² Under evaluation but a high share of the registrants self-declared the substance as a PBT.

point), makes that it requires persistency properties that would make it likely that any substitute for the same heat range with a similar performance would most likely also be a PBT/vPvB substance. To that extent comment#1171 indicates that dibenzylbenzene, ar-methyl derivative is self-classified as PBT. Terphenyl, hydrogenated has an expected service life of more than 20 years (as indicated in the consultation, >40% of the analyzed installations using terphenyl, hydrogenated as an HTF are older than 20 years).

- **A time-limited derogation does not imply that the manufacturers will spend resources searching for an alternative.** There are two main reasons supporting this: the argument presented previously (required properties for the use) and the possibility to switch to another existing alternative (which means regrettable substitution) or relocate outside the UE.
- **A time limit derogation will hamper new investments** in sites requiring the use of an HTF for the temperature range of 250-350 degrees in the EU **or force new sites to use an alternative substance (regrettable substitution).** As the lifetime of the industrial sites is longer than a time-limited derogation of 20 years, the introduction of a time-limited derogation will in practice act as an instant ban of terphenyl, hydrogenated for all new installations. The consequences are either regrettable substitution or investments locating outside the EU. Many of the plant installations are in the field of renewable energy sources and thus considered to be of special importance to society and of special importance to achieve the goals of for the EU New Green Deal. Petrochemicals have a great impact on economy (investments, employment, etc.) and renewable energy plants have a significant impact on the transition to decarbonization and green energy. Both consequences (no investments or regrettable substitution) would have negative consequences for the EU.
- **A time-limited derogation will stop new investments in existing plants** (as indicated in the first item, the lifespan of an establishment cannot be determined in many cases) A time-limited derogation will determine the life-time of most installations as retrofitting with alternatives at the end of the time-limit may not be economically feasible.) . In fact, there are currently investments in the EU of bn€ in existing plants manufacturing plastics- petrochemical). Closure, relocation, or regrettable substitution are the potential scenarios.
- An **time-unlimited derogation does not imply that it cannot change in the future.** If the situation changes (new technologies or new substances) it can be reviewed and cancelled.

SEAC's evaluation of the comments

SEAC did set as a premise that the time-limited derogation should be set based on the expected average lifetime of installations, to avoid that any premature substitution would result in regrettable substitution and require costly retrofitting in installations that normally have a long lifetime. The comments received (1171, 1174, 1175, 1177, 1178, 1184, 1190, 1193, 1194, 1199, 1206, 1216, 1217 and 1218) state that this premise is not fulfilled.

SEAC considers that a time-limited derogation of 20 years (or any other length of a time-limited derogation) will lead to a situation with potential regrettable substitution or investments relocated to outside the EU. It is important to remember that the current restriction only targets terphenyl hydrogenated, whereas in a recent RMOA of the Finnish authorities, it was concluded that the risk of regrettable substitution with substances similar to terphenyl, hydrogenated is considered to be high. The two foremost alternatives (EC-No. 258-649-2 and EC-No. 400-370-7) to terphenyl, hydrogenated (EC 262-967-7,

CAS 61788-32-7) have therefore considered together for further regulatory action into a "technical functional group" (Tukes, 2020) due to their use as Heat Transfer Fluid (HTF) within the same temperature range and the potential PBT/vPvB properties of the two alternatives.

Only one comment suggests (comment nr 1203) that a shorter length of the derogation would be more appropriate, the commenter based this comment on a comparison with authorisation and suggested that the length of the derogation should be harmonised with the long review period (12 yrs) that is commonly used in Application for Authorisation.

In this respect, SEAC notes that with the current targeting and scope of the proposal, focussing on terphenyl, hydrogenated there is a risk of regrettable substitution as actors could potentially use one of the substances from this functional group as a substitute. This could lead to regrettable substitution with actors merely using another PBT/vPvB (or likely to be PBT/vPvB) substance instead of terphenyl, hydrogenated.

In practice SEAC, foresees the following scenarios for existing and new plants, assuming a baseline in which no regulatory action will take place on the rest of the functional group.

Existing plants	Would adjust the OCs and RMMs to comply with the SCCS and ensure minimisation but then continue using terphenyl, hydrogenated until the expiration of the time-limited derogation. After that a retrofit would be performed to ensure that the installation would be capable of using one of the two known substitutes which could then further be used without controlled conditions.
New plants	Would not use terphenyl, hydrogenated but would use one of the two known alternatives which could be used in a non-controlled manner without the assurance (via e.g. monitoring) that emissions of a PBT/vPvB like substance would be minimised.

Based on this potential for regrettable substitution, that was already highlighted in the original submitted dossier but which is again underlined by the comments on the draft opinion. SEAC recommends that further regulatory action addressing the two known alternatives should be considered as well to avoid regrettable substitution and the possibility to use these two alternative substances in an uncontrolled environments.

As for the current situation where only terphenyl, hydrogenated is restricted, substitution with one of the other substances would lead to more emissions of a likely vPvB substance/likely SVHC, as the rest of the functional group does not currently have requirements of SCCS (besides the lifetime of the alternatives is shorter which implies that they have to be replaced more often). In addition, (confidential) comments to the SEAC draft opinion #1173 # 1177 indicate that the use of any of the other substances in the functional group would be less optimal from a technical and economical perspective – and substitution would likely lead to higher emissions and higher investment and operational costs. A situation with higher emissions and higher costs is clearly not proportionate. And last, but not least, the current restriction, not taking into account the functional group, will not ensure a level playing field between similar substances and might lead to disproportionate investments. The comments on the draft opinion also indicate that substitution could lead to emissions of CO₂ , see comment nr #1177). There has not been a real assessment of the substitution costs, not taking into account indications that the performance of the alternatives are less preferable and less safe and potentially more costly in investment and operation. The comments on the draft opinion also emphasize

that there is no reliable assessment of the behavioural responses regarding the fraction that would relocate and the fraction that would substitute. This implies that there is no reliable assessment of the potential consequences of relocation outside the EU.

SEAC is aware that a reliable assessment of these costs is lacking. SEAC is also aware that the costs presented by the Dossier Submitter for RO3 are likely significantly underestimated and SEAC finds that the comments on the draft opinion also give a clear indication that the costs for RO3 are likely significantly underestimated, although the information provided in the comments did not include reliable estimations of the potential costs for the society.

SEAC thus finds that based on the information available RO3, with a time-unlimited derogation is proportionate.

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

SEAC recommends that progress in substitution possibilities is reviewed after 10 years to assess whether new information has become available that would indicate that alternatives that would not pose risk of regrettable substitution would be available for the use as heat transfer fluid. This review should focus on the derogation for the use of the substance as a heat transfer fluid, with a specific focus to investigate whether this derogation should be upheld for new installations (i.e. installations to be constructed after the review has taken place)

The opinion has been updated to reflect the comments and SEAC's evaluation of the comments.

1.2 Impact on of time limit on profitability of installations and new investments and impact of shorter time period.

Question: What impact would a time- limited derogation for the use of terphenyl, hydrogenated as a heat transfer fluid for use in industrial sites (as described in question 1) have on the profitability of installations where heat transfer fluids are used and on investment decisions? What would be the impacted if the time limit were shorter than 20 years?

SEAC refers to its evaluation of responses to specific information request nr 1 on the appropriateness of a time-limited derogation. SEAC notes that the comment that suggested an alignment with the authorisation process and therefore time-limited derogation of 12 yrs does not contain any specific socio-economic information to justify a further shortening of the time limit of the derogation.

1.3 Impact of a derogation in applications of electromechanical temperature controls of ovens and stoves or of electrical capillary thermostats

Question 3) What would be the impact of not granting a derogation for the use of terphenyl, hydrogenated in applications of electromechanical

temperature controls of ovens and stoves or of electrical capillary thermostats?

Despite the Secretariat reaching out to several relevant stakeholder organisations, information in this subject was submitted in the consultation

The following organisations had been approached

Apia Europe	Home Appliance Europe
ERA	Electronics Representative Association
Iaeeee	International Association of Electrical, Electronic and Energy Engineering
ZVEI	Zentralverband Elektrotechnik-und Elektronikindustrie eV
ECEEE	European Council for an Energy Efficient Economy

No comments were submitted on this point, SEAC takes this as an indication that it is both technically and economically feasible to substitute away from Terphenyl, hydrogenated, and thus that a ban is proportionate.

Based on an absence of comments or any socio-economic data , SEAC does not support any derogation for this use.

1.4 Impact on other uses

Question 4: What would be the impact of a restriction of uses other than industrial HTF uses, uses in electromechanical temperature controls of ovens and stoves or in electrical capillary thermostats and uses in the aerospace and defence sector?

No information specific to this question had been submitted

Based on an absence of comments or any socio-economic data , SECA does not support any derogation for this use.

1.5 Other submitted comments

Comments to the stakeholder consultation from two industry association (ASD and AIA) were received (comment nr 1212) with more specific information on the derogation for aviation. The comments provided further arguments in support of the proposed derogations with a time limit of 10 years but also suggested to consider a review at the expiration of this derogation to evaluate whether more time is needed in case of unsuccessful substitution. More specifically the covered the following issues:

1. welcome the draft SEAC opinion and are pleased to see that our information has been well considered in the recommendation of an appropriate derogation for the sector; to allow certainty for the continued necessary use of PHT-containing formulations and articles whilst work to develop, qualify and introduce alternatives is undertaken over the next decade.

2. Review cause needed at end of derogation to verify need for further extension.
3. Majority of uses is in sealants and uses, rather than in coatings (as suggested in table 2 of the annex xv dossiers)
4. Use lower than assumed by DS, decrease due to substitution efforts
5. Even if an alternative sealant/adhesive (and it is not just one formulation, but many due to the necessary variations in properties that make each variety of sealant/adhesive suited to specific uses within an A&D product) would be ready for test by A&D companies in the near term, it is still expected to take at least 10 years to complete all required testing and introduce alternatives in all applications across the sector. Over this period as individual uses are substituted, reliance on PHT-based sealant/adhesive formulations is expected to be reducing.

The organisations provided further information on the use of the substances in coatings and sealants and provided further details on the volumes of use, of uses, article service life and end of life stage of the products that contain HTF.

Evaluation of the comments by SEAC

SEAC takes note of the comment that was submitted. Information on article service life and end of life as well as on the control of the substances during these stages was provided.

Based on the comments that were received and considering that no new evidence was provided substantiating the claim for reviewing the derogation, SEAC did not update the opinion on this aspect.